
WELSH STATUTORY INSTRUMENTS

2023 No. 1276 (W. 224)

AGRICULTURE, WALES

The Feed Additives (Authorisations) (Wales) Regulations 2023

Made - - - - 27 November 2023

Laid before Senedd Cymru 29 November 2023

Coming into force - - 22 December 2023

The Welsh Ministers make these Regulations in exercise of the powers conferred by Articles 9(1) and 18A(3) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition⁽¹⁾.

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety⁽²⁾.

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Feed Additives (Authorisations) (Wales) Regulations 2023.

(2) These Regulations—

- (a) extend to England and Wales;
- (b) apply in relation to Wales;
- (c) come into force on 22 December 2023.

Interpretation

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

(2) In Schedules 1 to 13—

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

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

- (a) expressions used to refer to species or categories of animals that are also used in Annex 4 (categories and definitions of target animals etc.) to Regulation 429/2008 have the same meaning as in that Annex;
- (b) any reference to a minor species is to be read in accordance with the definition of “minor species” in Article 1 of Regulation 429/2008.
- (3) In this regulation—
- “Regulation 1831/2003” (“*Rheoliad 1831/2003*”) means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;
- “Regulation 429/2008” (“*Rheoliad 429/2008*”) means Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives⁽³⁾;
- “Regulation 767/2009” (“*Rheoliad 767/2009*”) means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed⁽⁴⁾.

Authorisations

- 3.—(1) Schedules 1 to 13 contain authorisations of feed additives.
- (2) Subject to Article 14(4) (renewal of authorisation) of Regulation 1831/2003, the authorisations set out in Schedules 1 to 13 cease to have effect at the end of 21 December 2033.

Transitional provision: Endo-1,4-beta-xylanase (EC 3.2.1.8) (identification number 4a8i (formerly 4a8))

- 4.—(1) The relevant feed additive and premixtures containing it, which are produced and labelled before the end of 21 June 2024 in compliance with the conditions of the prior authorisation and the labelling requirements applicable before 22 December 2023, may continue to be placed on the market and used until stocks are exhausted.
- (2) Compound feed and feed materials containing the relevant feed additive and intended for food-producing animals, which are produced and labelled before the end of 21 December 2024 in compliance with the conditions of the prior authorisation and the labelling requirements applicable before 22 December 2023, may continue to be placed on the market and used until stocks are exhausted.
- (3) In this regulation—
- “relevant feed additive” (“*ychwanegyn bwyd anifeiliaid perthnasol*”) means the feed additive endo-1,4-beta-xylanase (EC 3.2.1.8), with the identification number 4a8, authorised under the prior authorisation⁽⁵⁾;
- “prior authorisation” (“*awdurdodiad ymlaen llaw*”) means the authorisation contained in Commission Regulation (EC) No 902/2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy)⁽⁶⁾.

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

(4) EUR 2009/767, amended by S.I. 2019/654. S.I. 2019/654 was amended by S.I. 2020/1504.

(5) See Schedule 9 to these Regulations for the renewed authorisation of this feed additive.

(6) EUR 2009/902. This Regulation is revoked by regulation 7 of, and Schedule 14 to, these Regulations.

Amendment of Commission Implementing Regulation (EU) No601/2013

5.—(1) Commission Implementing Regulation (EU) No601/2013 concerning the authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives(7) is amended as follows.

- (2) In the Annex, in the table, omit the entries for—
- (a) cobalt(II) acetate tetrahydrate (identification number 3b301);
 - (b) cobalt(II) carbonate (identification number 3b302);
 - (c) cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303);
 - (d) cobalt(II) sulphate heptahydrate (identification number 3b305).

Amendment of Commission Implementing Regulation (EU) 2019/221

6.—(1) Commission Implementing Regulation (EU) 2019/221 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives(8) is amended as follows.

- (2) Omit Article 4 (amendment to Regulation (EU) No9/2010).
- (3) Omit Article 7 (amendment to Implementing Regulation (EU) No528/2011).
- (4) Omit Article 9 (amendment to Implementing Regulation (EU) No1021/2012).

