



OFFERYNNAU STATUDOL CYMRU

2023 Rhif 1276 (Cy. 224)

AMAETHYDDIAETH, CYMRU

Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau)
(Cymru) 2023

<i>Gwnaed</i>	<i>27 Tachwedd 2023</i>
<i>Gosodwyd gerbron Senedd Cymru</i>	<i>29 Tachwedd 2023</i>
<i>Yn dod i rym</i>	<i>22 Rhagfyr 2023</i>

WELSH STATUTORY INSTRUMENTS

2023 No. 1276 (W. 224)

AGRICULTURE, WALES

The Feed Additives (Authorisations) (Wales) Regulations 2023

<i>Made</i>	<i>27 November 2023</i>
<i>Laid before Senedd Cymru</i>	<i>29 November 2023</i>
<i>Coming into force</i>	<i>22 December 2023</i>



OFFERYNNAU STATUDOL
CYMRU

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Rheoliadau Ychwanegion Bwyd
Anifeiliaid (Awdurdodiadau)
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The Feed Additives
(Authorisations) (Wales)
Regulations 2023

NODYN ESBONIADOL

(Nid yw'r nodyn hwn yn rhan o'r Rheoliadau)

EXPLANATORY NOTE

(This note is not part of the Regulations)

Mae Gweinidogion Cymru yn gwneud y Rheoliadau hyn yn unol â Rheoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid (EUR 1831/2003). Mae'r Rheoliadau hyn yn gwneud darpariaeth ar gyfer awdurdodi rhoi 13 o ychwanegion bwyd anifeiliaid ar y farchnad, eu prosesu a'u defnyddio.

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

Mae rheoliad 3, ac Atodlenni 1 i 13, yn darparu ar gyfer awdurdodi ychwanegion bwyd anifeiliaid.

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

Mae Atodlen 1 yn cynnwys adnewyddiad (ag addasiad) o awdurdodiad paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir o *Trichoderma reesei* (CBS 143953) (rhif adnabod 4a11), ac estyniad o'r defnydd awdurdodedig presennol i gwmpasu rhywogaethau/categoriâu ychwanegol o anifeiliaid. Yr addasiadau wrth adnewyddu'r awdurdodiad yw—

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

- mae'r rhif adnabod straen ar gyfer *Trichoderma reesei* wedi ei ddiweddarau i "CBS 142953" ("ATCC PTA 5588" yn flaenorol);
- mae isafswm cynnwys yr ychwanegyn bwyd anifeiliaid ar gyfer tyrcwn i'w pesgi wedi ei ostwng o 1,250 i 625 U/kg o fwyd anifeiliaid cyflawn.

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

Mae Atodlen 2 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Lacticaseibacillus rhamnosus* (IMI 507023) (rhif adnabod 1k21701).

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

Mae Atodlen 3 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Pediococcus pentosaceus* (IMI 507024) (rhif adnabod 1k21016).

Mae Atodlen 4 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Pediococcus pentosaceus* (IMI 507025) (rhif adnabod 1k21017).

Mae Atodlen 5 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Lactiplantibacillus plantarum* (IMI 507026) (rhif adnabod 1k21601).

Mae Atodlen 6 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Lactiplantibacillus plantarum* (IMI 507027) (rhif adnabod 1k21602).

Mae Atodlen 7 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Lactiplantibacillus plantarum* (IMI 507028) (rhif adnabod 1k21603).

Mae Atodlen 8 yn cynnwys awdurdodiad newydd, ar gyfer paratoad o *Lactiplantibacillus plantarum* (DSM 26571) (rhif adnabod 1k1604).

Mae Atodlen 9 yn cynnwys adnewyddiad (ag addasiad) o awdurdodiad endo-1,4-beta-sylanase a gynhyrchir o *Trichoderma reesei* (CBS 114044) (EC 3.2.1.8) (rhif adnabod 4a8i). Yr addasiadau wrth adnewyddu'r awdurdodiad yw—

- mae rhif adnabod yr ychwanegyn wedi ei newid o 4a8 i 4a8i;
- mae lefel isaf yr actifedd ensym stoc wedi ei gostwng i 160,000 BXU/g ar y ffurfiau solet a hylif (o 4,000,000 BXU/g ar y ffurf solet a 400,000 BXU/g ar y ffurf hylif).

Mae Atodlen 10 yn cynnwys adnewyddiad (ag addasiad) o awdurdodiad 6-ffytas (EC 3.1.3.26) a gynhyrchir o *Trichoderma reesei* (CBS 122001) (rhif adnabod 4a12). Yr addasiad wrth adnewyddu'r awdurdodiad yw—

- mae lefel isaf yr actifedd ensym stoc wedi ei gostwng i 5,000 PPU/g ar y ffurf hylif (o 10,000 PPU/g).

Mae Atodlen 11 yn cynnwys awdurdodiad newydd, ar gyfer sylfaen L-lysin (hylif) a gynhyrchir o *Corynebacterium glutamicum* (KCCM 80216 neu KCTC 12307BP) (rhif adnabod 3c326).

Mae Atodlen 12 yn cynnwys awdurdodiad newydd, ar gyfer L-lysin monohydroclorid a gynhyrchir o *Corynebacterium glutamicum* (KCCM 80216 neu KCTC 12307BP) (rhif adnabod 3c327).

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

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

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

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

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

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

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

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

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

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

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

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

Mae Atodlen 13 yn cynnwys awdurdodiad newydd, ar gyfer 3-nitrooxypropanol (rhif adnabod 4c1).

Mae rheoliad 3(2) yn darparu bod awdurdodiadau a roddir gan y Rheoliadau hyn yn ddilys am gyfnod o ddeng mlynedd yn unol ag Erthygl 9(7) o EUR 2003/1831. Mae hyn yn ddarostyngedig i Erthygl 14(4) o'r Rheoliad hwnnw, sy'n darparu ar gyfer estyn cyfnod yr awdurdodiad mewn amgylchiadau penodol pan fo cais i adnewyddu wedi ei gyflwyno.

Mae rheoliad 4 yn cynnwys darpariaeth drosiannol. Mae adnewyddu awdurdodiad yr ychwanegyn bwyd anifeiliaid o dan Atodlen 9 yn ddarostyngedig i newid i rif adnabod yr ychwanegyn (o "4a8" i "4a8i"). Mae rheoliad 4 yn caniatáu parhau i gynhyrchu a labelu cynhyrchion, am y cyfnodau cyfyngedig o amser a bennir, o dan amodau'r awdurdodiad ymlaen llaw a'r gofynion labelu sy'n gymwys yn union cyn i'r Rheoliadau hyn ddod i rym. Caniateir marchnata a defnyddio cynhyrchion a gynhyrchir o fewn y cyfnodau trosiannol hyd nes y bydd stociau wedi eu disbyddu.

Mae rheoliad 5 yn diwygio Rheoliad Gweithredu'r Comisiwn (EU) Rhif 601/2013 sy'n ymwneud ag awdurdodi cobalt(II) asetad tetrahydrad, cobalt(II) carbonad, cobalt(II) carbonad hydrocsid (2:3) monohydrad, cobalt(II) sylffad heptahydrad a cobalt(II) carbonad hydrocsid (2:3) monohydrad gronynnog araenedig fel ychwanegion bwyd anifeiliaid (EUR 2013/601), i ddileu cofnodion a ddisbyddwyd sy'n ymwneud â phedwar ychwanegyn bwyd anifeiliaid. Daeth yr awdurdodiadau ar gyfer yr ychwanegion bwyd anifeiliaid hynny i ben ar ddiwedd 14 Gorffennaf 2014. Mae'r pedwar ychwanegyn bwyd anifeiliaid hynny bellach wedi eu hawdurdodi dros dro am 5 mlynedd arall, o ran Cymru, drwy benderfyniad gweinyddol gan Weinidogion Cymru dyddiedig 20 Mehefin 2023, a wnaed yn unol ag Erthygl 15 o EUR 2003/1831. Rhagnodwyd ffurfiau'r awdurdodiadau ar gyfer yr ychwanegion bwyd anifeiliaid hynny gan Reoliadau Ychwanegion Bwyd Anifeiliaid (Ffurfi Awdurdodiadau Dros Dro) (Cyfansoddiad Cobalt(II)) (Cymru) 2023 (O.S. 2023/678 (Cy. 100)).

Mae rheoliad 6 yn dirymu, o ran Cymru, fân ddarpariaethau diwygio sy'n ymwneud ag offerynnau sydd wedi eu dirymu gan reoliad 7 (ac Atodlen 14).

