OFFERYNNAU STATUDOL CYMRU

2024 Rhif 1251 (Cy. 209)

AMAETHYDDIAETH, CYMRU

Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau) a Defnyddiau Bwyd Anifeiliaid a Fwriedir at Ddibenion Maethol Penodol (Diwygio Rheoliad y Comisiwn (EU) 2020/354) (Cymru) 2024

Gwnaed	*27 Tachwedd 2024*
Gosodwyd gerbron Senedd Cymru	*29 Tachwedd 2024*
Yn dod i rym	*20 Rhagfyr 2024*

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WELSH STATUTORY INSTRUMENTS

2024 No. 1251 (W. 209)

AGRICULTURE, WALES

The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024

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NODYN ESBONIADOL

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

Mae'r Rheoliadau hyn yn gwneud darpariaeth, o ran Cymru, mewn perthynas ag awdurdodiadau ychwanegion bwyd anifeiliaid, ac mewn perthynas â defnydd o fwyd anifeiliaid at ddiben maethol penodol.

Gwneir Rhan 2 o'r Rheoliadau hyn (rheoliadau 3 i 11, ac Atodlenni 1 i 20) drwy arfer pwerau yn Rheoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid (EUR 2003/1831). Mae Rhan 2 yn gwneud darpariaeth mewn perthynas ag awdurdodi rhoi ychwanegion bwyd anifeiliaid penodol ar y farchnad, eu prosesu a'u defnyddio.

Mae rheoliad 3, ac Atodlenni 1 i 20, yn darparu ar gyfer awdurdodi ychwanegion bwyd anifeiliaid.

- Mae Atodlen 1 yn cynnwys awdurdodiad newydd ar gyfer paratoad o gelad cromiwm o DL-methionin (rhif adnabod GB4d0001).

- Mae Atodlen 2 yn cynnwys adnewyddiad o awdurdodiad paratoad o *Saccharomyces cerevisiae* (MUCL 39885) (rhif adnabod 4b1710), ac awdurdodiad newydd sy'n estyn y defnydd awdurdodedig i gwmpasu rhywogaethau/categorïau ychwanegol o anifeiliaid).

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The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision, in relation to Wales, in relation to animal feed additive authorisations, and in relation to a use of feed for a particular nutritional purpose.

Part 2 of these Regulations (regulations 3 to 11, and Schedules 1 to 20) is made in exercise of powers in Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition (EUR 2003/1831). Part 2 makes provision in relation to the authorisation for the placing on the market, processing and use of certain feed additives.

Regulation 3, and Schedules 1 to 20, provide for the authorisation of feed additives.

- Schedule 1 contains a new authorisation for a preparation of chromium chelate of DL-methionine (identification number GB4d0001).
- Schedule 2 contains a renewal of an authorisation of a preparation of *Saccharomyces cerevisiae* (MUCL 39885) (identification number 4b1710), and new authorisation extending authorised uses to cover additional species/categories of animal.

- Mae Atodlen 3 yn cynnwys awdurdodiad newydd ar gyfer paratoad o *Pediococcus acidilactici* (CNCM I-4622) (rhif adnabod 4d1712).
- Mae Atodlenni 4 a 5 yn cynnwys adnewyddiadau o awdurdodiadau (ag addasiad) paratoadau o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (cludwyr: perlit ac (yn y drefn honno) calsiwm carbonad neu fran gwenith) (rhif adnabod 51701), ac awdurdodiad newydd sy'n estyn y defnydd awdurdodedig i gwmpasu categori ychwanegol o anifeiliaid. Yr addasiadau wrth adnewyddu'r awdurdodiad yw:
  - — Cywiriad i'r disgrifiad o rywogaeth/categori anifeiliaid (twrci) a gwmpesir.
  - — Dileu'r gofyniad am gyfnod cadw'n ôl o 1 diwrnod (cyn cigydda).
- Mae Atodlen 6 yn cynnwys adnewyddiad o awdurdodiad (ag addasiad) paratoad o 6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu â *Komagataella phaffii* (DSM 23036) (rhif adnabod 4a16), ac awdurdodiad newydd sy'n estyn y defnydd awdurdodedig i gwmpasu rhywogaethau/categorïau ychwanegol o anifeiliaid. Gweler rheoliad 12 ar gyfer darpariaeth drosiannol. Yr addasiadau wrth adnewyddu'r awdurdodiad yw:
  - — Mae enw'r straen bacterol wedi ei ddiweddaru i *Komagataella phaffii* (*Komagataella pastoris* yn flaenorol).
  - — Mae gofyniad o ran defnydd a restrir o dan "darpariaethau eraill" (sy'n ymwneud â chynnwys ffosfforws mewn bwyd anifeiliaid) wedi ei ddileu.
- Mae Atodlen 7 yn cynnwys adnewyddiad o awdurdodiadau (ag addasiad) o baratoad o *Bacillus velezensis* (DSM 15544) (rhif adnabod 4b1820), ac awdurdodiad newydd sy'n estyn ac yn cydgrynhoi y defnydd awdurdodedig i gwmpasu rhywogaethau ychwanegol o anifeiliaid. Gweler rheoliad 13 ar gyfer darpariaeth drosiannol. Yr addasiadau wrth adnewyddu'r awdurdodiad yw:
  - — Mae enw deiliad yr awdurdodiad wedi ei ddiweddaru.
  - — Mae enw'r straen bacterol wedi ei ddiweddaru i *Bacillus velezensis* (*Bacillus subtilis* yn flaenorol).

- Schedule 3 contains a new authorisation for a preparation of *Pediococcus acidilactici* (CNCM I-4622) (identification number 4d1712).
- Schedules 4 and 5 contain renewals of authorisations (with modification) of preparations of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (carriers: perlite and (respectively) calcium carbonate or wheat bran) (identification number 51701), and new authorisation extending authorised uses to cover an additional category of animal. The modifications on renewal are:
  - — A correction to the description of an animal species/category (turkey) covered.
  - — The removal of the requirement for a 1-day (before slaughter) withdrawal period.
- Schedule 6 contains a renewal of an authorisation (with modification) of a preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) (identification number 4a16), and new authorisation extending authorised uses to cover additional species/categories of animals. See regulation 12 for transitional provision. The modifications on renewal are:
  - — The name of the bacterial strain is updated to *Komagataella phaffii* (formerly *Komagataella pastoris*).
  - — A requirement as to use listed under "other provisions" (relating to phosphorus content in feed) is removed.
- Schedule 7 contains a renewal of authorisations (with modification) of a preparation of *Bacillus velezensis* (DSM 15544) (identification number 4b1820), and new authorisation extending and consolidating authorised uses to cover additional species of animal. See regulation 13 for transitional provision. The modifications on renewal are:
  - — The name of the authorisation holder is updated.
  - — The name of the bacterial strain is updated to *Bacillus velezensis* (formerly *Bacillus subtilis*).

— Mae'r gofyniad isafswm cynnwys ar gyfer ieir a fegir ar gyfer dodwy wedi ei leihau (o 5×10^8 i 3×10^8 CFU/kg) i alinio â'r gofyniad isafswm cynnwys ar gyfer rhywogaethau/categorïau eraill o adar.

- Mae Atodlen 8 yn cynnwys awdurdodiad newydd ar gyfer paratoad o L-histidin monohydroclorid monohydrad a gynhyrchir drwy eplesu ag *Escherichia coli* K-12 (KCCM 80212) (rhif adnabod 3c352i).
- Mae Atodlen 9 yn cynnwys awdurdodiad newydd ar gyfer paratoad o L-tryptoffan a gynhyrchir drwy eplesu ag *Escherichia coli* (KCCM 80210) (rhif adnabod 3c440i).
- Mae Atodlen 10 yn cynnwys awdurdodiad newydd ar gyfer paratoad o L-lysin sylffad a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80227) (rhif adnabod 3c324i).
- Mae Atodlen 11 yn cynnwys awdurdodiad newydd o'r sylwedd hydrocsianisol bwtyleiddiedig (BHA) (rhif adnabod 1b320) fel ychwanegyn bwyd anifeiliaid ar gyfer cathod. Mae BHA fel ychwanegyn bwyd anifeiliaid ar gyfer cathod yn 'cynnyrch presennol' ar wahân at ddibenion Erthygl 10 o EUR 2003/1831 – gweler rheoliad 8 ar gyfer dileu'r statws 'cynnyrch presennol' .
- Mae Atodlen 12 yn cynnwys awdurdodiad newydd o baratoad o sylfaen L-lysin (hylif) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183) (rhif adnabod 3c320).
- Mae Atodlen 13 yn cynnwys awdurdodiad newydd o'r sylwedd L-lysin monohydroclorid (pur yn dechnegol) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183) (rhif adnabod 3c322ii).
- Mae Atodlen 14 yn cynnwys awdurdodiad newydd o'r sylwedd disodiwm 5'-gwanilad (GMP) a gynhyrchir drwy eplesu â *Corynebacterium stationis* (KCCM 10530) ac *Escherichia coli* K-12 (KFCC 11067) (rhif adnabod 2b627i).
- Mae Atodlen 15 yn cynnwys awdurdodiad newydd o baratoad o fwramidas a gynhyrchir drwy eplesu â *Trichoderma reesei* (DSM 32338) (rhif adnabod 4d16).
- Mae Atodlen 16 yn cynnwys awdurdodiad newydd o baratoad o ffytomenadion (fitamin K_1) (rhif adnabod 3a712).

— The minimum content requirement for chickens reared for laying is reduced (from 5×10^8 to 3×10^8 CFU/kg) to align with the minimum content requirement for other avian species/categories.

- Schedule 8 contains a new authorisation for a preparation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) (identification number 3c352i).
- Schedule 9 contains a new authorisation for a preparation of L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) (identification number 3c440i).
- Schedule 10 contains a new authorisation for a preparation of L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) (identification number 3c324i).
- Schedule 11 contains a new authorisation of the substance butylated hydroxyanisole (BHA) (identification number 1b320) as a feed additive for cats. BHA as a feed additive for cats is separately an 'existing product' for the purpose of Article 10 of EUR 2003/1831 – see regulation 8 for removal of the 'existing product' status.
- Schedule 12 contains a new authorisation of a preparation of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c320).
- Schedule 13 contains a new authorisation of the substance L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c322ii).
- Schedule 14 contains a new authorisation of the substance disodium 5'-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) (identification number 2b627i).
- Schedule 15 contains a new authorisation of a preparation of muramidase produced by fermentation with *Trichoderma reesei* (DSM 32338) (identification number 4d16).
- Schedule 16 contains a new authorisation of a preparation of phytomenadione (vitamin K_1) (identification number 3a712).

- Mae Atodlen 17 yn cynnwys adnewyddiad o awdurdodiad (ag addasiad) o baratoad o gelad copor o analog hydrocsi o fethionin (rhif adnabod 3b410i). Gweler rheoliad 16 ar gyfer darpariaeth drosiannol. Yr addasiadau wrth adnewyddu yw:

  — Mae'r rhif adnabod wedi ei newid o 3b4.10 i 3b410i.

  — Mae newidiadau i gyfansoddiad y paratoad awdurdodedig.

  — Mae uchafswm ar gyfer nicel (20 ppm) wedi ei ychwanegu.

  — Mae'r dulliau dadansoddi wedi eu diweddaru.

- Mae Atodlen 18 yn cynnwys adnewyddiad o awdurdodiad (ag addasiad) o baratoad o gelad manganîs o analog hydrocsi o fethionin (rhif adnabod 3b510). Gweler rheoliad 16 ar gyfer darpariaeth drosiannol. Yr addasiadau wrth adnewyddu'r awdurdodiad yw:

  — Mae'r rhif adnabod wedi ei newid o 3b5.10 i 3b510.

  — Mae newidiadau i fanyleb y paratoad awdurdodedig.

  — Mae uchafswm ar gyfer nicel (170 ppm) wedi ei ychwanegu.

  — Mae'r dulliau dadansoddi wedi eu diweddaru.

- Mae Atodlen 19 yn cynnwys adnewyddiad o awdurdodiad (ag addasiad) o baratoad o gelad zinc o analog hydrocsi o fethionin (rhif adnabod 3b610). Gweler rheoliad 16 ar gyfer darpariaeth drosiannol. Yr addasiadau wrth adnewyddu'r awdurdodiad yw:

  — Mae'r rhif adnabod wedi ei newid o 3b6.10 i 3b610.

  — Mae newidiadau i fanyleb y paratoad awdurdodedig.

  — Mae uchafswm ar gyfer nicel (1.7 ppm) wedi ei ychwanegu.

  — Mae'r dulliau dadansoddi wedi eu diweddaru.

- Mae Atodlen 20 yn cynnwys awdurdodiad newydd ar gyfer paratoad o ffwmonisin esteras (EC 3.1.1.87) (rhif adnabod 1m03i).

- Schedule 17 contains a renewal of authorisation (with modification) of a preparation of copper chelate of hydroxy analogue of methionine (identification number 3b410i). See regulation 16 for transitional provision. The modifications on renewal are:

  — The identification number is changed from 3b4.10 to 3b410i.

  — There are changes to the composition of the authorised preparation.

  — A maximum level for nickel (20 ppm) is added.

  — The analytical methods are updated.

- Schedule 18 contains a renewal of authorisation (with modification) of a preparation of manganese chelate of hydroxy analogue of methionine (identification number 3b510). See regulation 16 for transitional provision. The modifications on renewal are:

  — The identification number is changed from 3b5.10 to 3b510.

  — There are changes to the specification of the authorised preparation.

  — A maximum level for nickel (170 ppm) is added.

  — The analytical methods are updated.

