

2023 No. 1196

AGRICULTURE, ENGLAND

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

<i>Made</i>	- - - -	<i>8th November 2023</i>
<i>Laid before Parliament</i>		<i>9th November 2023</i>
<i>Coming into force</i>		<i>22nd December 2023</i>

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The Secretary of State makes 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^(a).

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) there has been open and transparent public consultation during the preparation and evaluation of these Regulations.

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

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

Citation, commencement, extent, and application

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

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

Interpretation

2.—(1) In these Regulations—

- (a) “Regulation (EC) 1831/2003” means Regulation (EC) No. 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;
- (b) “Regulation (EC) 429/2008” means Commission Regulation (EC) No. 429/2008 on detailed rules for the implementation of Regulation (EC) 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives(a);
- (c) “Regulation (EC) 152/2009” means Commission Regulation (EC) No. 152/2009 laying down the methods of sampling and analysis for the official control of feed(b).

(2) Any expression used both in these Regulations and in Regulation (EC) 1831/2003 or Regulation (EC) No. 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed, etc(c) has the same meaning as it has in those Regulations.

(3) In Schedules 1 to 13, in the tables, in the row relating to “*Species or category of animal*”, expressions used that are also used in Annex 4 of Regulation (EC) 429/2008 (categories and definitions of target animals etc.) have the same meaning as in that Annex.

Authorisation of various feed additives

3. Schedules 1 to 13 have effect.

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

4. In the Annex to 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(d) omit—

- (a) the entry for cobalt(II) acetate tetrahydrate;
- (b) the entry for cobalt(II) carbonate;
- (c) the entry for cobalt(II) carbonate hydroxide (2:3) monohydrate;
- (d) the entry for cobalt(II) sulphate heptahydrate.

Amendment of Commission Implementing Regulation (EU) No. 2019/221

5.—(1) Commission Implementing Regulation (EU) No. 2019/221(e) is amended as follows.

(2) Omit Article 4 (Amendment to Commission Regulation (EU) No 9/2010).

(3) Omit Article 7 (Amendment to Commission Implementing Regulation (EU) No 528/2011).

(4) Omit Article 9 (Amendment to Commission Implementing Regulation (EU) No 1021/2012).

(a) EUR 2008/429, amended by S.I. 2019/654 and 2022/1351. S.I. 2019/654 was itself amended by S.I. 2020/1504.

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

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

(d) EUR 2013/601.

(e) EUR 2019/221.

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

6.—(1) Stocks of the relevant feed additive, and premixtures containing it, which are produced and labelled before the end of 21st June 2024 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 22nd December 2023, may continue to be placed on the market and used until they are exhausted.

(2) Stocks of feed materials and compound feed containing the relevant feed additive, intended for food-producing animals, which are produced and labelled before the end of 21st December 2024 in accordance with the conditions of the prior authorisation and the labelling requirements applicable before 22nd December 2023, may continue to be placed on the market and used until they are exhausted.

(3) In this regulation—

“relevant feed additive” means the feed additive 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)(a).

Revocation of retained direct EU legislation

7.—(1) The instruments in Part 1 of Schedule 14 are revoked.

(2) The instrument in Part 2 of Schedule 14 is revoked subject to regulation 6.

8th November 2023

Neil O’Brien
Parliamentary Under-Secretary of State,
Department of Health and Social Care

SCHEDULE 1

Regulation 3

Renewal of authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 143953, formerly 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 extending to the use for 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), belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition, in accordance with the specifications in the following table**(b)**.

(a) EUR 2009/902.

(b) This authorisation is a renewal 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(1) of, and Schedule 14 to these Regulations. This renewal differs from the previous authorisation by updating the bacterial strain from “ATCC PTA 5588” to “CBS 143953”. Additionally, 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.

<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 no: 9025-57-4⁽²⁾ • EC (IUBMB) no: 3.2.1.8⁽³⁾ • EINECS no: 232-800-2⁽⁴⁾ 	
<i>Analytical method</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>	Not applicable	
<i>Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	<ul style="list-style-type: none"> • For all poultry species: 625 U/kg • For piglets (suckling and weaned), pigs for fattening and minor porcine species: 2,000 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	

⁽¹⁾ 1 unit (U) 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.

⁽²⁾ 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>.

⁽³⁾ This is the identification number adopted by the European Commission which aligns with the numerical system of the International Union of Biochemistry and Molecular Biology (IUBMB) <https://iubmb.org>.

⁽⁴⁾ 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.

⁽⁵⁾ Details of the analytical method is set out in the document referenced “JRC.D.5/FSQ/CvH/DM/ag/ARES(2012)353089” and last updated on 6th 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 on updated 6th June 2016, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0007_en.