Mae rheoliad 7 ac Atodlen 14 yn dirymu, o ran Cymru, offerynnau a ddisbyddwyd, gan gynnwys yr awdurdodiadau ymlaen llaw ar gyfer yr ychwanegion bwyd anifeiliaid sydd bellach wedi eu hawdurdodi gan Atodlenni 1, 9 a 10.

Gellir cael rhagor o wybodaeth, gan gynnwys mewn perthynas ag unrhyw ddogfennaeth y cyfeirir ati yn yr Atodlenni, gan yr Asiantaeth Safonau Bwyd yng

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

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

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

Regulation 5 amends Commission Implementing Regulation (EU) 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 (EUR 2013/601), to remove spent entries relating to four feed additives. The authorisations for those feed additives expired at the end of 14 July 2014. Those four feed additives have now been provisionally authorised for a further 5 years, in relation to Wales, by administrative decision of the Welsh Ministers dated 20 June 2023, and made pursuant to Article 15 of EUR 2003/1831. The forms of authorisations for those feed additives were prescribed by the Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023 (S.I. 2023/678 (W. 100)).

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

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

Further information, including in relation to any documentation referenced in the Schedules, can be obtained from the Food Standards Agency in Wales,

Nghymru, Llawr 4, Adeilad Llywodraeth Cymru, Parc Cathays, Caerdydd, CF10 3NQ neu drwy ysgrifennu at: regulated.products.wales@food.gov.uk.

Ystyriwyd Cod Ymarfer Gweinidogion Cymru ar gynnal Aseidiadau Effaith Rheoleiddiol mewn perthynas â'r Rheoliadau hyn. O ganlyniad, ystyriwyd nad oedd yn angenrheidiol cynnal asesiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

4th Floor, Welsh Government Building, Cathays Park, Cardiff, CF10 3NQ or by writing to regulated.products.wales@food.gov.uk.

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

2023 Rhif 1276 (Cy. 224)

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AMAETHYDDIAETH, CYMRU

AGRICULTURE, WALES

**Rheoliadau Ychwanegion Bwyd
Anifeiliaid (Awdurdodiadau)
(Cymru) 2023**

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

Gwnaed 27 Tachwedd 2023

Made 27 November 2023

*Gosodwyd gerbron Senedd
Cymru* 29 Tachwedd 2023

Laid before Senedd Cymru 29 November 2023

Yn dod i rym 22 Rhagfyr 2023

Coming into force 22 December 2023

Mae Gweinidogion Cymru yn gwneud y Rheoliadau hyn drwy arfer y pwerau a roddir gan Erthyglau 9(1) a 18A(3) o Reoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid(1).

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

Cynhaliwyd ymgynghoriad fel sy'n ofynnol gan Erthygl 9 o Reoliad (EC) Rhif 178/2002 Senedd Ewrop a'r Cyngor sy'n gosod egwyddorion a gofynion cyffredinol cyfraith bwyd, yn sefydlu Awdurdod Diogelwch Bwyd Ewrop ac yn gosod gweithdrefnau o ran materion diogelwch bwyd(2).

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

Enwi, rhychwant, cymhwyso a dod i rym

Title, extent, application and coming into force

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau) (Cymru) 2023.

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

(2) Mae'r Rheoliadau hyn—

(2) These Regulations—

- (a) yn rhychwantu Cymru a Lloegr;
- (b) yn gymwys o ran Cymru;
- (c) yn dod i rym ar 22 Rhagfyr 2023.

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

(1) EUR 2003/1831, a ddiwygiwyd gan O.S. 2019/654, 2022/377 a 1351. Diwygiwyd O.S. 2019/654 gan O.S. 2020/1504. Mae'r termau "prescribe" ac "appropriate authority" wedi eu diffinio yn Erthygl 2 o EUR 2003/1831. Mae Erthygl 9(1) yn gymwys mewn perthynas ag adnewyddiadau yn unol ag Erthygl 14.

(2) EUR 2002/178, a ddiwygiwyd gan O.S. 2019/641. Diwygiwyd O.S. 2019/641 gan O.S. 2020/1504.

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

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

Dehongli

2.—(1) Mae i ymadroddion Cymraeg a ddefnyddir yn y Rheoliadau hyn sy'n cyfateb i ymadroddion Saesneg yn Rheoliad 1831/2003 neu Reoliad 767/2009 yr un ystyr ag yn Rheoliad 1831/2003 neu Reoliad 767/2009, yn y drefn honno.

(2) Yn Atodlenni 1 i 13—

- (a) mae i ymadroddion Cymraeg a ddefnyddir i gyfeirio at rywogaethau neu gategoriâu o anifeiliaid sy'n cyfateb i ymadroddion Saesneg a ddefnyddir yn Atodiad 4 (categoriâu a diffiniadau o anifeiliaid targed etc.) i Reoliad 429/2008 yr un ystyr ag yn yr Atodiad hwnnw;
- (b) mae unrhyw gyfeiriad at fân rywogaeth i'w ddarllen yn unol â'r diffiniad o "minor species" yn Erthygl 1 o Reoliad 429/2008.

(3) Yn y rheoliad hwn—

ystyr "Rheoliad 1831/2003" ("*Regulation 1831/2003*") yw Rheoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid;

ystyr "Rheoliad 429/2008" ("*Regulation 429/2008*") yw Rheoliad y Comisiwn (EC) Rhif 429/2008 ar reolau manwl ar gyfer gweithredu Rheoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor o ran llunio a chyflwyno ceisiadau ac asesu ac awdurdodi ychwanegion bwyd anifeiliaid(1);

ystyr "Rheoliad 767/2009" ("*Regulation 767/2009*") yw Rheoliad (EC) Rhif 767/2009 Senedd Ewrop a'r Cyngor ar roi bwyd anifeiliaid ar y farchnad a'i ddefnyddio(2).

Awdurdodiadau

3.—(1) Mae Atodlenni 1 i 13 yn cynnwys awdurdodiadau ychwanegion bwyd anifeiliaid.

(2) Yn ddarostyngedig i Erthygl 14(4) (adnewyddu awdurdodiad) o Reoliad 1831/2003, mae'r awdurdodiadau a nodir yn Atodlenni 1 i 13 yn peidio â chael effaith ar ddiwedd 21 Rhagfyr 2033.

Interpretation

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

(2) In Schedules 1 to 13—

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

(3) In this regulation—

"Regulation 1831/2003" ("*Rheoliad 1831/2003*") means Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition;

"Regulation 429/2008" ("*Rheoliad 429/2008*") means Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives(1);

"Regulation 767/2009" ("*Rheoliad 767/2009*") means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed(2).

Authorisations

3.—(1) Schedules 1 to 13 contain authorisations of feed additives.

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

(1) EUR 2008/429, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(2) EUR 2009/767, a ddiwygiwyd gan O.S. 2019/654. Diwygiwyd O.S. 2019/654 gan O.S. 2020/1504.

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

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

Darpariaeth drosiannol: Endo-1,4-beta-sylanas (EC 3.2.1.8) (rhif adnabod 4a8i (4a8 yn flaenorol))

4.—(1) Caniateir i'r ychwanegyn bwyd anifeiliaid perthnasol a'r rhag-gymysgeddau sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 21 Mehefin 2024 gan gydymffurfio ag amodau'r awdurdodiad ymlaen llaw a'r gofynion labelu sy'n gymwys cyn 22 Rhagfyr 2023, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu dihysbyddu.

(2) Caniateir i fwyd anifeiliaid cyfansawdd a deunyddiau bwyd anifeiliaid sy'n cynnwys yr ychwanegyn bwyd anifeiliaid perthnasol ac a fwriedir ar gyfer anifeiliaid sy'n cynhyrchu bwyd, a gynhyrchir ac a labelir cyn diwedd 21 Rhagfyr 2024 gan gydymffurfio ag amodau'r awdurdodiad ymlaen llaw a'r gofynion labelu sy'n gymwys cyn 22 Rhagfyr 2023, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu dihysbyddu.

(3) Yn y rheoliad hwn—

ystyr “awdurdodiad ymlaen llaw” (“*prior authorisation*”) yw'r awdurdodiad sydd wedi ei gynnwys yn Rheoliad y Comisiwn (EC) Rhif 902/2009 sy'n ymwneud ag awdurdodi paratoad ensym o endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (CBS 114044) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu, ieir i'w pesgi, ieir a fegir ar gyfer dodwy, tyrcwn i'w pesgi a thyrcwn a fegir ar gyfer bridio (deiliad awdurdodiad Roal Oy)(1);

ystyr “ychwanegyn bwyd anifeiliaid perthnasol” (“*relevant feed additive*”) yw'r ychwanegyn bwyd anifeiliaid endo-1,4-beta-sylanas (EC 3.2.1.8), sydd â'r rhif adnabod 4a8, a awdurdodwyd o dan yr awdurdodiad blaenorol(2).