- Schedule 19 contains a renewal of authorisation (with modification) of a preparation of zinc chelate of hydroxy analogue of methionine (identification number 3b610). See regulation 16 for transitional provision. The modifications on renewal are:

  — The identification number is changed from 3b6.10 to 3b610.

  — There are changes to the specification of the authorised preparation.

  — A maximum level for nickel (1.7 ppm) is added.

  — The analytical methods have been updated.

- Schedule 20 contains a new authorisation of a preparation of fumonisin esterase (EC 3.1.1.87) (identification number 1m03i).

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

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

Mae rheoliadau 4 i 6 yn diwygio offerynnau penodol sy'n cynnwys awdurdodiadau ar gyfer yr ychwanegyn bwyd anifeiliaid *Bacillus velezensis* (DSM 15544). Mae'r awdurdodiadau wedi eu haddasu i ddiweddaru enw deiliad yr awdurdodiad, ac i ddiweddaru enw'r straen bacterol *Bacillus velezensis* (*Bacillus subtilis* C-3102 yn flaenorol).

Regulations 4 to 6 amend certain instruments containing authorisations for the feed additive *Bacillus velezensis* (DSM 15544). The authorisations are modified to update the name of the authorisation holder, and to update the name of the bacterial strain *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102).

Mae rheoliad 4 hefyd yn diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2016/897 (EUR 2016/897) i ddileu'r awdurdodiad ar gyfer *Bacillus velezensis* (DSM 15544) mewn perthynas ag ieir dodwy. Mae'r awdurdodiad hwnnw wedi ei ddisodli gan yr awdurdodiad a geir yn Atodlen 7, ac wedi ei gydgrynhoi ynddo.

Regulation 4 also amends Commission Implementing Regulation (EU) 2016/897 (EUR 2016/897) to remove the authorisation for *Bacillus velezensis* (DSM 15544) in relation to laying hens. That authorisation is superseded by, and consolidated within, the authorisation contained in Schedule 7.

Mae rheoliad 7 yn diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2019/804 (EUR 2019/804), sy'n cynnwys awdurdodiad ar gyfer yr ychwanegyn bwyd anifeiliaid burum wedi ei seleneiddio a gynhyrchir drwy eplesu â *Saccharomyces cerevisiae* CNCM I-3060, anactifedig, sydd â'r rhif adnabod 3b810. Mae'r awdurdodiad wedi ei addasu mewn perthynas â chynnwys seleniwm a ganiateir yr ychwanegyn, ac i gyflwyno gofyniad mewn perthynas â photensial ysgeintio'r ychwanegyn. Gweler rheoliad 14 ar gyfer darpariaeth drosiannol.

Regulation 7 amends Commission Implementing Regulation (EU) 2019/804 (EUR 2019/804), which contains an authorisation for the feed additive selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated, with the identification number 3b810. The authorisation is modified in relation to the permitted selenium content of the additive, and to introduce a requirement in relation to the dusting potential of the additive. See regulation 14 for transitional provision.

Mae rheoliad 8 yn gwneud darpariaeth i ddileu'r awdurdodiad mewn perthynas â hydrocsianisol bwtyleiddiedig (BHA) fel ychwanegyn bwyd anifeiliaid ar gyfer cathod fel 'cynnyrch presennol' o dan Erthygl 10 o EUR 2003/1831. Er mwyn aros ar y farchnad fel ychwanegyn bwyd anifeiliaid ar gyfer cathod, rhaid i'r ychwanegyn gydymffurfio ag amodau'r awdurdodiad newydd sydd wedi ei gynnwys yn Atodlen 11 i'r Rheoliadau hyn. Ond mae rheoliad 15 yn gwneud darpariaeth drosiannol i ganiatáu i gynhyrchion presennol (na allant gydymffurfio â'r awdurdodiad newydd) a gynhyrchir ac a labelir o fewn cyfnodau penodedig barhau i gael eu marchnata a'u defnyddio hyd nes y bydd stociau wedi eu disbyddu.

Regulation 8 makes provision to remove the authorisation in relation to butylated hydroxyanisole (BHA) as a feed additive for cats as an 'existing product' under Article 10 of EUR 2003/1831. To remain on the market as feed additive for cats, the additive must comply with the conditions of the new authorisation contained in Schedule 11 to these Regulations. But regulation 15 makes transitional provision to allow existing products (that cannot comply with the new authorisation) produced and labelled within specified periods to continue be marketed and used until stocks are exhausted.

Mae rheoliadau 9 i 11 yn diwygio nifer o offerynnau i ddiweddaru enw deiliad yr awdurdodiad.

Regulations 9 to 11 amend a number of instruments to update the name of the authorisation holder.

Mae Rhan 3 (rheoliadau 12 i 16) yn cynnwys darpariaethau trosiannol mewn perthynas ag awdurdodiadau ychwanegion bwyd anifeiliaid sydd wedi eu haddasu neu eu hadnewyddu gan y Rheoliadau hyn. Mae'r darpariaethau trosiannol yn caniatáu parhau i gynhyrchu a labelu ychwanegion bwyd anifeiliaid penodedig a chynhyrchion sy'n eu cynnwys, am gyfnodau amser cyfyngedig, o dan amodau'r awdurdodiad a oedd yn gymwys yn union cyn i'r Rheoliadau hyn ddod i rym. Caniateir marchnata a defnyddio cynhyrchion a gynhyrchir ac a labelir o fewn y cyfnodau trosiannol hyd nes y bydd stociau wedi eu disbyddu.

Part 3 (regulations 12 to 16) contain transitional provisions in relation to feed additive authorisations that are modified or renewed by these Regulations. The transitional provisions allow the continued production and labelling of specified feed additives and products containing them, for limited time periods, under the conditions of authorisation applicable immediately before these Regulations come into force. Products produced and labelled within the transitional periods may be marketed and used until stocks are exhausted.

Gwneir Rhan 4 (rheoliad 17) drwy arfer pwerau yn Neddf Amaethyddiaeth 1970 (1970 p. 40). Mae Rheoliad 17 yn diwygio Rheoliad y Comisiwn (EU) 2020/354 sy'n sefydlu rhestr o ddefnyddiau arfaethedig o fwyd anifeiliaid a fwriedir at ddibenion maethol penodol (EUR 2020/354). Gwneir diwygiad i nodwedd faethol hanfodol ar gyfer marchnata yn gyfreithlon fwyd anifeiliaid y bwriedir ei ddefnyddio i leihau'r risg o dwymyn llaeth a chlwy'r llaeth is-glinigol.

Part 4 (regulation 17) is made in exercise of powers in the Agriculture Act 1970 (1970 c.40). Regulation 17 amends Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes (EUR 2020/354). An amendment is made to an essential nutritional characteristic for the lawful marketing of feed intended for use for the reduction of the risk of milk fever and subclinical hypocalcaemia.

Gwneir Rhan 5 (rheoliadau 18 i 20, ac Atodlen 21) drwy arfer pwerau yn EUR 2003/1831 ac mae'n cynnwys dirymiadau o ganlyniad i ddarpariaeth a wneir gan Ran 2.

Part 5 (regulations 18 to 20, and Schedule 21) is made in exercise of powers in EUR 2003/1831 and contains revocations in consequence of provision made by Part 2.

Mae rheoliadau 18 a 19 yn gwneud mân ddiwygiadau canlyniadol.

Regulations 18 and 19 make minor consequential amendments.

Mae rheoliad 20 ac Atodlen 21 yn dirymu, o ran Cymru, offerynnau a ddisbyddwyd, gan gynnwys y rhai sy'n cynnwys awdurdodiadau ymlaen llaw ar gyfer yr ychwanegion bwyd anifeiliaid sydd bellach wedi eu hadnewyddu gan y Rheoliadau hyn (sydd wedi eu cynnwys yn Atodlenni 2, 4 i 7, a 17 i 19).

Regulation 20 and Schedule 21 revoke, in relation to Wales, spent instruments including those containing prior authorisations for the feed additives now renewed by these Regulations (contained in Schedules 2, 4 to 7, and 17 to 19).

Gellir cael rhagor o wybodaeth, gan gynnwys mewn perthynas ag unrhyw ddogfennaeth y cyfeirir ati yn yr Atodlenni, gan yr Asiantaeth Safonau Bwyd yng Nghymru, Llawr 4, Adeilad Llywodraeth Cymru, Parc Cathays, Caerdydd, CF10 3NQ neu drwy ysgrifennu at: regulated.products.wales@food.gov.uk.

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

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

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.

2024 Rhif 1251 (Cy. 209)

AMAETHYDDIAETH, CYMRU

Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau) a Defnyddiau Bwyd Anifeiliaid a Fwriedir at Ddibenion Maethol Penodol (Diwygio Rheoliad y Comisiwn (EU) 2020/354) (Cymru) 2024

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Gosodwyd gerbron Senedd Cymru	*29 Tachwedd 2024*
Yn dod i rym	*20 Rhagfyr 2024*

Mae Gweinidogion Cymru yn gwneud y Rheoliadau hyn drwy arfer y pwerau a roddir gan Erthyglau 9(1), 10(5) a 18A(3) o Reoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid(**1**), ac adran 74A(1)(a) a (b) o Ddeddf Amaethyddiaeth 1970(**2**).

(**1**) EUR 2003/1831, a ddiwygiwyd gan O.S. 2019/654, 2022/377 a 1351. Diwygiwyd O.S. 2019/654 gan O.S. 2020/1504. Mae'r termau "prescribe" ac "appropriate authority" wedi eu diffinio yn Erthygl 2 o EUR 2003/1831. Mae Erthygl 9(1) yn gymwys mewn perthynas ag addasiadau neu adnewyddiadau yn unol ag Erthyglau 13 neu 14 yn y drefn honno.

(**2**) 1970 p. 40. Mewnosodwyd adran 74A gan baragraff 6 o Atodlen 4 i Ddeddf y Cymunedau Ewropeaidd 1972 (p. 68); diwygiwyd yr adran honno wedi hynny gan adran 33(3) o Ddeddf Amaethyddiaeth 2020 (p. 21); mae offerynnau diwygio eraill ond nid yw'r un ohonynt yn berthnasol.. Diffinnir y termau "the Ministers", "prescribed" a "regulations" yn adran 66(1) o Ddeddf Amaethyddiaeth 1970. Trosglwyddwyd swyddogaethau a oedd gynt yn arferadwy gan "the Ministers", i'r graddau y maent yn arferadwy o ran Cymru, i Gynulliad Cenedlaethol Cymru gan O.S. 1999/672. Mae'r swyddogaethau hynny bellach yn arferadwy gan Weinidogion Cymru yn rhinwedd adran 162 o Ddeddf Llywodraeth Cymru 2006, a pharagraff 30 o Atodlen 11 iddi.

2024 No. 1251 (W. 209)

AGRICULTURE, WALES

The Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024

Made	*27 November 2024*
Laid before Senedd Cymru	*29 November 2024*
Coming into force	*20 December 2024*

The Welsh Ministers make these Regulations in exercise of the powers conferred by Articles 9(1), 10(5) 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**), and section 74A(1)(a) and (b) of the Agriculture Act 1970(**2**).

(**1**) EUR 2003/1831, amended by S.I. 2019/654, 2022/377 and 1351. S.I. 2019/654 was amended by S.I. 2020/1504. The terms "prescribe" and "appropriate authority" are defined in Article 2 of EUR 2003/1831. Article 9(1) applies in relation to modifications or renewals in accordance with Articles 13 or 14 respectively.

(**2**) 1970 c. 40. Section 74A was inserted by paragraph 6 of Schedule 4 to the European Communities Act 1972 (c. 68); that section was subsequently amended by section 33(3) of the Agriculture Act 2020 (c. 21); there are other amending instruments but none is relevant. The terms "the Ministers", "prescribed" and "regulations" are defined in section 66(1) of the Agriculture Act 1970. Functions formerly exercisable by "the Ministers", so far as exercisable in relation to Wales, were transferred to the National Assembly for Wales by S.I. 1999/672. Those functions are now exercisable by the Welsh Ministers by virtue of section 162 of, and paragraph 30 of Schedule 11 to, the Government of Wales Act 2006.

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(**1**).

There has been consultation as required by Article 9 of Regulation (EC) No 178/2002 of the European Parliament and of the Council laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety(**1**).

RHAN 1

Cyflwyniad

PART 1

Introduction

Enwi, rhychwant, cymhwyso a dod i rym

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Ychwanegion Bwyd Anifeiliaid (Awdurdodiadau) a Defnyddiau Bwyd Anifeiliaid a Fwriedir at Ddibenion Maethol Penodol (Diwygio Rheoliad y Comisiwn (EU) 2020/354) (Cymru) 2024.

(2) Mae'r Rheoliadau hyn—

(a) yn rhychwantu Cymru a Lloegr;

(b) yn gymwys o ran Cymru;

(c) yn dod i rym ar 20 Rhagfyr 2024.

Title, extent, application and coming into force

1.—(1) The title of these Regulations is the Feed Additives (Authorisations) and Uses of Feed Intended for Particular Nutritional Purposes (Amendment of Commission Regulation (EU) 2020/354) (Wales) Regulations 2024.

(2) These Regulations—

(a) extend to England and Wales;

(b) apply in relation to Wales;

(c) come into force on 20 December 2024.

Dehongli

2.—(1) Mae i ymadroddion Cymraeg a ddefnyddir yn y Rheoliadau hyn sy'n cyfateb i ymadroddion Saesneg yn Rheoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid neu Reoliad (EC) Rhif 767/2009 Senedd Ewrop a'r Cyngor ar roi bwyd anifeiliaid ar y farchnad a'i ddefnyddio(**2**) yr un ystyr ag yn Rheoliad (EC) Rhif 1831/2003 neu Reoliad (EC) Rhif 767/2009, yn y drefn honno.

