



OFFERYNNAU STATUDOL CYMRU

2022 Rhif 1118 (Cy. 233)

AMAETHYDDIAETH, CYMRU

**Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau)
(Cymru) 2022**

<i>Gwnaed</i>	<i>31 Hydref 2022</i>
<i>Gosodwyd gerbron Senedd Cymru</i>	<i>2 Tachwedd 2022</i>
<i>Yn dod i rym</i>	<i>24 Tachwedd 2022</i>

WELSH STATUTORY INSTRUMENTS

2022 No. 1118 (W. 233)

AGRICULTURE, WALES

The Feed Additives (Authorisations) (Wales) Regulations 2022

<i>Made</i>	<i>31 October 2022</i>
<i>Laid before Senedd Cymru</i>	<i>2 November 2022</i>
<i>Coming into force</i>	<i>24 November 2022</i>

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CYMRU

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**Rheoliadau Ychwanegion Bwyd
Anifeiliaid (Awdurdodiadau)
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**The Feed Additives
(Authorisations) (Wales)
Regulations 2022**

NODYN ESBONIADOL

EXPLANATORY NOTE

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

(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 ("Rheoliad 1831/2003"). Mae'r Rheoliadau hyn yn gwneud darpariaeth ar gyfer awdurdodi 11 o ychwanegion bwyd anifeiliaid.

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 ("Regulation 1831/2003"). These Regulations make provision for the authorisation of eleven feed additives.

Mae rheoliad 3 ac Atodlenni 1 i 11 yn darparu ar gyfer awdurdodi'r ychwanegion bwyd anifeiliaid a ganlyn—

Regulation 3 and Schedules 1 to 11 provide for the authorisation of the following feed additives—

- mae Atodlen 1 yn awdurdodiad newydd, ar gyfer paratoad o gelad manganis o lysin ac asid glwtamid (rhif adnabod 3b509);
- mae Atodlen 2 yn awdurdodiad newydd, ar gyfer paratoad o *Lactobacillus buchneri* DSM 29026 (rhif adnabod 1k20759);
- mae Atodlen 3 yn awdurdodiad newydd, ar gyfer paratoad o Broteas serin (EC 3.4.21.-) a gynhyrchir gan *Bacillus licheniformis* (DSM 19670) (rhif adnabod 4a13);
- mae Atodlen 4 yn adnewyddu awdurdodiad Pyridocsin hydroclorid (fitamin B₆) (rhif adnabod 3a831);
- mae Atodlen 5 yn adnewyddu awdurdodiad paratoad o *Saccharomyces cerevisiae* CNCM I-4407 (rhif adnabod 4b1702). Mae enw'r straen bacterol wedi ei newid o "Saccharomyces cerevisiae NCYC Sc 47" i "Saccharomyces cerevisiae CNCM I-4407";
- Schedule 1 is a new authorisation, for a preparation of Manganese chelate of lysine and glutamic acid (identification number 3b509);
- Schedule 2 is a new authorisation, for a preparation of *Lactobacillus buchneri* DSM 29026 (identification number 1k20759);
- Schedule 3 is a new authorisation, for a preparation of Serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* (DSM 19670) (identification number 4a13);
- Schedule 4 is a renewal of the authorisation of Pyridoxine hydrochloride (vitamin B₆) (identification number 3a831);
- Schedule 5 is a renewal of the authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 (identification number 4b1702). The name of the bacterial strain is changed from "Saccharomyces cerevisiae NCYC Sc 47" to "Saccharomyces cerevisiae CNCM I-4407";

- mae Atodlen 6 yn adnewyddu awdurdodiad paratoad o *Bacillus velezensis* (ATCC PTA-6737) (rhif adnabod 4b1823) ac yn estyn y defnydd awdurdodedig presennol i gwmpasu pob mân rywogaeth dofednod (ac eithrio ar gyfer dodwy), adar addurnol, adar helwriaeth ac adar hela. Addaswyd yr awdurdodiad fel a ganlyn:
 - newidir enw'r straen bacterol o "*Bacillus subtilis*" i "*Bacillus velezensis*";
 - cynyddir isafswm cynnwys yr ychwanegyn bwyd anifeiliaid yn y paratoad o 1×10^{10} i 8×10^{10} o unedau ffurfio cytref fesul gram (CFU/g);
- mae Atodlen 7 yn awdurdodiad newydd ar gyfer paratoad o *Bacillus licheniformis* DSM 28710 (rhif adnabod 4b1828);
- mae Atodlen 8 yn adnewyddu awdurdodiadau paratoad o *Clostridium butyricum* (FERM BP-2789) (rhif adnabod 4b1830) ac yn ei awdurdodi ar gyfer defnydd newydd mewn bwyd anifeiliaid ar gyfer ieir i'w pesgi, perchyll sugno a mân rywogaethau teulu'r moch (sugno);
- mae Atodlen 9 yn awdurdodiad newydd, ar gyfer paratoad o 6-ffytas a gynhyrchir gan *Komagataella phaffii* DSM 32854 (rhif adnabod 4a32);
- mae Atodlen 10 yn awdurdodi fformiweiddiad newydd o ddecoquinad (Deccox[®]) (rhif adnabod E756) fel decoquinad (Deccox[®]) (rhif adnabod 51756i);
- mae Atodlen 11 yn awdurdodi ffurf addasedig o ddecoquinad (Deccox[®]) (rhif adnabod E756) fel decoquinad (Avi-Deccox[®] 60G) (rhif adnabod 51756ii). Mae'r ychwanegyn bwyd anifeiliaid hwn yn wahanol i ddecoquinad (Deccox[®]) o ran ei ffurf ffisegol ac oherwydd calsiwm sylffad dehydrad yw'r gwanedydd a ddefnyddir.
- Schedule 6 is a renewal of the authorisation of a preparation of *Bacillus velezensis* (ATCC PTA-6737) (identification number 4b1823), and an extension of existing authorised uses to cover all minor poultry species (except for laying), ornamental birds, sporting birds and game birds. The authorisation has been modified as follows:
 - the bacterial strain name is changed from "*Bacillus subtilis*" to "*Bacillus velezensis*";
 - the minimum content of the feed additive in the preparation is increased from 1×10^{10} to 8×10^{10} colony forming units per gram (CFU/g);
- Schedule 7 is a new authorisation of a preparation of *Bacillus licheniformis* DSM 28710 (identification number 4b1828);
- Schedule 8 is a renewal of the authorisations of a preparation of *Clostridium butyricum* (FERM BP-2789) (identification number 4b1830) and authorises it for a new use in feed for chickens for fattening, suckling piglets and minor porcine species (suckling);
- Schedule 9 is a new authorisation, for a preparation of 6-phytase produced by *Komagataella phaffii* DSM 32854 (identification number 4a32);
- Schedule 10 authorises a new formulation of decoquinad (Deccox[®]) (identification number E756) as decoquinad (Deccox[®]) (identification number 51756i);
- Schedule 11 authorises a modified form of decoquinad (Deccox[®]) (identification number E756) as decoquinad (Avi-Deccox[®] 60G) (identification number 51756ii). This feed additive differs from decoquinad (Deccox[®]) in physical form and in the dilutant used being calcium sulphate dihydrate.

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 Reoliad 1831/2003. Mae hyn yn ddarostyngedig i Erthygl 14(4) o'r Rheoliad hwnnw, sy'n darparu ar gyfer estyn cyfnod yr awdurdodiad o dan amgylchiadau penodol pan fo cais i adnewyddu wedi ei gyflwyno.

Mae rheoliadau 4 i 7 yn diwygio pedwar o Reoliadau'r UE a ddargedwir sy'n awdurdodi'r ychwanegyn bwyd anifeiliaid *Bacillus subtilis* ATCC PTA-6737 ar gyfer gwahanol is-grwpiau o ddofednod a moch. Mae enw'r straen bacterol wedi ei ddiweddarau o "*Bacillus subtilis*" i "*Bacillus velezensis*". Mae

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 Regulation 1831/2003. This is subject to Article 14(4) of that Regulation, which provides for an extension of the authorisation period in certain circumstances where an application for renewal has been submitted.

Regulations 4 to 7 amend four retained EU Regulations that authorise the feed additive *Bacillus subtilis* ATCC PTA-6737 for differing poultry and pig sub-groups. The name of the bacterial strain is updated from "*Bacillus subtilis*" to "*Bacillus velezensis*".

rheoliad 10(1) yn cynnwys darpariaeth drosiannol sy'n caniatáu i gynhyrchion a labelwyd gan ddefnyddio'r enw "*Bacillus subtilis*" barhau i gael eu marchnata a'u defnyddio o dan yr awdurdodiadau perthnasol er gwaethaf newid yr enw.

Mae rheoliad 8 ac Atodlen 12 yn dirymu, o ran Cymru, Reoliadau'r UE a ddargedwir sy'n cynnwys awdurdodiadau ymlaen llaw ar gyfer yr ychwanegion bwyd anifeiliaid sydd bellach wedi eu hawdurdodi gan Atodlenni 3, 4, 5, 6, 8 a 10.

Mae rheoliadau 9, 10(2) i (5) ac 11 yn cynnwys darpariaethau trosiannol sy'n caniatáu parhau i gynhyrchu a labelu cynhyrchion, am gyfnodau cyfyngedig o amser, o dan amodau awdurdodiadau ymlaen llaw o'r ychwanegion bwyd anifeiliaid perthnasol. Caiff yr ychwanegion bwyd anifeiliaid hynny eu hawdurdodi bellach gan Atodlenni 5, 6 a 10 yn y drefn honno.

Gellir cael rhagor o wybodaeth, gan gynnwys mewn perthynas ag unrhyw ddogfennaeth y cyfeirir ati yn yr Atodlenni, gan yr Asiantaeth Safonau Bwyd, Llawr 11, Tŷ Southgate, Caerdydd, CF10 1EW neu drwy anfon e-bost i 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 aseiad effaith rheoleiddiol o'r costau a'r manteision sy'n debygol o ddeillio o gydymffurfio â'r Rheoliadau hyn.

Regulation 10(1) contains a transitional provision that allows products labelled using the name "*Bacillus subtilis*" to continue to be marketed and used under the relevant authorisations despite the change to the name.

Regulation 8 and Schedule 12 revoke, in relation to Wales, retained EU Regulations that contain prior authorisations for the feed additives now authorised by Schedules 3, 4, 5, 6, 8 and 10.

Regulations 9, 10(2) to (5) and 11 contain transitional provisions that allow the continued production and labelling of products, for limited time periods, under the conditions of prior authorisations of the relevant feed additives. Those feed additives are now authorised by Schedules 5, 6 and 10 respectively.

Further information, including in relation to any documentation referenced in the Schedules, can be obtained from the Food Standards Agency, 11th Floor, Southgate House, Cardiff, CF10 1EW 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.

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Anifeiliaid (Awdurdodiadau)
(Cymru) 2022**

**The Feed Additives
(Authorisations) (Wales)
Regulations 2022**

Gwnaed 31 Hydref 2022

Made 31 October 2022

*Gosodwyd
Senedd Cymru* gerbron
2 Tachwedd 2022

Laid before Senedd Cymru 2 November 2022

Yn dod i rym 24 Tachwedd 2022

Coming into force 24 November 2022

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 chychwyn

Title, extent, application and commencement

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau) (Cymru) 2022.

1.—(1) The title of these Regulations is the Feed Additives (Authorisations) (Wales) Regulations 2022.

(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 24 Tachwedd 2022.

- (a) extend to England and Wales;
- (b) apply in relation to Wales;
- (c) come into force on 24 November 2022.

(1) EUR 2003/1831, a ddiwygiwyd gan O.S. 2019/654 a 2022/377. 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.

(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 and 2022/377. 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.

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

Dehongli

2.—(1) Yn y Rheoliadau hyn—

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 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(1).

(2) Mae i unrhyw ymadrodd Cymraeg a ddefnyddir yn y Rheoliadau hyn sy’n cyfateb i ymadrodd Saesneg yn Rheoliad 1831/2003 neu Rheoliad 767/2009 yr un ystyr â’r ymadrodd hwnnw yn Rheoliadau’r UE a ddargedwir.

Awdurdodiadau

3.—(1) Mae Atodlenni 1 i 11 yn cynnwys awdurdodiadau ychwanegion bwyd anifeiliaid.

(2) Yn ddarostyngedig i Erthygl 14(4) (adnewyddu awdurdodiad) o Rheoliad 1831/2003, mae’r awdurdodiadau a nodir yn Atodlenni 1 i 11 yn peidio â chael effaith ar ddiwedd 23 Tachwedd 2032.

Diwygio awdurdodiadau *Bacillus velezensis* ATCC PTA-6737 presennol

4.—(1) Mae Rheoliad Gweithredu’r Comisiwn (EU) Rhif 306/2013 sy’n ymwneud ag awdurdodiad paratoad o *Bacillus subtilis* (ATCC PTA-6737) ar gyfer perchyll wedi eu diddyfnu a Suidae wedi eu diddyfnu heblaw *Sus scrofa domesticus*(2) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn y tabl, yng ngholofnau 3 (yr ychwanegyn) a 4 (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), yn lle “*Bacillus subtilis*”, ym mhob lle y mae’n digwydd, rhodder “*Bacillus velezensis*”.