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

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

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

(3) In this regulation—

“relevant feed additive” (“*ychwanegyn bwyd anifeiliaid perthnasol*”) means the feed additive endo-1,4-beta-xylanase (EC 3.2.1.8), with the identification number 4a8, authorised under the prior authorisation(1);

“prior authorisation” (“*awdurdodiad ymlaen llaw*”) means the authorisation contained in Commission Regulation (EC) No 902/2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy)(2).

(1) EUR 2009/902. Mae'r Rheoliad hwn wedi ei ddirymu gan reoliad 7 o'r Rheoliadau hyn, ac Atodlen 14 iddynt.

(2) Gweler Atodlen 9 i'r Rheoliadau hyn ar gyfer awdurdodiad yr ychwanegyn bwyd anifeiliaid hwn a adnewyddwyd.

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

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

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) Rhif 601/2013

5.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) Rhif 601/2013 sy'n ymwneud ag awdurdodi cobalt(II) asetat tetrahydrad, cobalt(II) carbonad, cobalt(II) carbonad hydrocsid (2:3) monohydrad, cobalt(II) sylffad heptahydrad a cobalt(II) carbonad hydrocsid (2:3) monohydrad gronynnog araenedig fel ychwanegion bwyd anifeiliaid (1) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn y tabl, hepgorer y cofnodion ar gyfer—

- (a) cobalt(II) asetat tetrahydrad (rhif adnabod 3b301);
- (b) cobalt(II) carbonad (rhif adnabod 3b302);
- (c) cobalt(II) carbonad hydrocsid (2:3) monohydrad (rhif adnabod 3b303);
- (d) cobalt(II) sylffad heptahydrad (rhif adnabod 3b305).

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2019/221

6.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) 2019/221 sy'n diwygio Rheoliadau (EC) Rhif 785/2007, (EC) Rhif 379/2009, (EC) Rhif 1087/2009, (EU) Rhif 9/2010, (EU) Rhif 337/2011 a Rheoliadau Gweithredu (EU) Rhif 389/2011, (EU) Rhif 528/2011, (EU) Rhif 840/2012, (EU) Rhif 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 ac (EU) 2017/896 ynghylch enw deiliad yr awdurdodiad a chynrychiolydd deiliad yr awdurdodiad ar gyfer ychwanegion bwyd anifeiliaid penodol(2) wedi ei ddiwygio fel a ganlyn.

(2) Hefgorer Erthygl 4 (diwygio Rheoliad (EU) Rhif 9/2010).

(3) Hefgorer Erthygl 7 (diwygio Rheoliad Gweithredu (EU) Rhif 528/2011).

(4) Hefgorer Erthygl 9 (diwygio Rheoliad Gweithredu (EU) Rhif 1021/2012).

Dirymiadau

7. Mae'r offerynnau a restrir yn Atodlen 14 wedi eu dirymu.

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(1) is amended as follows.

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

- (a) cobalt(II) acetate tetrahydrate (identification number 3b301);
- (b) cobalt(II) carbonate (identification number 3b302);
- (c) cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303);
- (d) cobalt(II) sulphate heptahydrate (identification number 3b305).

Amendment of Commission Implementing Regulation (EU) 2019/221

6.—(1) Commission Implementing Regulation (EU) 2019/221 amending Regulations (EC) No 785/2007, (EC) No 379/2009, (EC) No 1087/2009, (EU) No 9/2010, (EU) No 337/2011 and Implementing Regulations (EU) No 389/2011, (EU) No 528/2011, (EU) No 840/2012, (EU) No 1021/2012, (EU) 2016/899, (EU) 2016/997, (EU) 2017/440 and (EU) 2017/896 as regards the name of the holder of the authorisation and the representative of the holder of the authorisation for certain feed additives(2) is amended as follows.

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

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

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

Revocations

7. The instruments listed in Schedule 14 are revoked.

(1) EUR 2013/601. Diwygiwyd y Rheoliad hwn cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) Rhif 131/2014.

(2) EUR 2019/221.

(1) EUR 2013/601. This Regulation was amended prior to implementation period completion day by Commission Implementing Regulation (EU) No 131/2014.

(2) EUR 2019/221.

Lynne Neagle

Y Dirprwy Weinidog Iechyd Meddwl a Llesiant, o dan
awdurdod y Gweinidog Iechyd a Gwasanaethau
Cymdeithasol, un o Weinidogion Cymru
27 Tachwedd 2023

Deputy Minister for Mental Health and Wellbeing,
under the authority of the Minister for Health and
Social Services, one of the Welsh Ministers
27 November 2023

Adnewyddu awdurdodiad paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir o *Trichoderma reesei* (CBS 143953) (*Trichoderma reesei* (ATCC PTA 5588) yn flaenorol) (rhif adnabod 4a11) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, ieir dodwy, tyrcwn i'w pesgi, hwyaid, mân rywogaethau dofednod, perchyll wedi eu diddyfnu, a pherchyll i'w pesgi, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu pob rhywogaeth dofednod, perchyll (sugno ac wedi eu diddyfnu), moch i'w pesgi a mân rywogaethau teulu'r moch

Mae'r paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sylweddau gwella treuliadwyedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	Endo-1,4-beta-sylanas (EC 3.2.1.8)
<i>Rhif adnabod</i>	4a11
<i>Deiliad yr awdurdodiad</i>	Danisco (UK) Ltd
<i>Categori yr ychwanegyn</i>	Ychwanegion sootechnegol
<i>Grŵp gweithredol</i>	Sylweddau gwella treuliadwyedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir drwy eplesu â <i>Trichoderma reesei</i> (CBS 143953) sydd ag isafswm actifedd ensym o 40,000 U/g ⁽¹⁾
<i>Nodweddiad y sylwedd(au) actif</i>	Endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir drwy eplesu â <i>Trichoderma reesei</i> (CBS 143953) <ul style="list-style-type: none"> • Rhif CAS: 9025-57-4⁽²⁾ • Rhif EC (IUBMB): 3.2.1.8⁽³⁾ • Rhif EINECS: 232-800-2⁽⁴⁾
<i>Dulliau dadansoddi</i> ^{(5) (6)}	I feintioli actifedd ensym endo-1,4-beta-sylanas yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau, y deunyddiau bwyd anifeiliaid a'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Y dull colorimetrig yn mesur llifyn dŵr-hydawdd a ryddheir drwy effaith endo-1,4-beta-sylanas o swbstrad arabino sylan gwenith trawsgysylltiedig asurin
<i>Rhywogaeth neu categori o anifail</i>	<ul style="list-style-type: none"> • Pob rhywogaeth dofednod • Perchyll (sugno ac wedi eu diddyfnu) • Moch i'w pesgi • Mân rywogaethau teulu'r moch
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽⁷⁾	Ar gyfer pob rhywogaeth dofednod: <ul style="list-style-type: none"> • 625 U/kg

(1) Mae'r awdurdodiad hwn yn cynnwys adnewyddiad (ag addasiad) o'r awdurdodiadau a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 9/2010, Rheoliad Gweithredu'r Comisiwn (EU) Rhif 528/2011 a Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1021/2012. Mae'r Rheoliadau hynny wedi eu dirymu gan reoliad 7 o'r Rheoliadau hyn, ac Atodlen 14 iddynt.

	Ar gyfer perchyll (sugno ac wedi eu diddyfnu), moch i'w pesgi, mân rywogaethau teulu'r moch: <ul style="list-style-type: none"> • 2000 U/kg
<i>Uchafswm cynnwys</i> ⁽⁷⁾	Dim
<i>Darpariaethau eraill</i>	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd

⁽¹⁾ 1 uned ("U") yw'r swm o ensym sy'n rhyddhau 0.48 micromol (μmol) o siwgr rhydwythol (cyfatebol â sylos) y funud o arabino sylan gwenith ar pH4.2 a 50 °C.

⁽²⁾ CAS Registry Number® a neilltuwyd i'r paratoad hwn gan y Gwasanaeth Crynodebu Cemegol <https://www.cas.org/cas-data/cas-registry>.

⁽³⁾ Rhif adnabod a ddyrannwyd gan yr Undeb Biocemeg a Bioleg Foleciwlaidd Rhyngwladol (IUBMB) <https://iubmb.org>.

⁽⁴⁾ Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C 146A, 15.6.90, t.1.

⁽⁵⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "JRC.D.5/FSQ/CvH/DM/ag/ARES(2012)353089" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2011-0030_en.