(2) Yn Atodlenni 1 i 20, mae i ymadroddion Cymraeg a ddefnyddir i gyfeirio at rywogaethau neu gategorïau o anifeiliaid sy'n cyfateb i ymadroddion Saesneg a ddefnyddir yn Atodiad 4 (categorïau a diffiniadau o anifeiliaid targed etc.) i Reoliad 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(**3**) yr un ystyr ag yn yr Atodiad hwnnw.

Interpretation

2.—(1) Expressions used in these Regulations and in Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition or Regulation 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed(**2**) have the same meaning as in Regulation (EC) No 1831/2003 or Regulation (EC) No 767/2009, respectively.

(2) In Schedules 1 to 20, expressions used to refer to species or categories of animals that are also used in Annex 4 (categories and definitions of target animals etc.) to Commission Regulation (EC) No 429/2008 on detailed rules for the implementation of Regulation (EC) No 1831/2003 of the European Parliament and of the Council as regards the preparation and the presentation of applications and the assessment and the authorisation of feed additives(**3**) have the same meaning as in that Annex.

(**1**) EUR 2002/178, a ddiwygiwyd gan O.S. 2019/641. Diwygiwyd O.S. 2019/641 gan O.S. 2020/1504.
(**2**) EUR 2009/767, a ddiwygiwyd gan O.S. 2019/654, 2022/1351. Diwygiwyd O.S. 2019/654 gan O.S. 2020/1504.
(**3**) EUR 2008/429, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(**1**) EUR 2002/178, amended by S.I. 2019/641. S.I. 2019/641 was amended by S.I. 2020/1504.
(**2**) EUR 2009/767, amended by S.I. 2019/654, 2022/1351. S.I. 2019/654 was amended by S.I. 2020/1504.
(**3**) EUR 2008/429, to which there are amendments not relevant to these Regulations.

RHAN 2

Awdurdodiadau ychwanegion bwyd anifeiliaid

Awdurdodiadau

3.—(1) Mae Atodlenni 1 i 20 yn cynnwys awdurdodiadau ychwanegion bwyd anifeiliaid.

(2) Yn ddarostyngedig i Erthygl 14(4) (adnewyddu awdurdodiad) o Reoliad (EC) Rhif 1831/2003, mae'r awdurdodiadau a nodir yn Atodlenni 1 i 20 yn peidio â chael effaith ar ddiwedd 19 Rhagfyr 2034.

Addasu awdurdodiadau: paratoad o *Bacillus velezensis* (DSM 15544) (rhif adnabod 4b1820)

4.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) 2016/897 sy'n ymwneud ag awdurdodi paratoad o *Bacillus subtilis* (C-3102) (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy a physgod addurnol (deiliad yr awdurdodiad Asahi Calpis Wellness Co Ltd, a gynrychiolir yn yr Undeb Ewropeaidd gan Pen & Tec Consulting S.L.U.) a Rheoliadau diwygio (EC) Rhif 1444/2006, (EU) Rhif 333/2010 ac (EU) Rhif 184/2011(**1**) wedi ei ddiwygio fel a ganlyn.

(2) Hepgorer Erthyglau 2 i 4.

(3) Yn yr Atodiad, yn y tabl—

(a) yn yr ail golofn (enw deiliad yr awdurdodiad), yn lle "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." rhodder "Asahi Biocycle Co., Ltd";

(b) yn y drydedd golofn (yr ychwanegyn) a'r bedwaredd golofn (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), ar gyfer "*Bacillus subtilis* C-3102", ym mhob lle mae'n digwydd, rhodder "*Bacillus velezensis"*;

(c) yn y bumed golofn (rhywogaeth neu gategori o anifail), hepgorer "Laying hens";

(d) Yn y seithfed golofn (isafswm cynnwys), hepgorer "3×10^{8}".

5.—(1) Yn Rheoliad Gweithredu'r Comisiwn (EU) 2017/2312 sy'n ymwneud ag awdurdodi defnydd newydd o baratoad o *Bacillus subtilis* C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer hychod, perchyll sugno a chŵn (deiliad yr

(**1**) EUR 2016/897. Gweler rheoliad 13 o'r Rheoliadau hyn ar gyfer darpariaeth drosiannol. Diwygiwyd EUR 2016/897 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2020/146 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

PART 2

Feed additive authorisations

Authorisations

3.—(1) Schedules 1 to 20 contain authorisations of feed additives.

(2) Subject to Article 14(4) (renewal of authorisation) of Regulation (EC) No 1831/2003, the authorisations set out in Schedules 1 to 20 cease to have effect at the end of 19 December 2034.

Modification of authorisations: preparation of *Bacillus velezensis* (DSM 15544) (identification number 4b1820)

4.—(1) Commission Implementing Regulation (EU) 2016/897 concerning the authorisation of a preparation of *Bacillus subtilis* (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.) and amending Regulations (EC) No 1444/2006, (EU) No 333/2010 and (EU) No 184/2011(**1**) is amended as follows.

(2) Omit Articles 2 to 4.

(3) In the Annex, in the table—

(a) in the second column (name of the holder of authorisation), for "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." substitute "Asahi Biocycle Co., Ltd";

(b) in the third column (additive) and the fourth column (composition, chemical formula, description, analytical method), for "*Bacillus subtilis* C-3102", in each place it occurs, substitute "*Bacillus velezensis"*;

(c) in the fifth column (species or category of animal), omit "Laying hens";

(d) in the seventh column (minimum content), omit "3×10^{8}".

5.—(1) In Commission Implementing Regulation (EU) 2017/2312 concerning the authorisation of a new use of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for sows, suckling piglets and dogs (holder of the authorisation Asahi

(**1**) EUR 2016/897. See regulation 13 of these Regulations for transitional provision. EUR 2016/897 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 and Schedule 21 to these Regulations.

awdurdodiad Asahi Calpis Wellness Co. Ltd, a gynrychiolir yn yr Undeb Ewropeaidd gan Pen & Tec Consulting S.L.U.) (**1**), yn yr Atodiad, diwygir y tabl fel a ganlyn.

(2) Yn yr ail golofn (enw deiliad yr awdurdodiad), yn lle "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." rhodder "Asahi Biocycle Co., Ltd".

(3) Yn y drydedd golofn (yr ychwanegyn), yn lle "*Bacillus subtilis*" rhodder "*Bacillus velezensis*".

(4) Yn y bedwaredd golofn (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi)—

(a) yn yr adran o dan y pennawd "*Additive composition",* yn lle "*Bacillus subtilis* C-3102" rhodder "*Bacillus velezensis*";

(b) yn yr adran o dan y pennawd "*Characterisation of the active substance*, yn lle"*Bacillus subtilis"* rhodder "*Bacillus velezensis"*.

6.—(1) Yn Rheoliad Gweithredu'r Comisiwn (EU) 2018/1081 sy'n ymwneud ag awdurdodi paratoad o *Bacillus subtilis* C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer moch i'w pesgi (deiliad yr awdurdodiad Asahi Calpis Wellness Co. Ltd, a gynrychiolir yn yr Undeb Ewropeaidd gan Pen & Tec Consulting S.L.U.) (**2**), yn yr Atodiad, diwygir y tabl fel a ganlyn.

(2) Yn yr ail golofn (enw deiliad yr awdurdodiad), yn lle "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." rhodder "Asahi Biocycle Co., Ltd".

(3) Yn y drydedd golofn (yr ychwanegyn) a'r bedwaredd golofn (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), yn lle "*Bacillus subtilis* C-3102", ym mhob lle y mae'n digwydd, rhodder "*Bacillus velezensis*".

Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**1**), in the Annex, the table is amended as follows.

(2) In the second column (name of the holder of authorisation), for "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." substitute "Asahi Biocycle Co., Ltd".

(3) In the third column (additive), for "*Bacillus subtilis*" substitute "*Bacillus velezensis*".

(4) In the fourth column (composition, chemical formula, description, analytical method)—

(a) in the section headed "*Additive composition",* for "*Bacillus subtilis* C-3102" substitute "*Bacillus velezensis*";

(b) in the section headed "*Characterisation of the active substance*, for "*Bacillus subtilis"* substitute "*Bacillus velezensis"*.

6.—(1) In Commission Implementing Regulation (EU) 2018/1081 concerning the authorisation of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for pigs for fattening (holder of the authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**2**), in the Annex, the table is amended as follows.

(2) In the second column (name of the holder of authorisation), for "Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U." substitute "Asahi Biocycle Co., Ltd".

(3) In the third column (additive) and the fourth column (composition, chemical formula, description, analytical method), for "*Bacillus subtilis* C-3102", in each place it occurs, substitute "*Bacillus velezensis*".

(**1**) EUR 2017/2312. Gweler rheoliad 13 o'r Rheoliadau hyn ar gyfer darpariaeth drosiannol. Diwygiwyd EUR 2017/2312 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2020/146 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

(**2**) EUR 2018/1081 Gweler rheoliad 13 o'r Rheoliadau hyn ar gyfer darpariaeth drosiannol. Diwygiwyd EUR 2018/1081 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2020/146 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

(**1**) EUR 2017/2312. See regulation 13 of these Regulations for transitional provision. EUR 2017/2312 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 and Schedule 21 to these Regulations.

(**2**) EUR 2018/1081. See regulation 13 of these Regulations for transitional provision. EUR 2018/1081 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 and Schedule 21 to these Regulations.

Addasu awdurdodiad: burum wedi ei seleneiddio a gynhyrchir drwy eplesu â *Saccharomyces cerevisiae* CNCM I-3060, anactifedig (rhif adnabod 3b810)

7.—(1) Yn Rheoliad Gweithredu'r Comisiwn (EU) 2019/804 sy'n ymwneud ag adnewyddu awdurdodiad ffurf organig o seleniwm a gynhyrchir gan *Saccharomyceas cerevisiae* CNCM I-3060 ac o selenomethionin a gynhyrchir gan *Saccharomyces cerevisiae* NCYC R397 fel ychwanegion bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**1**), yn yr Atodiad, mae'r cofnod ar gyfer "3b810" wedi ei ddiwygio fel a ganlyn.

(2) Yn y bedwaredd golofn (cyfansoddiad, fformiwla gemegol, disgrifiad, dull dadansoddi), yn lle'r adran o dan y pennawd "Additive composition" rhodder—

"*Additive composition* Preparation of organic selenium (Se) produced by fermentation with *Saccharomyces cerevisiae* (CNCM I-3060) containing 2000 to 3500 mg Se/kg with the below components: • Organic selenium: 97% minimum of total selenium • Selenomethionine: 63% minimum of total selenium".

(3) Yn y nawfed golofn (darpariaethau eraill), ar ôl pwynt 4 mewnosoder—

"5. The dusting potential of the additive must ensure a maximum selenium exposure of 0.2 mg Se/m^3."

Dileu awdurdodiad hydrocsianisol bwtyleiddiedig fel cynnyrch presennol at ddibenion Erthygl 10 o Reoliad (EC) Rhif 1831/2003

8. Ni chaniateir i hydrocsianisol bwtyleiddiedig (E 320) gael ei roi ar y farchnad na'i ddefnyddio fel ychwanegyn bwyd anifeiliaid ar gyfer cathod mwyach o dan Erthygl 10 o Reoliad (EC) No 1831/2003(**2**).

Modification of authorisation: selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated (identification number 3b810)

7.—(1) In Commission Implementing Regulation (EU) 2019/804 concerning the renewal of the authorisation of organic form of selenium produced by *Saccharomyces cerevisiae* CNCM I-3060 and of selenomethionine produced by *Saccharomyces cerevisiae* NCYC R397 as feed additives for all animal species(**1**), in the Annex, the entry for "3b810" is amended as follows.

(2) In the fourth column (composition, chemical formula, description, analytical method), for the section headed "Additive composition" substitute—

"*Additive composition* Preparation of organic selenium (Se) produced by fermentation with *Saccharomyces cerevisiae* (CNCM I-3060) containing 2000 to 3500 mg Se/kg with the below components: • Organic selenium: 97% minimum of total selenium • Selenomethionine: 63% minimum of total selenium".

(3) In the ninth column (other provisions), after point 4 insert—

"5. The dusting potential of the additive must ensure a maximum selenium exposure of 0.2 mg Se/m^3."

Removal of authorisation of butylated hydroxyanisole as an existing product for the purposes of Article 10 of Regulation (EC) No 1831/2003

8. Butylated hydroxyanisole (E 320) may no longer be placed on the market or used as a feed additive for cats under Article 10 of Regulation (EC) No 1831/2003(**2**).

(**1**) EUR 2019/804. Gweler rheoliad 14 o'r Rheoliadau hyn ar gyfer darpariaeth drosiannol.
(**2**) Ond gweler rheoliad 15 o'r Rheoliadau hyn ar gyfer darpariaeth drosiannol. Gweler Atodlen 11 i'r Rheoliadau hyn ar gyfer awdurdodiad newydd i hydrocsianisol bwtyleiddiedig fel ychwanegyn bwyd anifeiliaid ar gyfer cathod.

(**1**) EUR 2019/804. See regulation 14 of these Regulations for transitional provision.
(**2**) But see regulation 15 of these Regulations for transitional provision. See Schedule 11 to these Regulations for the new authorisation of butylated hydroxyanisole as a feed additive for cats.