5.—(1) Mae Rheoliad Gweithredu’r Comisiwn (EU) Rhif 787/2013 sy’n ymwneud ag awdurdodiad paratoad o *Bacillus subtilis* (ATCC PTA-6737) fel ychwanegyn bwyd anifeiliaid ar gyfer tyrcwn i’w pesgi a thyrcwn a fegir ar gyfer bridio(3) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn y tabl, yng ngholofnau 3 (yr ychwanegyn) a 4 (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), yn lle “*Bacillus subtilis*”, ym mhob lle y mae’n digwydd, rhodder “*Bacillus velezensis*”.

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

(2) EUR 2013/306.

(3) EUR 2013/787.

Interpretation

2.—(1) In these Regulations—

“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 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(1).

(2) Any expression used both in these Regulations and in Regulation 1831/2003 or Regulation 767/2009 has the same meaning as it has in those retained EU Regulations.

Authorisations

3.—(1) Schedules 1 to 11 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 11 cease to have effect at the end of 23 November 2032.

Amendment of existing *Bacillus velezensis* ATCC PTA-6737 authorisations

4.—(1) Commission Implementing Regulation (EU) No 306/2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) for weaned piglets and weaned Suidae other than *Sus scrofa domesticus*(2) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for “*Bacillus subtilis*”, in each place it occurs, substitute “*Bacillus velezensis*”.

5.—(1) Commission Implementing Regulation (EU) No 787/2013 concerning the authorisation of a preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for turkeys for fattening and turkeys reared for breeding(3) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for “*Bacillus subtilis*”, in each place it occurs, substitute “*Bacillus velezensis*”.

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

(2) EUR 2013/306.

(3) EUR 2013/787.

6.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) 2015/1020 sy'n ymwneud ag awdurdodiad paratoad o *Bacillus subtilis* (ATCC PTA-6737) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy a mân rywogaethau dofednod ar gyfer dodwy(1) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn y tabl, yng ngholofnau 3 (yr ychwanegyn) a 4 (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), yn lle "*Bacillus subtilis*", ym mhob lle y mae'n digwydd, rhodder "*Bacillus velezensis*".

7.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) 2017/2276 sy'n ymwneud ag awdurdodiad defnydd newydd o'r paratoad o *Bacillus subtilis* (ATCC PTA-6737) fel ychwanegyn bwyd anifeiliaid ar gyfer hychod(2) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn y tabl, yng ngholofnau 3 (yr ychwanegyn) a 4 (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), yn lle "*Bacillus subtilis*", ym mhob lle y mae'n digwydd, rhodder "*Bacillus velezensis*".

Dirymiadau

8. Mae'r offerynnau a restrir yn Atodlen 12 wedi eu dirymu.

Darpariaethau trosiannol: *Saccharomyces cerevisiae* CNCM I-4407 (*Saccharomyces cerevisiae* NCYC Sc 47 yn flaenorol) (rhif adnabod 4b1702)

9.—(1) Caniateir i'r ychwanegyn bwyd anifeiliaid perthnasol a rhag-gymysgeddau sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 23 Mai 2023 yn unol ag amodau'r awdurdodiad ymlaen llaw, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd y stociau presennol 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 23 Tachwedd 2023 yn unol ag amodau'r awdurdodiad ymlaen llaw, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd y stociau presennol wedi eu dihysbyddu.

6.—(1) Commission Implementing Regulation (EU) 2015/1020 concerning the authorisation of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for laying hens and minor poultry species for laying(1) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for "*Bacillus subtilis*" in each place it occurs substitute "*Bacillus velezensis*".

7.—(1) Commission Implementing Regulation (EU) 2017/2276 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for sows(2) is amended as follows.

(2) In the Annex, in the table, in columns 3 (additive) and 4 (composition, chemical formula, description, analytical method), for "*Bacillus subtilis*", in each place it occurs, substitute "*Bacillus velezensis*".

Revocations

8. The instruments listed in Schedule 12 are revoked.

Transitional provisions: *Saccharomyces cerevisiae* CNCM I-4407 (formerly *Saccharomyces cerevisiae* NCYC Sc 47) (identification number 4b1702)

9.—(1) The relevant feed additive and premixtures containing it, which are produced and labelled before the end of 23 May 2023 in accordance with the conditions of the prior authorisation may continue to be placed on the market and used until the existing 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 23 November 2023 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(1) EUR 2015/1020.
(2) EUR 2017/2276.

(1) EUR 2015/1020.
(2) EUR 2017/2276.

(3) Yn y rheoliad hwn—

mae “yr awdurdodiad ymlaen llaw” (“*the prior authorisation*”) yn cyfeirio at yr awdurdodiad a gynhwysir yn Rheoliad y Comisiwn (EU) Rhif 883/2010 sy’n ymwneud ag awdurdodi defnydd newydd o *Saccharomyces cerevisiae* NCYC Sc 47 fel ychwanegyn bwyd anifeiliaid ar gyfer lloi magu(1);

mae “ychwanegyn bwyd anifeiliaid perthnasol” (“*relevant feed additive*”) yn cyfeirio at yr ychwanegyn bwyd anifeiliaid *Saccharomyces cerevisiae* CNCM I-4407, neu fel y’i dynodwyd yn flaenorol, *Saccharomyces cerevisiae* NCYC Sc 47 sydd â’r rhif adnabod 4b1702, a awdurdodwyd yn flaenorol o dan yr awdurdodiad ymlaen llaw.

Darpariaethau trosiannol: *Bacillus velezensis* ATCC PTA-6737 (*Bacillus subtilis* ATCC PTA-6737 yn flaenorol) (rhif adnabod 4b1823)

10.—(1) Caniateir i unrhyw sylwedd neu gynnyrch a labelwyd “*Bacillus subtilis* ATCC PTA-6737” neu a labelwyd fel sylwedd neu gynnyrch sy’n cynnwys “*Bacillus subtilis* ATCC PTA-6737”, ond sydd fel arall wedi cael ei gynhyrchu a’i labelu yn unol ag awdurdodiad sydd wedi ei gynnwys mewn offeryn a grybwyllir yn rheoliadau 4 i 7, barhau i gael ei roi ar y farchnad a’i ddefnyddio o dan yr awdurdodiad hwnnw.

(2) Caniateir i’r ychwanegyn bwyd anifeiliaid perthnasol a rhag-gymysgeddau sy’n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 23 Mai 2023 yn unol ag amodau’r awdurdodiad ymlaen llaw, barhau i gael ei roi neu eu rhoi ar y farchnad a’i ddefnyddio neu eu defnyddio hyd nes y bydd y stociau presennol wedi eu dihysbyddu.

(3) 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 23 Tachwedd 2023 yn unol ag amodau’r awdurdodiad ymlaen llaw, barhau i gael ei roi neu eu rhoi ar y farchnad a’i ddefnyddio neu eu defnyddio hyd nes y bydd y stociau presennol wedi eu dihysbyddu.

(4) Caniateir i fwyd anifeiliaid cyfansawdd a deunyddiau bwyd anifeiliaid sy’n cynnwys yr ychwanegyn bwyd anifeiliaid perthnasol ac a fwriedir ar gyfer anifeiliaid nad ydynt yn cynhyrchu bwyd, a gynhyrchir ac a labelir cyn diwedd 23 Tachwedd 2024 yn unol ag amodau’r awdurdodiad ymlaen llaw, barhau i gael ei roi neu eu rhoi ar y farchnad a’i ddefnyddio neu eu defnyddio hyd nes y bydd y stociau presennol wedi eu dihysbyddu.

(3) In this regulation—

“relevant feed additive” (“*ychwanegyn bwyd anifeiliaid perthnasol*”) refers to the feed additive *Saccharomyces cerevisiae* CNCM I-4407, or as formerly designated, *Saccharomyces cerevisiae* NCYC Sc 47, with the identification number 4b1702, which was previously authorised under the prior authorisation;

“the prior authorisation” (“*yr awdurdodiad ymlaen llaw*”) refers to the authorisation contained in Commission Regulation (EU) Regulation No 883/2010 concerning the authorisation of a new use of *Saccharomyces cerevisiae* NCYC Sc 47 as a feed additive for calves for rearing(1).

Transitional provisions: *Bacillus velezensis* ATCC PTA-6737 (formerly *Bacillus subtilis* ATCC PTA-6737) (identification number 4b1823)

10.—(1) Any substance or product labelled “*Bacillus subtilis* ATCC PTA-6737” or as containing “*Bacillus subtilis* ATCC PTA-6737”, but otherwise produced and labelled in accordance with an authorisation contained in an instrument mentioned in regulations 4 to 7, may continue to be placed on the market and used under that authorisation.

(2) The relevant feed additive and premixtures containing it, which are produced and labelled before the end of 23 May 2023 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(3) 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 23 November 2023 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(4) Compound feed and feed materials containing the relevant feed additive and intended for non-food-producing animals, which are produced and labelled before the end of 23 November 2024 in accordance with the conditions of the prior authorisation, may continue to be placed on the market and used until the existing stocks are exhausted.

(1) EUR 2010/883. Mae’r Rheoliad hwn wedi ei ddirymu gan reoliad 8 o’r Rheoliadau hyn.

(1) EUR 2010/883. This Regulation is revoked by regulation 8 of these Regulations.

(5) Yn y rheoliad hwn—

mae “yr awdurdodiad ymlaen llaw” (“*the prior authorisation*”) yn cyfeirio at awdurdodiad sydd wedi ei gynnwys yn—

Rheoliad y Comisiwn (EU) Rhif 107/2010 sy’n ymwneud ag awdurdodi *Bacillus subtilis* ATCC PTA-6737 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i’w pesgi(1), neu

Reoliad Gweithredu’r Comisiwn (EU) Rhif 885/2011 sy’n ymwneud ag awdurdodi *Bacillus subtilis* (ATCC PTA-6737) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy, hwyaid i’w pesgi, soffieir, ffesantod, petris, ieir gini, colomennod, gwyddau i’w pesgi ac estrysiaid(2);

mae “ychwanegyn bwyd anifeiliaid perthnasol” (“*relevant feed additive*”) yn cyfeirio at yr ychwanegyn bwyd anifeiliaid *Bacillus velezensis* ATCC PTA-6737 neu, fel y’i dynodwyd yn flaenorol, *Bacillus subtilis* ATCC PTA-6737, sydd â’r rhif adnabod 4b1823, a awdurdodwyd yn flaenorol o dan yr awdurdodiad ymlaen llaw.

Darpariaeth drosiannol: Decocwinad (Deccox®) (rhif adnabod 51756i (E756 yn flaenorol))

11.—(1) Caniateir i’r ychwanegyn bwyd anifeiliaid perthnasol a bwyd anifeiliaid sy’n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 23 Mai 2023 yn unol ag amodau’r awdurdodiad ymlaen llaw, barhau i gael eu rhoi ar y farchnad a’u defnyddio hyd nes y bydd y stociau presennol wedi eu dihybyddu.

(2) Yn y rheoliad hwn—

mae “yr awdurdodiad ymlaen llaw” (“*the prior authorisation*”) yn cyfeirio at yr awdurdodiad sydd wedi ei gynnwys yn Rheoliad y Comisiwn (EC) Rhif 1289/2004 sy’n ymwneud ag awdurdodi am 10 mlynedd yr ychwanegyn Deccox® mewn bwydydd anifeiliaid, sy’n perthyn i’r grŵp o gocsidiostatau a sylweddu meddyginiaethol eraill(3);

mae “ychwanegyn bwyd anifeiliaid perthnasol” (“*relevant feed additive*”) yn cyfeirio at yr ychwanegyn bwyd anifeiliaid Decocwinad (Deccox®) a awdurdodwyd yn flaenorol o dan yr awdurdodiad ymlaen llaw sydd â’r rhif adnabod E756.

(5) In this regulation—

“relevant feed additive” (“*ychwanegyn bwyd anifeiliaid perthnasol*”) refers to the feed additive *Bacillus velezensis* ATCC PTA-6737 or, as formerly designated, *Bacillus subtilis* ATCC PTA-6737, with the identification number 4b1823, which was previously authorised under the prior authorisation;

“the prior authorisation” (“*yr awdurdodiad ymlaen llaw*”) refers to an authorisation contained in—

Commission Regulation (EU) No 107/2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (1), or

Commission Implementing Regulation (EU) No 885/2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches(2).

Transitional provision: Decoquinat (Deccox®) (identification number 51756i (formerly E756))

11.—(1) The relevant feed additive and feed containing it, which are produced and labelled before the end of 23 May 2023 in accordance with the conditions of the prior authorisation may, continue to be placed on the market and used until the existing stocks are exhausted.

(2) In this regulation—

“relevant feed additive” (“*ychwanegyn bwyd anifeiliaid perthnasol*”) refers to the feed additive Decoquinat (Deccox®) which was previously authorised under the prior authorisation with the identification number E756;

“the prior authorisation” (“*yr awdurdodiad ymlaen llaw*”) refers to the authorisation contained in Commission Regulation (EC) No 1289/2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances(3).

(1) EUR 2010/107. Mae’r Rheoliad hwn wedi ei ddirymu gan reoliad 8 o’r Rheoliadau hyn.

(2) EUR 2011/885. Mae’r Rheoliad hwn wedi ei ddirymu gan reoliad 8 o’r Rheoliadau hyn.

(3) EUR 2004/1289. Mae’r Rheoliad hwn wedi ei ddirymu gan reoliad 8 o’r Rheoliadau hyn.