⁽⁶⁾ Diffinnir yr actifedd ensym ar gyfer endo-1,4-beta-sylanas yn y ddogfen sydd â'r cyfeirnod "JRC.DG.D.6/CvH/DM/hn/ARES(2010)-375745" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0007_en.

⁽⁷⁾ Cynnwys endo-1,4-beta-sylanas (unedau actifedd/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

Awdurdodi paratoad o *Lacticaseibacillus rhamnosus* (*Lactobacillus rhamnosus* yn flaenorol) (IMI 507023) (rhif adnabod 1k21701) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Lacticaseibacillus rhamnosus* (IMI 507023) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Rhif adnabod</i>	1k21701
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Lacticaseibacillus rhamnosus</i> (IMI 507023) sy'n cynnwys isafswm o 1×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Dulliau dadansoddi⁽¹⁾</i>	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Y dull plât taenu ar agar MRS (BS EN 15787:2021⁽²⁾) I adnabod y straen bacterol: <ul style="list-style-type: none"> • Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	Isafswm cynnwys yr ychwanegyn pan y'i defnyddir heb ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Uchafswm cynnwys⁽³⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Nid yw'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio ond mewn deunydd ffres sy'n hawdd i'w silweirio neu'n gymedrol anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)1687524 – 08/03/2021" a "JRC F.5/CvH/ZE /AS/Ares", ac a ddiweddarwyd ddiwethaf ar 21 Ebrill 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. Y rhif cyfeirnod ffeil perthnasol yw "FAD-2020-0075".

⁽²⁾ O dan y cyfeirnod BS EN 15787:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Lactobacillus* spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Rhagfyr 2021 (ISBN 978 0 580 99831 7). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres.

Awdurdodi paratoad o *Pediococcus pentosaceus* (IMI 507024) (rhif adnabod 1k21016) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad *Pediococcus pentosaceus* (IMI 507024) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Pediococcus pentosaceus</i> (IMI 507024)
<i>Rhif adnabod</i>	1k21016
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Pediococcus pentosaceus</i> (IMI 507024) sy'n cynnwys isafswm o 1×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Pediococcus pentosaceus</i> (IMI 507024)
<i>Dulliau dadansoddi</i> ⁽¹⁾	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> Y dull plât taenu ar agar MRS (BS EN 15786:2021⁽²⁾) I adnabod straen bacterol: <ul style="list-style-type: none"> Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽³⁾	Isafswm cynnwys yr ychwanegyn bwyd anifeiliaid pan y'i defnyddir heb ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> 1×10^9 CFU/kg
<i>Uchafswm cynnwys</i> ⁽³⁾	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Nid yw'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio ond mewn deunydd ffres sy'n hawdd i'w silweirio neu'n gymedrol anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)1902366 – 16/03/2021" a "JRC F.5/CvH/MGH/AS/Ares", ac a ddiweddarwyd ddiwethaf ar 21 Ebrill 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. Y rhif cyfeirnod ffeil yw "FAD-2020-0076".

⁽²⁾ O dan y cyfeirnod BS EN 15786:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of Bacillus spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Tachwedd 2021 (ISBN 978 0 580 99830 0). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres.

Awdurdodi paratoad o *Pediococcus pentosaceus* (IMI 507025) (rhif adnabod 1k21017) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Pediococcus pentosaceus* (IMI 507025) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Pediococcus pentosaceus</i> (IMI 507025)
<i>Rhif adnabod</i>	1k21017
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Pediococcus pentosaceus</i> (IMI 507025) sy'n cynnwys isafswm o 1×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Pediococcus pentosaceus</i> (IMI 507025)
<i>Dulliau dadansoddi</i> ⁽¹⁾	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> Y dull plât taenu ar agar MRS (BS EN 15786:2021)⁽²⁾ I adnabod straen bacterol: <ul style="list-style-type: none"> Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽³⁾	Isafswm cynnwys yr ychwanegyn pan nad yw wedi ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> 1×10^9 CFU/kg
<i>Uchafswm cynnwys</i> ⁽³⁾	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Nid yw'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio ond mewn deunydd ffres sy'n hawdd i'w silweirio neu'n gymedrol anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)1902366 – 16/03/2021" a "JRC F.5/CvH/MGH /AS/Ares", ac a ddiweddarwyd ddiwethaf ar 21 Ebrill 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00760077_en. Y rhif cyfeirnod ffeil perthnasol yw "FAD-2020-0077".

⁽²⁾ O dan y cyfeirnod BS EN 15786:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Bacillus* spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Tachwedd 2021 (ISBN 978 0 580 99830 0). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres.

Awdurdodi paratoad o *Lactiplantibacillus plantarum* (*Lactobacillus plantarum* yn flaenorol) (IMI 507026) (rhif adnabod 1k21601) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Lactiplantibacillus plantarum* (IMI 507026) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507026)
<i>Rhif adnabod</i>	1k21601
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Lactiplantibacillus plantarum</i> (IMI 507026) sy'n cynnwys isafswm o 1×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Lactiplantibacillus plantarum</i> (IMI 507026)
<i>Dulliau dadansoddi</i> ⁽¹⁾	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Y dull plât taenu ar agar MRS (BS EN 15787:2021⁽²⁾) I adnabod straen bacterol: <ul style="list-style-type: none"> • Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽³⁾	Isafswm cynnwys yr ychwanegyn pan nad yw wedi ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Uchafswm cynnwys</i> ⁽³⁾	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Nid yw'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio ond mewn deunydd ffres sy'n hawdd i'w silweirio neu'n gymedrol anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)1687524-08/-3/2021" a "JRC F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 21 Ebrill 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. Y rhif cyfeirnod ffeil perthnasol yw "FAD-2020-0078".

⁽²⁾ O dan y cyfeirnod BS EN 15787:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Lactobacillus* spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Rhagfyr 2021 (ISBN 978 0 580 99831 7). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres.

Awdurdodi paratoad o *Lactiplantibacillus plantarum* (*Lactobacillus plantarum* yn flaenorol) (IMI 507027) (rhif adnabod 1k21602) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Lactiplantibacillus plantarum* (IMI 507027) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507027)
<i>Rhif adnabod</i>	1k21602
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Lactiplantibacillus plantarum</i> (IMI 507027) sy'n cynnwys isafswm o 1×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Lactiplantibacillus plantarum</i> (IMI 507027)
<i>Dulliau dadansoddi⁽¹⁾</i>	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Y dull plât taenu ar agar MRS (BS EN 15787:2021⁽²⁾) I adnabod straen bacterol: <ul style="list-style-type: none"> • Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	Isafswm cynnwys yr ychwanegyn pan nad yw wedi ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Uchafswm cynnwys⁽³⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Nid yw'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio ond mewn deunydd ffres sy'n hawdd i'w silweirio neu'n gymedrol anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)1687524 – 08/03/2021" a "JRC F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 21 Ebrill 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. Y rhif cyfeirnod ffeil perthnasol yw "FAD-2020-0079".

⁽²⁾ O dan y cyfeirnod BS EN 15787:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Lactobacillus* spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Rhagfyr 2021 (ISBN 978 0 580 99831 7). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres.

Awdurdodi paratoad o *Lactiplantibacillus plantarum* (*Lactobacillus plantarum* yn flaenorol) (IMI 507028) (rhif adnabod 1k21603) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Lactiplantibacillus plantarum* (IMI 507028) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Lactiplantibacillus plantarum</i> (IMI 507028)
<i>Rhif adnabod</i>	1k21603
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Lactiplantibacillus plantarum</i> (IMI 507028) sy'n cynnwys isafswm o 1×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Lactiplantibacillus plantarum</i> (IMI 507028)
<i>Dulliau dadansoddi</i> ⁽¹⁾	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Y dull plât taenu ar agar MRS (BS EN 15787:2021⁽²⁾) I adnabod straen bacterol: <ul style="list-style-type: none"> • Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽³⁾	Isafswm cynnwys yr ychwanegyn pan nad yw wedi ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Uchafswm cynnwys</i> ⁽³⁾	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Nid yw'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio ond mewn deunydd ffres sy'n hawdd i'w silweirio neu'n gymedrol anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)1687524 – 08/03/2021" a "JRC F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 21 Ebrill 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. Y rhif cyfeirnod ffeil perthnasol yw "FAD-2020-0080".

⁽²⁾ O dan y cyfeirnod BS EN 15787:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Lactobacillus* spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Rhagfyr 2021 (ISBN 978 0 580 99831 7). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres.