Newidiadau o ran deiliad awdurdodiad: diwygio Rheoliad Gweithredu'r Comisiwn (EU) Rhif 887/2011 a Rheoliadau Gweithredu'r Comisiwn (EU) 2017/961 a 2020/1395

9.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) Rhif 887/2011 sy'n ymwneud ag awdurdodi paratoad o *Enterococcus faecium* CECT 4515 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi (deiliad yr awdurdodiad Evonik Nutrition & Care GmbH) (**1**) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn yr ail dabl (awdurdodiad yn dod i ben 28 Mehefin 2027), yn yr ail golofn (enw deiliad yr awdurdodiad), yn lle "Evonik Nutrition & Care GmbH)" rhodder "Evonik Operations GmbH".

10.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) 2017/961 dyddiedig 7 Mehefin 2017 sy'n ymwneud ag awdurdodi paratoad o *Enterococcus faecium* CECT 4515 fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu, a defnydd newydd mewn dŵr i'w yfed ar gyfer perchyll wedi eu diddyfnu ac ieir i'w pesgi, ac sy'n diwygio Rheoliad (EC) Rhif 2036/2005 a Rheoliad (EU) Rhif 887/2011 (deiliad yr awdurdodiad Evonik Nutrition & Care GmbH)(**2**) wedi ei ddiwygio fel a ganlyn.

(2) Yn Atodiad 1, yn y tabl, yn yr ail golofn (enw deiliad yr awdurdodiad), yn lle "Evonik Nutrition & Care GmbH)" rhodder "Evonik Operations GmbH".

11.—(1) Mae Rheoliad Gweithredu'r Comisiwn (EU) 2020/1395 sy'n ymwneud ag adnewyddu awdurdodiad o *Bacillus amyloliquefaciens* CECT 5940 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, a'i awdurdodiad ar gyfer ieir a fegir ar gyfer dodwy, ac sy'n diddymu Rheoliad (EC) Rhif 1292/2008 (deiliad yr awdurdodiad Evonik Nutrition & Care GmbH) (**3**) wedi ei ddiwygio fel a ganlyn.

(2) Yn yr Atodiad, yn y tabl, yn yr ail golofn (enw deiliad yr awdurdodiad), yn lle"Evonik Nutrition & Care GmbH" rhodder "Evonik Operations GmbH".

(**1**) EUR 2011/887, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2017/173 a 961.
(**2**) EUR 2017/961.
(**3**) EUR 2020/1395.

Changes of authorisation holder: amendment of Commission Implementing Regulation (EU) No 887/2011 and Commission Implementing Regulations (EU) 2017/961 and 2020/1395

9.—(1) Commission Implementing Regulation (EU) No 887/2011 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as feed additive for chickens for fattening (holder of the authorisation Evonik Nutrition & Care GmbH)(**1**) is amended as follows.

(2) In the Annex, in the second table (authorisation expiring 28 June 2027), in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH)" substitute "Evonik Operations GmbH".

10.—(1) Commission Implementing Regulation (EU) 2017/961 of 7 June 2017 concerning the authorisation of a preparation of *Enterococcus faecium* CECT 4515 as a feed additive for weaned piglets, and a new use in water for drinking for weaned piglets and chickens for fattening, and amending Regulation (EC) No 2036/2005 and Regulation (EU) No 887/2011 (holder of authorisation Evonik Nutrition & Care GmbH)(**2**) is amended as follows.

(2) In Annex 1, in the table, in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH)" substitute "Evonik Operations GmbH".

11.—(1) Commission Implementing Regulation (EU) 2020/1395 concerning the renewal of the authorisation of *Bacillus amyloliquefaciens* CECT 5940 as a feed additive for chickens for fattening, its authorisation for chickens reared for laying, and repealing Regulation (EC) No 1292/2008 (holder of authorisation Evonik Nutrition & Care GmbH)(**3**) is amended as follows.

(2) In the Annex, in the table, in the second column (name of the holder of authorisation), for "Evonik Nutrition & Care GmbH" substitute "Evonik Operations GmbH".

(**1**) EUR 2011/887, amended prior to implementation period completion day by Commission Implementing Regulations (EU) 2017/173 and 961.
(**2**) EUR 2017/961.
(**3**) EUR 2020/1395.

RHAN 3

Darpariaethau Trosiannol

Darpariaeth drosiannol: 6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu â *Komagataella phaffii* (*Komagataella pastoris* yn flaenorol) (DSM 23036) (rhif adnabod 4a16)

12.—(1) Caniateir i'r ychwanegyn bwyd anifeiliaid perthnasol a'r rhag-gymysgeddau, y bwyd anifeiliaid cyfansawdd neu ddeunyddiau bwyd anifeiliaid sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 19 Mehefin 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu dihysbyddu.

(2) Ym mharagraff (1), mae'r cyfeiriad at yr "ychwanegyn bwyd anifeiliaid perthnasol" yn gyfeiriad at yr ychwanegyn bwyd anifeiliaid 6-ffytas (EC 3.1.3.26) (rhif adnabod 4a16)(**1**) fel y'i hawdurdodwyd yn union cyn 20 Rhagfyr 2024 o dan Reoliad Gweithredu'r Comisiwn (EU) Rhif 98/2012 sy'n ymwneud ag awdurdodi 6-ffytas (EC 3.1.3.26) a gynhyrchir gan *Pichia pastoris* (DSM 23036) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a thwrcwn i'w pesgi, ieir a fegir ar gyfer dodwy, tyrcwn a fegir ar gyfer bridio, ieir dodwy, rhywogaethau eraill o adar i'w pesgi ac ar gyfer dodwy, perchyll wedi eu diddyfnu, moch i'w pesgi a hychod(**2**).

Darpariaeth drosiannol: *Bacillus velezensis* (*Bacillus subtilis* C-3102 yn flaenorol) (DSM 15544) (rhif adnabod 4b1820)

13.—(1) Caniateir i unrhyw sylwedd neu gynnyrch a labelwyd "*Bacillus subtilis* C-3102" neu a labelwyd fel sylwedd neu gynnyrch sy'n cynnwys "*Bacillus subtilis* C-3102", 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 6 o'r Rheoliadau hyn, 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'r rhag-gymysgeddau sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 19 Mehefin 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r

(**1**) Gweler Atodlen 6 i'r Rheoliadau hyn ar gyfer yr awdurdodiad perthnasol a adnewyddwyd ar gyfer yr ychwanegyn bwyd anifeiliaid hwn.

(**2**) EUR 2012/98, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2016/348 (EUR 2016/348). Mae EUR 2012/98 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

PART 3

Transitional provisions

Transitional provision: 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) (identification number 4a16)

12.—(1) The relevant feed additive and premixtures, compound feed or feed materials containing it, which are produced and labelled before the end of 19 June 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) In paragraph (1), the reference to the "relevant feed additive" is a reference to the feed additive 6-phytase (EC 3.1.3.26) (identification number 4a16)(**1**) as authorised immediately before 20 December 2024 under Commission Implementing Regulation (EU) No 98/2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows(**2**).

Transitional provision: *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544) (identification number 4b1820)

13.—(1) Any substance or product labelled "*Bacillus subtilis* C-3102" or as containing "*Bacillus subtilis* C-3102", but otherwise produced and labelled in accordance with an authorisation contained in an instrument mentioned in regulations 4 to 6 of these Regulations, 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 19 June 2025 in compliance with the conditions of authorisation and the labelling

(**1**) See Schedule 6 to these Regulations for relevant renewed authorisation of this feed additive.

(**2**) EUR 2012/98, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2016/348 (EUR 2016/348). EUR 2012/98 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(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 19 Rhagfyr 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(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 19 Rhagfyr 2026 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(5) Yn y rheoliad hwn, mae cyfeiriadau at yr "ychwanegyn bwyd anifeiliaid perthnasol" yn gyfeiriadau at yr ychwanegyn bwyd anifeiliaid *Bacillus velezensis* (*Bacillus subtilis* C-3102 yn flaenorol) (DSM 15544), sydd â'r rhif adnabod 4b1820(**1**), fel y'i hawdurdodwyd yn union cyn 20 Rhagfyr 2024 o dan—

(a) Rheoliad y Comisiwn (EU) Rhif 333/2010 sy'n ymwneud ag awdurdodi defnydd newydd o *Bacillus su*btilis C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu(**2**);

(b) Rheoliad y Comisiwn (EU) Rhif 184/2011 sy'n ymwneud ag awdurdodi *Bacillus subtilis* C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy, tyrcwn, mân rywogaethau adar ac adar addurnol ac adar hela eraill(**3**);

requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until 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 19 December 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until 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 19 December 2026 in compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(5) In this regulation, references to the "relevant feed additive" are references to the feed additive *Bacillus velezensis* (formerly *Bacillus subtilis* C-3102) (DSM 15544), with the identification number 4b1820(**1**), as authorised immediately before 20 December 2024 under—

(a) Commission Regulation (EU) No 333/2010 concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets(**2**);

(b) Commission Regulation (EU) No 184/2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds(**3**);

(**1**) Gweler Atodlen 7 i'r Rheoliadau hyn ar gyfer awdurdodiad yr ychwanegyn bwyd anifeiliaid perthnasol a adnewyddwyd ac a gydgrynhowyd.

(**2**) EUR 2010/333, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2010/333 a 2020/146 wedi eu dirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

(**3**) EUR 2011/184, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2011/184 a 2020/146 wedi eu dirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt

(**1**) See Schedule 7 to these Regulations for relevant renewed and consolidated authorisation of this feed additive.

(**2**) EUR 2010/333, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2010/333 and 2020/146 are revoked by regulation 20 of, and Schedule 21 to, these Regulations

(**3**) EUR 2011/184, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2011/184 and 2020/146 are revoked by regulation 20 of, and Schedule 21 to, these Regulations

(c) Rheoliad Gweithredu'r Comisiwn (EU) 2016/897 sy'n ymwneud ag awdurdodi paratoad o *Bacillus subtilis* (C-3102) (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir dodwy a physgod addurniadol(**1**);

(d) Rheoliad Gweithredu'r Comisiwn (EU) 2019/893 sy'n ymwneud ag adnewyddu awdurdodiad o *Bacillus subtilis* DSM 15544 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi(**2**).

(c) Commission Implementing Regulation (EU) 2016/897 concerning the authorisation of a preparation of *Bacillus subtilis* (C-3102) (DSM 15544) as a feed additive for laying hens and ornamental fish(**1**);

(d) Commission Implementing Regulation (EU) 2019/893 concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening(**2**).

Darpariaeth drosiannol: Burum wedi ei seleneiddio a gynhyrchir drwy eplesu â *Saccharomyces cerevisiae* CNCM I-3060, anactifedig (rhif adnabod 3b810)

14.—(1) Caniateir i'r ychwanegyn bwyd anifeiliaid perthnasol a'r rhag-gymysgeddau sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 19 Mehefin 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(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 19 Rhagfyr 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(3) 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 19 Rhagfyr 2026 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(4) Yn y rheoliad hwn, mae cyfeiriadau at yr "ychwanegyn bwyd anifeiliaid perthnasol" yn gyfeiriadau at yr ychwanegyn bwyd anifeiliaid burum wedi ei seleneiddio a gynhyrchir drwy eplesu â *Saccharomyces cerevisiae* CNCM I-3060, anactifedig,

Transitional provision: Selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated (identification number 3b810)

14.—(1) The relevant feed additive and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing the relevant feed additive and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(3) 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 19 December 2026 in compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation, references to the "relevant feed additive" are references to the feed additive selenised yeast produced by fermentation with *Saccharomyces cerevisiae* CNCM I-3060, inactivated, with the identification number 3b810, as authorised

(**1**) Gweler rheoliad 4 o'r Rheoliadau hyn ar gyfer diwygiadau i EUR 2016/897.

(**2**) EUR 2019/893, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2019/893 a 2020/146 wedi eu dirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

(**1**) See regulation 4 of these Regulations for amendments to EUR 2016/897.

(**2**) EUR 2019/893, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2019/893 and 2020/146 are revoked by regulation 20 of, and Schedule 21 to, these Regulations.

sydd â'r rhif adnabod 3b810, fel y'i hawdurdodwyd yn union cyn 20 Rhagfyr 2024 o dan Reoliad Gweithredu'r Comisiwn (EU) 2019/804(**1**).

Darpariaeth drosiannol: Hydrocsianisol bwtyleiddiedig fel ychwanegyn bwyd anifeiliaid ar gyfer cathod

15.—(1) Caniateir i hydrocsianisol bwtyleiddiedig fel ychwanegyn bwyd anifeiliaid ar gyfer cathod a'r rhag-gymysgeddau sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 19 Mehefin 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(2) Caniateir i fwyd anifeiliaid cyfansawdd a deunyddiau bwyd anifeiliaid sy'n cynnwys hydrocsianisol bwtyleiddiedig ac a fwriedir ar gyfer cathod, a gynhyrchir ac a labelir cyn diwedd 19 Rhagfyr 2026 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

Darpariaethau trosiannol: Celadau copor, manganîs, a zinc o analog hydrocsi o fethionin (rhifau adnabod 3b410i, 3b510 a 3b610 yn y drefn honno)

16.—(1) Caniateir i ychwanegyn bwyd anifeiliaid perthnasol a'r rhag-gymysgeddau sy'n ei gynnwys, a gynhyrchir ac a labelir cyn diwedd 19 Mehefin 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(2) Caniateir i fwyd anifeiliaid cyfansawdd a deunyddiau bwyd anifeiliaid sy'n cynnwys ychwanegyn bwyd anifeiliaid perthnasol ac a fwriedir ar gyfer anifeiliaid sy'n cynhyrchu bwyd, a gynhyrchir ac a labelir cyn diwedd 19 Rhagfyr 2025 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys yn union cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(**1**) Gweler rheoliad 7 o'r Rheoliadau hyn ar gyfer diwygiadau i EUR 2019/804.

immediately before 20 December 2024 under Commission Implementing Regulation (EU) 2019/804(**1**).

