

2023 No. 339

AGRICULTURE

**The Feed Additives (Authorisations) (Scotland) Regulations
2023**

Made - - - - *8th November 2023*

Laid before the Scottish Parliament *10th November 2023*

Coming into force - - *22nd December 2023*

The Scottish Ministers make the following 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(a), and all other powers enabling them to do so.

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

Citation, commencement and extent

1.—(1) These Regulations may be cited as the Feed Additives (Authorisations) (Scotland) Regulations 2023 and come into force on 22 December 2023.

(2) These Regulations extend to Scotland only.

Interpretation

2.—(1) In these Regulations—

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

“Regulation 429/2008” means Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives(c),

“Regulation 152/2009” means Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed(d),

(a) EUR 2003/1831; relevant amending instruments are S.I. 2019/654, S.I. 2022/377 and 1351. S.I. 2019/654 was amended by S.I. 2020/1504. See Article 2 for the definitions of “prescribe” and “appropriate authority”. Article 9(1) applies in relation to renewals in accordance with Article 14.

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

(c) EUR 2008/429; relevant amending instruments are S.I. 2019/654 and S.I. 2022/1351. S.I. 2019/654 was amended by S.I. 2020/1504.

(d) EUR 2009/152; relevant amending instruments are S.I. 2019/654 and S.I. 2022/1351.

“Regulation 767/2009” means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, amending European Parliament and Council Regulation (EC) No 1831/2003 and repealing Council Directive 79/373/EEC, Commission Directive 80/511/EEC, Council Directives 82/471/EEC, 83/228/EEC, 93/74/EEC, 93/113/EC and 96/25/EC and Commission Decision 2004/217/EC(a).

(2) Unless the contrary intention appears, any expression used both in these Regulations and in Regulation 1831/2003 or Regulation 767/2009 has the same meaning as it has in those Regulations, respectively.

(3) In schedules 1 to 13—

- (a) expressions used to refer to species or categories of animals that are also used in Annex 4 (categories and definitions of target animals and indication of the minimum duration of efficacy studies) of Regulation 429/2008 have the same meaning as in that Annex,
- (b) any reference to a minor species is to be read in accordance with the definition of “minor species” in Article 1 (definitions) of Regulation 429/2008.

Authorisations

3.—(1) Schedules 1 to 13 have effect.

(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 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” means the feed additive endo-1,4-beta-xylanase (EC 3.2.1.8), with the identification number 4a8, authorised under the prior authorisation,

“prior authorisation” 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)(b).

Amendment of Commission Implementing Regulation (EU) No 601/2013

5.—(1) Commission Implementing Regulation (EU) No 601/2013 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(c) is amended as follows.

(2) In the Annex, in the table, omit the entries for—

- (a) cobalt(II) acetate tetrahydrate (identification number 3b301),

(a) EUR 2009/767, amended by S.I. 2019/654 and S.I. 2022/1351.

(b) EUR 2009/902, to which there are amendments not relevant to this instrument.

(c) EUR 2013/601, amended by EUR 2014/131.

- (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) No 2019/221

6.—(1) Commission Implementing Regulation (EU) No 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(a) is amended as follows.

(2) The following Articles are omitted—

- (a) Article 4 (Amendment to Commission Regulation (EU) No 9/2010),
- (b) Article 7 (Amendment to Commission Implementing Regulation (EU) No 528/2011),
- (c) Article 9 (Amendment to Commission Implementing Regulation (EU) No 1021/2012).

Revocations

7.—(1) The instrument listed in paragraph 1 of schedule 14 is revoked subject to regulation 4.

(2) The instruments listed in paragraphs 2 to 10 of schedule 14 are revoked.

JENNI MINTO

Authorised to sign by the Scottish Ministers

St Andrew's House,
Edinburgh
8th November 2023

(a) EUR 2019/221.

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

Authorisation

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

Table

<i>Column 1</i>	<i>Column 2</i>
<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 (b)
<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 No: 9025-57-4(c) • EC (IUBMB) No: 3.2.1.8(d) • EINECS No: 232-800-2(e)
<i>Analytical method(f)</i>	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

(a) This authorisation is a renewal (with modifications) of the authorisations granted under Commission Regulation (EU) No 9/2010, Commission Implementing Regulation (EU) No 528/2011 and Commission Implementing Regulation (EU) No 1021/2012. Those Regulations are revoked by regulation 7, and schedule 14, of these Regulations. The explanatory note to these Regulations sets out the modifications made to those authorisations.

(b) Enzyme activity: one unit is the amount of enzyme which releases 0.48 micromoles (µmol) of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH 4.2 and 50°C.

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

(e) 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.

(f) 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.