Awdurdodi paratoad o *Lactiplantibacillus plantarum* (*Lactobacillus plantarum* yn flaenorol) (DSM 26571) (rhif adnabod 1k1604) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Lactiplantibacillus plantarum* (DSM 26571) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "ychwanegion silwair", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Lactiplantibacillus plantarum</i> (DSM 26571)
<i>Rhif adnabod</i>	1k1604
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet o <i>Lactiplantibacillus plantarum</i> (DSM 26571) sy'n cynnwys isafswm o 1×10^{11} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Lactiplantibacillus plantarum</i> (DSM 26571)
<i>Dulliau dadansoddi⁽¹⁾</i>	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Y dull plât taenu ar agar MRS (BS EN 15787:2021⁽²⁾) I adnabod straen bacterol: <ul style="list-style-type: none"> • Electrofforesis jel maes pylsedig (PFGE)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	Isafswm cynnwys yr ychwanegyn pan nad yw wedi ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: <ul style="list-style-type: none"> • 1×10^8 CFU/kg
<i>Uchafswm cynnwys⁽³⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Mae'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio mewn deunydd ffres sy'n hawdd i'w silweirio, yn gymedrol anodd i'w silweirio, neu'n anodd i'w silweirio ⁽⁴⁾

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)5563084 – 15/10/2020" a "JRC.F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 16 Hydref 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0091_en.

⁽²⁾ O dan y cyfeirnod BS EN 15787:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Lactobacillus* spp. used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Rhagfyr 2021 (ISBN 978 0 580 99831 7). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽³⁾ Unedau ffurfio cytref (CFU) o'r ychwanegyn/kg o ddeunydd ffres.

⁽⁴⁾ Porthiant sy'n hawdd i'w silweirio: > 3% o garbohydradau hydawdd mewn deunydd ffres; porthiant sy'n gymedrol anodd i'w silweirio: 1.5 i 3.0% o garbohydradau hydawdd yn y deunydd ffres; porthiant sy'n anodd i'w silweirio: <1.5% o garbohydradau hydawdd yn y deunydd ffres.

Adnewyddu awdurdodiad paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir o *Trichoderma reesei* (CBS 114044) (rhif adnabod 4a8i) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll (wedi eu diddyfnu), ieir i'w pesgi, ieir a fegir ar gyfer dodwy, tyrcwn i'w pesgi, a thyrcwn a fegir ar gyfer bridio

Mae'r paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sylweddau gwella treuliadwyedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	Endo-1,4-beta-sylanas (EC 3.2.1.8)
<i>Rhif adnabod</i>	4a8i
<i>Deiliad yr awdurdodiad</i>	Roal Oy
<i>Categori ychwanegion</i>	Ychwanegion sootechnegol
<i>Grŵp gweithredol</i>	Sylweddau gwella treuliadwyedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir drwy eplesu â <i>Trichoderma reesei</i> (CBS 114044) sydd ag isafswm actifedd ensym o 160,000 BXU/g ar gyfer y ffurfiau solet a hylif ⁽¹⁾
<i>Nodweddiad y sylwedd(au) actif</i>	Endo-1,4-beta-sylanas (EC 3.2.1.8) a gynhyrchir drwy eplesu â <i>Trichoderma reesei</i> (CBS 114044) <ul style="list-style-type: none"> • Rhif CAS: 9025-57-4⁽²⁾ • Rhif EC (IUBMB): 3.2.1.8⁽³⁾ • Rhif EINECS: 232-800-2⁽⁴⁾
<i>Dulliau dadansoddi⁽⁵⁾</i>	I feintioli endo-1,4-beta-sylanas (EC 3.2.1.8) yn yr ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau: <ul style="list-style-type: none"> • Y dull colorimetrig yn seiliedig ar adwaith ensymatig endo-1,4-beta-sylanas ar y swbstrad sylan bedwen ar pH 5.3 a 50°C I feintioli endo-1,4-beta-sylanas (EC 3.2.1.8) mewn deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Y dull colorimetrig yn seiliedig ar adwaith ensymatig endo-1,4-beta-sylanas ar y swbstrad arabino sylan gwenith trawsgysylltiedig asurin ar pH 5.3 a 50°C
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Perchyll (wedi eu diddyfnu) • Ieir i'w pesgi • Ieir a fegir ar gyfer dodwy • Tyrcwn i'w pesgi • Tyrcwn a fegir ar gyfer bridio
<i>Oedran hynaf</i>	Dim

(1) Mae'r awdurdodiad hwn yn adnewyddiad o'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EC) 902/2009, sydd wedi ei ddirymu gan reoliad 7 o'r Rheoliadau hyn, ac Atodlen 14 iddynt, ond gweler y ddarpariaeth drosiannol yn rheoliad 4. Awdurdodwyd yr ychwanegyn bwyd anifeiliaid hwn yn flaenorol hefyd fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy, mân rywogaethau dofednod a moch i'w pesgi o dan Reoliad Gweithredu'r Comisiwn (EU) Rhif 1110/2011, a ddaeth i ben ar 24 Tachwedd 2021 ac sydd wedi ei ddirymu gan reoliad 7 o'r Rheoliadau hyn, ac Atodlen 14 iddynt.

<i>Isafswm cynnwys</i> ⁽⁶⁾	Ar gyfer perchyll (wedi eu diddyfnu): <ul style="list-style-type: none"> • 24,000 BXU/kg Ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy: <ul style="list-style-type: none"> • 8,000 BXU/kg Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: <ul style="list-style-type: none"> • 16,000 BXU/kg
<i>Uchafswm cynnwys</i> ⁽⁶⁾	Dim
<i>Darpariaethau eraill</i>	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd

⁽¹⁾ Mynegir actifedd ensym mewn unedau sylan bedw (BXU), lle 1 BXU yw'r swm o ensym sy'n rhyddhau 1 nanomol (nmol) o siwgrau rhydwythol yr eiliad fel sylos o'r sylan bedwen ar pH 5.3 a 50°C

⁽²⁾ CAS Registry Number® a neilltuwyd i'r paratoad hwn gan y Gwasanaeth Crynodebu Cemegol <https://www.cas.org/cas-data/cas-registry>.

⁽³⁾ Rhif adnabod a ddyrannwyd gan yr Undeb Biocemeg a Bioleg Foleciwlaidd Rhyngwladol (IUBMB) <https://iubmb.org>.

⁽⁴⁾ Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C 146A, 15.6.90, t.1.

⁽⁵⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2019)3101222-10/05/2019" a "JRC F.5/CvH/MGH/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 2 Gorffennaf 2019. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0071_en.

⁽⁶⁾ Cynnwys endo-1,4-beta-sylanau (unedau actifedd/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

Adnewyddu awdurdodiad paratoad o 6-ffytas (EC 3.1.3.26) a gynhrychir o *Trichoderma reesei* (CBS 122001) (rhif adnabod 4a12) fel ychwanegyn bwyd anifeiliaid ar gyfer moch, dofednod ar gyfer bridio, dofednod i'w pesgi, a dofednod ar gyfer dodwy

Mae'r paratoad o 6-ffytas (EC 3.1.3.26) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sylweddau gwella treuliadwyedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	6-ffytas (EC 3.1.3.26)
<i>Rhif adnabod</i>	4a12
<i>Deiliad yr awdurdodiad</i>	Roal Oy
<i>Categori ychwanegion</i>	Ychwanegion sootechnegol
<i>Grŵp gweithredol</i>	Sylweddau gwella treuliadwyedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o 6-ffytas (EC 3.1.3.26) a gynhrychir drwy eplesu â <i>Trichoderma reesei</i> (CBS 122001) sydd ag isafswm actifedd ensym o 40,000 PPU/g ar gyfer y ffurf solet a 5,000 PPU/g ar gyfer y ffurf hylif ⁽¹⁾ :
<i>Nodweddiad y sylwedd(au) actif</i>	6-ffytas (EC 3.1.3.26) a gynhrychir drwy eplesu â <i>Trichoderma reesei</i> (CBS 122001) <ul style="list-style-type: none"> • Rhif CAS: 9001-89-2⁽²⁾ • Rhif EC (IUBMB): 3.1.3.26⁽³⁾ • Rhif EINECS: 232-630-9⁽⁴⁾
<i>Dulliau dadansoddi⁽⁵⁾</i>	I feintioli actifedd ffytas yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau, y deunyddiau bwyd anifeiliaid a'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Y dull colorimetrig yn meintioli actifedd ensymatig 6-ffytas drwy fesur ffosffad anorganig a ryddheir o sodiwm ffytad drwy ddadansoddi'r lliw a grëir gan rydwytho cymhlygyn ffosffomolybdad
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Moch • Dofednod ar gyfer bridio • Dofednod i'w pesgi • Dofednod ar gyfer dodwy
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁶⁾</i>	Ar gyfer moch, dofednod i'w pesgi, a dofednod ar gyfer bridio: <ul style="list-style-type: none"> • 250 PPU/kg Ar gyfer dofednod ar gyfer dodwy: <ul style="list-style-type: none"> • 125 PPU/kg
<i>Uchafswm cynnwys⁽⁶⁾</i>	Dim
<i>Darpariaethau eraill</i>	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd

(1) Mae'r awdurdodiad hwn yn adnewyddiad o'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 277/2010, Rheoliad y Comisiwn (EU) Rhif 891/2010 a Rheoliad Gweithredu'r Comisiwn (EU) Rhif 886/2011. Mae'r Rheoliadau hynny wedi eu dirymu gan reoliad 7 o'r Rheoliadau hyn, ac Atodlen 14 iddynt.