(1) EUR 2010/107. This Regulation is revoked by regulation 8 of these Regulations.

(2) EUR 2011/885. This Regulation is revoked by regulation 8 of these Regulations.

(3) EUR 2004/1289. This Regulation is revoked by regulation 8 of these Regulations.

Lynne Neagle

Y Dirprwy Weinidog Iechyd Meddwl a Llesiant, o dan
awdurdod y Gweinidog Iechyd a Gwasanaethau
Cymdeithasol, un o Weinidogion Cymru
31 Hydref 2022

Deputy Minister for Mental Health and Wellbeing,
under the authority of the Minister for Health and
Social Services, one of the Welsh Ministers
31 October 2022

Awdurdodi paratoad o gelad manganîs o lysin ac asid glwtamig (rhif adnabod 3b509) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "cyfansoddion elfennau hybrin", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	Celad manganîs o lysin ac asid glwtamig
<i>Rhif adnabod yr ychwanegyn</i>	3b509
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Cyfansoddion elfennau hybrin
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o geladau manganîs gyda lysin a cheladau manganîs gydag asid glwtamig mewn cymhareb o 1:1 fel powdr gyda'r cydrannau a ganlyn: <ul style="list-style-type: none"> • Manganîs 15-17% • Lysin 20-21.5% • Asid glwtamig 22-24% • Lleithder – uchafswm o 3.5% • Nicel – uchafswm o 4 ppm
<i>Nodweddiad y sylwedd(au) actif</i>	Manganîs-2, asid 6-diaminohecsanoïg, clorid a halwyn hydrogen sylffad (C ₆ H ₁₉ ClN ₂ O ₈ SMn) Asid manganîs-2-aminopentanedioïg, sodiwm a halwyn hydrogen sylffad (C ₅ H ₁₀ NN _a O ₉ SMn)
<i>Dulliau dadansoddi⁽¹⁾</i>	<p>I feintioli cyfanswm y manganîs yn yr ychwanegyn bwyd anifeiliaid :</p> <ul style="list-style-type: none"> • Sbectrometreg Amsugniad Atomig (AAS) (BS EN ISO 6869:2001⁽²⁾), neu • Sbectrometreg Allyriant Atomig â Phlasma a Gyplyswyd yn Anwythol ar ôl treulio drwy bwysedd (ICP-AES) (BS EN 15621:2017⁽⁴⁾). <p>I feintioli cyfanswm y manganîs yn y rhag-gymysgeddau:</p> <ul style="list-style-type: none"> • Sbectrometreg Amsugniad Atomig (AAS) (BS EN ISO 6869:2001⁽²⁾), • Sbectrometreg Allyriant Atomig â Phlasma a Gyplyswyd yn Anwythol (ICP-AES) (BS EN 15510:2017⁽³⁾), • Sbectrometreg Allyriant Atomig â Phlasma a Gyplyswyd yn Anwythol ar ôl treulio drwy bwysedd (ICP-AES) (BS EN 15621:2017⁽⁴⁾), neu • Sbectrometreg Mâs â Phlasma a Gyplyswyd yn Anwythol (ICP-MS) (BS EN 17053:2018⁽⁵⁾). <p>I feintioli cyfanswm y manganîs yn y deunyddiau bwyd anifeiliaid a'r bwyd anifeiliaid cyfansawdd:</p> <ul style="list-style-type: none"> • Sbectrometreg Amsugniad Atomig (AAS) – Rheoliad y Comisiwn (EC) Rhif 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol (Atodiad 4-C)(1), • Sbectrometreg Amsugniad Atomig (AAS) (BS EN ISO 6869:2001⁽²⁾),

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

	<ul style="list-style-type: none"> • Sbectrometreg Allyriant Atomig â Phlasma a Gyplyswyd yn Anwythol (ICP-AES) (BS EN 15510:2017⁽³⁾), • Sbectrometreg Allyriant Atomig â Phlasma a Gyplyswyd yn Anwythol ar ôl treulio drwy bwysedd (ICP-AES) (BS EN 15621:2017⁽⁴⁾), neu • Sbectrometreg Mâs â Phlasma a Gyplyswyd yn Anwythol (ICP-MS) (BS EN 17053:2018⁽⁵⁾).
	<p>I feintioli cynnwys lysin ac asid glwtamig yn yr ychwanegyn bwyd anifeiliaid:</p> <ul style="list-style-type: none"> • Cromatograffi cyfnewid iönu a gyplysir â deilliant ôl-golofn a synhwyrdd ffotometrigrig (IEC-VIS) (BS EN ISO 13903:2005⁽⁶⁾).
	<p>I ganfod ffurf geladedig yr ychwanegyn bwyd anifeiliaid:</p> <ul style="list-style-type: none"> • Sbectrometreg isgoch canol (IR) ynghyd â chanfod cynnwys yr elfennau hybrin a'r lysin a'r asid glwtamig yn yr ychwanegyn bwyd anifeiliaid.
<i>Rhywogaeth neu categori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁷⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁷⁾</i>	Pysgod: 100mg/kg (cyfanswm)
	Pob rhywogaeth arall o anifail: 150mg/kg (cyfanswm)
<i>Darpariaethau eraill</i>	Rhaid ymgorffori'r ychwanegyn bwyd anifeiliaid yn y bwyd anifeiliaid ar ffurf rhag-gymysgedd.

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2018)3918699 - 24/07/2018" a'r ddogfen sydd â'r cyfeirnod "Ares(2019)7167892 - 20/11/2019" a ddiweddarwyd ddiwethaf ar 28 Ionawr 2020. Mae'r dogfennau hyn ar gael ar y cyfeiriad a ganlyn:

<https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0009?search&form-return>

⁽²⁾ O dan y cyfeirnod BS EN ISO 6869:2001 "Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 15 Mawrth 2001 (ISBN 0 580 36933 1). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽³⁾ O dan y cyfeirnod BS EN 15510:2017 "Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Awst 2017 (ISBN 978 0 580 94541 0). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁴⁾ O dan y cyfeirnod BS EN 15621:2017 "Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Awst 2017 (ISBN 978 0 580 94543 4). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁵⁾ O dan y cyfeirnod BS EN 17053:2018 "Animal feeding stuffs: Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 28 Chwefror 2018 (978 0 580 94471 0). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁶⁾ O dan y cyfeirnod BS EN ISO 13903:2005 "Animal feeding stuffs. Determination of amino acids content". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 24 Hydref 2005 (ISBN 0 580 46218 8). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁷⁾ Cynnwys yr elfen (Mn) mewn mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Awdurdodi paratoad o *Lactobacillus buchneri* DSM 29026 (rhif adnabod 1k20759) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad 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>Lactobacillus buchneri</i> DSM 29026
<i>Rhif adnabod yr ychwanegyn</i>	1k20759
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion technolegol
<i>Grŵp gweithredol</i>	Ychwanegion silwair
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o <i>Lactobacillus buchneri</i> DSM 29026 sy'n cynnwys isafswm o 2×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd hyfyw <i>Lactobacillus buchneri</i> DSM 29026
<i>Dulliau dadansoddi</i> ⁽¹⁾	Ar gyfer cyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> 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 bwyd anifeiliaid pan nad yw wedi ei gyfuno â micro-organeddau eraill fel ychwanegion silwair: 5×10^7 CFU/kg o ddeunydd ffres sy'n hawdd ac yn gymedrol anodd i'w silweirio ⁽⁴⁾
<i>Uchafswm cynnwys</i> ⁽³⁾	Dim
<i>Darpariaethau eraill</i>	Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio.

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2019)4747322 - 22/07/2019" ac a ddiweddarwyd ddiwethaf ar 18 Hydref 2019. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0093>.

⁽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 gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>

⁽³⁾ Cynnwys yr elfen *Lactobacillus buchneri* DSM 29026 mewn CFU o ychwanegyn/kg o ddeunydd ffres.

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

(1) EUR 2008/429, a ddiwygiwyd gan O.S. 2019/654. Diwygiwyd O.S. 2019/654 gan O.S. 2020/1504.

Awdurdodi paratoad o broteas serin (EC 3.4.21.-) a gynhyrchir gan *Bacillus licheniformis* DSM 19670 (rhif adnabod 4a13) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi

Mae'r paratoad 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.

<i>Yr ychwanegyn</i>	Proteas serin (EC 3.4.21.-)
<i>Rhif adnabod yr ychwanegyn</i>	4a13
<i>Deiliad yr awdurdodiad</i>	DSM Nutritional Products Ltd (Y Swistir)
<i>Categori ychwanegion</i>	Ychwanegion sootechnegol
<i>Grŵp gweithredol</i>	Sylweddau gwella treuliadwyedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad solet a hylifol o broteas serin (EC 3.4.21.-): <ul style="list-style-type: none"> • a gynhyrchir gan <i>Bacillus licheniformis</i> DSM 19670 • sydd ag isafswm actifedd o 75,000 PROT⁽¹⁾/g
<i>Nodweddiad y sylwedd(au) actif</i>	<ul style="list-style-type: none"> • Proteas serin (EC 3.4.21.-) a gynhyrchir gan <i>Bacillus licheniformis</i> DSM 19670 • Rhif CAS⁽²⁾: 37259-58-8 (proteas serin) • Rhif EINECS⁽³⁾: 253-431-3 • Rhif IUB⁽⁴⁾: 3.4.21.-
<i>Dulliau dadansoddi⁽⁵⁾</i>	I feintio actifedd proteas serin yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau, y bwyd anifeiliaid cyfansawdd a'r deunyddiau bwyd anifeiliaid: <ul style="list-style-type: none"> • y dull colorimetrig ar sail adwaith ensymatig proteas serin ar y swbstrad Suc-Ala-Ala-Pro-Phe-pNA.
<i>Rhywogaeth neu gategori o anifail</i>	Ieir i'w pesgi
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁶⁾</i>	15,000 PROT ⁽¹⁾ /kg
<i>Uchafswm cynnwys⁽⁶⁾</i>	Dim
<i>Darpariaethau eraill</i>	Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.

⁽¹⁾ Un PROT yw'r swm o broteas serin sy'n rhyddhau un micromol/munud o bara-nitroanilin (pNA) o 1 milimolar (mM) o swbstrad Suc-Ala-Ala-Pro-Phe-pNA ar pH 9 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⁾ Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, y rhif fel y'i cyhoeddwyd yn OJ Rhif C 146 A, 15.6.90, t.1.

⁽⁴⁾ Rhif adnabod a neilltuwyd gan yr Undeb Biocemeg Rhyngwladol (IUB), sef yr Undeb Biocemeg a Bioleg Foleciwlaidd Rhyngwladol (IUBMB) bellach iubmb.org.

⁽⁵⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2019)6802984 - 04/11/2019" ac a ddiweddarwyd ddiwethaf ar 27 Ionawr 2020. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0010>.

⁽⁶⁾ Cynnwys Proteas serin mewn PROT/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Adnewyddu awdurdodiad pyridocsin hydroclorid (fitamin B₆) (rhif adnabod 3a831) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r sylwedd a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "fitaminau, pro-fitamiau a sylweddau wedi eu diffinio'n dda yn gemegol sydd ag effaith debyg", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	Pyridocsin hydroclorid (fitamin B ₆)
<i>Rhif adnabod yr ychwanegyn</i>	3a831
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Fitaminau, pro-fitamiau a sylweddau wedi eu diffinio'n dda yn gemegol sydd ag effaith debyg
<i>Cyfansoddiad yr ychwanegyn</i>	Pyridocsin hydroclorid, gyda meini prawf puredd heb fod yn llai na 98.5%
<i>Nodweddiad y sylwedd(au) actif</i>	<ul style="list-style-type: none"> • Pyridocsin hydroclorid: C₈H₁₁NO₃·HCl • Rhif CAS⁽¹⁾:58-56-0 • Rhif EINECS⁽²⁾: 200-386-2
<i>Dulliau dadansoddi⁽³⁾</i>	I ganfod pyridocsin hydroclorid (fitamin B ₆) yn yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Titradiad ag asid perclorig (Ph. Eur. 10fed argraffiad, monograff 0245⁽⁴⁾).
	I ganfod pyridocsin hydroclorid (fitamin B ₆) mewn rhag-gymysgeddau: <ul style="list-style-type: none"> • Cromatograffaeth Hylif Perfformiad Uchel gwedd wrthdro wedi ei gplysu â synhwyrydd Uwch Fioled (RP-HPLC-UV) (VDLUF 13.9.1⁽⁵⁾).
	I ganfod pyridocsin hydroclorid (fitamin B ₆) mewn bwyd anifeiliaid a dŵr: <ul style="list-style-type: none"> • Cromatograffaeth Hylif Perfformiad Uchel gwedd wrthdro wedi ei gplysu â synhwyrydd fflworoleuedd (RP-HPLC-FLD) – dull yn seiliedig ar BS EN 14164:2014⁽⁶⁾.
<i>Rhywogaeth neu gategori o anifail</i>	Pob rhywogaeth o anifail
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁷⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁷⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres ac mewn dŵr.
	2. Gellir defnyddio pyridocsin hydroclorid (fitamin B ₆) mewn dŵr i'w yfed.

(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, y rhif fel y'i cyhoeddwyd yn OJ Rhif C 146 A, 15.6.90, t.1.