Revocations

7. The instruments listed in Schedule 14 are revoked.

Lynne Neagle
Deputy Minister for Mental Health and
Wellbeing, under the authority of the Minister
for Health and Social Services, one of the Welsh
Ministers

27 November 2023

(7) EUR 2013/601. This Regulation was amended prior to implementation period completion day by Commission Implementing Regulation (EU) No131/2014.

(8) EUR 2019/221.

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SCHEDULE 1

Regulation 3(1)

Renewal of authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 143953) (formerly *Trichoderma reesei* (ATCC PTA 5588)) (identification number 4a11) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks, minor poultry species, weaned piglets, and piglets for fattening, and its authorisation as a feed additive extending existing uses to cover all poultry species, piglets (suckling and weaned), pigs for fattening, and minor porcine species

The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “digestibility enhancers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(9).

<i>Additive</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8)
<i>Identification number</i>	4a11
<i>Authorisation holder</i>	Danisco (UK) Ltd
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 143953) with a minimum enzyme activity of 40,000 U/g ⁽¹⁾
<i>Characterisation of the active substance(s)</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 143953) <ul style="list-style-type: none"> • CAS number: 9025-57-4⁽²⁾ • EC (IUBMB) number: 3.2.1.8⁽³⁾ • EINECS number: 232-800-2⁽⁴⁾
<i>Analytical methods</i> ⁽⁵⁾⁽⁶⁾	For quantification of endo-1,4-beta-xylanase enzyme activity in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method measuring water soluble dye released by action of endo-1,4-beta-xylanase from azurine cross-linked wheat arabino xylan substrate
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • All poultry species • Piglets (suckling and weaned) • Pigs for fattening • Minor porcine species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	For all poultry species: <ul style="list-style-type: none"> • 625 U/kg For piglets (suckling and weaned), pigs for fattening, minor porcine species: <ul style="list-style-type: none"> • 2000 U/kg
<i>Maximum content</i> ⁽⁷⁾	None

(9) This authorisation contains a renewal (with modification) of the authorisations granted under [Commission Regulation \(EU\) No 9/2010](#), [Commission Implementing Regulation \(EU\) No528/2011](#) and [Commission Implementing Regulation \(EU\) No1021/2012](#). Those Regulations are revoked by regulation 7 of, and Schedule 14 to, these Regulations.

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<i>Other provisions</i>	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture
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- (1) 1 unit (“U”) is the amount of enzyme that releases 0.48 micromoles (µmol) of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH4.2 and 50°C.
- (2) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (3) Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) <https://iubmb.org>.
- (4) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.
- (5) Details of the analytical methods are set out in the document referenced “JRC.D.5/FSQ/CvH/DM/ag/ARES(2012)353089” and last updated 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2011-0030_en.
- (6) The enzyme activity for endo-1,4-beta-xylanase is defined in the document referenced “JRC.DG.D.6/CvH/DM/hn/ARES(2010)-375745” and last updated 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0007_en.
- (7) Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%).

SCHEDULE 2

Regulation 3(1)

Authorisation of a preparation of *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus rhamnosus*) (IMI 507023) (identification number 1k21701) as a feed additive for all animal species

The preparation of *Lacticaseibacillus rhamnosus* (IMI 507023) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	<i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Identification number</i>	1k21701
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Lacticaseibacillus rhamnosus</i> (IMI 507023) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15787:2021⁽²⁾)

- (1) Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and “JRC F.5/CvH/ZE/AS/Ares”, and last updated 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0075”.
- (2) Under reference BS EN 15787:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive”. Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available at: <https://knowledge.bsigroup.com>.
- (3) CFU (colony-forming unit) additive/kg of fresh material.
- (4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

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	For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	Minimum content of the additive when used without combination with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

- (1) Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and “JRC F.5/CvH/ZE/AS/Ares”, and last updated 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0075”.
- (2) Under reference BS EN 15787:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive”. Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available at: <https://knowledge.bsigroup.com>.
- (3) CFU (colony-forming unit) additive/kg of fresh material.
- (4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

SCHEDULE 3

Regulation 3(1)

Authorisation of a preparation of *Pediococcus pentosaceus* (IMI 507024) (identification number 1k21016) as a feed additive for all animal species

The preparation *Pediococcus pentosaceus* (IMI 507024) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	<i>Pediococcus pentosaceus</i> (IMI 507024)
<i>Identification number</i>	1k21016
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives

- (1) Details of the analytical methods are set out in the document referenced “Ares(2021)1902366 – 16/03/2021” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The dossier reference number is “FAD-2020-0076”.
- (2) Under reference BS EN 15786:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Pediococcus* spp. used as feed additive”. Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99830 0). Available at: <https://knowledge.bsigroup.com>.
- (3) CFU (colony-forming unit) additive/kg of fresh material.
- (4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

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<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Pediococcus pentosaceus</i> (IMI 507024) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Pediococcus pentosaceus</i> (IMI 507024)
<i>Analytical methods⁽¹⁾</i>	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15786:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content⁽³⁾</i>	Minimum content of the additive when used without combination with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content⁽³⁾</i>	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

(1) Details of the analytical methods are set out in the document referenced “Ares(2021)1902366 – 16/03/2021” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The dossier reference number is “FAD-2020-0076”.

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

(3) CFU (colony-forming unit) additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

SCHEDULE 4

Regulation 3(1)

Authorisation of a preparation of *Pediococcus pentosaceus* (IMI 507025) (identification number 1k21017) as a feed additive for all animal species

The preparation of *Pediococcus pentosaceus* (IMI 507025) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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<i>Additive</i>	<i>Pediococcus pentosaceus</i> (IMI 507025)
<i>Identification number</i>	1k21017
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Pediococcus pentosaceus</i> (IMI 507025) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Pediococcus pentosaceus</i> (IMI 507025)
<i>Analytical methods⁽¹⁾</i>	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15786:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content⁽³⁾</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content⁽³⁾</i>	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

(1) Details of the analytical methods are set out in the document referenced “Ares(2021)1902366 – 16/03/2021” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The relevant dossier reference number is “FAD-2020-0077”.

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

(3) CFU (colony-forming unit) additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

SCHEDULE 5

Regulation 3(1)

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507026) (identification number 1k21601) as a feed additive for all animal species
The preparation of *Lactiplantibacillus plantarum* (IMI 507026) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507026)
<i>Identification number</i>	1k21601
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Lactiplantibacillus plantarum</i> (IMI 507026) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lactiplantibacillus plantarum</i> (IMI 507026)
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15787:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	Minimum content of the additive when not combined with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

(1) Details of the analytical methods are set out in the document referenced “Ares(2021)1687524-08/-3/2021” and “JRC F.5/ CvH/ZE/AS/Ares”, and last updated on 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0078”.

(2) Under reference BS EN 15787:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive”. Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available at: <https://knowledge.bsigroup.com>.

(3) CFU (colony-forming unit) additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

SCHEDULE 6

Regulation 3(1)

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507027) (identification number 1k21602) as a feed additive for all animal species
The preparation of *Lactiplantibacillus plantarum* (IMI 507027) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507027)
<i>Identification number</i>	1k21602
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Lactiplantibacillus plantarum</i> (IMI 507027) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lactiplantibacillus plantarum</i> (IMI 507027)
<i>Analytical methods⁽¹⁾</i>	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15787:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content⁽³⁾</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content⁽³⁾</i>	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

(1) Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and “JRC F.5/ CvH/ZE/AS/Ares”, and last updated on 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0079”.

(2) Under reference BS EN 15787:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive”. Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available at: <https://knowledge.bsigroup.com>.

(3) CFU (colony-forming unit) additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

SCHEDULE 7

Regulation 3(1)

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507028) (identification number 1k21603) as a feed additive for all animal species
The preparation of *Lactiplantibacillus plantarum* (IMI 507028) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507028)
<i>Identification number</i>	1k21603
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Lactiplantibacillus plantarum</i> (IMI 507028) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lactiplantibacillus plantarum</i> (IMI 507028)
<i>Analytical methods⁽¹⁾</i>	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15787:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content⁽³⁾</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9CFU/kg
<i>Maximum content⁽³⁾</i>	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

(1) Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and “JRC F.5/ CvH/ZE/AS/Ares”, and last updated on 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0080”.

(2) Under reference BS EN 15787:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive”. Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available at: <https://knowledge.bsigroup.com>.

(3) CFU (colony-forming unit) additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in the fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material.