<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>		No maximum
<i>Content of endo-1,4-beta-xylanase (EC 3.2.1.8) (units of activity/kg of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	<ul style="list-style-type: none"> • All poultry species: 625 U/kg • Piglets (suckling and weaned), pigs for fattening and minor porcine species: 2000 U/kg
	<i>Maximum content</i>	No maximum
<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

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

Authorisation

1. The preparation 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.

Table

<i>Column 1</i>	<i>Column 2</i>	
<i>Additive</i>	<i>Lacticaseibacillus rhamnosus</i> (IMI 507023)	
<i>Identification number</i>	1k21701	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	1. For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15787: 2021(d) 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>	No maximum	
<i>Colony forming units of additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp) and moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0075”.

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

	moderately difficult to ensile 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

Authorisation

1. The preparation 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.

Table

<i>Column 1</i>	<i>Column 2</i>	
<i>Additive</i>	<i>Pediococcus pentosaceus</i> (IMI 507024)	
<i>Identification number</i>	1k21016	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15786: 2021(d) 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>	No maximum	
<i>Colony forming units of additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp) and moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The relevant dossier reference number is “FAD-2020-0076”.

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

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

Authorisation

1. The preparation 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.

Table

<i>Column 1</i>	<i>Column 2</i>	
<i>Additive</i>	<i>Pediococcus pentosaceus</i> (IMI 507025)	
<i>Identification number</i>	1k21017	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	1. For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15786: 2021(d) 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>	No maximum	
<i>Colony forming units of the additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp) and moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The relevant dossier reference number is “FAD-2020-0077”.

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

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

Authorisation

1. The preparation 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.

Table

<i>Column 1</i>	<i>Column 2</i>	
<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507026)	
<i>Identification number</i>	1k21601	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	1. For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15787: 2021(d) 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>	No maximum	
<i>Colony forming units of the additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp) and moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is "FAD-2020-0078".

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

	moderately difficult to ensile 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

Authorisation

1. The preparation 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.

Table

Column 1	Column 2	
<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507027)	
<i>Identification number</i>	1k21602	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	1. For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15787: 2021(d) 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>	No maximum	
<i>Colony forming units of the additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp) and moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0079”.

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

	moderately difficult to ensile 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

Authorisation

1. The preparation 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.

Table

Column 1	Column 2	
<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507028)	
<i>Identification number</i>	1k21603	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	1. For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15787:2021(d) 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>	No maximum	
<i>Colony forming units of the additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp) and moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0080”.

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

	moderately difficult to ensile 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

Authorisation

1. The preparation 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.

Table

Column 1	Column 2	
<i>Additive</i>	<i>Lactiplantibacillus plantarum</i> (DSM 26571)	
<i>Identification number</i>	1k1604	
<i>Authorisation holder(a)</i>	None	
<i>Additive category</i>	Technological additives	
<i>Functional group</i>	Silage(b) 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(c)</i>	1. For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar in accordance with BS EN 15787: 2021(d) 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>	No maximum	
<i>Colony forming units of the additive/kg of fresh material</i>	<i>Minimum content</i>	Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^8 CFU/kg
	<i>Maximum content</i>	No maximum
<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	

(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) The categories of silage are easy to ensile forage: >3% soluble carbohydrates in fresh material (e.g. whole plant maize, ryegrass, brome grass or sugar beet pulp), moderately difficult to ensile forage: 1.5–3% soluble carbohydrates in the fresh material (e.g. meadow grass, fescue or wilted alfalfa) and difficult to ensile forage: <1.5% soluble carbohydrates in the fresh material (e.g. orchard grass or leguminous plants) (see paragraph 1.4 of Annex III of Regulation 429/2008).

(c) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0091_en.

(d) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

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

Authorisation

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

Table

<i>Column 1</i>	<i>Column 2</i>
<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(b)
<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 No: 9025-57-4(c) • EC (IUBMB) No: 3.2.1.8(d) • EINECS No: 232-800-2(e)
<i>Analytical methods(f)</i>	1. 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 2. For the quantification of endo-1,4-beta-xylanase (EC 3.2.1.8) in feed materials and compound feed:

(a) This authorisation is a renewal (with modifications) of the authorisation granted under Commission Regulation (EC) No 902/2009. That Regulation is revoked by regulation 7, and schedule 14, of these Regulations. The explanatory note to these Regulations sets out the modifications made to that authorisation.

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

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

(e) 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.

(f) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0071_en.