Transitional provision: Butylated hydroxyanisole as a feed additive for cats

15.—(1) Butylated hydroxyanisole as a feed additive for cats and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing butylated hydroxyanisole intended for cats, which are produced and labelled before the end of 19 December 2026 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

Transitional provisions: Copper, manganese and zinc chelates of hydroxy analogue of methionine (identification numbers 3b410i, 3b510 and 3b610 respectively)

16.—(1) A relevant feed additive and premixtures containing it, which are produced and labelled before the end of 19 June 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(2) Compound feed and feed materials containing a relevant feed additive and intended for food-producing animals, which are produced and labelled before the end of 19 December 2025 in compliance with the conditions of authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(**1**) See regulation 7 of these Regulations for amendments to EUR 2019/804.

(3) Caniateir i fwyd anifeiliaid cyfansawdd a deunyddiau bwyd anifeiliaid sy'n cynnwys ychwanegyn bwyd anifeiliaid perthnasol ac a fwriedir ar gyfer anifeiliaid nad ydynt yn cynhyrchu bwyd, a gynhyrchir ac a labelir cyn diwedd 19 Rhagfyr 2026 gan gydymffurfio ag amodau'r awdurdodiad a'r gofynion labelu sy'n gymwys cyn 20 Rhagfyr 2024, barhau i gael ei roi neu eu rhoi ar y farchnad a'i ddefnyddio neu eu defnyddio hyd nes y bydd stociau wedi eu disbyddu.

(4) Yn y rheoliad hwn, mae cyfeiriadau at "ychwanegyn bwyd anifeiliaid perthnasol" yn gyfeiriadau at bob un o'r ychwanegion bwyd anifeiliaid a ganlyn.

Celad copor o analog hydrocsi o fethionin

(a) Yr ychwanegyn bwyd anifeiliaid celad copor o analog hydrocsi o fethionin, sydd â'r rhif adnabod 3b410i (3b4.10 yn flaenorol)(**1**) fel y'i hawdurdodwyd yn union cyn 20 Rhagfyr 2024 o dan Reoliad y Comisiwn (EU) Rhif 349/2010 sy'n ymwneud ag awdurdodi celad copor o analog hydrocsi o fethionin fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**2**).

Celad manganîs o analog hydrocsi o fethionin

(b) Yr ychwanegyn bwyd anifeiliaid celad manganîs o analog hydrocsi o fethionin, sydd â'r rhif adnabod 3b510 (3b5.10 yn flaenorol)(**3**) fel y'i hawdurdodwyd yn union cyn 20 Rhagfyr 2024 o dan Reoliad y Comisiwn (EU) Rhif 350/2010 sy'n ymwneud ag awdurdodi celad manganîs o analog hydrocsi o fethionin fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**4**).

(3) Compound feed and feed materials containing a relevant feed additive and intended for non-food-producing animals, which are produced and labelled before the end of 19 December 2026 in compliance with the conditions of the authorisation and the labelling requirements applicable immediately before 20 December 2024, may continue to be placed on the market and used until stocks are exhausted.

(4) In this regulation, references to a "relevant feed additive" are references to each of the following feed additives.

Copper chelate of hydroxy analogue of methionine

(a) The feed additive copper chelate of hydroxy analogue of methionine, with the identification number 3b410i (formerly 3b4.10)(**1**) as authorised immediately before 20 December 2024 under Commission Regulation (EU) No 349/2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species(**2**).

Manganese chelate of hydroxy analogue of methionine

(b) The feed additive manganese chelate of hydroxy analogue of methionine, with the identification number 3b510 (formerly 3b5.10)(**3**) as authorised immediately before 20 December 2024 under Commission Regulation (EU) No 350/2010 concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species(**4**).

(**1**) Gweler Atodlen 17 i'r Rheoliadau hyn ar gyfer awdurdodiad yr ychwanegyn bwyd anifeiliaid hwn a adnewyddwyd.
(**2**) EUR 2010/349, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2018/1039 (EUR 2018/1039). Mae EUR 2010/349 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.
(**3**) Gweler Atodlen 18 i'r Rheoliadau hyn ar gyfer awdurdodiad yr ychwanegyn bwyd anifeiliaid hwn a adnewyddwyd.
(**4**) EUR 2010/350. Mae EUR 2010/350 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

(**1**) See Schedule 17 to these Regulations for the renewed authorisation of this feed additive.
(**2**) EUR 2010/349, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2018/1039 (EUR 2018/1039). EUR 2010/349 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.
(**3**) See Schedule 18 to these Regulations for the renewed authorisation of this feed additive.
(**4**) EUR 2010/350. EUR 2010/350 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Celad zinc o analog hydrocsi o methionin

(c) Yr ychwanegyn bwyd anifeiliaid celad zinc o analog hydrocsi o fethionin, sydd â'r rhif adnabod 3b610 (3b6.10 yn flaenorol)(**1**) fel y'i hawdurdodwyd yn union cyn 20 Rhagfyr 2024 o dan Reoliad y Comisiwn (EU) Rhif 335/2010 sy'n ymwneud ag awdurdodi celad zinc o analog hydrocsi o fethionin fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**2**).

Zinc chelate of hydroxy analogue of methionine

(c) The feed additive zinc chelate of hydroxy analogue of methionine, with the identification number 3b610 (formerly 3b6.10)(**1**) as authorised immediately before 20 December 2024 under Commission Regulation (EU) No 335/2010 concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species(**2**).

RHAN 4

Defnydd o fwyd anifeiliaid a fwriedir at ddibenion maethol penodol

Addasu nodwedd faethol hanfodol ar gyfer bwyd anifeiliaid a fwriedir i leihau'r risg o dwymyn llaeth a chlwy'r llaeth is-glinigol

17.—(1) Yn Rheoliad y Comisiwn (EU) 2020/354 sy'n sefydlu rhestr o ddefnyddiau arfaethedig o fwyd anifeiliaid a fwriedir at ddibenion maethol penodol(**3**), yn yr Atodiad, yn Rhan B (rhestr o ddefnyddiau arfaethedig), diwygir y tabl fel a ganlyn.

(2) Yng nghofnod 60 (lleihau'r risg o dwymyn llaeth a chlwy'r llaeth is-glinigol), yng ngholofn rhif 2 (nodweddion maethol hanfodol), yn adran y cofnod sy'n dechrau â "Low cations/anions ratio", yn lle "Objective: 0 < $DCAD^s$ (mEq/kg dry matter) < 100" rhodder "Objective: Range from -200 mEq/kg dry matter $DCAD^s$ to <100 mEq/kg dry matter DCAD".

PART 4

Uses of feed intended for particular nutritional purposes

Modification of an essential nutritional characteristic for feed intended to reduce the risk of milk fever and subclinical hypocalcaemia

17.—(1) In Commission Regulation (EU) 2020/354 establishing a list of intended uses of feed intended for particular nutritional purposes(**3**), in the Annex, in Part B (list of intended uses), the table is amended as follows.

(2) In entry 60 (reduction of the risk of milk fever and subclinical hypocalcaemia), in column number 2 (essential nutritional characteristics), in the section of the entry starting "Low cations/anions ratio", for "Objective: 0 < $DCAD^s$ (mEq/kg dry matter) < 100" substitute "Objective: Range from -200 mEq/kg dry matter $DCAD^s$ to <100 mEq/kg dry matter DCAD".

RHAN 5

Dirymiadau

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2016/1095

18. Yn Rheoliad Gweithredu'r Comisiwn (EU) 2016/1095 sy'n ymwneud ag awdurdodi Zinc asetad deuhydrad, Zinc clorid anhydrus, Zinc ocsid, Zinc sylffad heptahydrad, Zinc sylffad monohydrad, celad Zinc o asidau amino hydrad, celad Zinc o hydrolysadau protein, celad Zinc o glycin hydrad

PART 5

Revocations

Amendment of Commission Implementing Regulation (EU) 2016/1095

18. In Commission Implementing Regulation (EU) 2016/1095 concerning the authorisation of Zinc acetate dihydrate, Zinc chloride anhydrous, Zinc oxide, Zinc sulphate heptahydrate, Zinc sulphate monohydrate, Zinc chelate of amino acids hydrate, Zinc chelate of protein hydrolysates, Zinc chelate of glycine hydrate

(**1**) Gweler Atodlen 19 i'r Rheoliadau hyn ar gyfer awdurdodiad yr ychwanegyn bwyd anifeiliaid hwn a adnewyddwyd.
(**2**) EUR 2010/335, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2016/1095 (EUR 2016/1095). Mae EUR 2010/335 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.
(**3**) EUR 2020/354, y mae diwygiadau iddo nad ydynt yn berthnasol i'r Rheoliadau hyn.

(**1**) See Schedule 19 to these Regulations for the renewed authorisation of this feed additive.
(**2**) EUR 2010/335, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2016/1095 (EUR 2016/1095). EUR 2010/335 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.
(**3**) EUR 2020/354, to which there are amendments not relevant to these Regulations.

(solet) a chelad Zinc o glycin hydra (hylif) fel ychwanegion bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**1**), hepgorer Erthygl 4 (diwygio Rheoliad (EU) Rhif 335/2010).

(solid) and Zinc chelate of glycine hydrate (liquid) as feed additives for all animal species(**1**), omit Article 4 (amendment to Regulation (EU) No 335/2010).

Diwygio Rheoliad Gweithredu'r Comisiwn (EU) 2018/1039

19. Yn Rheoliad Gweithredu'r Comisiwn (EU) 2018/1039 sy'n ymwneud ag awdurdodi Copor(II) diacetad monohydrad, Copor(II) carbonad deuhydrosci monohydrad, Copor(II) clorid deuhydrad, Copor(II) ocsid, Copor(II) sylffad pentahydrad, celad Copor(II) o asidau amino hydrad, celad Copor(II) o hydrolysadau protein, celad Copor(II) o glycin hydrad (solet) a chelad Copor(II) o glycin hydrad (hylif) fel ychwanegion bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**2**), hepgorer Erthygl 5 (diwygio Rheoliad (EU) Rhif 349/2010).

Amendment of Commission Implementing Regulation (EU) 2018/1039

19. In Commission Implementing Regulation (EU) 2018/1039 concerning the authorisation of Copper(II) diacetate monohydrate, Copper(II) carbonate dihydroxy monohydrate, Copper(II) chloride dihydrate, Copper(II) oxide, Copper(II) sulphate pentahydrate, Copper(II) chelate of amino acids hydrate, Copper(II) chelate of protein hydrolysates, Copper(II) chelate of glycine hydrate (solid) and Copper(II) chelate of glycine hydrate (liquid) as feed additives for all animal species(**2**), omit Article 5 (amendment to Regulation (EU) No 349/2010).

Dirymiadau

20. Mae'r offerynnau a restrir yn Atodlen 21 wedi eu dirymu.

Revocations

20. The instruments listed in Schedule 21 are revoked.

Sarah Murphy

Y Gweinidog Iechyd Meddwl a Llesiant, o dan awdurdod Ysgrifennydd y Cabinet dros Iechyd a Gofal Cymdeithasol, un o Weinidogion Cymru
27 Tachwedd 2024

Minister for Mental Health and Wellbeing, under the authority of the Cabinet Secretary for Health and Social Care, one of the Welsh Ministers
27 November 2024

(**1**) EUR 2016/1095.
(**2**) EUR 2018/1039.

(**1**) EUR 2016/1095.
(**2**) EUR 2018/1039.

YR ATODLENNI

ATODLEN 1

Rheoliad 3(1)

Awdurdodi paratoad o gelad cromiwm o DL-methionin (rhif adnabod GB4d0001) fel ychwanegyn bwyd anifeiliaid ar gyfer buchod godro

Mae'r paratoad o gelad cromiwm o DL-methionin a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sootechnegol arall", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	Celad cromiwm o DL-methionin
Rhif adnabod	GB4d0001
Deiliad yr awdurdodiad	Zinpro Animal Nutrition (Europe), Inc
Categori ychwanegion	Ychwanegion sootechnegol
Grŵp gweithredol	Sootechnegol arall
Cyfansoddiad yr ychwanegyn	Paratoad solet o geladau cromiwm (Cr) gyda DL-methionin gyda'r cydrannau a ganlyn: • Calsiwm carbonad: 95.6% • Cromiwm-DL-Methionin: 3.4% • Olew llysiau: 1.0%
Nodweddiad y sylwedd(au) actif	Celad cromiwm o DL-methionin ($[CH_3S(CH_2)_2CH(NH_2)COO]_3$ Cr)
Dulliau dadansoddi[(1)]	I feintioli cromiwm yn yr ychwanegyn bwyd anifeiliaid: • Sbectrometreg màs â phlasma a gyplyswyd yn anwythol (ICP-MS) (BS EN 17053:2018[(2)]) I feintioli methionin yn yr ychwanegyn bwyd anifeiliaid: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod ffotometrig (IEC-VIS) (BS EN ISO 13903:2005[(3)]) I brofi ffurf geladedig yr ychwanegyn bwyd anifeiliaid: • Sbectrometreg isgoch canol (IR) ynghyd â chanfod cynnwys y cromiwm a'r methionin yn yr ychwanegyn bwyd anifeiliaid
Rhywogaeth neu gategori o anifail	Buchod godro
Oedran hynaf	Dim
Isafswm cynnwys[(4)]	0.2 mg/kg
Uchafswm cynnwys[(4)]	0.5 mg/kg
Darpariaethau eraill	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd

[(1)] Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2019)6115119 – 03/10/2019" a "JRC F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 18 Hydref 2019. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0021_en.

[(2)] 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 (ISBN 978 0 580 94471 0). Ar gael yn: https://knowledge.bsigroup.com.