SCHEDULE 2

Regulation 3

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), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Identification number</i>		1k21701
<i>Authorisation holder</i> ⁽¹⁾		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> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of the additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy or moderately difficult to ensile fresh materials only. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and last updated on 21st April 2021, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The dossier reference number is FAD-2020-0075.

⁽³⁾ 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 31st December 2021 (ISBN 978 0 580 99831 7) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 3

Regulation 3

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

The preparation of *Pediococcus pentosaceus* (IMI 507024), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Pediococcus pentosaceus</i> (IMI 507024)
<i>Identification number</i>		1k21016
<i>Authorisation holder</i> ⁽¹⁾		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 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</i> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of the additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy or moderately difficult to ensile fresh materials only. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1902366 – 16/03/2021” and last updated on 21st April 2021, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The dossier reference number is FAD-2020-0076.

⁽³⁾ 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 30th November 2021 (ISBN 978 0 580 99830 0) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 4

Regulation 3

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), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Pediococcus pentosaceus</i> (IMI 507025)
<i>Identification number</i>		1k21017
<i>Authorisation holder</i> ⁽¹⁾		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 active substance(s)</i>		Viable cells of <i>Pediococcus pentosaceus</i> (IMI 507025)
<i>Analytical methods</i> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of the additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy or moderately difficult to ensile fresh materials only. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1902366 – 16/03/2021” and last updated on 21st April 2021, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. The dossier reference number is FAD-2020-0077.

⁽³⁾ 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 30th November 2021 (ISBN 978 0 580 99830 0) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 5

Regulation 3

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), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Lactiplantibacillus plantarum</i> (IMI 507026)
<i>Identification number</i>		1k21601
<i>Authorisation holder</i> ⁽¹⁾		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> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of the additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy or moderately difficult to ensile fresh materials only. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1687524-08/-3/2021” and last updated on 21st April 2021, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The dossier reference number is FAD-2020-0078.

⁽³⁾ 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 31st December 2021 (ISBN 978 0 580 99831 7) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 6

Regulation 3

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), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Lactiplantibacillus plantarum</i> (IMI 507027)
<i>Identification number</i>		1k21602
<i>Authorisation holder</i> ⁽¹⁾		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</i> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of the additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy or moderately difficult to ensile fresh materials only. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and last updated on 21st April 2021, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The dossier reference number is FAD-2020-0079.

⁽³⁾ 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 31st December 2021 (ISBN 978 0 580 99831 7) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 7

Regulation 3

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), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Lactiplantibacillus plantarum</i> (IMI 507028)
<i>Identification number</i>		1k21603
<i>Authorisation holder</i> ⁽¹⁾		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</i> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of the additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy or moderately difficult to ensile fresh materials only. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^9 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and last updated on 21st April 2021, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The dossier reference number is FAD-2020-0080.

⁽³⁾ 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 31st December 2021 (ISBN 978 0 580 99831 7) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 8

Regulation 3

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), belonging to the additive category ‘technological additives’ and to the functional group ‘silage additives’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>		<i>Lactiplantibacillus plantarum</i> (DSM 26571)
<i>Identification number</i>		1k1604
<i>Authorisation holder</i> ⁽¹⁾		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</i> ⁽²⁾		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⁽³⁾
		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>		Not applicable
<i>Colony-forming units (CFU) of additive/kg of fresh material</i>	<i>Minimum content</i>	For use in easy, moderately difficult and difficult to ensile fresh materials. Minimum content of the additive when not combined with other micro-organisms as silage additives: 1×10^8 CFU/kg ⁽⁴⁾
	<i>Maximum content</i>	No maximum
<i>Other provisions</i>		The storage conditions must be stated in the directions for use of the feed additive and premixture

⁽¹⁾ 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.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2020)5563084 – 15/10/2020” and last updated on 16th October 2020, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0091_en.

⁽³⁾ 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 31st December 2021 (ISBN 978 0 580 99831 7) and available at: <https://knowledge.bsigroup.com>.

⁽⁴⁾ Easy to ensile forage: > 3 % soluble carbohydrates in fresh material; moderately difficult to ensile forage: 1.5-3.0 % soluble carbohydrates in the fresh material; difficult to ensile forage: <1.5 % soluble carbohydrates in the fresh material in accordance with Regulation (EC) 429/2008.

SCHEDULE 9

Regulation 3

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

The preparation of endo-1,4-beta-xylanase (EC 3.2.1.8), belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table(a).