SCHEDULE 8

Regulation 3(1)

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (DSM 26571) (identification number 1k1604) as a feed additive for all animal species
The preparation of *Lactiplantibacillus plantarum* (DSM 26571) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Status: This is the original version (as it was originally made). This item of legislation is currently only available in its original format.

<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (DSM 26571)
<i>Identification number</i>	1k1604
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Lactiplantibacillus plantarum</i> (DSM 26571) containing a minimum of 1×10^{11} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lactiplantibacillus plantarum</i> (DSM 26571)
<i>Analytical methods⁽¹⁾</i>	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15787:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content⁽³⁾</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^8 CFU/kg
<i>Maximum content⁽³⁾</i>	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use in easy to ensile, moderately difficult to ensile, or difficult to ensile fresh material ⁽⁴⁾

(1) Details of the analytical methods are set out in the document referenced “Ares(2020)5563084 – 15/10/2020” and “JRC.F.5/CvH/ZE/AS/Ares”, and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0091_en.

(2) Under reference BS EN 15787:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Lactobacillus spp. used as feed additive”. Published by the British Standards Institution on 31 December 2021 (ISBN 978 0 580 99831 7). Available at: <https://knowledge.bsigroup.com>.

(3) CFU (colony-forming unit) additive/kg of fresh material.

(4) Easy to ensile forage: > 3% soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5 to 3.0% soluble carbohydrates in the fresh material; difficult to ensile forage: < 1.5% soluble carbohydrates in the fresh material.

SCHEDULE 9

Regulation 3(1)

Renewal of authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 114044) (identification

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number 4a8i) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening, and turkeys reared for breeding

The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “digestibility enhancers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(10).

<i>Additive</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8)
<i>Identification number</i>	4a8i
<i>Authorisation holder</i>	Roal Oy
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 114044) having a minimum enzyme activity of 160,000 BXU/g for both solid and liquid forms ⁽¹⁾
<i>Characterisation of the active substance(s)</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 114044) <ul style="list-style-type: none"> • CAS number: 9025-57-4⁽²⁾ • EC (IUBMB) number: 3.2.1.8⁽³⁾ • EINECS number: 232-800-2⁽⁴⁾
<i>Analytical methods</i> ⁽⁵⁾	For the quantification of endo-1,4-beta-xylanase (EC 3.2.1.8) in the feed additive and premixtures: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of endo-1,4-beta-xylanase on the birch xylan substrate at pH 5.3 and 50°C For the quantification of endo-1,4-beta-xylanase (EC 3.2.1.8) in feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of endo-1,4-beta-xylanase on the azurine cross-linked wheat arabino xylan substrate at pH 5.3 and 50°C
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Piglets (weaned) • Chickens for fattening

(1) Enzyme activity expressed in birch xylan units (BXU), where 1 BXU is the amount of enzyme which liberates 1 nanomole (nmol) of reducing sugars as xylose from birch xylan per second at pH 5.3 and 50°C

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

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

(4) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.

(5) Details of the analytical methods are set out in the document referenced “Ares(2019)3101222-10/05/2019” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 2 July 2019. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0071_en.

(6) Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%).

(10) This authorisation is a renewal of the authorisation granted under Commission Regulation (EC) 902/2009, which is revoked by regulation 7 of, and Schedule 14 to, these Regulations, but see the transitional provision in regulation 4. This feed additive was also previously authorised as a feed additive for laying hens, minor poultry species and pigs for fattening under Commission Implementing Regulation (EU) No1110/2011, which expired on 24 November 2021 and is revoked by regulation 7 of, and Schedule 14 to, these Regulations.

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	<ul style="list-style-type: none"> • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁶⁾	<p>For piglets (weaned):</p> <ul style="list-style-type: none"> • 24,000 BXU/kg <p>For chickens for fattening, chickens reared for laying:</p> <ul style="list-style-type: none"> • 8,000 BXU/kg <p>For turkeys for fattening, turkeys reared for breeding:</p> <ul style="list-style-type: none"> • 16,000 BXU/kg
<i>Maximum content</i> ⁽⁶⁾	None
<i>Other provisions</i>	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

- (1) Enzyme activity expressed in birch xylan units (BXU), where 1 BXU is the amount of enzyme which liberates 1 nanomole (nmol) of reducing sugars as xylose from birch xylan per second at pH 5.3 and 50°C
- (2) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (3) Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) <https://iubmb.org>.
- (4) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.
- (5) Details of the analytical methods are set out in the document referenced “Ares(2019)3101222-10/05/2019” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 2 July 2019. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0071_en.
- (6) Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%).