[3] 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 yn: https://knowledge.bsigroup.com.

[4] Cynnwys cromiwm (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 2

Rheoliad 3(1)

Adnewyddu awdurdodiad paratoad o *Saccharomyces cerevisiae* (MUCL 39885) (rhif adnabod 4b1710) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu pob *Suidae* heblaw hychod a pherchyll sugno, cathod, a chŵn

Mae'r paratoad o *Saccharomyces cerevisiae* (MUCL 39885) 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**).

Yr ychwanegyn	*Saccharomyces cerevisiae* (MUCL 39885)
Rhif adnabod	4b1710
Deiliad yr awdurdodiad	Prosol S.p.A
Categori ychwanegion	Ychwanegion sootechnegol
Grŵp gweithredol	Sefydlogyddion fflora'r perfedd
Categori ychwanegion	Paratoad solet o *Saccharomyces cerevisiae* (MUCL 39885) sy'n cynnwys isafswm o 1×10^9 o unedau ffurfio cytref (CFU)/g
Nodweddiad y sylwedd(au) actif	Celloedd hyfyw *Saccharomyces cerevisiae* (MUCL 39885)
Dulliau dadansoddi[(1)]	I gyfrifo: • Y dull plât arllwys gan ddefnyddio agar CGYE (cloramffenicol, glwcos, echdynnyn burum) (BS EN 15789:2021[(2)]) I adnabod y straen burum: • Y dull adwaith cadwynol polymerasau (PCR) (DD CEN/TS 15790:2008[(3)])
Rhywogaeth neu gategori o anifail	• Pob rhywogaeth o *Suidae* heblaw perchyll sugno neu hychod • Cathod • Cŵn
Oedran hynaf	Dim
Isafswm cynnwys[(4)]	Ar gyfer *Suidae*: • *Suidae* heblaw perchyll sugno, hychod a *Suidae* at ddibenion atgenhedlu: 3×10^9 CFU/kg • *Suidae* at ddibenion atgenhedlu ac eithrio hychod: 6.4×10^9 CFU/kg Ar gyfer cathod • 7×10^{10} CFU/kg Ar gyfer cŵn: • 7×10^{10} CFU/kg
Uchafswm cynnwys[(4)]	Dim
Darpariaethau eraill	Rhaid nodi'r amodau storio yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddu'r awdurdodiad a roddwyd o dan Reoliad Gweithredu'r Comisiwn (EU) Rhif 170/2011 (EUR2011/170). Mae EUR 2011/170 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

[1] Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "D06/FSQ/CVH/CMP/mdr/ARES (2010)58412" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en.

[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 yn: 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 yn: https://knowledge.bsigroup.com.

[4] Unedau ffurfio cytref (CFU) o ychwanegyn/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

ATODLEN 3

Rheoliad 3(1)

Awdurdodi paratoad o *Pediococcus acidilactici* (CNCM I-4622) ((rhif adnabod 4d1712) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o *Pediococcus acidilactici* (CNCM I-4622) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grwpiau gweithredol "rheolydd asidedd" a "sylweddau gwella cyflwr hylendid", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	*Pediococcus acidilactici* (CNCM I-4622)
Rhif adnabod	4d1712
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion technolegol
Grŵp gweithredol	• Rheolyddion asidedd • Sylweddau gwella cyflwr hylendid
Cyfansoddiad yr ychwanegyn	Paratoad solet o *Pediococcus acidilactici* (CNCM I-4622) sy'n cynnwys o leiaf 1×10^{10} o unedau ffurfio cytref (CFU)/g
Nodweddiad y sylwedd(au) actif	Celloedd hyfyw *Pediococcus acidilactici* (CNCM I-4622)
Dulliau dadansoddi(1)	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: • Y dull plât taenu gan ddefnyddio agar MRS (BS EN 15786:2021(2)) I adnabod y straen bacterol: • Electrofforesis jel maes pylsedig (PFGE)
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys(3)	1×10^9 CFU/kg
Uchafswm cynnwys(3)	Dim
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Dim ond i'w ddefnyddio mewn bwyd anifeiliaid cyfansawdd stwnsh a fwriedir ar gyfer paratoi bwyd anifeiliaid hylifol ar fferm, neu ddeunyddiau bwyd anifeiliaid solet a fwriedir ar gyfer paratoi bwyd anifeiliaid hylifol ar fferm. 3. Os yw *Pediococcus acidilactici* (CNCM I-4622) 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: • Decocwinad • Deuclaswril • Halofwginon • Nicarbasin • Robenidin

(1) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2014)1202206 - 16/04/2014" a "JRC.D.5/SFB/CvH/JO /mds/Ares", ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2013-0031_en.

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

(3) Unedau ffurfio cytref (CFU) o ychwanegyn/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

ATODLEN 4

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (cludwr: perlit, calsiwm carbonad) (rhif adnabod 51701) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy, a thyrcwn i'w pesgi, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu tyrcwn a fegir ar gyfer bridio

Mae'r paratoad o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) 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**).

Yr ychwanegyn	Monensin sodiwm
Rhif adnabod	51701
Deiliad yr awdurdodiad	Huvepharma NV
Categori ychwanegion	Cocsidiostatau a histomonostatau
Grŵp gweithredol	Dim
Cyfansoddiad yr ychwanegyn	Paratoad o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) ar ffurf powdr gyda'r cydrannau a ganlyn: • Sylwedd technegol monensin sodiwm: 250 g/kg sy'n cynnwys: — Monensin A: isafswm o 90% — Monensin A + B: isafswm o 95% — Monensin C: 0.2 – 0.3% • Perlit: 150 – 200 g/kg • Calsiwm carbonad: 550 – 600 g/kg
Nodweddiad y sylwedd(au) actif	Sylwedd technegol monensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419). • Monensin sodiwm A ($C_{36}H_{61}NaO_{11}$) • Monensin sodiwm B ($C_{35}H_{59}NaO_{11}$) • Monensin sodiwm C ($C_{37}H_{63}NaO_{11}$) • Rhif CAS[(1)]: 22373-78-0
Dulliau dadansoddi[(2)]	I feintioli monensin yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau a'r bwyd anifeiliaid cyfansawdd: • Cromatograffaeth hylif perfformiad uchel gwedd wrthdroi gan ddefnyddio deilliant ôl-golofn a gyplysir â chanfod sbectroffotometrig (RP-HPLC-PCD-UV-VIS) (BS EN ISO 14183: 2008[(3)])

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddiad (ag addasiad) o'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EC) Rhif 109/2007 (EUR 2007/109) a Rheoliad Gweithredu'r Comisiwn (EU) Rhif 140/2012 (EUR 2012/140). Mae EUR 2007/109 a 2012/140 wedi eu dirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

	I feintioli monensin sodiwm mewn meinweoedd ieir a thyrcwn: • Cromatograffaeth hylif perfformiad uchel gwedd wrthdroi a gyplysir â sbectrometr màs pedrypol triphlyg (RP-HPLC-MS/MS) neu unrhyw ddulliau cyfatebol.
Rhywogaeth neu gategori o anifail	• Ieir i'w pesgi • Ieir a fegir ar gyfer dodwy • Tyrcwn i'w pesgi • Tyrcwn a fegir ar gyfer bridio
Oedran hynaf	Ar gyfer ieir i'w pesgi: • Dim Ar gyfer ieir a fegir ar gyfer dodwy: • 16 wythnos Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: • 16 wythnos
Isafswm cynnwys[4]	Ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy: • 100 mg/kg Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: • 60 mg/kg
Uchafswm cynnwys[4]	Ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy: • 125 mg/kg Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: • 100 mg/kg
Uchafswm terfynau gweddillion (MRLs) monensin sodiwm mewn bwyd sy'n dod o anifeiliaid	Ar gyfer croen gwlyb ar y cyd â braster gwlyb: • 25 µg/kg Ar gyfer afu gwlyb; aren wlyb; cyhyrau gwlyb: • 8 µg/kg
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Rhaid ymgorffori'r ychwanegyn bwyd anifeiliaid yn y bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd. 3. Ni chaniateir cymysgu monensin sodiwm â chocsidiostatau eraill. 4. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, yn y cyfarwyddiadau ar gyfer defnyddio: • Yn Saesneg: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances". • Yn Gymraeg: "Yn beryglus i geffylau. Mae'r bwyd anifeiliaid hwn yn cynnwys ionoffor. Dylid osgoi ei roi ar yr un pryd â tiamwlin, a dylid monitro ar gyfer adweithiau andwyol posibl wrth ei ddefnyddio gyda sylweddau meddygol eraill". 5. Rhaid i ddeiliad yr awdurdodiad gynnal rhaglen fonitro ar ôl rhyddhau ar y farchnad ar gyfer ymwrthedd i facteria ac *Eimeria* spp. Rhaid cyflwyno adroddiad yn cynnwys canlyniad y rhaglen honno i Weinidogion Cymru cyn diwedd 19 Rhagfyr 2033.

[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(2017)1087313 – 01/03/2017" a "JRC F.5/CvH/MGH /mds/Ares", ac a ddiweddarwyd ddiwethaf ar 27 Ebrill 2017. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en.

(3) O dan y cyfeirnod BS EN ISO 14183:2008 "Animal feeding stuffs. Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivatization". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 24 Ionawr 2006 (ISBN 978 0 580 62955 6). Ar gael yn: https://knowledge.bsigroup.com.

(4) Cynnwys monensin (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 5

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (cludwr: perlit, bran gwenith) (rhif adnabod 51701) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, a thyrcwn i'w pesgi, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu ieir a fegir ar gyfer dodwy, a thyrcwn a fegir ar gyfer bridio

Mae'r paratoad o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) 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**).

Yr ychwanegyn	Monensin sodiwm
Rhif adnabod	51701.
Deiliad yr awdurdodiad	Huvepharma NV
Categori ychwanegion	Cocsidiostatau a histomonostatau
Grŵp gweithredol	Dim
Cyfansoddiad yr ychwanegyn	Paratoad o fonensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) ar ffurf powdr gyda'r cydrannau a ganlyn: • Sylwedd technegol monensin sodiwm: 250g/kg sy'n cynnwys: — Monensin A: isafswm o 90% — Monensin A + B: isafswm o 95% — Monensin C: 0.2 – 0.3% • Perlit: 150 – 200 g/kg • Bran gwenith: 550 – 600 g/kg
Nodweddiad y sylwedd(au) actif	Sylwedd technegol monensin sodiwm a gynhyrchir drwy eplesu â *Streptomyces cinnamonensis* 28682 (NBIMCC 3419). • Monensin sodiwm A ($C_{36}H_{61}NaO_{11}$) • Monensin sodiwm B ($C_{35}H_{59}NaO_{11}$) • Monensin sodiwm C ($C_{37}H_{63}NaO_{11}$) • Rhif CAS[(2)]: 22373-78-0
Dulliau dadansoddi[(2)]	I feintioli monensin yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau a'r bwyd anifeiliaid cyfansawdd: • Cromatograffaeth hylif perfformiad uchel gwedd wrthdroi gan ddefnyddio deilliant ôl-golofn a gyplysir â chanfod sbectroffotometrig (RP-HPLC-PCD-UV-VIS) (BS EN ISO 14183: 2008[(3)])

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddiad (ag addasiad) o'r awdurdodiad a roddwyd o dan Reoliad Gweithredu'r Comisiwn (EC) Rhif 109/2007 (EUR 2007/109). Mae EUR 2007/109 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

	I feintioli monensin sodiwm mewn meinweoedd ieir a thyrcwn: • Cromatograffaeth hylif perfformiad uchel gwedd wrthdroi a gyplysir â sbectrometr màs pedrypol triphlyg (RP-HPLC-MS/MS) neu unrhyw ddulliau cyfatebol.
Rhywogaeth neu gategori o anifail	• Ieir i'w pesgi • Ieir a fegir ar gyfer dodwy • Tyrcwn i'w pesgi • Tyrcwn a fegir ar gyfer bridio
Oedran hynaf	Ar gyfer ieir i'w pesgi: • Dim Ar gyfer ieir a fegir ar gyfer dodwy: • 16 wythnos Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: • 16 wythnos
Isafswm cynnwys[4]	Ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy: • 100 mg/kg Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: • 60 mg/kg
Uchafswm cynnwys[4]	Ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy: • 125 mg/kg Ar gyfer tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio: • 100 mg/kg
Uchafswm terfynau gweddillion (MRLs) monensin sodiwm mewn bwyd sy'n dod o anifeiliaid	Ar gyfer croen gwlyb ar y cyd â braster gwlyb: • 25 µg/kg Ar gyfer afu gwlyb; aren wlyb; cyhyrau gwlyb: • 8 µg/kg
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Rhaid ymgorffori'r ychwanegyn bwyd anifeiliaid yn y bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd. 3. Ni chaniateir cymysgu monensin sodiwm â chocsidiostatau eraill. 4. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, yn y cyfarwyddiadau ar gyfer defnyddio: • Yn Saesneg: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances". • Yn Gymraeg: "Yn beryglus i geffylau. Mae'r bwyd anifeiliaid hwn yn cynnwys ionoffor. Dylid osgoi ei roi ar yr un pryd â thiamwlin, a dylid monitro ar gyfer adweithiau andwyol posibl wrth ei ddefnyddio gyda sylweddau meddygol eraill". 5. Rhaid i ddeiliad yr awdurdodiad gynnal rhaglen fonitro ar ôl rhyddhau ar y farchnad ar gyfer ymwrthedd i facteria ac *Eimeria* spp. Rhaid cyflwyno adroddiad yn cynnwys canlyniad y rhaglen honno i Weinidogion Cymru cyn diwedd 19 Rhagfyr 2033.