(1) Mae'r awdurdodiad hwn yn adnewyddu'r awdurdodiad a roddwyd o dan Reoliad Gweithredu'r Comisiwn (EU) Rhif 515/2011. Mae'r Rheoliad hwnnw wedi ei ddirymu gan reoliad 8 o'r Rheoliadau hyn.

- (3) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "JRC.DG.D.6/CvH/GB/ag/ARES(2011)356822" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0139>.
- (4) European Pharmacopoeia, Cyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd, 10fed argraffiad. Cyhoeddwyd 1 Gorffennaf 2019 (ISBN 9789999146111).
- (5) Llyfr Dull Cymdeithas Sefydliadau Dadansoddi ac Ymchwilio Amaethyddol yr Almaen (VDLUFA), Cyfrol III, 6ed atodiad 2006, Dadansoddi Bwydydd Anifeiliaid yn Gemegol (ISBN 978 3 941273 14 6), <https://vdlufa.de>.
- (6) O dan y cyfeirnod BS EN 14164:2014 "Foodstuffs. Determination of vitamin B₆ by high performance chromatography". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Mehefin 2014 (ISBN 978 0 580 77941 1). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.
- (7) Cynnwys pyridocsin hydroclorid (fitamin B₆) mewn mg o ychwanegyn/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Adnewyddu awdurdodiad paratoad o *Saccharomyces cerevisiae* CNCM I-4407 (*Saccharomyces cerevisiae* NCYC Sc 47 yn flaenorol) (rhif adnabod 4b1702) fel ychwanegyn bwyd anifeiliaid ar gyfer lloi magu

Mae'r paratoad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sefydlogyddion fflora'r perfedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	<i>Saccharomyces cerevisiae</i> CNCM I-4407
<i>Rhif adnabod yr ychwanegyn</i>	4b1702
<i>Deiliad yr awdurdodiad</i>	S.I. Lesaffre
<i>Categori ychwanegion</i>	Ychwanegion sootechnegol
<i>Grŵp gweithredol</i>	Sefydlogyddion fflora'r perfedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o <i>Saccharomyces cerevisiae</i> CNCM I-4407 ar ffurf solet sy'n cynnwys isafswm o 5×10^9 CFU/g
<i>Nodweddiad y sylwedd(au) actif</i>	Celloedd sych hyfyw <i>Saccharomyces cerevisiae</i> CNCM I-4407
<i>Dulliau dadansoddi</i> ⁽¹⁾	Ar gyfer cyfrifo (cyfrif cytrefi) 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 plât arllwys gan ddefnyddio agar CGED (cloramffenicol, glwcos, echdynnyn burum) (BS EN 15789:2021⁽²⁾).
	Ar gyfer adnabod y straen burum: <ul style="list-style-type: none"> Y dull adwaith cadwynol polymerasau (PCR) (DD CEN/TS 15790:2008⁽³⁾).
<i>Rhywogaeth neu gategori o anifail</i>	Lloi magu
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽⁴⁾	1.5×10^9 CFU/kg
<i>Uchafswm cynnwys</i> ⁽⁴⁾	Dim
<i>Darpariaethau eraill</i>	Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "JRC.DG.D.6/CvH/DM/mds/ARES(2010)967257" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0038>.

⁽²⁾ O dan y cyfeirnod BS EN 15789:2021 "Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Saccharomyces cerevisiae* used as feed additive". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Tachwedd 2021 (ISBN 978 0 580 99832 4). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽³⁾ O dan y cyfeirnod DD CEN/TS 15790:2008 "Animal Feeding Stuffs – PCR typing of probiotic strains of *Saccharomyces cerevisiae* (yeast)". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Ionawr 2009 (ISBN 978 0 580 61806 2). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁴⁾ Cynnwys *Saccharomyces cerevisiae* CNCM I-4407 mewn CFU/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

(1) Mae'r awdurdodiad hwn yn adnewyddu'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 883/2010. Mae'r Rheoliad hwnnw wedi ei ddirymu gan reoliad 8 o'r Rheoliadau hyn, ond gweler y ddarpariaeth drosiannol yn rheoliad 9.

Adnewyddu awdurdodiad (ag addasiad) paratoad o *Bacillus velezensis* ATCC PTA-6737 (*Bacillus Subtilis* ATCC PTA-6737 yn flaenorol) (rhif adnabod 4b1823) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy, hwyaid i'w pesgi, soffieir, ffesantod, petris, ieir gini, colomennod, gwyddau i'w pesgi ac estrysiaid, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu pob mân rywogaeth dofednod (ac eithrio ar gyfer dodwy), adar addurnol, adar helwriaeth ac adar hela

Mae'r paratoad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sefydlogyddion fflora'r perfedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	<i>Bacillus velezensis</i> ATCC PTA-6737
<i>Rhif adnabod yr ychwanegyn</i>	4b1823
<i>Deiliad yr awdurdodiad</i>	Kemin Europa N.V.
<i>Categori ychwanegion</i>	Ychwanegion sootechnegol
<i>Grŵp gweithredol</i>	Sefydlogyddion fflora'r perfedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o <i>Bacillus velezensis</i> ATCC PTA-6737 sy'n cynnwys isafswm o 8×10^{10} CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Sborau hyfyw <i>Bacillus velezensis</i> ATCC PTA-6737
<i>Dulliau dadansoddi⁽¹⁾</i>	Ar gyfer cyfrifo (cyfrif cytrefi) 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 plât taenu gan ddefnyddio agar soia trypton gan rag-drin y samplau bwyd anifeiliaid â gwres⁽²⁾.
	I adnabod straen bacterol: <ul style="list-style-type: none"> Electrofforesis jel maes pylsedig (PFGE).
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> Ieir i'w pesgi Ieir a fegir ar gyfer dodwy Mân rywogaethau dofednod (ac eithrio ar gyfer dodwy) Adar addurnol Adar helwriaeth Adar hela
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	1×10^7 CFU/kg
<i>Uchafswm cynnwys⁽³⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.
	2. Os yw <i>Bacillus velezensis</i> ATCC PTA-6737 i'w ddefnyddio mewn bwyd anifeiliaid sy'n cynnwys cocsidiostatau, awdurdodir defnyddio'r ychwanegyn bwyd anifeiliaid hwn gyda'r cocsidiostatau a ganlyn yn unig,

(1) Mae'r awdurdodiad hwn yn adnewyddu'r awdurdodiadau a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 107/2010 a Rheoliad Gweithredu'r Comisiwn (EU) Rhif 885/2011. Mae'r Rheoliadau hynny wedi eu dirymu gan reoliad 8 o'r Rheoliadau hyn, ond gweler y ddarpariaeth drosiannol yn rheoliad 10.

	<p>ac yn unol â'u meini prawf awdurdodi unigol:</p> <ul style="list-style-type: none"> • Decocwinad • Deuclaswritl • Lasalosisid A sodiwm • Madwramisin amoniwm • Monensin sodiwm • Narasin • Narasin/Nicarbasin (i'w defnyddio ar y cyd yn unig) • Robenidin hydroclorid • Salinomisin sodiwm
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⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "D08/FSQ/CVH/SY/Ares(2009)61627" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039>.

⁽²⁾ Nid yw'r dull hwn yn addas ar gyfer canfod *Bacillus velezensis* ATCC PTA-6737 mewn deunyddiau bwyd anifeiliaid na bwyd anifeiliaid cyfansawdd ar grynodiadau islaw lefel yr isafswm cynnwys.

⁽³⁾ Cynnwys *Bacillus velezensis* ATCC PTA-6737 mewn CFU/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Awdurdodi paratoad o *Bacillus licheniformis* DSM 28710 (rhif adnabod 4b1828) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy, mân rywogaethau dofednod ar gyfer dodwy, rhywogaethau dofednod ar gyfer bridio ac adar addurnol

Mae'r paratoad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sefydlogyddion fflora'r perfedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	<i>Bacillus licheniformis</i> DSM 28710
<i>Rhif adnabod yr ychwanegyn</i>	4b1828
<i>Deiliad yr awdurdodiad</i>	HuvePharma NV
<i>Categori ychwanegion</i>	Ychwanegyn bwyd anifeiliaid sootechnegol
<i>Grŵp gweithredol</i>	Sefydlogyddion fflora'r perfedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o <i>Bacillus licheniformis</i> DSM 28710 ar ffurf solet sy'n cynnwys isafswm o 3.2×10^9 CFU/g o ychwanegyn.
<i>Nodweddiad y sylwedd(au) actif</i>	Sborau hyfyw <i>Bacillus licheniformis</i> DSM 28710.
<i>Dulliau dadansoddi⁽¹⁾</i>	Ar gyfer cyfrifo (cyfrif cytrefi) 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 plât taenu (BS EN 15784:2021⁽²⁾).
	I adnabod straen bacterol: <ul style="list-style-type: none"> • Electrofforesis Jel Maes Pylsedig (PFGE).
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Ieir dodwy • Mân rywogaethau dofednod ar gyfer dodwy • Rhywogaethau dofednod ar gyfer bridio • Adar addurnol
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	1.6×10^9 CFU/kg
<i>Uchafswm cynnwys⁽³⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.
	2. Os yw <i>Bacillus licheniformis</i> DSM 28710 i'w ddefnyddio mewn bwyd anifeiliaid sy'n cynnwys cocsidiostatau, awdurdodir defnyddio'r ychwanegyn bwyd anifeiliaid hwn gyda'r cocsidiostatau a ganlyn yn unig, ac yn unol â'u meini prawf awdurdodi unigol: <ul style="list-style-type: none"> • Deuc拉斯wrl • Lasalosisid A sodiwm

⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2015)4524025 - 23/10/2015" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2015-0016>.

⁽²⁾ O dan y cyfeirnod BS EN 15784:2021 "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 99829 4). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽³⁾ Cynnwys *Bacillus licheniformis* DSM 28710 mewn CFU/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Adnewyddu awdurdodiad paratoad o *Clostridium butyricum* FERM BP-2789 (rhif adnabod 4b1830) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy, tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio, mân rywogaethau adar (ac eithrio adar dodwy), perchyll wedi eu diddyfnu a mân rywogaethau teulu'r moch wedi eu diddyfnu, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, perchyll sugno a mân rywogaethau teulu'r moch sy'n sugno

Mae'r paratoad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sefydlogyddion fflora'r perfedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	<i>Clostridium butyricum</i> FERM BP-2789
<i>Rhif adnabod yr ychwanegyn</i>	4b1830
<i>Deiliad yr awdurdodiad</i>	Miyarisan Pharmaceutical Co Ltd
<i>Categori ychwanegion</i>	Ychwanegyn sootechnegol
<i>Grŵp gweithredol</i>	Sefydlogyddion fflora'r perfedd
<i>Cyfansoddiad yr ychwanegyn</i>	Paratoad o <i>Clostridium butyricum</i> FERM BP-2789 ar ffurf solet sy'n cynnwys isafswm o 5×10^8 CFU/g o'r ychwanegyn
<i>Nodweddiad y sylwedd(au) actif</i>	Sborau hyfyw <i>Clostridium butyricum</i> FERM BP-2789
<i>Dulliau dadansoddi⁽¹⁾</i>	Ar gyfer cyfrifo (cyfrif cytrefi) 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 plât arllwys yn seiliedig ar BS ISO 15213:2003⁽²⁾.
	I adnabod straen bacterol: <ul style="list-style-type: none"> • Electrofforesis jel maes pylsedig (PFGE).
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Ieir i'w pesgi • Ieir a fegir ar gyfer dodwy • Tyrcwn i'w pesgi • Tyrcwn a fegir ar gyfer bridio • Mân rywogaethau adar (ac eithrio adar dodwy) • Perchyll (sugno ac wedi eu diddyfnu) • Mân rywogaethau teulu'r moch (sugno ac wedi eu diddyfnu)
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽³⁾</i>	Ar gyfer tyrcwn i'w pesgi a thyrwn a fegir ar gyfer bridio: 1.25×10^8 CFU/kg
	Ar gyfer y rhywogaethau/categoriâu eraill: 2.5×10^8 CFU/kg
<i>Uchafswm cynnwys⁽³⁾</i>	Dim
<i>Darpariaethau eraill</i>	1. Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.
	2. Os yw <i>Clostridium butyricum</i> FERM BP-2789) i'w ddefnyddio mewn

(1) Mae'r awdurdodiad hwn yn adnewyddu'r awdurdodiadau a roddwyd o dan Reoliadau Gweithredu'r Comisiwn (EU) Rhif 373/2011, Rhif 374/2013 a Rhif 1108/2014. Mae'r Rheoliadau hynny wedi eu dirymu gan reoliad 8 o'r Rheoliadau hyn.

	<p>bwyd anifeiliaid sy'n cynnwys cocsidiostatau, awdurdodir defnyddio'r ychwanegyn bwyd anifeiliaid hwn gyda'r cocsidiostatau a ganlyn yn unig, ac yn unol â'u meini prawf awdurdodi unigol:</p> <ul style="list-style-type: none"> • Decocwinad • Deuclaswrit • Lasalosid A sodiwm • Madwramisin amoniwm • Monensin sodiwm, • Narasin, • Narasin/Nicarbasin (i'w defnyddio ar y cyd) • Robenidin hydroclorid • Salinomisin sodiwm • Semdwramisin sodiwm
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⁽¹⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "JRC.DG.D.6.CvH/DM/hn/ARES (2010)-355411" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0005>.