SCHEDULE 10

Regulation 3(1)

Renewal of authorisation of a preparation of 6-phytase (EC 3.1.3.26) produced from *Trichoderma reesei* (CBS 122001) (identification number 4a12) as a feed additive for pigs, poultry for breeding, poultry for fattening, and poultry for laying

The preparation of 6-phytase (EC 3.1.3.26) specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “digestibility enhancers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(11).

(11) This authorisation is a renewal of the authorisation granted under [Commission Regulation \(EU\) No 277/2010](#), [Commission Regulation \(EU\) No 891/2010](#) and Commission Implementing [Regulation \(EU\) No 886/2011](#). Those Regulations are revoked by regulation 7 of, and Schedule 14 to, these Regulations.

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<i>Additive</i>	6-phytase (EC 3.1.3.26)
<i>Identification number</i>	4a12
<i>Authorisation holder</i>	Roal Oy
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with <i>Trichoderma reesei</i> (CBS 122001) having a minimum enzyme activity of 40,000 PPU/g for the solid form and 5,000 PPU/g for the liquid form ⁽¹⁾ :
<i>Characterisation of the active substance(s)</i>	6-phytase (EC 3.1.3.26) produced by fermentation with <i>Trichoderma reesei</i> (CBS 122001) <ul style="list-style-type: none"> • CAS number: 9001-89-2⁽²⁾ • EC (IUBMB) number: 3.1.3.26⁽³⁾ • EINECS number: 232-630-9⁽⁴⁾
<i>Analytical methods</i> ⁽⁵⁾	For the quantification of phytase activity in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method quantifying the enzymatic activity of 6-phytase by measuring released inorganic phosphate from sodium phytate by analysing the colour formed by reduction of a phosphomolybdate complex
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Pigs • Poultry for breeding • Poultry for fattening • Poultry for laying
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁶⁾	For pigs, poultry for fattening, and poultry for breeding: <ul style="list-style-type: none"> • 250 PPU/kg For poultry for laying: <ul style="list-style-type: none"> • 125 PPU/kg
<i>Maximum content</i> ⁽⁶⁾	None
<i>Other provisions</i>	The storage conditions and stability for heat treatment must be stated in the directions for use of the feed additive and premixture

(1) Enzyme activity expressed in PPU units, where 1 PPU is the amount of enzyme which liberates 1 micromole (μmol) of inorganic phosphate from sodium phytate per minute at pH 5.0 and 37°C.

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

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

(4) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.

(5) Details of the analytical methods are set out in the document referenced “D08/FSQ/CVH/SY/D/Ares(2009)173372” and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2008-0040_en.

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

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SCHEDULE 11

Regulation 3(1)

Authorisation of L#lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c326) as a feed additive for all animal species
The substance L#lysine base (liquid) specified in the table, belonging to the additive category “nutritional additives” and to the functional group “amino acids, their salts and analogues”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	L#lysine base (liquid)
<i>Identification number</i>	3c326
<i>Authorisation holder</i>	None
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Amino acids, their salts and analogues
<i>Additive composition</i>	Aqueous solution with a minimum of 50% L-lysine
<i>Characterisation of the active substance(s)</i>	L#lysine base (liquid) produced by fermentation with <i>Corynebacterium glutamicum</i> (KCCM 80216 or KCTC 12307BP) L#lysine (C ₆ H ₁₄ N ₂ O ₂) <ul style="list-style-type: none"> • CAS number: 56-87-1⁽¹⁾ • EINECS number: 200-294-2⁽²⁾
<i>Analytical methods</i> ⁽³⁾	For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013⁽⁴⁾) For the quantification of lysine in premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 laying down the methods of sampling and analysis for the official control of feed⁽¹²⁾ (Annex 3-F) For the quantification of lysine in water:

- (1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (2) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.
- (3) Details of the analytical methods are set out in the document referenced “Ares(2020)4503369-31/08/2020” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.
- (4) Under reference BS EN ISO 17180:2013 “Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures”. Published by the British Standards Institution on 30 April 2013 (ISBN 978 0 580 76077 8). Available at: <https://knowledge.bsigroup.com>.
- (5) Content of L-lysine (mg/kg of complete feed with a moisture content of 12%).