[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(2017)1087313 – 01/03/2017" a "JRC F.5/CvH/MGH /mds/Ares", ac a ddiweddarwyd ddiwethaf ar 27 Ebrill 2017. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en.

(3) O dan y cyfeirnod BS EN ISO 14183:2008 "Animal feeding stuffs. Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivatization". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 24 Ionawr 2006 (ISBN 978 0 580 62955 6). Ar gael yn: https://knowledge.bsigroup.com.

(4) Cynnwys monensin (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 6

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o 6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu â *Komagataella phaffii* (*pastoris Komagataella* yn flaenorol) (DSM 23036) (rhif adnabod 4a16) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi, ieir a fegir ar gyfer dodwy, ieir dodwy, tyrcwn i'w pesgi, tyrcwn a fegir ar gyfer bridio, rhywogaethau adar eraill i'w pesgi ac ar gyfer dodwy, hychod, moch i'w pesgi a pherchyll wedi eu diddyfnu, a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu pob rhywogaeth o adar a phob *Suidae*

Mae'r paratoad o 6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu ag *Komagataella phaffii* (DSM 23036) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "sylweddau gwella treuliadwyedd", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(**1**).

Yr ychwanegyn	6-ffytas (EC 3.1.3.26)
Rhif adnabod	4a16
Deiliad yr awdurdodiad	Huvepharma NV
Categori ychwanegion	Ychwanegion sootechnegol
Grŵp gweithredol	Sylweddau gwella treuliadwyedd
Cyfansoddiad yr ychwanegyn	Paratoad o 6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu â *Komagataella phaffii* (DSM 23036) sydd ag isafswm actifedd ensym o: • 4,000 OTU/g[(1)] ar ffurf solet • 8,000 OTU/g ar ffurf hylif
Nodweddiad y sylwedd(au) actif	6-ffytas (EC 3.1.3.26) a gynhyrchir drwy eplesu â *Komagataella phaffii* (DSM 23036) • Rhif CAS[(2)]: 9001-89-2 • Rhif EC (IUBMB):[(3)]: 3.1.3.26
Dulliau dadansoddi[(4)]	I feintioli actifedd ffytas yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau a'r bwyd anifeiliaid cyfansawdd: • Dull colorimetrig yn seiliedig ar feintioli'r ffosffad anorganig a ryddheir gan yr ensym o'r sodiwm ffytad
Rhywogaeth neu gategori o anifail	• Pob rhywogaeth o adar • Pob *Suidae*
Oedran hynaf	Dim
Isafswm cynnwys[(5)]	Ar gyfer rhywogaethau adar: • Pob rhywogaeth o adar ac eithrio tyrcwn: 125 OTU/kg • Tyrcwn: 250 OTU/kg Ar gyfer *Suidae*: • Pob *Suidae* ac eithrio perchyll: 125 OTU/kg • Perchyll: 250 OTU/kg
Uchafswm cynnwys[(5)]	Dim

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddiad (ag addasiad) o'r awdurdodiad a roddwyd o dan Reoliad Gweithredu'r Comisiwn (EC) Rhif 98/2012 (EUR 2012/98). Mae EUR 2012/98 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

Darpariaethau eraill	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd.

(1) Unedau technegol OptiPhos (gweithgaredd ffytas): 1 OTU yw faint o ensym sy'n catalyddu rhyddhau 1 µmol o ffosffad anorganig y funud o 5.1 mM sodiwm ffytad mewn byffer citrad pH 5.5 ar 37ºC, wedi ei fesur fel y lliw cymhleth P-molybdad glas ar 820 nm

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

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

(4) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2016)5971303 – 17/10/2016" a "JRC F.5/CvH/MGH /mds/Ares", ac a ddiweddarwyd ddiwethaf ar 17 Tachwedd 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0019_en.

(6) Cynnwys 6-ffytas (EC 3.1.3.26) (unedau actifedd (OTU)/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 7

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o *Bacillus velezensis* (*Bacillus subtilis* yn flaenorol) (DSM 15544) (rhif adnabod 4b1820) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu, ieir a fegir ar gyfer dodwy, tyrcwn, mân rywogaethau adar, adar addurnol ac adar hela; cydgrynhoi defnyddiau awdurdodedig presennol ar gyfer ieir dodwy a ieir i'w pesgi; a'i awdurdodi fel ychwanegyn bwyd anifeiliaid gan estyn y defnydd presennol i gwmpasu pob rhywogaeth o adar

Mae'r paratoad o *Bacillus velezensis* (DSM 15544) 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**).

Yr ychwanegyn	*Bacillus velezensis* (DSM 15544)
Rhif adnabod	4b1820
Deiliad yr awdurdodiad	Asahi Biocycle Co., Ltd
Categori ychwanegion	Ychwanegion sootechnegol
Grŵp gweithredol	Sefydlogyddion fflora'r perfedd
Cyfansoddiad yr ychwanegyn	Paratoad solet o *Bacillus velezensis* (DSM 15544) sy'n cynnwys isafswm o 1×10^{10} o unedau ffurfio cytref (CFU)/g
Nodweddiad y sylwedd(au) actif	Sborau hyfyw *Bacillus velezensis* (DSM 15544)
Dulliau dadansoddi[(1)]	I gyfrifo (cyfrif cytrefi) yr ychwanegyn bwyd anifeiliaid: • Y dull plât taenu gan ddefnyddio agar soia trypton ym mhob matrics targed (BS EN 15784:2021[(2)]) I adnabod yr ychwanegyn bwyd anifeiliaid • Electrofforesis jel maes pylsedig (PFGE)
Rhywogaeth neu categori o anifail	• Perchyll wedi eu diddyfnu • Pob rhywogaeth o adar
Oedran hynaf	Dim
Isafswm cynnwys[(3)]	3×10^8 CFU/kg
Uchafswm cynnwys[(3)]	Dim
Darpariaethau eraill	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd.

[(1)] Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "D08/FSQ/CVH/CMP/mds/ARES (2009)347415" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0013_en.

[(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 yn: https://knowledge.bsigroup.com.

[(3)] Unedau ffurfio cytref (CFU)/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%.

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddu'r awdurdodiadau a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 333/2010 (EUR 2010/333) a Rheoliad y Comisiwn (EU) Rhif 184/2011 (EUR 2011/184) ac yn cydgrynhoi awdurdodiadau ar gyfer categorïau o rywogaethau adar a roddwyd o dan Reoliadau Gweithredu'r Comisiwn (EU) 2016/897 (EUR 2016/897) a 2019/893 (EUR 2019/893). Mae EUR 2016/897 wedi ei ddiwygio gan reoliad 4 o'r Rheoliadau hyn. Mae EUR 2010/333, 2011/184 a 2019/893 wedi eu dirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

ATODLEN 8

Rheoliad 3(1)

Awdurdodi paratoad o L-histidin monohydroclorid monohydrad a gynhyrchir drwy eplesu ag *Escherichia coli* K-12 (KCCM 80212) (rhif adnabod 3c352i) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o L-histidin monohydroclorid monohydrad a gynhyrchir drwy eplesu ag *Escherichia coli* K-12 (KCCM 80212) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	L-histidin monohydroclorid monohydrad
Rhif adnabod	3c352i
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Asidau amino, eu halwynau a'u hanalogau
Cyfansoddiad yr ychwanegyn	L-histidin monohydroclorid monohydrad gyda maen prawf puredd heb fod yn llai na 98% fel powdr gyda'r cydrannau a ganlyn: • Lleithder: uchafswm o 1% • Histidin: isafswm o 72% • Histamin: uchafswm o 100ppm
Nodweddiad y sylwedd(au) actif	L-histidin monohydroclorid monohydrad a gynhyrchir drwy eplesu ag *Escherichia coli* K-12 (KCCM 80212) ($C_6H_{12}ClN_3O_3$) • Rhif CAS: 5934-29-2[(1)] • Rhif EINECS: 611-821-4[(2)]
Dulliau dadansoddi[(3)]	I feintioli histidin yn yr ychwanegyn bwyd anifeiliaid: • Cromatograffaeth hylif perfformiad uchel a gyplysir â chanfod ffotometrig (HPLC-UV) (BS EN ISO 13903: 2005[(4)]), neu • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) I feintioli histidin mewn rhag-gymysgeddau, deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod ffotometrig (IEC-VIS) (Rheoliad y Comisiwn (EC) Rhif 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol(**1**) - Atodiad 3, F) I feintioli histamin yn yr ychwanegyn bwyd anifeiliaid: • Cromatograffaeth hylif perfformiad uchel a gyplysir â chanfod ffotometrig (HPLC-UV) (BS EN ISO 13903: 2005[(4)])
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[(5)]	Dim
Uchafswm cynnwys[(5)]	Dim

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

Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Caniateir rhoi L-histidin monohydroclorid monohydrad ar y farchnad a'i ddefnyddio fel ychwanegyn sy'n baratoad. 3. Rhaid nodi'r cynnwys histidin ar label yr ychwanegyn a'r rhag-gymysedd. 4. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label yr ychwanegyn a'r rhag-gymysgedd: • Yn Saesneg: "The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depend on the species, the physiological state of the animal, the performance level, the environmental conditions, the level of other amino acids in the diet and the level essential trace elements such as copper and zinc". • Yn Gymraeg: "Rhaid i'r ychwanegiad â L-histidin monohydroclorid monohydrad fod yn gyfyngedig i ofynion maethol yr anifail targed, sy'n dibynnu ar y rhywogaeth, cyflwr ffisiolegol yr anifail, lefel perfformiad, yr amodau amgylcheddol, lefel asidau amino eraill yn y diet a lefel elfennau hybrin hanfodol fel copor a zinc". 5. Rhaid i gynnwys endotocsin yr ychwanegyn a'i botensial ysgeintio sicrhau amlygiad endotocsin mwyaf posibl o 1600 IU endotocsinau/m^3 aer[6].

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

[2] Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C146A, 15.6.90, t.1.

[3] Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)3718494 – 14/07/2020" a "JRC F.5/CvH/ZE/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 16 Hydref 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0016_en.

[4] 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 yn: https://knowledge.bsigroup.com.

[5] Cynnwys L-histidin monohydroclorid monohydrad (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

[6] Amlygiad a gyfrifir yn seiliedig ar lefel endotocsin a photensial ysgeintio'r ychwanegyn yn unol â'r dull a ddefnyddir gan Awdurdod Diogelwch Bwyd Ewrop (EFSA Journal 2015;13(2):4015); dull dadansoddi: European Pharmacopoeia (Ph. Eur.): Supplement 6.6 (official January 1, 2010), Bacterial Endotoxins (cyfeirnod 01/2010:20614).

ATODLEN 9

Rheoliad 3(1)

Awdurdodi paratoad o L-tryptoffan a gynhyrchir drwy eplesu ag *Escherichia coli* (KCCM 80210) (rhif adnabod 3c440i) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o L-tryptoffan a gynhyrchir drwy eplesu ag *Escherichia coli* (KCCM 80210) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	L–tryptoffan
Rhif adnabod	3c440i
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Asidau amino, eu halwynau a'u hanalogau
Cyfansoddiad yr ychwanegyn	L-tryptoffan gyda maen prawf puredd ar sail deunydd sych heb fod yn llai na 98% fel powdr gyda'r cydrannau a ganlyn: • Cynnwys lleithder: uchafswm o 1% • 1,1'-ethyliden-bis-L-tryptoffan: uchafswm o 10 mg/kg
Nodweddiad y sylwedd(au) actif	L-tryptoffan a gynhyrchir drwy eplesu ag *Escherichia coli* (KCCM 80210) ($C_{11}H_{12}N_2O_2$) • Rhif CAS: 73-22-3[(1)] • Rhif EINECS: 200-795-6[(2)]
Dulliau dadansoddi[(3)]	I adnabod L-tryptoffan yn yr ychwanegyn bwyd anifeiliaid: • Food Chemical Codex "L-tryptophan monograph"[(4)] I ganfod tryptoffan yn yr ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau: • Cromatograffaeth hylif perfformiad uchel â chanfod fflworoleuedd (HPLC-FLD) (BS EN ISO 13904:2016[(5)]) I ganfod tryptoffan mewn deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Cromatograffaeth hylif perfformiad uchel â chanfod fflworoleuedd (HPLC-FLD) (Rheoliad y Comisiwn (EC) Rhif 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol - Atodiad 3, G)
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[(6)]	Dim
Uchafswm cynnwys[(6)]	Dim
Darpariaethau eraill	1. Rhaid i L-tryptophan fod yn ddiogel i'r rwmen pan gaiff ei roi i anifeiliaid cnoi cil. 2. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label yr ychwanegyn a'r rhag-gymysgedd: • yn Saesneg: "The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances". • Yn Gymraeg: "Rhaid i'r atchwanegiad ag L-tryptophan ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi

	anghydbwysedd”. 3. Rhaid i gynnwys endotocsin yr ychwanegyn a’i botensial ysgeintio sicrhau amlygiad endotocsin mwyaf posibl o 1600 IU endotocsinau/m^3 aer(7).

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

(2) Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y’i cyhoeddwyd yn OJ Rhif C146A, 15.6.90, t.1.

(3) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â’r cyfeirnod “Ares(2020)7146784 – 27/11/2020” a “JRC F.5/CvH/ZE/AS/Ares” ac a ddiweddarwyd ddiwethaf ar 19 Rhagfyr 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0038_en.

(4) Food Chemicals Codex (FCC), 13eg argraffiad (Dull: monograff FCC L-tryptophan wedi ei gyhoeddi). Cyhoeddwyd gan Gonfensiwn Cyffuriadol yr Unol Daleithiau ar 1 Mawrth 2022 (ISSN 2153-1455). Ar gael yn: https://www.foodchemicalscodex.org.