⁽²⁾ O dan y cyfeirnod BS ISO 15213:2003 "Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 16 Mai 2003 (ISBN 0 580 41892 8). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽³⁾ Cynnwys *Clostridium butyricum* FERM BP-2789 mewn CFU/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Awdurdodi paratoad o 6-ffytas (EC 3.1.3.26) (rhif adnabod 4a32) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o ddofednod, adar addurnol, perchyll, moch i'w pesgi, hychod, mân rywogaethau teulu'r moch i'w pesgi neu ar gyfer atgenhedlu

Mae'r paratoad 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.

<i>Yr ychwanegyn</i>	6-ffytas (EC 3.1.3.26)
<i>Rhif adnabod yr ychwanegyn</i>	4a32
<i>Deiliad yr awdurdodiad</i>	Huvepharma EOOD
<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 gynhyrchir gan <i>Komagataella phaffii</i> DSM 32854 sydd ag isafswm actifedd o 5000 FTU ⁽¹⁾ /g ar ffurf ronynnol, araenedig neu hylifol
<i>Nodweddiad y sylwedd(au) actif</i>	6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu â <i>Komagataella phaffii</i> DSM 32854
<i>Dulliau dadansoddi⁽²⁾</i>	I feintioli actifedd ffytas yn yr ychwanegyn bwyd anifeiliaid: <ul style="list-style-type: none"> • Y dull colorimetrig yn seiliedig ar adwaith ensymatig y ffytas ar y ffytad (VDLUFA 27.1.4⁽³⁾).
	I feintioli actifedd ffytas yn y rhag-gymysgeddau: <ul style="list-style-type: none"> • Y dull colorimetrig yn seiliedig ar adwaith ensymatig y ffytas ar y ffytad (VDLUFA 27.1.3⁽⁴⁾).
	I feintioli actifedd ffytas yn y deunyddiau bwyd anifeiliaid a'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Y dull colorimetrig yn seiliedig ar adwaith ensymatig y ffytas ar y ffytad (BS EN ISO 30024:2009⁽⁵⁾).
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Pob rhywogaeth o ddofednod • Adar addurnol • Perchyll • Moch i'w pesgi • Hychod • Mân rywogaethau teulu'r moch i'w pesgi neu ar gyfer atgenhedlu
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁶⁾</i>	250 FTU/kg
<i>Uchafswm cynnwys⁽⁶⁾</i>	Dim
<i>Darpariaethau eraill</i>	Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.

⁽¹⁾ FTU = unedau ensym ffytas. Un FTU yw'r swm o'r ensym sy'n rhyddhau 1 micromol (µm) o ffosffad anorganig o sodiwm ffytad y funud o dan amgylchiadau adweithio o pH 5.5 a 37°C.

⁽²⁾ Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)762221 - 06/02/2020" ac a ddiweddarwyd ddiwethaf ar 4 Mai 2020. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0052>.

- ⁽³⁾ Llyfr Dull Cymdeithas Sefydliadau Dadansoddi ac Ymchwilio Amaethyddol yr Almaen (VDLUFA), Cyfrol III, Dulliau sengl newydd 2016, Dadansoddi Bwydydd Anifeiliaid yn Gemegol (ISBN 978 3 941273 14 6), <https://vdlufa.de>.
- ⁽⁴⁾ Llyfr Dull Cymdeithas Sefydliadau Dadansoddi ac Ymchwilio Amaethyddol yr Almaen (VDLUFA), Cyfrol III, 8fed atodiad 2012, Dadansoddi Bwydydd Anifeiliaid yn Gemegol (ISBN 978 3 941273 14 6), <https://vdlufa.de>.
- ⁽⁵⁾ O dan y cyfeirnod BS EN ISO 30024:2009 “Animal feeding stuffs. Determination of phytase activity”. Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 30 Medi 2009 (ISBN 978 0 580 62651 7). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.
- ⁽⁶⁾ Cynnwys 6-ffytas mewn FTU/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Awdurdodi decocwinad (Deccox®) (rhif adnabod 51756i) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi

Mae'r sylwedd decocwinad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "cocsidiostatau a histomonostatau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	Decocwinad (Deccox®)
<i>Rhif adnabod yr ychwanegyn</i>	51756i
<i>Deiliad yr awdurdodiad</i>	Zoetis Belgium SA
<i>Categori ychwanegion</i>	Cocsidiostatau a Histomonostatau
<i>Grŵp gweithredol</i>	Dim
<i>Cyfansoddiad yr ychwanegyn</i>	<ul style="list-style-type: none"> • Decocwinad, 60.0 g/kg • Olew soia diarogleuedig puredig, 28.5 g/kg • Silica coloidaidd, 0.6 g/kg • Eilion gwenith, q.s. 1kg
<i>Nodweddiad y sylwedd(au) actif</i>	Decocwinad: (Ethyl 6-desyclocsi-7-ethocsi-4-hydrocsicwinolin-3-carbocsylad) <ul style="list-style-type: none"> • Fformiwla gemegol: C₂₄H₃₅NO₅ • Rhif CAS⁽¹⁾: 18507-89-6
	Amhureddau cysylltiedig: <ul style="list-style-type: none"> • Methyl-6-desyclocsi-7-ethocsi-4-hydrocsicwinolin-3-carbocsilad: < 1.0% • Asid 6-desyclocsi-7-ethocsi-4-hydrocsicwinolin-3-carbocsylog: < 0.5% • Deuethyl-4-desyclocsi-3-ethocsianilinomethylenemalonad: < 0.5%
<i>Dulliau dadansoddi⁽¹⁾</i>	I feintioli decocwinad yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau, y deunyddiau bwyd anifeiliaid a'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Cromatograffaeth Hylif Perfformiad Uchel gwedd wrthdro wedi ei gplysio â synhwyrdd fflworoleuedd (RP-HPLC-FL) (BS EN 16162:2012⁽³⁾).
	I feintioli decocwinad mewn meinweoedd: <ul style="list-style-type: none"> • Cromatograffaeth Hylif Perfformiad Uchel gwedd wrthdro wedi ei gplysio â sbectrometr mäs pedrypol triphlyg (RP-HPLC-MS/MS⁽⁴⁾).
<i>Rhywogaeth neu categori o anifail</i>	Ieir i'w pesgi
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁵⁾</i>	30 mg/kg
<i>Uchafswm cynnwys⁽⁵⁾</i>	40 mg/kg

(1) Mae'r awdurdodiad hwn yn disodli awdurdodiad decocwinad (Deccox®) o dan Reoliad y Comisiwn (EC) Rhif 1289/2004. Mae'r Rheoliad hwn wedi ei ddirymu gan reoliad 8 o'r Rheoliadau hyn, ond gweler y ddarpariaeth drosiannol yn rheoliad 11. Gweler hefyd Atodlen 11 i'r Rheoliadau hyn sy'n cynnwys ailawdurdodiad ar wahân ar gyfer decocwinad (Deccox®), ond ar ffurf addasedig - decocwinad (Avi-Deccox® 60G).

<i>Darpariaethau eraill</i>	1. Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.
	2. Rhaid ymgorffori'r ychwanegyn bwyd anifeiliaid mewn bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd.
	3. Ni chaniateir cymysgu decocwinad gyda chocsidiostatau eraill.
	4. Ni chaniateir defnyddio decocwinad mewn bwyd anifeiliaid sy'n cynnwys bentonit.
	5. Rhaid i ddeiliad yr awdurdodiad gynnal rhaglen fonitro ar ôl rhyddhau ar y farchnad ar gyfer ymwrthedd i facteria ac <i>Eimeria</i> spp. Rhaid cyflwyno adroddiad yn cynnwys canlyniad y rhaglen honno i Weinidogion Cymru erbyn diwedd 23 Tachwedd 2031.

⁽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(2013)3639174 - 04/12/2013 " ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2013-0034>.

⁽³⁾ O dan y cyfeirnod BS EN 16162:2012 "Animal feeding stuffs. Determination of decoquinat by HPLC with fluorescence detection". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Mawrth 2012 (ISBN 978 0 580 67002 2). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁴⁾ "Safety and efficacy of Deccox® (decoquinat) for chickens for fattening". Cyhoeddwyd gan Awdurdod Diogelwch Bwyd Ewrop (EFSA) yng Nghyfnodolyn yr EFSA, Cyfrol 17, Rhifyn 1 ar 14 Ionawr 2019. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: <https://www.efsa.europa.eu/en/efsajournal/pub/5541>.

⁽⁵⁾ Cynnwys decocwinad (Deccox®) mewn mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Awdurdodi decocwinad (Avi-Deccox[®] 60G) (rhif adnabod 51756ii) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi

Mae'r sylwedd decocwinad a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "cocsidiostatau a histomonostatau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(1).

<i>Yr ychwanegyn</i>	Decocwinad (Avi-Deccox [®] 60G)
<i>Rhif adnabod yr ychwanegyn</i>	51756ii
<i>Deiliad yr awdurdodiad</i>	Zoetis Belgium SA
<i>Categori ychwanegion</i>	Cocsidiostatau a histomonostatau
<i>Grŵp gweithredol</i>	Dim
<i>Cyfansoddiad yr ychwanegyn</i>	<ul style="list-style-type: none"> • Decocwinad, 60.0 g/kg • Silica coloidaidd, 0.6 g/kg • Silicon deuocsid, 4.0 g/kg • Sodiwm carbocsimethylcellwlos, 30.0 g/kg • Calsiwm sylffad deuhydrad, q.s. ad 1kg
<i>Nodweddiad y sylwedd(au) actif</i>	Decocwinad: (Ethyl 6-desyclocsi-7-ethocsi-4-hydrocsicwinolin-3-carbocsylad) <ul style="list-style-type: none"> • Fformiwla gemegol: C₂₄H₃₅NO₅ • Rhif CAS⁽¹⁾: 18507-89-6
	Amhureddau cysylltiedig: <ul style="list-style-type: none"> • Methyl-6-desyclocsi-7-ethocsi-4-hydrocsicwinolin-3-carbocsylad: < 1.0% • Asid 6-desyclocsi-7-ethocsi-4-hydrocsicwinolin-3-carbocsylyg: < 0.5% • Deuethyl-4-desyclocsi-3-ethocsianilinomethylenemalonad: < 0.5%
<i>Dulliau dadansoddi⁽²⁾</i>	I feintioli decocwinad yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau, y deunyddiau bwyd anifeiliaid a'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Cromatograffaeth Hylif Perfformiad Uchel gwedd wrthdro gyda synhwyrdd fflworoleuedd (RP-HPLC-FL) (BS EN 16162:2012⁽³⁾).
	I feintioli decocwinad mewn meinweoedd: <ul style="list-style-type: none"> • Cromatograffaeth Hylif Perfformiad Uchel gwedd wrthdro wedi ei gplysu â sbectrometr màs pedrypol triphlyg (RP-HPLC-MS/MS⁽⁴⁾) neu unrhyw ddull dadansoddi arall sy'n cydymffurfio â'r gofynion a osodir gan Benderfyniad y Comisiwn 2002/657/EC ynghylch perfformiad dulliau dadansoddi a dehongli canlyniadau(2).
<i>Rhywogaeth neu gategori o anifail</i>	Ieir i'w pesgi
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁵⁾</i>	30 mg/kg

(1) Mae'r awdurdodiad hwn ar gyfer decocwinad (Deccox[®]) ar ffurf addasedig, a awdurdodwyd yn flaenorol o dan Reoliad y Comisiwn (EC) Rhif 1289/2004, ac sydd bellach wedi ei awdurdodi o dan Atodlen 10 i'r Rheoliadau hyn.

(2) EUD 2002/657, a ddiwygiwyd gan O.S. 2020/1461.

<i>Uchafswm cynnwys</i> ⁽⁵⁾	40 mg/kg
<i>Darpariaethau eraill</i>	<p>1. Yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau, rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres.</p> <p>2. Rhaid ymgorffori'r ychwanegyn bwyd anifeiliaid yn y bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd.</p> <p>3. Ni chaniateir cymysgu decocwinad â chocsidiostatau eraill.</p> <p>4. Ni chaniateir defnyddio decocwinad mewn bwyd anifeiliaid sy'n cynnwys bentonit.</p> <p>5. Rhaid i ddeiliad yr awdurdodiad gynnal rhaglen fonitro ar ôl rhyddhau ar y farchnad ar gyfer ymwrthedd i facteria ac <i>Eimeria</i> spp. Rhaid cyflwyno adroddiad yn cynnwys canlyniad y rhaglen honno i Weinidogion Cymru erbyn diwedd 23 Tachwedd 2031.</p>

⁽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(2014)2704635 - 18/08/2014" a "JRC.D.5/SFB/CvH/MGH /mds/Ares" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen ar gael ar y cyfeiriad a ganlyn: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2014-0014>.

⁽³⁾ O dan y cyfeirnod BS EN 16162:2012 "Animal feeding stuffs. Determination of decoquinat by HPLC with fluorescence detection". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Mawrth 2012 (ISBN 978 0 580 67002 2). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

⁽⁴⁾ "Safety and efficacy of Deccox® (decoquinat) for chickens for fattening". Cyhoeddwyd gan Awdurdod Diogelwch Bwyd Ewrop (EFSA) yng Nghyfnodolyn yr EFSA, Cyfrol 17, Rhifyn 1 ar 14 Ionawr 2019. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: <https://www.efsa.europa.eu/en/efsajournal/pub/5541>.