- (1) Mynegir actifedd ensym mewn unedau PPU, lle 1 PPU yw'r swm o ensym sy'n rhyddhau 1 micromol (μmol) o ffosffad anorganig y funud o sodiwm ffytad ar pH 5.0 a 37 °C.
- (2) CAS Registry Number® a neilltuwyd i'r paratoad hwn gan y Gwasanaeth Crynodebu Cemegol <https://www.cas.org/cas-data/cas-registry>.
- (3) Rhif adnabod a ddyrannwyd gan yr Undeb Biocemeg a Bioleg Foleciwlaidd Rhyngwladol (IUBMB) <https://iubmb.org>.
- (4) Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C 146A, 15.6.90, t.1.
- (5) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "D08/FSQ/CVH/SY/D/Ares(2009)173372" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2008-0040_en.
- (6) Cynnwys 6-ffytas (unedau actifedd (PPU)/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

Awdurdodi sylfaen L-lysin (hylif) a gynhyrchir o *Corynebacterium glutamicum* (KCCM 80216 neu KCTC 12307BP) (rhif adnabod 3c326) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifeiliaid

Mae'r sylwedd sylfaen L-lysin (hylif) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegyn "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	Sylfaen L-lysin (hylif)
<i>Rhif adnabod</i>	3c326
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Asidau amino, eu halwynau a'u hanalogau
<i>Cyfansoddiad yr ychwanegyn</i>	Hydoddiant dyfrllyd sy'n cynnwys o leiaf 50% L-lysin
<i>Nodweddiad y sylwedd(au) actif</i>	Sylfaen L-lysin (hylif) a gynhyrchir drwy epleu â <i>Corynebacterium glutamicum</i> (KCCM 80216 neu KCTC 12307BP) L-lysin (C ₆ H ₁₄ N ₂ O ₂) <ul style="list-style-type: none"> • Rhif CAS: 56-87-1⁽¹⁾ • Rhif EINECS: 200-294-2⁽²⁾
<i>Dulliau dadansoddi⁽³⁾</i>	I feintioli lysin yn yr ychwanegyn bwyd anifeiliaid a rhag-gymysgeddau sy'n cynnwys mwy na 10% lysin: <ul style="list-style-type: none"> • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013⁽⁴⁾) I feintioli lysin mewn rhag-gymysgeddau, deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod ffotometrig (IEC-VIS) yn unol â Rheoliad y Comisiwn (EC) 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol(1) (Atodiad 3-F) I feintioli lysin mewn dŵr: <ul style="list-style-type: none"> • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013⁽⁴⁾), neu • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS) yn unol â Rheoliad y Comisiwn (EC) 152/2009 (Atodiad 3-F)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁵⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁵⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r cynnwys lysin ar label yr ychwanegyn 2. Caniateir rhoi sylfaen L-lysin (hylif) ar y farchnad a'i ddefnyddio fel ychwanegyn sy'n baratoad

(1) EUR 2009/152, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

- (1) CAS Registry Number® a neilltuwyd i'r paratoad hwn gan y Gwasanaeth Crynodebu Cemegol <https://www.cas.org/cas-data/cas-registry>.
- (2) Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C 146A, 15.6.90, t.1.
- (3) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)4503369-31/08/2020" a "JRC F.5/CvH/MGH/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 16 Hydref 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.
- (4) O dan y cyfeirnod BS EN ISO 17180:2013 "Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Ebrill 2013 (ISBN 978 0 580 76077 8). Ar gael yn: <https://knowledge.bsigroup.com>.
- (5) Cynnwys L-lysin (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

Awdurdodi L-lysin monohydroclorid (pur yn dechnegol) a gynhyrchir o *Corynebacterium glutamicum* (KCCM 80216 neu KCTC 12307BP) (rhif adnabod 3c327) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifeiliaid

Mae'r sylwedd L-lysin monohydroclorid (pur yn dechnegol) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegyn "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	L-lysin monohydroclorid (pur yn dechnegol)
<i>Rhif adnabod</i>	3c327
<i>Deiliad yr awdurdodiad</i>	Dim
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Asidau amino, eu halwynau a'u hanalogau
<i>Cyfansoddiad yr ychwanegyn</i>	Powdr L-lysin monohydroclorid sydd o leiaf 78% L-lysin ac sydd ag uchafswm cynnwys lleithder o 1.5%
<i>Nodweddiad y sylwedd(au) actif</i>	L-lysin monohydroclorid (pur yn dechnegol) a gynhyrchir drwy eplesu â <i>Corynebacterium glutamicum</i> (KCCM 80216 neu KCTC 12307BP) L-lysin monohydroclorid (C ₆ H ₁₅ ClN 2 O ₂) <ul style="list-style-type: none"> • Rhif CAS: 657-27-2⁽¹⁾ • Rhif EINECS: 211-519-9⁽²⁾
<i>Dulliau dadansoddi⁽³⁾</i>	I adnabod L-lysin monohydroclorid yn yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Monograff L-lysin monohydroclorid y Food Chemicals Codex⁽⁴⁾ I feintioli lysin yn yr ychwanegyn bwyd anifeiliaid a rhag-gymysgeddau sy'n cynnwys mwy na 10% lysin: <ul style="list-style-type: none"> • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013⁽⁵⁾) I feintioli lysin mewn rhag-gymysgeddau, deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod ffitometrig (IEC-VIS) yn unol â Rheoliad y Comisiwn (EC) 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol (Atodiad 3-F) I feintioli lysin mewn dŵr: <ul style="list-style-type: none"> • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013); neu • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS) yn unol â Rheoliad y Comisiwn (EC) 152/2009 (Atodiad 3-F)
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁶⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁶⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Rhaid nodi'r cynnwys lysin ar label yr ychwanegyn

	2. Caniateir rhoi L-lysin monohydroclorid (pur yn dechnegol) ar y farchnad a'i ddefnyddio fel ychwanegyn sydd ar ffurf paratoad
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⁽¹⁾ CAS Registry Number® a neilltuwyd i'r paratoad hwn gan y Gwasanaeth Crynodebu Cemegol <https://www.cas.org/cas-data/cas-registry>.

⁽²⁾ Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C 146A, 15.6.90, t.1.

⁽³⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)4503369-31/08/2020" a "JRC F.5/CvH/MGH/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 16 Hydref 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0008_en.

⁽⁴⁾ Food Chemicals Codex, Confensiwn Cyffuriadol yr Unol Daleithiau, 13^{eg} argraffiad (ar-lein). Cyhoeddwyd gan US Pharmacopeia (USP) ar 1 Mawrth 2022 (ISSN 2153-1455). Ar gael yn <https://www.foodchemicalscodex.org>.

⁽⁵⁾ O dan y cyfeirnod BS EN ISO 17180:2013 "Animal feeding stuffs. Determination of lysine, methionine and threonine in commercial amino acid products and premixtures". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Ebrill 2013 (ISBN 978 0 580 76077 8). Ar gael yn: <https://knowledge.bsigroup.com>.