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

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	<ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013⁽⁴⁾), or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 (Annex 3-F)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁵⁾	None
<i>Maximum content</i> ⁽⁵⁾	None
<i>Other provisions</i>	<p>1. The lysine content must be stated on the labelling of the additive</p> <p>2. L-lysine base (liquid) may be placed on the market and used as an additive consisting of a preparation</p>

- (1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (2) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.
- (3) Details of the analytical methods are set out in the document referenced “Ares(2020)4503369-31/08/2020” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.
- (4) Under reference BS EN ISO 17180:2013 “Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures”. Published by the British Standards Institution on 30 April 2013 (ISBN 978 0 580 76077 8). Available at: <https://knowledge.bsigroup.com>.
- (5) Content of L-lysine (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 12

Regulation 3(1)

Authorisation of L#lysine monohydrochloride (technically pure) produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c327) as a feed additive for all animal species

The substance L#lysine monohydrochloride (technically pure) specified in the table, belonging to the additive category “nutritional additives” and to the functional group “amino acids, their salts and analogues”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	L#lysine monohydrochloride (technically pure)
<i>Identification number</i>	3c327
<i>Authorisation holder</i>	None
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Amino acids, their salts and analogues
<i>Additive composition</i>	Powder of L-lysine monohydrochloride with a minimum of 78% L-lysine and a maximum moisture content of 1.5%

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<i>Characterisation of the active substance(s)</i>	<p>L-lysine monohydrochloride (technically pure) produced by fermentation with <i>Corynebacterium glutamicum</i> (KCCM 80216 or KCTC 12307BP)</p> <p>L-lysine monohydrochloride (C₆H₁₅ClN₂O₂)</p> <ul style="list-style-type: none"> • CAS number: 657-27-2⁽¹⁾ • EINECS number: 211-519-9⁽²⁾
<i>Analytical methods</i> ⁽³⁾	<p>For the identification of L-lysine monohydrochloride in the feed additive:</p> <ul style="list-style-type: none"> • Food Chemicals Codex L-lysine monohydrochloride monograph⁽⁴⁾ <p>For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine:</p> <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013)⁽⁵⁾ <p>For the quantification of lysine in premixtures, feed materials and compound feed:</p> <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 3-F) <p>For the quantification of lysine in water:</p> <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (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 3-F)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁶⁾	None
<i>Maximum content</i> ⁽⁶⁾	None
<i>Other provisions</i>	<ol style="list-style-type: none"> 1. The lysine content must be stated on the labelling of the additive 2. L-lysine monohydrochloride (technically pure) may be placed on the market and used as an additive consisting of a preparation

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

(2) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.

(3) Details of the analytical methods are set out in the document referenced “Ares(2020)4503369-31/08/2020” and “JRC F.5/CvH/MGH/AS/Ares”, and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.

(4) Food Chemicals Codex, United States Pharmacopeial Convention, 13th edition (online). Published by US Pharmacopeia (USP) on 1 March 2022 (ISSN 2153-1455). Available at <https://www.foodchemicalscodex.org>.

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- (5) Under reference BS EN ISO 17180:2013 “Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures”. Published by the British Standards Institution on 30 April 2013 (ISBN 978 0 580 76077 8). Available at: <https://knowledge.bsigroup.com>.
- (6) Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 13

Regulation 3(1)

Authorisation of a preparation of 3-nitrooxypropanol (identification number 4c1) as a feed additive for ruminants for milk production and ruminants for reproduction