<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 no: 9025-57-4⁽²⁾ • EC (IUBMB) no: 3.2.1.8⁽³⁾ • EINECS no: 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 • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
<i>Maximum age</i>		Not applicable
<i>Content of Endo-1,4-beta-xylanase (units of activity (BXU)/kg of complete feed with a moisture</i>	<i>Minimum content</i>	<ul style="list-style-type: none"> • For chickens for fattening and chickens reared for laying: 8,000 BXU/kg • For turkeys for fattening and turkeys reared for breeding: 16,000 BXU/kg • For piglets (weaned): 24,000 BXU/kg
	<i>Maximum</i>	No maximum

(a) This authorisation is a renewal of the authorisation granted under Commission Regulation (EC) 902/2009. 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) No 1110/2011 (“EUR 2011/1110”). EUR 2011/1110 expired on 24 November 2021. EUR 902/2009 and 2011/1110 are revoked by regulation 7 of, and Schedule 14 to, these Regulations. This renewal differs from the previous authorisation as the identification number has been updated from “4a8” to “4a8i” and the minimum level of stock enzyme is reduced from 4,000,000 BXU/g in solid form and 400,000 BXU/g in liquid form.

<i>content of 12%)</i>	<i>content</i>	
<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 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.

⁽²⁾ 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>.

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

⁽⁴⁾ 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.

⁽⁵⁾ Details of the analytical method is set out in the document referenced “Ares(2019)3101222-10/05/2019” and last updated on 2nd July 2019, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0071_en.

SCHEDULE 10

Regulation 3

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), belonging to the additive category ‘zootechnical additives’ and to the functional group ‘digestibility enhancers’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table(a).

<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 no: 9001-89-2⁽²⁾ • EC (IUBMB) no: 3.1.3.26⁽³⁾ • EINECS no: 232-630-9⁽⁴⁾
<i>Analytical method</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

(a) 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(1) of, and Schedule 14 these Regulations. This renewal differs from the previous authorisation as the minimum level of stock enzyme activity is reduced from 10,000 PPU/g to 5,000 PPU/g in the liquid forms.

		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 and poultry for laying
<i>Maximum age</i>		Not applicable
<i>Content of 6-phytase (units of activity (PPU)/kg of complete feed with a moisture content of 12%)</i>	<i>Minimum content</i>	<ul style="list-style-type: none"> • For pigs, poultry for breeding and poultry for fattening: 250 PPU/kg • For poultry for laying: 125 PPU/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

(1) Enzyme activity 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.

(2) 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>.

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

(4) 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.

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

SCHEDULE 11

Regulation 3

Authorisation of L-lysine base (liquid) produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c326) as a feed additive for all for all animal species

The substance of L-lysine base (liquid), belonging to the additive category 'nutritional additives' and to the functional group 'amino acids, their salts and analogues', is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	L-lysine base (liquid)
<i>Identification number</i>	3c326
<i>Authorisation holder</i> ⁽¹⁾	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>	<p>L-lysine base (liquid) ($\text{C}_6\text{H}_{14}\text{N}_2\text{O}_2$) produced by fermentation with <i>Corynebacterium glutamicum</i> (KCCM 80216 or KCTC 12307BP)</p> <ul style="list-style-type: none"> • CAS no: 56-87-1⁽²⁾ • EINECS no: 200-294-2⁽³⁾

<i>Analytical methods</i> ⁽⁴⁾	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⁽⁵⁾ 	
	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 (Annex 3-F) 	
	For the quantification of lysine in water: <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⁽⁵⁾; 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>	Not applicable	
<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 	

⁽¹⁾ 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.

⁽²⁾ 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>.

⁽³⁾ 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.

⁽⁴⁾ Details of the analytical methods is set out in the document referenced “Ares(2020)4503369-31/08/2020” and last updated on 16th October 2020, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.

⁽⁵⁾ BS EN ISO 17180:2013 “*Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures*”. Published by the British Standards Institution on 30th April 2013 (ISBN 978 0 580 76077 8) and available at: <https://knowledge.bsigroup.com>.

SCHEDULE 12

Regulation 3

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), belonging to the additive category ‘nutritional additives’ and to the functional group ‘amino acids, their salts and analogues’, is authorised as an additive in animal nutrition in accordance with the specifications in the following table.

<i>Additive</i>	L-lysine monohydrochloride (technically pure)
<i>Identification number</i>	3c327
<i>Authorisation holder</i> ⁽¹⁾	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) (C ₆ H ₁₅ ClN ₂ O ₂) produced by fermentation with <i>Corynebacterium glutamicum</i> (KCCM 80216 or KCTC 12307BP) <ul style="list-style-type: none"> • CAS no: 657-27-2⁽²⁾ • EINECS no: 211-519-9⁽³⁾
<i>Analytical methods</i> ⁽⁴⁾	For the identification of L-lysine monohydrochloride in the feed additive: <ul style="list-style-type: none"> • Food Chemicals Codex⁽⁵⁾ “L-lysine monohydrochloride monograph”
	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⁽⁶⁾
	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 (Annex 3-F)
	For the quantification of lysine in water: <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⁽⁶⁾; 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>	Not applicable
<i>Content of L-</i>	<i>Minimum</i>
	No minimum

<i>lysine monohydrochloride (mg/kg of complete feed with a moisture content of 12%)</i>	<i>content</i>	
	<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 monohydrochloride (technically pure) may be placed on the market and used as an additive consisting of a preparation

(1) 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.