⁽⁵⁾ Cynnwys decocwinad (Avi-Deccox®) mewn mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

Dirymu deddfwriaeth uniongyrchol yr UE a ddargedwir

Rheoliad y Comisiwn (EC) Rhif 1289/2004 sy'n ymwneud ag awdurdodi am 10 mlynedd yr ychwanegyn Deccox[®] mewn bwydydd anifeiliaid, sy'n perthyn i'r grŵp o gocsidiostatau a sylweddau meddyginaethol eraill(1).

Rheoliad y Comisiwn (EC) Rhif 903/2009 sy'n ymwneud ag awdurdodi paratoad o *Clostridium butyricum* FERM-BP 2789 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi (deiliad yr awdurdodiad Miyarisan Pharmaceutical Co. Ltd, a gynrychiolir gan Huvepharma NV Belgium)(2).

Rheoliad y Comisiwn (EU) Rhif 8/2010 sy'n ymwneud ag awdurdodi'r proteas serin a gynhyrchir gan *Bacillus licheniformis* (DSM 19670) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi (deiliad yr awdurdodiad DSM Nutritional Products Ltd, a gynrychiolir gan DSM Nutritional Products Sp.Z.o.o)(3).

Rheoliad y Comisiwn (EU) Rhif 107/2010 sy'n ymwneud ag awdurdodi *Bacillus subtilis* ATCC PTA-6737 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi (deiliad yr awdurdodiad Kemin Europa NV)(4).

Rheoliad y Comisiwn (EU) Rhif 883/2010 sy'n ymwneud ag awdurdodi defnydd newydd o *Saccharomyces cerevisiae* NCYC Sc 47 fel ychwanegyn bwyd anifeiliaid ar gyfer lloi magu (deiliad yr awdurdodiad Société industrielle Lesaffre)(5).

Rheoliad y Comisiwn (EU) Rhif 168/2011 sy'n diwygio Rheoliad (EU) Rhif 107/2010 ynghylch y defnydd o'r ychwanegyn bwyd anifeiliaid *Bacillus subtilis* ATCC PTA-6737 mewn bwyd anifeiliaid sy'n cynnwys madwramisin amoniwm, monensin sodiwm, narasin, neu robenidin hydroclorid(6).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 373/2011 sy'n ymwneud ag awdurdodi paratoad o *Clostridium butyricum* FERM-BP 2789 fel ychwanegyn bwyd anifeiliaid ar gyfer mân rywogaethau adar ac eithrio adar dodwy, perchyll wedi eu diddyfnu a mân rywogaethau teulu'r moch (wedi'u diddyfnu) ac yn diwygio Rheoliad (EC) Rhif 903/2009 (deiliad yr awdurdodiad Miyarisan Pharmaceutical Co. Ltd, a gynrychiolir gan Huvepharma NV Belgium)(7).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 515/2011 sy'n ymwneud ag awdurdodi fitamin B₆ fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(8).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 885/2011 sy'n ymwneud ag awdurdodi *Bacillus subtilis* (ATCC PTA-6737) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy, hwyaid i'w pesgi, sofflieir, ffesantod, petris, ieir gini, colomennod, gwyddau i'w pesgi ac estrysiaid (deiliad yr awdurdodiad Kemin Europa NV)(9).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 357/2013 sy'n diwygio Rheoliad (EC) Rhif 903/2009 a Rheoliad Gweithredu (EU) Rhif 373/2011 ynghylch isafswm cynnwys paratoad o *Clostridium butyricum* (FERM BP-2789) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi a mân rywogaethau adar (ac eithrio adar dodwy) (deiliad yr awdurdodiad Miyarisan Pharmaceutical Co. Ltd a gynrychiolir gan Miyarisan Pharmaceutical Europe S.L.U.)(10).

(1) EUR 2004/1289.
 (2) EUR 2009/903.
 (3) EUR 2010/8.
 (4) EUR 2010/107
 (5) EUR 2010/883.
 (6) EUR2011/168.
 (7) EUR 2011/373.
 (8) EUR 2011/515.
 (9) EUR 2011/885.
 (10)EUR 2013/357.

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 374/2013 sy'n ymwneud ag awdurdodi paratoad o *Clostridium butyricum* (FERM-BP 2789) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy (deiliad yr awdurdodiad Miyarisan Pharmaceutical Co. Ltd a gynrychiolir gan Huvepharma NV Belgium)(1).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 291/2014 sy'n diwygio Rheoliad (EC) Rhif 1289/2004 ynghylch y cyfnod cadw'n ôl a therfynau gweddillion uchaf yr ychwanegyn bwyd anifeiliaid decocwinad(2).

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1108/2014 sy'n ymwneud ag awdurdodi paratoad o *Clostridium butyricum* (FERM-BP 2789) fel ychwanegyn bwyd anifeiliaid ar gyfer tyrcwn a fegir ar gyfer bridio (deiliad yr awdurdodiad Miyarisan Pharmaceutical Co. Ltd a gynrychiolir gan Huvepharma NV Belgium)(3).

Rheoliad Gweithredu'r Comisiwn (EU) 2017/1126 sy'n diwygio Rheoliad (EC) Rhif 903/2009 a Rheoliadau Gweithredu (EU) Rhif 373/2011, (EU) Rhif 374/2013 ac (EU) Rhif 1108/2014 ynghylch enw cynrychiolydd yn yr UE ddeiliad awdurdodiad paratoad o *Clostridium butyricum* (FERM-BP 2789)(4).

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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 2013/374.
(2) EUR 2014/291.
(3) EUR 2014/1108.
(4) EUR 2017/1126.

SCHEDULE 1

Regulation 3(1)

Authorisation of a preparation of manganese chelate of lysine and glutamic acid (identification number 3b509) as a feed additive for all animal species

The preparation specified in the table, belonging to the additive category “nutritional additives” and to the functional group “compounds of trace elements”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	Manganese chelate of lysine and glutamic acid
<i>Identification number of the additive</i>	3b509
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	<p>A preparation of chelates of manganese with lysine and chelates of manganese with glutamic acid in a ratio of 1:1 as a powder with the following components:</p> <ul style="list-style-type: none"> • Manganese 15-17% • Lysine 20-21.5% • Glutamic acid 22-24% • Moisture 3.5% maximum • Nickel 4 ppm maximum
<i>Characterisation of the active substance(s)</i>	Manganese-2,6-diaminohexanoic acid, chloride and hydrogen sulphate salt (C ₆ H ₁₉ ClN ₂ O ₈ SMn)Manganese-2-aminopentanedioic acid, sodium and hydrogen sulphate salt (C ₅ H ₁₀ NN _a O ₉ SMn)
<i>Analytical methods</i> ⁽¹⁾	<p>For quantification of total manganese in the feed additive:</p> <ul style="list-style-type: none"> • Atomic Absorption Spectrometry (AAS) (BS EN ISO 6869:2001⁽²⁾), or • Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017⁽⁴⁾). <p>For quantification of total manganese in premixtures:</p> <ul style="list-style-type: none"> • Atomic Absorption Spectrometry (AAS) (BS EN ISO 6869:2001⁽²⁾), • Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES) (BS EN 15510:2017⁽³⁾), • Inductively Coupled Plasma-Atomic Emission Spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017⁽⁴⁾), or • Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) (BS EN 17053:2018⁽⁵⁾). <p>For quantification of total manganese in feed materials and compound feed:</p> <ul style="list-style-type: none"> • Atomic Absorption Spectrometry (AAS) – Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed (Annex 4-C)(1), • Atomic Absorption Spectrometry (AAS) (BS EN ISO 6869:2001⁽²⁾), • Inductively Coupled Plasma-Atomic Emission Spectrometry (ICP-AES) (BS EN 15510:2017⁽³⁾), • Inductively Coupled Plasma-Atomic Emission Spectrometry after

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

	<p>pressure digestion (ICP-AES) (BS EN 15621:2017⁽⁴⁾), or</p> <ul style="list-style-type: none"> Inductively Coupled Plasma-Mass Spectrometry (ICP-MS) (BS EN 17053:2018⁽⁵⁾).
	<p>For quantification of lysine and glutamic acid content in the feed additive:</p> <ul style="list-style-type: none"> Ion exchange chromatography coupled with post-column derivatisation and photometric detection (IEC-VIS) (BS EN ISO 13903:2005⁽⁶⁾).
	<p>For determination of the chelated form of the feed additive:</p> <ul style="list-style-type: none"> Mid-infrared (IR) spectrometry together with the determination of the content of trace element and lysine and glutamic acid in the feed additive.
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	None
<i>Maximum content</i> ⁽⁷⁾	Fish: 100mg/kg (total)
	All other animal species: 150mg/kg (total)
<i>Other provisions</i>	The feed additive must be incorporated into the feed in the form of a premixture.

⁽¹⁾ Details of the analytical methods are set out in the document referenced “Ares(2018)3918699 - 24/07/2018” and the document referenced “Ares(2019)7167892 - 20/11/2019” and last updated 28 January 2020. These documents are available at the following address:

<https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0009?search&form-return>

⁽²⁾ Under reference BS EN ISO 6869:2001 “Animal feeding stuffs. Determination of the contents of calcium, copper, iron, magnesium, manganese, potassium, sodium and zinc. Method using atomic absorption spectrometry”. Published by the British Standards Institution on 15 March 2001 (ISBN 0 580 36933 1). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽³⁾ Under reference BS EN 15510:2017 “Animal feeding stuffs. Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, iron, zinc, copper, manganese, cobalt, molybdenum and lead by ICP-AES”. Published by the British Standards Institution on 30 August 2017 (ISBN 978 0 580 94541 0). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁴⁾ Under reference BS EN 15621:2017 “Animal feeding stuffs: Methods of sampling and analysis. Determination of calcium, sodium, phosphorus, magnesium, potassium, sulphur, iron, zinc, copper, manganese and cobalt after pressure digestion by ICP-AES”. Published by the British Standards Institution on 31 August 2017 (ISBN 978 0 580 94543 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁵⁾ Under reference BS EN 17053:2018 “Animal feeding stuffs: Methods of sampling and analysis. Determination of trace elements, heavy metals and other elements in feed by ICP-MS (multi-method)”. Published by the British Standards Institution on 28 February 2018 (978 0 580 94471 0). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁶⁾ Under reference BS EN ISO 13903:2005 “Animal feeding stuffs. Determination of amino acids content”. Published by the British Standards Institution on 24 October 2005 (ISBN 0 580 46218 8). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁷⁾ Content of element (Mn) in mg/kg of complete feed with a moisture content of 12%.

**Authorisation of a preparation of *Lactobacillus buchneri* DSM 29026
(identification number 1k20759) as a feed additive for all animal species**

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

<i>Additive</i>	<i>Lactobacillus buchneri</i> DSM 29026
<i>Identification number of the additive</i>	1k20759
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Technological additives
<i>Functional group</i>	Silage additives
<i>Additive composition</i>	Preparation of <i>Lactobacillus buchneri</i> DSM 29026 containing a minimum of 2×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable cells of <i>Lactobacillus buchneri</i> DSM 29026
<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 feed additive when not combined with other micro-organisms as silage additives: 5×10^7 CFU/kg of easy and moderately difficult to ensile fresh material ⁽⁴⁾
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	In the directions for use of the feed additive and premixtures, the storage conditions must be indicated.

⁽¹⁾ Details of the analytical methods set out in the document referenced “Ares(2019)4747322 - 22/07/2019” and last updated 18 October 2019. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2018-0093>.

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

⁽³⁾ Content of element *Lactobacillus buchneri* DSM 29026 in CFU of additive/kg of fresh material.

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

(1) EUR 2008/429, amended by S.I. 2019/654. S.I. 2019/654 was amended by S.I. 2020/1504.

SCHEDULE 3

Regulation 3(1)

Authorisation of a preparation of serine protease (EC 3.4.21.-) produced by *Bacillus licheniformis* DSM 19670 (identification number 4a13) as a feed additive for chickens for fattening

The preparation specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “digestibility enhancers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	Serine protease (EC 3.4.21.-)
<i>Identification number of the additive</i>	4a13
<i>Authorisation holder</i>	DSM Nutritional Products Ltd (Switzerland)
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Digestibility enhancers
<i>Additive composition</i>	Solid and liquid preparation of serine protease (EC 3.4.21.-): <ul style="list-style-type: none"> • produced by <i>Bacillus licheniformis</i> DSM 19670 • having a minimum activity of 75,000 PROT⁽¹⁾/g
<i>Characterisation of the active substance(s)</i>	<ul style="list-style-type: none"> • Serine protease (EC 3.4.21.-) produced by <i>Bacillus licheniformis</i> DSM 19670 • CAS number⁽²⁾: 37259-58-8 (serine protease) • EINECS number⁽³⁾: 253-431-3 • IUB number⁽⁴⁾: 3.4.21.-
<i>Analytical methods⁽⁵⁾</i>	For quantification of serine protease activity in the feed additive, premixtures, compound feed and feed materials: <ul style="list-style-type: none"> • Colourimetric method based on the enzymatic reaction of serine protease on the Suc-Ala-Ala-Pro-Phe-pNA substrate.
<i>Species or category of animal</i>	Chickens for fattening
<i>Maximum age</i>	None
<i>Minimum content⁽⁶⁾</i>	15,000 PROT ⁽¹⁾ /kg
<i>Maximum content⁽⁶⁾</i>	None
<i>Other provisions</i>	In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

⁽¹⁾ One PROT is the amount of serine protease that liberates one micromole/minute of para-nitroaniline (pNA) from 1 millimolar (mM) Suc-Ala-Ala-Pro-Phe-pNA substrate at pH 9 & 37°C.