The preparation of 3-nitrooxypropanol specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “substances which favourably affect the environment”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	3-nitrooxypropanol
<i>Identification number</i>	4c1
<i>Authorisation holder</i>	DSM Nutritional Products Ltd (Switzerland)
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Substances which favourably affect the environment
<i>Additive composition</i>	Preparation of 3-nitrooxypropanol containing a minimum of 10% additive Granular powder; particles with a diameter < 50 µm: 0.4%
<i>Characterisation of the active substance(s)</i>	3-nitrooxypropanol (C ₃ H ₇ NO ₄) • CAS number: 100502-66-7 ⁽¹⁾
<i>Analytical methods⁽²⁾</i>	For the quantification of 3-nitrooxypropanol in the feed additive, premixtures and compound feed: • Reversed phase high performance liquid chromatography with spectrophotometric detection (HPLC-UV)
<i>Species or category of animal</i>	• Ruminants for milk production • Ruminants for reproduction
<i>Maximum age</i>	None
<i>Minimum content⁽³⁾</i>	53 mg/kg
<i>Maximum content⁽³⁾</i>	88 mg/kg
<i>Other provisions</i>	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

- (1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (2) Details of the analytical methods are set out in the document referenced “Ares(2020)981992-15/02/2020” and “JRC F.5/CvH/ZE/AS/Ares”, and last updated on 4 May 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en.
- (3) Content of 3-nitrooxypropanol (mg/kg of complete feed with a moisture content of 12%).

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	2. The additive must be incorporated into feed in the form of a premixture
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- (1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (2) Details of the analytical methods are set out in the document referenced “Ares(2020)981992-15/02/2020” and “JRC F.5/CvH/ZE/AS/Ares”, and last updated on 4 May 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en.
- (3) Content of 3-nitrooxypropanol (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 14

Regulation 7

Revocations

[Commission Regulation \(EC\) No 902/2009](#) concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy)(13).

[Commission Regulation \(EU\) No 9/2010](#) concerning the authorisation of the endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for chickens for fattening, laying hens, ducks and turkeys for fattening (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)(14).

[Commission Regulation \(EU\) No 277/2010](#) concerning the authorisation of 6-phytase as a feed additive for poultry for fattening and breeding other than turkeys for fattening, for poultry for laying and for pigs other than sows (holder of authorisation Roal Oy)(15).

[Commission Regulation \(EU\) No 891/2010](#) concerning the authorisation of a new use of 6-phytase as a feed additive for turkeys (holder of authorisation Roal Oy)(16).

Commission Implementing [Regulation \(EU\) No528/2011](#) concerning the authorisation of endo-1,4-β-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for weaned piglets and pigs for fattening (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)(17).

Commission Implementing [Regulation \(EU\) No886/2011](#) concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Trichoderma reesei* (CBS 122001) as a feed additive for sows (holder of authorisation Roal Oy)(18).

Commission Implementing [Regulation \(EU\) No1110/2011](#) concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy)(19).

Commission Implementing [Regulation \(EU\) No1021/2012](#) concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for

(13) EUR 2009/902.

(14) EUR 2010/9. This Regulation was amended prior to implementation period completion day by Commission Implementing [Regulation \(EU\) No1196/2012](#) and Commission Implementing [Regulation \(EU\) 2019/221](#). EUR 2012/1196 is revoked by regulation 7 of, and Schedule 14 to, these Regulations. See regulation 6 for amendments to EUR 2019/221.

(15) EUR 2010/277.

(16) EUR 2010/891.

(17) EUR 2011/528. This Regulation was amended prior to implementation period completion day by Commission Implementing [Regulation \(EU\) 2019/221](#). See regulation 6 for amendments to EUR 2019/221.

(18) EUR 2011/886.

(19) EUR 2011/1110.

minor poultry species other than ducks (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)(20).

Commission Implementing Regulation (EU) No1196/2012 amending Regulation (EU) No9/2010 as regards the minimum content of a preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive in feed for laying hens (holder of authorisation Danisco Animal Nutrition)(21).

Commission Implementing Regulation (EU) 2018/1569 amending Implementing Regulation (EU) No1110/2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy)(22).

EXPLANATORY NOTE

(This note is not part of the Regulations)

The Welsh Ministers make these Regulations pursuant to Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (EUR 2003/1831). These Regulations make provision for the authorisation for the placing on the market, processing and use of 13 feed additives.

Regulation 3, and Schedules 1 to 13, provide for the authorisation of feed additives.

Schedule 1 contains a renewal (with modification) of an authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 143953) (identification number 4a11), and an extension of existing authorised uses to cover additional species/categories of animal. The modifications on renewal of the authorisation are—

- the strain identification number for *Trichoderma reesei* is updated to “CBS 142953” (formerly “ATCC PTA 5588”);
- the minimum content of feed additive for turkeys for fattening is reduced from 1,250 to 625 U/kg of complete feed.