⁽⁶⁾ Cynnwys L-lysin monohydroclorid (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

Awdurdodi paratoad o 3-nitroocsypropanol (rhif adnabod 4c1) fel ychwanegyn bwyd anifeiliaid ar gyfer anifeiliaid cnoi cil ar gyfer cynhyrchu llaeth ac anifeiliaid cnoi cil ar gyfer atgenhedlu

Mae'r paratoad o 3-nitroocsypropanol a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootecnegol" ac i'r grŵp gweithredol "sylweddau sy'n cael effaith ffafriol ar yr amgylchedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	3-nitroocsypropanol
<i>Rhif adnabod</i>	4c1
<i>Deiliad yr awdurdodiad</i>	DSM Nutritional Products Ltd (Y Swistir)
<i>Categori ychwanegion</i>	Ychwanegion sootecnegol
<i>Grŵp gweithredol</i>	Sylweddau sy'n cael effaith ffafriol ar yr amgylchedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o 3-nitroocsypropanol sy'n cynnwys o leiaf 10% ychwanegyn Powdr gronnol; gronnau sydd â diamedr < 50 µm: 0.4%
<i>Nodweddiad y sylwedd(au) actif</i>	3-nitroocsypropanol (C ₃ H ₇ NO ₄) <ul style="list-style-type: none"> • Rhif CAS: 100502-66-7⁽¹⁾
<i>Dulliau dadansoddi⁽²⁾</i>	I feintio 3-nitroocsypropanol yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau a'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Cromatograffaeth hylif perfformiad uchel gwedd wrthdroi gyda chanfod sbectroffotometrigrig (HPLC-UV)
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Anifeiliaid cnoi cil ar gyfer cynhyrchu llaeth • Anifeiliaid cnoi cil ar gyfer atgenhedlu
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	53 mg/kg
<i>Uchafswm cynnwys⁽³⁾</i>	88 mg/kg
<i>Darpariaethau eraill</i>	<ol style="list-style-type: none"> 1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd 2. Rhaid ymgorffori'r ychwanegyn yn y bwyd anifeiliaid ar ffurf rhag-gymysgedd

⁽¹⁾ CAS Registry Number® a neilltuwyd i'r paratoad hwn gan y Gwasanaeth Crynodebu Cemegol <https://www.cas.org/cas-data/cas-registry>.

⁽²⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)981992-15/02/2020" a "JRC F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 4 Mai 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en.

⁽³⁾ Cynnwys 3-nitroocsypropanol (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

Dirymiadau

Rheoliad y Comisiwn (EC) Rhif 902/2009 sy'n ymwneud ag awdurdodi paratoad ensym o endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (CBS 114044) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu, ieir i'w pesgi, ieir a fegir ar gyfer dodwy, tyrcwn i'w pesgi a thyrcwn a fegir ar gyfer bridio (deiliad awdurdodiad Roal Oy)(1).

Rheoliad y Comisiwn (EU) Rhif 9/2010 sy'n ymwneud ag awdurdodi endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (ATCC PTA 5588) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, ieir dodwy, hwyaid a thyrcwn i'w pesgi (deiliad awdurdodiad Danisco (UK) Ltd, yn masnachu fel Danisco Animal Nutrition ac a gynrychiolir gan Genencor International B.V.)(2).

Rheoliad y Comisiwn (EU) Rhif 277/2010 sy'n ymwneud ag awdurdodi 6-ffytas fel ychwanegyn bwyd anifeiliaid ar gyfer dofednod i'w pesgi ac ar gyfer bridio ac eithrio tyrcwn i'w pesgi, ar gyfer dofednod ar gyfer dodwy ac ar gyfer moch heblaw hychod (deiliad awdurdodiad Roal Oy)(3).

Rheoliad y Comisiwn (EU) Rhif 891/2010 sy'n ymwneud ag awdurdodi defnydd newydd o 6-ffytas fel ychwanegyn bwyd anifeiliaid ar gyfer tyrcwn (deiliad awdurdodiad Roal Oy)(4).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 528/2011 sy'n ymwneud ag awdurdodi endo-1,4- β -sylanas a gynhyrchir gan *Trichoderma reesei* (ATCC PTA 5588) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu a moch i'w pesgi (deiliad awdurdodiad Danisco (UK) Ltd, sy'n masnachu fel Danisco Animal Nutrition ac a gynrychiolir gan Genencor International B.V.)(5).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 886/2011 sy'n ymwneud ag awdurdodi 6-ffytas (EC 3.1.3.26) a gynhyrchir gan *Trichoderma reesei* (CBS 122001) fel ychwanegyn bwyd anifeiliaid ar gyfer hychod (deiliad awdurdodiad Roal Oy)(6).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1110/2011 sy'n ymwneud ag awdurdodi paratoad ensym o endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (CBS 114044) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy, mân rywogaethau dofednod a moch i'w pesgi (deiliad awdurdodiad Roal Oy)(7).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1021/2012 sy'n ymwneud ag awdurdodi endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (ATCC PTA 5588) fel ychwanegyn bwyd anifeiliaid ar gyfer mân rywogaethau dofednod ac eithrio hwyaid (deiliad awdurdodiad Danisco (UK) Ltd, yn masnachu fel Danisco Animal Nutrition ac a gynrychiolir gan Genencor International B.V.)(8).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1196/2012 sy'n diwygio Rheoliad (EU) Rhif 9/2010 o ran isafswm cynnwys paratoad o endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (ATCC PTA 5588) fel ychwanegyn bwyd anifeiliaid ym mwyd anifeiliaid ar gyfer ieir dodwy (deiliad awdurdodiad Danisco Animal Nutrition)(9).

(1) EUR 2009/902.

(2) EUR 2010/9. Diwygiwyd y Rheoliad hwn cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) Rhif 1196/2012 a Rheoliad Gweithredu'r Comisiwn (EU) 2019/221. Mae EUR 2012/1196 wedi ei ddirymu gan reoliad 7 o'r Rheoliadau hyn, ac Atodlen 14 iddynt. Gweler rheoliad 6 am ddiwygiadau i EUR 2019/221.

(3) EUR 2010/277.

(4) EUR 2010/891.

(5) EUR 2011/528. Diwygiwyd y Rheoliad hwn cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2019/221. Gweler rheoliad 6 am ddiwygiadau i EUR 2019/221.

(6) EUR 2011/886.

(7) EUR 2011/1110.

(8) EUR 2012/1021. Diwygiwyd y Rheoliad hwn cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2019/221. Gweler rheoliad 6 am ddiwygiadau i EUR 2019/221.

(9) EUR 2012/1196.

Rheoliad Gweithredu'r Comisiwn (EU) 2018/1569 sy'n diwygio Rheoliad Gweithredu (EU) Rhif 1110/2011 sy'n ymwneud ag awdurdodi paratoad ensym o endo-1,4-beta-sylanas a gynhyrchir gan *Trichoderma reesei* (CBS 114044) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy, mân rywogaethau dofednod a moch i'w pesgi (deiliad awdurdodiad Roal Oy)(1).

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Argraffwyd a chyhoeddwyd yn y DU gan Y Llyfrfa Cyf dan awdurdod a goruchwyliaeth Jeff James, Rheolwr Llyfrfa Ei Fawrhydi ac Argraffydd Deddfau Senedd y Brenin.

(1) EUR 2018/1569.

SCHEDULE 1

Regulation 3(1)

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

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

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

(1) This authorisation contains a renewal (with modification) 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 of, and Schedule 14 to, these Regulations.

	For piglets (suckling and weaned), pigs for fattening, minor porcine species: <ul style="list-style-type: none"> • 2000 U/kg
<i>Maximum content</i> ⁽⁷⁾	None
<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 that releases 0.48 micromoles (µmol) of reducing sugar (xylose equivalent) per minute from wheat arabino xylan at pH4.2 and 50°C.

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

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

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

⁽⁵⁾ Details of the analytical methods are set out in the document referenced “JRC.D.5/FSQ/CvH/DM/ag/ARES(2012)353089” and last updated 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2011-0030_en.

⁽⁶⁾ The enzyme activity for endo-1,4-beta-xylanase is defined in the document referenced “JRC.DG.D.6/CvH/DM/hn/ARES(2010)-375745” and last updated 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0007_en.

⁽⁷⁾ Content of endo-1,4-beta-xylanase (units of activity/kg of complete feed with a moisture content of 12%).

SCHEDULE 2

Regulation 3(1)

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

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

<i>Additive</i>	<i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Identification number</i>	1k21701
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Solid preparation of <i>Lacticaseibacillus rhamnosus</i> (IMI 507023) containing a minimum of 1×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lacticaseibacillus rhamnosus</i> (IMI 507023)
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15787:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	Minimum content of the additive when used without combination with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

⁽¹⁾ Details of the analytical methods are set out in the document referenced “Ares(2021)1687524 – 08/03/2021” and “JRC F.5/CvH/ZE/AS/Ares”, and last updated 21 April 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0075007800790080_en. The relevant dossier reference number is “FAD-2020-0075”.