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

⁽³⁾ European Inventory of Existing Commercial Substances, number as published in OJ No C 146 A, 15.6.90, p.1.

⁽⁴⁾ Identification number assigned by the International Union of Biochemistry (IUB), now the International Union of Biochemistry and Molecular Biology (IUBMB) iubmb.org.

⁽⁵⁾ Details of the analytical methods set out in the document referenced “Ares(2019)6802984 - 04/11/2019” and last updated 27 January 2020. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0010>.

⁽⁶⁾ Content of Serine protease in PROT/kg of complete feed with a moisture content of 12%.

SCHEDULE 4

Regulation 3(1)

Renewal of authorisation of pyridoxine hydrochloride (vitamin B₆) (identification number 3a831) as a feed additive for all animal species

The substance specified in the table, belonging to the additive category “nutritional additives” and to the functional group “vitamins, pro-vitamins and chemical well-defined substances having a similar effect”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

<i>Additive</i>	Pyridoxine hydrochloride (vitamin B ₆)
<i>Identification number of the additive</i>	3a831
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Vitamins, pro-vitamins and chemically well-defined substances having similar effect
<i>Additive composition</i>	Pyridoxine hydrochloride, with a purity criteria not less than 98.5%
<i>Characterisation of the active substance(s)</i>	<ul style="list-style-type: none"> • Pyridoxine hydrochloride: C₈H₁₁NO₃·HCl • CAS number⁽¹⁾: 58-56-0 • EINECS number⁽²⁾: 200-386-2
<i>Analytical methods</i> ⁽³⁾	For determination of pyridoxine hydrochloride (vitamin B ₆) in the feed additive: <ul style="list-style-type: none"> • Titration with perchloric acid (Ph. Eur. 10th edition, monograph 0245⁽⁴⁾).
	For determination of pyridoxine hydrochloride (vitamin B ₆) in premixtures: <ul style="list-style-type: none"> • Reversed phase High Performance Liquid Chromatography coupled to UV detector (RP-HPLC-UV) (VDLUFA 13.9.1⁽⁵⁾).
	For determination of pyridoxine hydrochloride (vitamin B ₆) in feed and water: <ul style="list-style-type: none"> • Reversed phase High Performance Liquid Chromatography coupled to fluorescence detector (RP-HPLC-FLD) – method based on BS EN 14164:2014⁽⁶⁾.
<i>Species or category of animal</i>	All animal species
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	None
<i>Maximum content</i> ⁽⁷⁾	None
<i>Other provisions</i>	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment and in water must be indicated.
	2. Pyridoxine hydrochloride (vitamin B ₆) may be used via water for drinking.

⁽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, number as published in OJ No C 146 A, 15.6.90, p.1.

⁽³⁾ Details of the analytical methods set out in the document referenced “JRC.DG.D.6/CvH/GB/ag/ARES(2011)356822” and last updated 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0139>.

(1) This authorisation is a renewal of the authorisation granted under Commission Implementing Regulation (EU) No 515/2011. That Regulation is revoked by regulation 8 of these Regulations.

- (4) European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 10th edition. Published 1 July 2019 (ISBN 9789999146111).
- (5) The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method Book, Volume III, 6th supplement 2006, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6), <https://vdlufa.de>.
- (6) Under reference BS EN 14164:2014 “Foodstuffs. Determination of vitamin B₆ by high performance chromatography”. Published by the British Standards Institution on 30 June 2014 (ISBN 978 0 580 77941 1). Available from the British Standards Institution <https://knowledge.bsigroup.com>.
- (7) Content of pyridoxine hydrochloride (vitamin B₆) in mg of additive/kg of complete feed with a moisture content of 12%.

SCHEDULE 5

Regulation 3(1)

Renewal of authorisation of a preparation of *Saccharomyces cerevisiae* CNCM I-4407 (formerly *Saccharomyces cerevisiae* NCYC Sc 47) (identification number 4b1702) as a feed additive for calves for rearing

The preparation specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “gut flora stabilisers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

<i>Additive</i>	<i>Saccharomyces cerevisiae</i> CNCM I-4407
<i>Identification number of the additive</i>	4b1702
<i>Authorisation holder</i>	S.I. Lesaffre
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Solid form preparation of <i>Saccharomyces cerevisiae</i> CNCM I-4407 containing a minimum of 5x10 ⁹ CFU/g
<i>Characterisation of the active substance(s)</i>	Viable dried cells <i>Saccharomyces cerevisiae</i> CNCM I-4407
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Pour plate method using CGYE (chloramphenicol, glucose, yeast extract) agar (BS EN 15789:2021⁽²⁾).
	For identification of yeast strain: <ul style="list-style-type: none"> • Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008⁽³⁾).
<i>Species or category of animal</i>	Calves for rearing
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁴⁾	1.5 x 10 ⁹ CFU/kg
<i>Maximum content</i> ⁽⁴⁾	None
<i>Other provisions</i>	In the directions of use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

⁽¹⁾ Details of the analytical methods set out in the document referenced “JRC.DG.D.6/CvH/DM/mds/ARES(2010)967257” and last updated 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0038>.

⁽²⁾ Under reference BS EN 15789:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Saccharomyces cerevisiae* used as feed additive”. Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99832 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽³⁾ Under reference DD CEN/TS 15790:2008 “Animal Feeding Stuffs – PCR typing of probiotic strains of *Saccharomyces cerevisiae* (yeast)”. Published by British Standards Institution on 31 January 2009 (ISBN 978 0 580 61806 2). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁴⁾ Content of *Saccharomyces cerevisiae* CNCM I-4407 in CFU/kg of complete feed with a moisture content of 12%.

(1) This authorisation is a renewal of the authorisation granted under Commission Regulation (EU) No 883/2010. That Regulation is revoked by regulation 8 of these Regulations but see the transitional provision in regulation 9.

SCHEDULE 6

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* ATCC PTA-6737 (formerly *Bacillus Subtilis* ATCC PTA-6737) (identification number 4b1823) as a feed additive for chickens for fattening, chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches, and its authorisation as a feed additive extending existing uses to cover all minor poultry species (except for laying), ornamental birds, sporting birds and game birds

The preparation specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “gut flora stabilisers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

<i>Additive</i>	<i>Bacillus velezensis</i> ATCC PTA-6737
<i>Identification number of the additive</i>	4b1823
<i>Authorisation holder</i>	Kemin Europa N.V.
<i>Additive category</i>	Zootechnical additives
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Preparation of <i>Bacillus velezensis</i> ATCC PTA-6737 containing a minimum of 8×10^{10} CFU/g additive
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Bacillus velezensis</i> ATCC PTA-6737
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Spread plate method using tryptone soya agar with pre-heat treatment of feed samples⁽²⁾.
	For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-field gel electrophoresis (PFGE).
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Chickens for fattening • Chickens reared for laying • Minor poultry species (except for laying) • Ornamental birds • Sporting birds • Game birds
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	1×10^7 CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. If <i>Bacillus velezensis</i> ATCC PTA-6737 is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only, and in accordance with their individual authorisation criteria: <ul style="list-style-type: none"> • Decoquate

(1) This authorisation is a renewal of the authorisations granted under Commission Regulation (EU) No 107/2010 and Commission Implementing Regulation (EU) No 885/2011. Those Regulations are revoked by regulation 8 of these Regulations but see the transitional provision in regulation 10.

	<ul style="list-style-type: none"> • Diclazuril • Lasalocid A sodium • Maduramicin ammonium • Monensin sodium • Narasin • Narasin/Nicarbazin (as combined use only) • Robenidine hydrochloride • Salinomycin sodium
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⁽¹⁾ Details of the analytical methods set out in the document referenced “D08/FSQ/CVH/SY/Ares(2009)61627” and last updated 6 June 2016. This document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2008-0039>.

⁽²⁾ This method is not suitable for the detection of *Bacillus velezensis* ATCC PTA-6737 in feed materials and compound feed at concentrations below the minimum content level.

⁽³⁾ Content of *Bacillus velezensis* ATCC PTA-6737 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 7

Regulation 3(1)

Authorisation of a preparation of *Bacillus licheniformis* DSM 28710 (identification number 4b1828) as a feed additive for laying hens, minor poultry species for laying, poultry species for breeding and ornamental birds

The preparation specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “gut flora stabilisers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	<i>Bacillus licheniformis</i> DSM 28710
<i>Identification number of the additive</i>	4b1828
<i>Authorisation holder</i>	HuvePharma NV
<i>Additive category</i>	Zootechnical feed additive
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Solid form preparation of <i>Bacillus licheniformis</i> DSM 28710 containing a minimum of 3.2×10^9 CFU/g of additive
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Bacillus licheniformis</i> DSM 28710
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Spread plate method (BS EN 15784:2021⁽²⁾).
	For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed Field Gel Electrophoresis (PFGE).
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Laying hens • Minor poultry species for laying • Poultry species for breeding • Ornamental birds
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	1.6 x 10 ⁹ CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. If <i>Bacillus licheniformis</i> DSM 28710 is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only, and in accordance with their individual authorisation criteria: <ul style="list-style-type: none"> • Diclazuril • Lasalocid A sodium

⁽¹⁾ Details of the analytical methods set out in the document referenced “Ares(2015)4524025 – 23/10/2015” and last updated 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2015-0016>.

⁽²⁾ Under reference BS EN 15784:2021 “Animal feeding stuffs: Methods of sampling and analysis. Detection and enumeration of *Bacillus* spp. Used as feed additive”. Published by the British Standards Institution on 30 November 2021 (ISBN 978 0 580 99829 4). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽³⁾ Content of *Bacillus licheniformis* DSM 28710 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 8

Regulation 3(1)

Renewal of authorisation of a preparation of *Clostridium butyricum* FERM BP-2789 (identification number 4b1830) as a feed additive for chickens reared for laying, turkeys for fattening, turkeys reared for breeding, minor avian species (excluding laying birds), weaned piglets and weaned minor porcine species, and its authorisation as a feed additive for chickens for fattening, suckling piglets and suckling minor porcine species

The preparation specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “gut flora stabilisers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

<i>Additive</i>	<i>Clostridium butyricum</i> FERM BP-2789
<i>Identification number of the additive</i>	4b1830
<i>Authorisation holder</i>	Miyarisan Pharmaceutical Co Ltd
<i>Additive category</i>	Zootechnical additive
<i>Functional group</i>	Gut flora stabilisers
<i>Additive composition</i>	Solid form preparation of <i>Clostridium butyricum</i> FERM BP-2789 containing a minimum of 5×10^8 CFU/g of additive
<i>Characterisation of the active substance(s)</i>	Viable spores of <i>Clostridium butyricum</i> FERM BP-2789
<i>Analytical methods</i> ⁽¹⁾	For enumeration (colony count) in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Pour plate method based on BS ISO 15213:2003⁽²⁾.
	For identification of bacterial strain: <ul style="list-style-type: none"> • Pulsed-field gel electrophoresis (PFGE).
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding • Minor avian species (excluding laying birds) • Piglets (suckling and weaned) • Minor porcine species (suckling and weaned)
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽³⁾	For turkeys for fattening and turkeys reared for breeding: 1.25×10^8 CFU/kg
	For the other species/categories: 2.5×10^8 CFU/kg
<i>Maximum content</i> ⁽³⁾	None
<i>Other provisions</i>	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. If <i>Clostridium butyricum</i> FERM BP-2789 is to be used in feed containing coccidiostats, this feed additive is authorised for use with the following coccidiostats only, and in accordance with their individual authorisation criteria:

(1) This authorisation is a renewal of the authorisations granted under Commission Implementing Regulations (EU) No 373/2011, No 374/2013 and No 1108/2014. Those Regulations are revoked by regulation 8 of these Regulations.

	<ul style="list-style-type: none"> • Decoquinate • Diclazuril • Lasalocid A sodium • Maduramicin ammonium • Monensin sodium • Narasin • Narasin/Nicarbazin (as combined use) • Robenidine hydrochloride • Salinomycin sodium • Semduramicin sodium
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⁽¹⁾ Details of the analytical methods set out in the document referenced “JRC.DG.D.6.CvH/DM/hn/ARES (2010)-355411” and last updated 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2010-0005>.

⁽²⁾ Under reference BS ISO 15213:2003 “Microbiology of food and animal feeding stuffs – Horizontal method for the enumeration of sulfite-reducing bacteria growing under anaerobic conditions”. Published by the British Standards Institution on 16 May 2003 (ISBN 0 580 41892 8). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽³⁾ Content of *Clostridium butyricum* FERM BP-2789 in CFU/kg of complete feed with a moisture content of 12%.