		<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 arabinoxylan 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 • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
<i>Maximum age</i>		No maximum
<i>Content of endo-1,4-beta-xylanase (EC 3.2.1.8) (units of activity (BXU/kg) of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	<ul style="list-style-type: none"> • Chickens for fattening, chickens reared for laying: 8,000 BXU/kg • Turkeys for fattening, turkeys reared for breeding: 16,000 BXU/kg • Piglets (weaned): 24,000 BXU/kg
	<i>Maximum content</i>	No maximum
<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

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 poultry for fattening, poultry for breeding, poultry for laying and pigs

Authorisation

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

Table

<i>Column 1</i>	<i>Column 2</i>
<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(b)/g for the solid form and 5000 PPU/g for the liquid form
<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 No: 9001-89-2(c) • EC (IUBMB) No: 3.1.3.26(d) • EINECS No: 232-630-9(e)
<i>Analytical methods(f)</i>	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

- (a) This authorisation is a renewal (with modification) of the authorisations 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, and schedule 14, of these Regulations. The explanatory note to these Regulations sets out the modification made to those authorisations.
- (b) Enzyme activity is expressed in PPU units, where one 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.
- (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 assigned by the International Union of Biochemistry and Molecular Biology (IUBMB) <https://iubmb.org>.
- (e) 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.
- (f) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2008-0040_en.

<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>		No maximum	
<i>Content of 6-phytase (units of activity (PPU/kg) of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	Pigs	250 PPU/kg
		Poultry for breeding Poultry for fattening	
	<i>Maximum content</i>	Poultry for laying	125 PPU/kg
<i>Other provisions</i>		No maximum	
		The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture	

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

Authorisation

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

Table

<i>Column 1</i>	<i>Column 2</i>
<i>Additive</i>	L-lysine base (liquid)
<i>Identification number</i>	3c326
<i>Authorisation holder(a)</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 No: 56-87-1(b) • EINECS No: 200-294-2(c)
<i>Analytical methods(d)</i>	<p>1. 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) in accordance with BS EN ISO 17180: 2013(e) <p>2. 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 Regulation 152/2009 (Annex III, Part F) <p>3. For the quantification of lysine in water:</p>

(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 substance 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)4503369-31/08/2020” and “JRC F.5/CvH/MGH/AS/Ares” and last updated on 16 October 2020. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.

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

		<ul style="list-style-type: none"> • 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 Regulation 152/2009 (Annex III, Part F)
<i>Species or category of animal</i>		All animal species
<i>Maximum age</i>		No maximum
<i>Content of L-lysine (mg/kg of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	No minimum
	<i>Maximum content</i>	No maximum
<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 base (liquid) may be placed on the market and used as an additive consisting of a preparation

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

Authorisation

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

Table

<i>Column 1</i>	<i>Column 2</i>
<i>Additive</i>	L-lysine monohydrochloride (technically pure)
<i>Identification number</i>	3c327
<i>Authorisation holder(a)</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%
<i>Characterisation of the active substance(s)</i>	L-lysine monohydrochloride (technically pure) produced by fermentation with <i>Corynebacterium glutamicum</i> (KCCM 80216 or KCTC 12307BP) L-lysine monohydrochloride (C ₆ H ₁₅ ClN ₂ O ₂) <ul style="list-style-type: none"> • CAS No: 657-27-2(b) • EINECS No: 211-519-9(c)
<i>Analytical methods(d)</i>	1. For the identification of L-lysine monohydrochloride in the feed additive: <ul style="list-style-type: none"> • Food Chemicals Codex “L-lysine monohydrochloride monograph”(e) 2. 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) in accordance with BS EN ISO 17180: 2013(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 substance 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)4503369-31/08/2020” and “JRC F.5/CvH/MGH/AS/Ares” and last updated on 16 October 2020. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.

(e) 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>

(f) 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 from the British Standards Institution <https://knowledge.bsigroup.com>.

		<p>3. 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 Regulation 152/2009 (Annex III, Part F) <p>4. 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) 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 Regulation 152/2009 (Annex III, Part F)
<i>Species or category of animal</i>		All animal species
<i>Maximum age</i>		No maximum
<i>Content of L-lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	No minimum
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		<p>1. The lysine content must be stated on the labelling of the additive</p> <p>2. L-lysine monohydrochloride (technically pure) may be placed on the market and used as an additive consisting of a preparation</p>

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 for reproduction

Authorisation

1. The preparation 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.

Table

<i>Column 1</i>	<i>Column 2</i>	
<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, consisting of particles with a diameter < 50µm: 0.4%	
<i>Characterisation of the active substance(s)</i>	3-nitrooxypropanol (C ₃ H ₇ NO ₄) <ul style="list-style-type: none"> • CAS No: 100502-66-7(a) 	
<i>Analytical methods(b)</i>	For quantification of 3-nitrooxypropanol in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Reversed phase high performance liquid chromatography with spectrophotometric detection (HPLC-UV) 	
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Ruminants for milk production • Ruminants for reproduction 	
<i>Maximum age</i>	No maximum	
<i>Content of 3-nitrooxypropanol (mg/kg of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	53 mg/kg
	<i>Maximum content</i>	88 mg/kg
<i>Other provisions</i>	<ol style="list-style-type: none"> 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 feed in the form of a premixture 	

(a) 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>.