Schedule 2 contains a new authorisation, for a preparation of *Lacticaseibacillus rhamnosus* (IMI 507023) (identification number 1k21701).

Schedule 3 contains a new authorisation, for a preparation of *Pediococcus pentosaceus* (IMI 507024) (identification number 1k21016).

Schedule 4 contains a new authorisation, for a preparation of *Pediococcus pentosaceus* (IMI 507025) (identification number 1k21017).

Schedule 5 contains a new authorisation, for a preparation of *Lactiplantibacillus plantarum* (IMI 507026) (identification number 1k21601).

Schedule 6 contains a new authorisation, for a preparation of *Lactiplantibacillus plantarum* (IMI 507027) (identification number 1k21602).

(20) EUR 2012/1021. This Regulation was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2019/221. See regulation 6 for amendments to EUR 2019/221.

(21) EUR 2012/1196.

(22) EUR 2018/1569.

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Schedule 7 contains a new authorisation, for a preparation of *Lactiplantibacillus plantarum* (IMI 507028) (identification number 1k21603).

Schedule 8 contains a new authorisation, for a preparation of *Lactiplantibacillus plantarum* (DSM 26571) (identification number 1k1604).

Schedule 9 contains a renewal (with modification) of an authorisation of endo-1,4-beta-xylanase produced from *Trichoderma reesei* (CBS 114044) (EC 3.2.1.8) (identification number 4a8i). The modifications on renewal of the authorisation are—

- the identification number of the additive is changed from 4a8 to 4a8i;
- the minimum level of stock enzyme activity is reduced to 160,000 BXU/g in both solid and liquid forms (from 4,000,000 BXU/g in the solid form and 400,000 BXU/g in the liquid form).

Schedule 10 contains a renewal (with modification) of an authorisation of 6-phytase (EC 3.1.3.26) produced from *Trichoderma reesei* (CBS 122001) (identification number 4a12). The modification on renewal of the authorisation is—

- the minimum level of stock enzyme activity is reduced to 5,000 PPU/g in the liquid form (from 10,000 PPU/g).

Schedule 11 contains a new authorisation, for L#lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c326).

Schedule 12 contains a new authorisation, for L#lysine monohydrochloride produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c327).

Schedule 13 contains a new authorisation, for 3-nitrooxypropanol (identification number 4c1).

Regulation 3(2) provides that authorisations granted by these Regulations are valid for a period of ten years in accordance with Article 9(7) of EUR 2003/1831. This is subject to Article 14(4) of that Regulation, which provides for an extension of the authorisation period in certain circumstances where an application for renewal has been submitted.

Regulation 4 contains transitional provision. The renewal of authorisation of the feed additive under Schedule 9 is subject to a change to the identification number of the additive (from “4a8” to “4a8i”). Regulation 4 allows the continued production and labelling of products, for the specified limited time periods, under the conditions of the prior authorisation and the labelling requirements applicable immediately before the coming into force of these Regulations. Products produced within the transitional periods may be marketed and used until stocks are exhausted.

Regulation 5 amends Commission Implementing [Regulation \(EU\) No601/2013](#) concerning the authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate, cobalt(II) sulphate heptahydrate and coated granulated cobalt(II) carbonate hydroxide (2:3) monohydrate as feed additives (EUR 2013/601), to remove spent entries relating to four feed additives. The authorisations for those feed additives expired at the end of 14 July 2014. Those four feed additives have now been provisionally authorised for a further 5 years, in relation to Wales, by administrative decision of the Welsh Ministers dated 20 June 2023, and made pursuant to Article 15 of EUR 2003/1831. The forms of authorisations for those feed additives were prescribed by the Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023 ([S.I. 2023/678 \(W. 100\)](#)).

Regulation 6 revokes, in relation to Wales, minor amendment provisions relating to instruments that are revoked by regulation 7 (and Schedule 14).

Regulation 7 and Schedule 14 revoke, in relation to Wales, spent instruments including the prior authorisations for the feed additives now authorised by Schedules 1, 9 and 10.

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

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