(2) 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>.

(3) 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.

(4) Details of the analytical methods is set out in the document referenced “Ares(2020)4503369-31/08/2020” and last updated on 16th October 2020, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.

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

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

SCHEDULE 13

Regulation 3

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

The preparation of 3-nitrooxypropanol 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, in accordance with the specifications in the following 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 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⁽¹⁾
<i>Analytical method⁽²⁾</i>	For the 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>		Not applicable
<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

⁽¹⁾ 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>.

⁽²⁾ Details of the analytical method is set out in the document referenced “Ares(2020)981992-15/02/2020” and last updated on 4th May 2020, available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en.

SCHEDULE 14

Regulation 7

Revocation of retained direct EU legislation

PART 1

Revocation of retained direct EU legislation in accordance with regulation 7(1)

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.)(a).

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)(b).

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)(c).

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.)(d).

(a) EUR 2010/9.
(b) EUR 2010/277.
(c) EUR 2010/891.
(d) EUR 2011/528.

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)(a).

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)(b).

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.)(c).

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)(d).

Commission Implementing Regulation (EU) 2018/1569 amending 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)(e).

PART 2

Revocation of retained direct EU legislation in accordance with regulation 7(2)

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)(f).

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations authorise the placing on the market of specific feed additives in England.

Regulation 3 and Schedules 1 – 13 contain the following authorisations—

- Schedule 1 renews 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) and authorises it for a new use to be used in feed by extending to all poultry species and to suckling piglets and minor porcine species;
- Schedule 2 authorises a new preparation of *Lacticaseibacillus rhamnosus* (IMI 507023) (identification number 1k21701);
- Schedule 3 authorises a new preparation of *Pediococcus pentosaceus* (IMI 507024) (identification number 1k21016);
- Schedule 4 authorises a new preparation of *Pediococcus pentosaceus* (IMI 507025) (identification number 1k21017);

(a) EUR 2011/886.
(b) EUR 2011/1110.
(c) EUR 2012/1021.
(d) EUR 2012/1196.
(e) EUR 2018/1569.
(f) EUR 2009/902.

- Schedule 5 authorises a new preparation of *Lactiplantibacillus plantarum* (IMI 507026) (identification number 1k21601);
- Schedule 6 authorises a new preparation of *Lactiplantibacillus plantarum* (IMI 507027) (identification number 1k21602);
- Schedule 7 authorises a new preparation of *Lactiplantibacillus plantarum* (IMI 507028) (identification number 1k21603);
- Schedule 8 authorises a new preparation of *Lactiplantibacillus plantarum* (DSM 26571) (identification number 1k1604);
- Schedule 9 renews the authorisation for a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 114044) (identification number 4a8i);
- Schedule 10 renews the authorisation for a preparation of 6-phytase (EC 3.1.3.26) produced from *Trichoderma reesei* (CBS 122001) (identification number 4a12);
- Schedule 11 authorises a new feed additive L-lysine base produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c326);
- Schedule 12 authorises a new feed additive L-lysine monohydrochloride produced from *Corynebacterium glutamicum* (KCCM 80216 or KCTC 12307BP) (identification number 3c327);
- Schedule 13 authorises a new preparation of 3-nitrooxypropanol (identification number 4c1).

Authorisations granted by these Regulations are valid for a period of ten 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 where an application for renewal has been submitted.

Regulation 4 amends Regulation (EU) No. 601/2013 by removing authorisation of cobalt(II) acetate tetrahydrate, cobalt(II) carbonate, cobalt(II) carbonate hydroxide (2:3) monohydrate and cobalt(II) sulphate heptahydrate. These feed additives have been provisionally authorised by the Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (England) Regulations 2023 (S.I. 2023/689).

Regulation 5 revokes minor amendment provisions relating to instruments that are revoked by regulation 7 and Schedule 14.

Regulation 6 is a transitional provision that enables the continued production and labelling of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 114044), for limited periods, under the conditions of its previous authorisation. Endo-1,4-beta-xylanase (EC 3.2.1.8) is now authorised under Schedule 9.

Regulation 7 and Schedule 14 revoke, in relation to England, retained EU Regulations that contain previous authorisations for feed additives now authorised by Schedules 1, 9 and 10.

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

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

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