(b) 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. The document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en.

SCHEDULE 14

Regulation 7

Revocations

1. 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)(a).

2. 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.)(b).

3. 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)(c).

4. 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)(d).

5. Commission Implementing Regulation (EU) No 528/2011 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.)(e).

6. Commission Implementing Regulation (EU) No 886/2011 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)(f).

7. Commission Implementing Regulation (EU) No 1110/2011 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)(g).

8. Commission Implementing Regulation (EU) No 1021/2012 concerning the authorisation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (ATCC PTA 5588) as a feed additive for minor poultry species other than ducks (holder of authorisation Danisco (UK) Ltd, trading as Danisco Animal Nutrition and represented by Genencor International B.V.)(h).

9. Commission Implementing Regulation (EU) No 1196/2012 amending Regulation (EU) No 9/2010 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)(i).

10. Commission Implementing Regulation (EU) No 2018/1569 amending Commission Implementing Regulation (EU) No 1110/2011 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed

-
- (a) EUR 2009/902.
 - (b) EUR 2010/9.
 - (c) EUR 2010/277.
 - (d) EUR 2010/891.
 - (e) EUR 2011/528.
 - (f) EUR 2011/886.
 - (g) EUR 2011/1110.
 - (h) EUR 2012/1021.
 - (i) EUR 2012/1196.

additive for laying hens, minor poultry species and pigs for fattening (holder of authorisation Roal Oy)(a).

(a) EUR 2018/1569.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision regarding the authorisation of feed additives under Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (“Regulation (EC) 1831/2003”) in Scotland.

Regulation 3(1) and schedules 1 to 13 provide for the authorisation of 13 feed additives.

Schedule 1 contains a renewal of the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 143953) (identification number 4a11). The authorisation has been modified as follows:—

- the strain identification number for *Trichoderma reesei* is updated from “ATCC PTA 5588” to “CBS 142953”,
- the minimum content of the feed additive for turkeys for fattening is reduced from 1,250 to 625 units of activity per kilogram of complete feed (U/kg), to provide that the minimum content is 625 U/kg for all poultry species.

Schedule 2 contains a new authorisation, for a preparation of *Lacticaseibacillus rhamnosus* (formerly *Lactobacillus 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* (formerly *Lactobacillus plantarum*) (IMI 507026) (identification number 1k21601).

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

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

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

Schedule 9 contains a renewal of the authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 114044) (identification number 4a8i). The authorisation has been modified as follows:—

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

Schedule 10 contains a renewal of the authorisation of a preparation of 6-phytase (EC 3.1.3.26) produced from *Trichoderma reesei* (CBS 122001) (identification number 4a12). The authorisation has been modified as follows:—

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

Schedule 11 contains a new authorisation, for L-lysine (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 a preparation of 3-nitrooxypropanol (identification number 4c1).

Regulation 3(2) provides that the authorisations are valid for a period of 10 years, in accordance with Article 9(7) of Regulation (EC) 1831/2003. This is subject to Article 14(4) of that Regulation, which provides for an extension of the authorisation period in certain circumstances following the submission of an application for renewal.

Regulation 4 makes transitional provision in relation to the feed additive endo-1,4-beta-xylanase (EC 3.2.1.8) the authorisation of which is renewed under schedule 9. Under the renewal of the authorisation the identification number of the feed additive is changed. 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) No 601/2013 by removing from the Annex the authorisations for cobalt (II) acetate tetrahydrate, cobalt (II) carbonate, cobalt (II) carbonate hydroxide (2:3) monohydrate and cobalt (II) sulphate heptahydrate. This is consequential to the Feed Additives (Form of Provisional Authorisations) (Cobalt (II) Compounds) (Scotland) Regulations 2023 (S.S.I. 2023/170) which provisionally authorised these feed additives.

Regulation 6 amends Commission Implementing Regulation (EU) No 2019/221 by revoking articles which amend Commission Regulation (EU) No 9/2010 and Commission Implementing Regulations (EU) No 528/2011 and 1021/2012. Those Regulations are revoked by regulation 7 and schedule 14.

Regulation 7 and schedule 14 revoke retained direct EU legislation that contains previous authorisations for the feed additives now authorised by schedules 1, 9 and 10.

A business and regulatory impact assessment has not been produced for this instrument as no significant impact on the private or voluntary sector is foreseen.

© Crown copyright 2023

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, the King's Printer for Scotland.

£8.14

<http://www.legislation.gov.uk/id/ssi/2023/339>

ISBN 978-0-11-105853-4



9 780111 058534