SCHEDULE 9

Regulation 3(1)

Authorisation of a preparation of 6-phytase (EC 3.1.3.26) (identification number 4a32) as a feed additive for all poultry species, ornamental birds, piglets, pigs for fattening, sows, minor porcine species for fattening or reproduction

The preparation specified in the table, belonging to the additive category “zootechnical additives” and to the functional group “digestibility enhancers”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

<i>Additive</i>	6-phytase (EC 3.1.3.26)
<i>Identification number of the additive</i>	4a32
<i>Authorisation holder</i>	Huvepharma EOOD
<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 <i>Komagataella phaffii</i> DSM 32854 with a minimum activity of 5000 FTU ⁽¹⁾ /g in granular, coated or liquid forms
<i>Characterisation of the active substance(s)</i>	6-phytase (EC 3.1.3.26) produced by fermentation with <i>Komagataella phaffii</i> DSM 32854
<i>Analytical methods</i> ⁽²⁾	For quantification of phytase activity in the feed additive: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of phytase on the phytate (VDLUFA 27.1.4⁽³⁾).
	For quantification of phytase activity in premixtures: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of phytase on the phytate (VDLUFA 27.1.3⁽⁴⁾).
	For quantification of phytase activity in feed materials and compound feed: <ul style="list-style-type: none"> • Colorimetric method based on the enzymatic reaction of phytase on the phytate (BS EN ISO 30024:2009⁽⁵⁾).
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • All poultry species • Ornamental birds • Piglets • Pigs for fattening • Sows • Minor porcine species for fattening or reproduction
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁶⁾	250 FTU/kg
<i>Maximum content</i> ⁽⁶⁾	None
<i>Other provisions</i>	In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.

⁽¹⁾ FTU = phytase enzyme units. One FTU is the amount of enzyme that releases 1 micromole (µm) of inorganic phosphate from sodium phytate per minute under reaction conditions of pH 5.5 and 37°C.

⁽²⁾ Details of the analytical methods set out in the document referenced “Ares(2020)762221 – 06/02/2020” and last updated 4 May 2020. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2019-0052>.

⁽³⁾ The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method Book, Volume III, New single methods 2016, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6), <https://vdlufa.de>.

⁽⁴⁾ The Association of German Agricultural Analytical and Research Institutes (VDLUFA) Method Book, Volume III, 8th supplement 2012, the Chemical Analysis of Feedingstuffs (ISBN 978 3 941273 14 6), <https://vdlufa.de>.

⁽⁵⁾ Under reference BS EN ISO 30024:2009 “Animal feeding stuffs. Determination of phytase activity”. Published by the British Standards Institution on 30 September 2009 (ISBN 978 0 580 62651 7). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁶⁾ Content of 6-phytase in FTU/kg of complete feed with a moisture content of 12%.

SCHEDULE 10

Regulation 3(1)

Authorisation of decoquinat (Deccox[®]) (identification number 51756i) as a feed additive for chickens for fattening

The substance decoquinat specified in the table, belonging to the additive category ‘coccidiostats and histomonostats’, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

<i>Additive</i>	Decoquinat (Deccox [®])
<i>Identification number of the additive</i>	51756i
<i>Authorisation holder</i>	Zoetis Belgium SA
<i>Additive category</i>	Coccidiostats and Histomonostats
<i>Functional group</i>	None
<i>Additive composition</i>	<ul style="list-style-type: none"> • Decoquinat, 60.0 g/kg • Refined deodorised soya oil, 28.5 g/kg • Colloidal silica, 0.6 g/kg • Wheat middlings, q.s. 1kg
<i>Characterisation of the active substance(s)</i>	Decoquinat: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate) <ul style="list-style-type: none"> • Chemical formula: C₂₄H₃₅NO₅ • CAS number⁽¹⁾: 18507-89-6
	Related impurities: <ul style="list-style-type: none"> • Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1.0% • 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0.5% • Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0.5%
<i>Analytical methods</i> ⁽²⁾	For quantification of decoquinat in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) (BS EN 16162:2012⁽³⁾).
	For quantification of decoquinat in tissues: <ul style="list-style-type: none"> • Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS⁽⁴⁾).
<i>Species or category of animal</i>	Chickens for fattening
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁵⁾	30 mg/kg
<i>Maximum content</i> ⁽⁵⁾	40 mg/kg
<i>Other provisions</i>	1. In the directions for use of the feed additive and premixtures, the storage conditions and stability to heat treatment must be indicated.
	2. The feed additive must be incorporated in compound feed in the form of a premixture.

(1) This authorisation replaces the authorisation of decoquinat (Deccox[®]) under Commission Regulation (EC) No 1289/2004. That Regulation is revoked by regulation 8 of these Regulations but see the transitional provision in regulation 11. See also Schedule 11 to these Regulations, which contains a separate re-authorisation of decoquinat (Deccox[®]), but in a modified form - decoquinat (Avi-Deccox[®] 60G).

	3. Decoquate must not be mixed with other coccidiostats.
	4. Decoquate must not be used in feed containing bentonite.
	5. A post-market monitoring programme must be carried out by the holder of authorisation for resistance to bacteria and <i>Eimeria</i> spp. A report containing the outcome of that programme must be submitted to the Welsh Ministers by the end of 23 November 2031.

⁽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 set out in the document referenced “Ares(2013)3639174 - 04/12/2013 ” and last updated 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2013-0034>.

⁽³⁾ Under reference BS EN 16162:2012 “Animal feeding stuffs. Determination of decoquate by HPLC with fluorescence detection”. Published by the British Standards Institution on 31 March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁴⁾ “Safety and efficacy of Deccox® (decoquate) for chickens for fattening”. Published by the European Food Safety Authority (EFSA) in the EFSA Journal, Volume 17, Issue 1 on 14 January 2019. This document is available at the following address: <https://www.efsa.europa.eu/en/efsajournal/pub/5541>.

⁽⁵⁾ Content of decoquate (Deccox®) in mg/kg of complete feed with a moisture content of 12%.

SCHEDULE 11

Regulation 3(1)

Authorisation of decoquinatate (Avi-Deccox[®] 60G) (identification number 51756ii) as a feed additive for chickens for fattening

The substance decoquinatate specified in the table, belonging to the additive category ‘coccidiostats and histomonostats’, is authorised as an additive in animal nutrition subject to the conditions set out in the table(1).

<i>Additive</i>	Decoquinatate (Avi-Deccox [®] 60G)
<i>Identification number of the additive</i>	51756ii
<i>Authorisation holder</i>	Zoetis Belgium SA
<i>Additive category</i>	Coccidiostats and histomonostats
<i>Functional group</i>	None
<i>Additive composition</i>	<ul style="list-style-type: none"> • Decoquinatate, 60.0 g/kg • Colloidal silica, 0.6 g/kg • Silicon dioxide, 4.0 g/kg • Carboxymethylcellulose sodium, 30.0 g/kg • Calcium sulphate dihydrate, q.s. ad 1kg
<i>Characterisation of the active substance(s)</i>	Decoquinatate: (Ethyl 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate) <ul style="list-style-type: none"> • Chemical formula: C₂₄H₃₅NO₅ • CAS number⁽¹⁾: 18507-89-6
	Related impurities: <ul style="list-style-type: none"> • Methyl-6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylate: < 1.0% • 6-decycloxy-7-ethoxy-4-hydroxyquinoline-3-carboxylic acid: < 0.5% • Diethyl-4-decycloxy-3-ethoxyanilinomethylenemalonate: < 0.5%
<i>Analytical methods</i> ⁽²⁾	For quantification of decoquinatate in the feed additive, premixtures, feed materials and compound feed: <ul style="list-style-type: none"> • Reversed-Phase High Performance Liquid Chromatography with fluorescence detection (RP-HPLC-FL) (BS EN 16162:2012⁽³⁾).
	For quantification of decoquinatate in tissues: <ul style="list-style-type: none"> • Reversed-Phase High Performance Liquid Chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS⁽⁴⁾) or any other analytical method complying with the requirements set by Commission Decision 2002/657/EC concerning the performance of analytical methods and the interpretation of results⁽²⁾.
<i>Species or category of animal</i>	Chickens for fattening
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁵⁾	30 mg/kg
<i>Maximum content</i> ⁽⁵⁾	40 mg/kg
<i>Other provisions</i>	1. In the directions for use of the feed additive and premixtures, the storage

(1) This authorisation is for a modified form of decoquinatate (Deccox[®]), which was previously authorised under Commission Regulation (EC) No 1289/2004, and now authorised under Schedule 10 to these Regulations.

(2) EUD 2002/657, amended by S.I. 2020/1461.

	conditions and stability to heat treatment must be indicated.
	2. The feed additive must be incorporated in compound feed in the form of a premixture.
	3. Decoquinate must not be mixed with other coccidiostats.
	4. Decoquinate must not be used in feed containing bentonite.
	5. A post-market monitoring programme must be carried out by the holder of authorisation for resistance to bacteria and <i>Eimeria</i> spp. A report containing the outcome of that programme must be submitted to the Welsh Ministers by the end of 23 November 2031.

⁽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 set out in the document referenced “Ares(2014)2704635 - 18/08/2014” and “JRC.D.5/SFB/CvH/MGH /mds/Ares” and last updated 6 June 2016. The document is available at the following address: <https://ec.europa.eu/jrc/en/eurl/feed-additives/evaluation-reports/fad-2014-0014>.

⁽³⁾ Under reference BS EN 16162:2012 “Animal feeding stuffs. Determination of decoquinate by HPLC with fluorescence detection”. Published by the British Standards Institution on 31 March 2012 (ISBN 978 0 580 67002 2). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

⁽⁴⁾ “Safety and efficacy of Deccox® (decoquinate) for chickens for fattening”. Published by the European Food Safety Authority (EFSA) in the EFSA Journal, Volume 17, Issue 1 on 14 January 2019. This document is available at the following address: <https://www.efsa.europa.eu/en/efsajournal/pub/5541>.

⁽⁵⁾ Content of decoquinate (Avi-Deccox®) in mg/kg of complete feed with a moisture content of 12%.

Revocation of retained direct EU legislation

Commission Regulation (EC) No 1289/2004 concerning the authorisation for 10 years of the additive Deccox® in feedingstuffs, belonging to the group of coccidiostats and other medicinal substances(1).

Commission Regulation (EC) No 903/2009 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for chickens for fattening (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(2).

Commission Regulation (EU) No 8/2010 concerning the authorisation of the serine protease produced by *Bacillus licheniformis* (DSM 19670) as a feed additive for chickens for fattening (holder of authorisation DSM Nutritional Products Ltd, represented by DSM Nutritional Products Sp.Z.o.o)(3).

Commission Regulation (EU) No 107/2010 concerning the authorisation of *Bacillus subtilis* ATCC PTA-6737 as a feed additive for chickens for fattening (holder of authorisation Kemin Europa NV)(4).

Commission Regulation (EU) No 883/2010 concerning the authorisation of a new use of *Saccharomyces cerevisiae* NCYC Sc 47 as a feed additive for calves for rearing (holder of the authorisation Société industrielle Lesaffre)(5).

Commission Regulation (EU) No 168/2011 amending Regulation (EU) No 107/2010 as regards the use of the feed additive *Bacillus subtilis* ATCC PTA-6737 in feed containing maduramycin ammonium, monensin sodium, narasin, or robenidine hydrochloride(6).

Commission Implementing Regulation (EU) No 373/2011 concerning the authorisation of the preparation of *Clostridium butyricum* FERM-BP 2789 as a feed additive for minor avian species except laying birds, weaned piglets and minor porcine species (weaned) and amending Regulation (EC) No 903/2009 (holder of authorisation Miyarisan Pharmaceutical Co. Ltd, represented by Huvepharma NV Belgium)(7).

Commission Implementing Regulation (EU) No 515/2011 concerning the authorisation of vitamin B₆ as a feed additive for all animal species(8).

Commission Implementing Regulation (EU) No 885/2011 concerning the authorisation of *Bacillus subtilis* (ATCC PTA-6737) as a feed additive for chickens reared for laying, ducks for fattening, quails, pheasants, partridges, guinea fowl, pigeons, geese for fattening and ostriches (holder of authorisation Kemin Europa NV)(9).

Commission Implementing Regulation (EU) No 357/2013 amending Regulation (EC) No 903/2009 and Implementing Regulation (EU) No 373/2011 as regards the minimum content of a preparation of *Clostridium butyricum* (FERM BP-2789) as a feed additive for chickens for fattening and minor avian species (excluding laying birds) (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Miyarisan Pharmaceutical Europe S.L.U.)(10).

(1) EUR 2004/1289.
(2) EUR 2009/903.
(3) EUR 2010/8.
(4) EUR 2010/107
(5) EUR 2010/883.
(6) EUR2011/168.
(7) EUR 2011/373.
(8) EUR 2011/515.
(9) EUR 2011/885.
(10)EUR 2013/357.

Commission Implementing Regulation (EU) No 374/2013 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for chickens reared for laying (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(1).

Commission Implementing Regulation (EU) No 291/2014 amending Regulation (EC) No 1289/2004 as regards the withdrawal time and maximum residues limits of the feed additive decoquinate(2).

Commission Implementing Regulation (EU) No 1108/2014 concerning the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789) as a feed additive for turkeys reared for breeding (holder of authorisation Miyarisan Pharmaceutical Co. Ltd represented by Huvepharma NV Belgium)(3).

Commission Implementing Regulation (EU) 2017/1126 amending Regulation (EC) No 903/2009 and Implementing Regulations (EU) No 373/2011, (EU) No 374/2013 and (EU) No 1108/2014 as regards the name of the EU representative of the holder of the authorisation of a preparation of *Clostridium butyricum* (FERM-BP 2789)(4).

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(1) EUR 2013/374.
(2) EUR 2014/291.
(3) EUR 2014/1108.
(4) EUR 2017/1126.



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