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

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

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

SCHEDULE 3

Regulation 3(1)

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

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

<i>Additive</i>	<i>Pediococcus pentosaceus</i> (IMI 507024)
<i>Identification number</i>	1k21016
<i>Authorisation holder</i>	None
<i>Additive category</i>	Technological additives
<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> ⁽¹⁾	For enumeration (colony count) of the feed additive: <ul style="list-style-type: none"> • Spread plate method on MRS agar (BS EN 15786:2021⁽²⁾) For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-Field Gel Electrophoresis (PFGE)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	Minimum content of the additive when used without combination with other micro-organisms as silage additives: <ul style="list-style-type: none"> • 1×10^9 CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. The storage conditions must be stated in the directions for use of the feed additive and premixture 2. The additive is authorised for use only in easy to ensile or moderately difficult to ensile fresh material ⁽⁴⁾

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

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

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

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

SCHEDULE 4

Regulation 3(1)

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

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

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

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

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

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

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

SCHEDULE 5

Regulation 3(1)

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507026) (identification number 1k21601) as a feed additive for all animal species

The preparation of *Lactiplantibacillus plantarum* (IMI 507026) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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

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

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

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

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

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507027) (identification number 1k21602) as a feed additive for all animal species

The preparation of *Lactiplantibacillus plantarum* (IMI 507027) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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

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

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

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

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

SCHEDULE 7

Regulation 3(1)

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (IMI 507028) (identification number 1k21603) as a feed additive for all animal species

The preparation of *Lactiplantibacillus plantarum* (IMI 507028) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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

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

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

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

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

Authorisation of a preparation of *Lactiplantibacillus plantarum* (formerly *Lactobacillus plantarum*) (DSM 26571) (identification number 1k1604) as a feed additive for all animal species

The preparation of *Lactiplantibacillus plantarum* (DSM 26571) specified in the table, belonging to the additive category “technological additives” and to the functional group “silage additives”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

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

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

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

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

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

SCHEDULE 9

Regulation 3(1)

Renewal of authorisation of a preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced from *Trichoderma reesei* (CBS 114044) (identification number 4a8i) as a feed additive for piglets (weaned), chickens for fattening, chickens reared for laying, turkeys for fattening, and turkeys reared for breeding

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

<i>Additive</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8)
<i>Identification number</i>	4a8i
<i>Authorisation holder</i>	Roal Oy
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Preparation of endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 114044) having a minimum enzyme activity of 160,000 BXU/g for both solid and liquid forms ⁽¹⁾
<i>Characterisation of the active substance(s)</i>	Endo-1,4-beta-xylanase (EC 3.2.1.8) produced by fermentation with <i>Trichoderma reesei</i> (CBS 114044) <ul style="list-style-type: none"> • CAS number: 9025-57-4⁽²⁾ • EC (IUBMB) number: 3.2.1.8⁽³⁾ • EINECS number: 232-800-2⁽⁴⁾
<i>Analytical methods</i> ⁽⁵⁾	For the quantification of endo-1,4-beta-xylanase (EC 3.2.1.8) in the feed additive and premixtures: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of endo-1,4-beta-xylanase on the birch xylan substrate at pH 5.3 and 50°C For the quantification of endo-1,4-beta-xylanase (EC 3.2.1.8) in feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of endo-1,4-beta-xylanase on the azurine cross-linked wheat arabino xylan substrate at pH 5.3 and 50°C
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Piglets (weaned) • Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁶⁾	For piglets (weaned): <ul style="list-style-type: none"> • 24,000 BXU/kg

(1) This authorisation is a renewal of the authorisation granted under Commission Regulation (EC) 902/2009, which is revoked by regulation 7 of, and Schedule 14 to, these Regulations, but see the transitional provision in regulation 4. This feed additive was also previously authorised as a feed additive for laying hens, minor poultry species and pigs for fattening under Commission Implementing Regulation (EU) No 1110/2011, which expired on 24 November 2021 and is revoked by regulation 7 of, and Schedule 14 to, these Regulations.

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

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

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

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

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

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

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

SCHEDULE 10

Regulation 3(1)

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

The preparation of 6-phytase (EC 3.1.3.26) specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “digestibility enhancers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

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

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

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

- (2) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.
- (3) Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) <https://iubmb.org>.
- (4) European Inventory of Existing Commercial Substances, as published in OJ No C 146A, 15.6.90, p.1.
- (5) Details of the analytical methods are set out in the document referenced “D08/FSQ/CVH/SY/D/Ares(2009)173372” and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2008-0040_en.
- (6) Content of 6-phytase (units of activity (PPU)/kg of complete feed with a moisture content of 12%).

SCHEDULE 11

Regulation 3(1)

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

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

<i>Additive</i>	L-lysine base (liquid)
<i>Identification number</i>	3c326
<i>Authorisation holder</i>	None
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Amino acids, their salts and analogues
<i>Additive composition</i>	Aqueous solution with a minimum of 50% L-lysine
<i>Characterisation of the active substance(s)</i>	L-lysine base (liquid) produced by fermentation with <i>Corynebacterium glutamicum</i> (KCCM 80216 or KCTC 12307BP) L-lysine (C ₆ H ₁₄ N ₂ O ₂) <ul style="list-style-type: none"> • CAS number: 56-87-1⁽¹⁾ • EINECS number: 200-294-2⁽²⁾
<i>Analytical methods</i> ⁽³⁾	For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013⁽⁴⁾) For the quantification of lysine in premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 laying down the methods of sampling and analysis for the official control of feed⁽¹⁾ (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) (BS EN ISO 17180:2013⁽⁴⁾), or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 (Annex 3-F)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁵⁾	None
<i>Maximum content</i> ⁽⁵⁾	None
<i>Other provisions</i>	1. The lysine content must be stated on the labelling of the additive

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

	2. L-lysine base (liquid) may be placed on the market and used as an additive consisting of a preparation
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(1) CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.

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

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

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

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

SCHEDULE 12

Regulation 3(1)

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

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

<i>Additive</i>	L-lysine monohydrochloride (technically pure)
<i>Identification number</i>	3c327
<i>Authorisation holder</i>	None
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Amino acids, their salts and analogues
<i>Additive composition</i>	Powder of L-lysine monohydrochloride with a minimum of 78% L-lysine and a maximum moisture content of 1.5%
<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 number: 657-27-2⁽¹⁾ • EINECS number: 211-519-9⁽²⁾
<i>Analytical methods</i> ⁽³⁾	For the identification of L-lysine monohydrochloride in the feed additive: <ul style="list-style-type: none"> • Food Chemicals Codex L-lysine monohydrochloride monograph⁽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) (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 laying down the methods of sampling and analysis for the official control of feed (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) (BS EN ISO 17180:2013); or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) in accordance with Commission Regulation (EC) 152/2009 (Annex 3-F)
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁶⁾	None
<i>Maximum content</i> ⁽⁶⁾	None

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

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

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

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

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

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

SCHEDULE 13

Regulation 3(1)

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

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

<i>Additive</i>	3-nitrooxypropanol
<i>Identification number</i>	4c1
<i>Authorisation holder</i>	DSM Nutritional Products Ltd (Switzerland)
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Substances which favourably affect the environment
<i>Additive composition</i>	Preparation of 3-nitrooxypropanol containing a minimum of 10% additive Granular powder; particles with a diameter < 50 µm: 0.4%
<i>Characterisation of the active substance(s)</i>	3-nitrooxypropanol (C ₃ H ₇ NO ₄) <ul style="list-style-type: none"> • CAS number: 100502-66-7⁽¹⁾
<i>Analytical methods</i> ⁽²⁾	For the quantification of 3-nitrooxypropanol in the feed additive, premixtures 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>	None
<i>Minimum content</i> ⁽³⁾	53 mg/kg
<i>Maximum content</i> ⁽³⁾	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⁾ CAS Registry Number® assigned to this preparation by the Chemical Abstracts Service <https://www.cas.org/cas-data/cas-registry>.

⁽²⁾ Details of the analytical methods are set out in the document referenced “Ares(2020)981992-15/02/2020” and “JRC F.5/CvH/ZE/AS/Ares”, and last updated on 4 May 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0057_en.

⁽³⁾ Content of 3-nitrooxypropanol (mg/kg of complete feed with a moisture content of 12%).

Revocations

Commission Regulation (EC) No 902/2009 concerning the authorisation of an enzyme preparation of endo-1,4-beta-xylanase produced by *Trichoderma reesei* (CBS 114044) as a feed additive for weaned piglets, chickens for fattening, chickens reared for laying, turkeys for fattening and turkeys reared for breeding (holder of authorisation Roal Oy)(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.)(2).

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)(3).

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)(4).

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.)(5).

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)(6).

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)(7).

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.)(8).

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)(9).

(1) EUR 2009/902.

(2) EUR 2010/9. This Regulation was amended prior to implementation period completion day by Commission Implementing Regulation (EU) No 1196/2012 and Commission Implementing Regulation (EU) 2019/221. EUR 2012/1196 is revoked by regulation 7 of, and Schedule 14 to, these Regulations. See regulation 6 for amendments to EUR 2019/221.

(3) EUR 2010/277.

(4) EUR 2010/891.

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

(6) EUR 2011/886.

(7) EUR 2011/1110.

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

(9) EUR 2012/1196.

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)(1).

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(1) EUR 2018/1569.



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