(5) O dan y cyfeirnod BS EN ISO 13904:2016 “Animal feeding stuffs. Determination of tryptophan content”. Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Mawrth 2016 (ISBN 978 0 580 84452 2). Ar gael yn: https://knowledge.bsigroup.com.

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

(7) Amlygiad a gyfrifir yn seiliedig ar lefel endotocsin a photensial ysgeintio’r ychwanegyn yn unol â’r dull a ddefnyddir gan Asiantaeth Diogelwch Bwyd Ewrop (EFSA Journal 2015;13(2):4015); dull dadansoddi: European Pharmacopoeia (Ph. Eur.): Supplement 6.6 (official January 1, 2010), Bacterial Endotoxins (cyfeirnod 01/2010:20614).

ATODLEN 10

Rheoliad 3(1)

Awdurdodi paratoad o L-lysin sylffad a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80227) (rhif adnabod 3c324i) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o L-lysin sylffad a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80227) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	L-lysin sylffad
Rhif adnabod	3c324i
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Asidau amino, eu halwynau a'u hanalogau
Cyfansoddiad yr ychwanegyn	Paratoad gronynnol o L-lysin sylffad sydd ag o leiaf 52% o L-lysin, uchafswm o 24% o sylffad ac sydd ag uchafswm cynnwys lleithder o 4%
Nodweddiad y sylwedd(au) actif	L-lysin sylffad a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80227) ($C_{12}H_{28}N_4O_4 \cdot H_2SO_4$) • Rhif CAS: 60343-69-3[1]
Dulliau dadansoddi[2]	I feintioli lysin yn yr ychwanegyn bwyd anifeiliaid a rhag-gymysgeddau sy'n cynnwys mwy na 10% lysin: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013[3]) I adnabod sylffad yn yr ychwanegyn bwyd anifeiliaid: • Monograff yr European Pharmacopoeia 20301[4] I feintioli lysin mewn rhag-gymysgeddau, deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod ffotometrig (IEC-VIS) (Rheoliad y Comisiwn (EC) Rhif 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol - Atodiad 3, F) I feintioli lysin mewn dŵr: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013[3])
Rhywogaeth neu categori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[5]	Dim
Uchafswm cynnwys[5]	10,000 mg/kg
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Rhaid nodi'r cynnwys L-lysin ar label yr ychwanegyn. 3. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label yr ychwanegyn a'r rhag-gymysgedd: • Yn Saesneg: "The supplementation with L-lysine should take into account all essential and conditionally essential amino acids in order to avoid imbalances".

	• Yn Gymraeg: “Dylai’r atchwanegiad ag L-lysin ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd”.

(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(2021)2533252 – 14/04/2021” a “JRC F.5/CvH/ZE/AS/Ares” ac a ddiweddarwyd ddiwethaf ar 2 Gorffennaf 2021. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00820085_en

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

(4) Monograff yr European Pharmacopoeia – Ph. Eur. 6.0, 01/2008:20301: “Identification reactions of ions and functional groups – sulphates”. Cyhoeddwyd ar-lein gan y Gyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd. Ar gael yn: https://pheur.edqm.eu/home.

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

ATODLEN 11 Rheoliad 3(1)

Awdurdodi'r sylwedd hydrocsianisol bwtyleiddiedig (rhif adnabod 1b320) fel ychwanegyn bwyd anifeiliaid ar gyfer cathod

Mae'r sylwedd hydrocsianisol bwtyleiddiedig (rhif adnabod 1b320) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technegol" ac i'r grŵp gweithredol "gwrthocsidyddion", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl(**1**).

Yr ychwanegyn	Hydrocsianisol bwtyleiddiedig
Rhif adnabod	1b320
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion technolegol
Grŵp gweithredol	Gwrthocsidyddion
Cyfansoddiad yr ychwanegyn	Hydrocsianisol bwtyleiddiedig gydag isafswm cynnwys o 98.5% mewn ffurf solet cwyrog
Nodweddiad y sylwedd(au) actif	Hydrocsianisol bwtyleiddiedig sy'n cynnwys cymysgedd o 2-tert-bwtyl-4-hydrocsianisol ac o leiaf 85% 3-tert-bwtyl-4-hydrocsianisol ($C_{11}H_{16}O_2$) • Rhif CAS: 25013-16-5[(1)]
Dulliau dadansoddi[(2)]	I feintioli hydrocsianisol bwtyleiddiedig mewn ychwanegion bwyd anifeiliaid: • Cromatograffaeth nwy a gyplysir â chanfod ïoneiddio â fflam (GC-FID) (Dull Food Chemical Codex 7fed argraffiad[(3)]) I feintioli hydrocsianisol bwtyleiddiedig mewn rhag-gymysgeddau a bwyd anifeiliaid cyfansawdd: • Cromatograffaeth hylif perfformiad uchel gwedd wrthdroi a gyplysir â chanfod aráe-deuodau-uwchfioled (RP-HPLC-UV-DAD, 285 nm)
Rhywogaeth neu gategori o anifail	Cathod
Oedran hynaf	Dim
Isafswm cynnwys[(4)]	Dim
Uchafswm cynnwys[(4)]	150 mg/kg
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Mae hydrocsianisol bwtyleiddiedig wedi ei awdurdodi i'w ddefnyddio ar y cyd â hydrocsitolwen bwtyleiddiedig hyd at uchafswm cynnwys cyfunol o 150 mg/kg o fwyd anifeiliaid cyflawn.

[(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 "JRC.D.5/FSQ/CvH/SB/ag/ARES(2012)40826" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0132_en.

(**1**) Mae'r Atodlen hon yn cynnwys awdurdodiad newydd ar gyfer sylwedd sydd ar y farchnad ar hyn o bryd fel 'cynnyrch presennol' o dan Erthygl 10 o EUR 2003/1831. Cyn diwrnod cwblhau'r cyfnod gweithredu, cyflwynwyd cais i'r Comisiwn Ewropeaidd, yn unol ag Erthygl 10(2) o Reoliad (EC) Rhif 1831/2003, ar gyfer ail-werthuso hydrocsianisol bwtyleiddiedig (BHA) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail. Yn ddiweddarach, tynnodd yr ymgeisydd y cais yn ôl mewn perthynas â chathod. Ail-werthuswyd BHA ac fe'i hawdurdodwyd wedyn fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail ac eithrio cathod o dan Reoliad Gweithredu'r Comisiwn (EU) 2020/1399 (EUR 2020/1399). Fel ychwanegyn bwyd anifeiliaid ar gyfer cathod, mae awdurdodiad BHA fel 'cynnyrch presennol' o dan Erthygl 10 o EUR 2003/1831 wedi ei dynnu yn ôl gan reoliad 8 o'r Rheoliadau hyn, ond gweler rheoliad 15 am ddarpariaeth drosiannol.

(3) Food Chemicals Codex (FCC), 7fed argraffiad (Dull: monograff BHA-FCC V1 wedi ei gyhoeddi). Cyhoeddwyd gan Gonfensiwn Cyffuriadol yr Unol Daleithiau ar 1 Mawrth 2010. Ar gael yn: https://www.foodchemicalscodex.org.

(4) Cynnwys hydrocsianisol bwtyleiddiedig (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 12

Rheoliad 3(1)

Awdurdodi paratoad o sylfaen L-lysin (hylif) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183) (rhif adnabod 3c320) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o sylfaen L-lysin (hylif) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	Sylfaen L-lysin (hylif)
Rhif adnabod	3c320
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Asidau amino, eu halwynau a'u hanalogau
Cyfansoddiad yr ychwanegyn	Hydoddiant dyfrllyd sy'n cynnwys o leiaf 50% L-lysin
Nodweddiad y sylwedd(au) actif	Sylfaen L-lysin (hylif) ($NH_2(CH_2)$ CH (NH_2) COOH) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183). • Rhif CAS: 56-87-1[(1)]
Dulliau dadansoddi[(2)]	I feintioli lysin yn yr ychwanegyn bwyd anifeiliaid a rhag-gymysgeddau sy'n cynnwys mwy na 10% lysin: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013[(3)]) I feintioli lysin mewn rhag-gymysgeddau, deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS) (Rheoliad y Comisiwn (EC) Rhif 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol - Atodiad 3, F) I feintioli lysin mewn dŵr: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013[(3)]), neu • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS) (Rheoliad y Comisiwn (EC) Rhif 152/2009 - Atodiad 3, F)
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[(4)]	Dim
Uchafswm cynnwys[(4)]	Dim
Darpariaethau eraill	1. Rhaid nodi'r cynnwys L-lysin ar label yr ychwanegyn. 2. Caniateir defnyddio'r ychwanegyn drwy ddŵr i'w yfed.

	3. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label yr ychwanegyn a'r rhag-gymysgedd: • Yn Saesneg: "Dylai'r ychwanegiad gyda L-lysin, yn enwedig trwy ddŵr i'w yfed, ystyried yr holl asidau amino hanfodol a hanfodol amodol er mwyn osgoi anghydbwysedd". • Yn Gymraeg: "Dylai'r atchwanegiad ag L-lysin, yn arbennig drwy ddŵr i'w yfed, ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

(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(2019)7003671 – 12/11/2019" a "JRC F.5/CvH/SB/AS/Ares", ac a ddiweddarwyd ddiwethaf ar 27 Ionawr 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en.

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

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

ATODLEN 13

Rheoliad 3(1)

Awdurdodi'r sylwedd L-lysin monohydroclorid (pur yn dechnegol) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183) (rhif adnabod 3c322ii) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifeiliaid

Mae'r sylwedd L-lysin monohydroclorid (pur yn dechnegol) a gynhyrchir drwy eplesu â *Corynebacterium glutamicuma* (KCCM 80183) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "asidau amino, eu halwynau a'u hanalogau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	L-lysin monohydroclorid (pur yn dechnegol)
Rhif adnabod	3c322ii
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Asidau amino, eu halwynau a'u hanalogau
Cyfansoddiad yr ychwanegyn	Powdr L-lysin monohydroclorid sydd o leiaf 78% L-lysin ac sydd ag uchafswm cynnwys lleithder o 1.5%
Nodweddiad y sylwedd(au) actif	L-lysin monohydroclorid (pur yn dechnegol) ($NH_2(CH_2)_4CH(NH_2)COOH$) a gynhyrchir drwy eplesu â *Corynebacterium glutamicum* (KCCM 80183) • Rhif CAS: 657-27-2[(1)]
Dulliau dadansoddi[(2)]	I adnabod L-lysin monohydroclorid yn yr ychwanegyn bwyd anifeiliaid: • "Monograff L-lysin monohydroclorid" y Food Chemicals Codex[(3)] I feintioli lysin yn yr ychwanegyn bwyd anifeiliaid a rhag-gymysgeddau sy'n cynnwys mwy na 10% lysin: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013[(4)]) I feintioli lysin mewn rhag-gymysgeddau, deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS) (Rheoliad y Comisiwn (EC) Rhif 152/2009 sy'n gosod y dulliau samplu a dadansoddi ar gyfer rheoli bwyd anifeiliaid yn swyddogol - Atodiad 3, F) I feintioli lysin mewn dŵr: • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS/FLD) (BS EN ISO 17180:2013[(4)]), neu • Cromatograffaeth cyfnewid iönau a gyplysir â deilliant ôl-golofn a chanfod optegol (IEC-VIS) (Rheoliad y Comisiwn (EC) Rhif 152/2009 - Atodiad 3, F)
Rhywogaeth neu categori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys	Dim
Uchafswm cynnwys	Dim
Darpariaethau eraill	1. Rhaid nodi'r cynnwys L-lysin ar label yr ychwanegyn. 2. Gellir defnyddio'r ychwanegyn drwy ddŵr i'w yfed.

	3. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label yr ychwanegyn a'r rhag-gymysgedd: • Yn Saesneg: "The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances"; • Yn Gymraeg: "Dylai'r atchwanegiad ag L-lysin, yn arbennig drwy ddŵr i'w yfed, ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

(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(2019)7003671 – 12/11/2019" a "JRC F.5/CvH/SB /AS/Ares", ac a ddiweddarwyd ddiwethaf ar 27 Ionawr 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en.

(3) Food Chemicals Codex (FCC), 13eg argraffiad (Dull: monograff monohydroclorid L-lysin FCC wedi ei gyhoeddi). Cyhoeddwyd gan Gonfensiwn Cyffuriadol yr Unol Daleithiau ar 1 Mawrth 2022 (ISSN 2153-1455). Ar gael yn: https://www.foodchemicalscodex.org/.

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

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

ATODLEN 14

Rheoliad 3(1)

Awdurdodi'r sylwedd disodiwm 5'-gwanilad (GMP) a gynhyrchir drwy eplesu â *Corynebacterium stationis* (KCCM 10530) ac *Escherichia coli* K-12 (KFCC 11067) (rhif adnabod 2b627i) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r sylwedd disodiwm 5'-gwanilad (GMP) a gynhyrchir drwy eplesu â *Corynebacterium stationis* (KCCM 10530) ac *Escherichia coli* K-12 (KFCC 11067) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion synhwyraidd" ac i'r grŵp gweithredol "cyfansoddion cyflasu", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	Disodiwm 5'-gwanilad
Rhif adnabod	2b627i
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion synhwyraidd
Grŵp gweithredol	Cyfansoddion cyflasu
Cyfansoddiad yr ychwanegyn	Powdr disodiwm 5'-gwanilad â meini prawf purdeb lleiaf o 97%.
Nodweddiad y sylwedd(au) actif	Ffurf wedi ei hydradu ar ddisodiwm 5'-gwanilad (GMP) a gynhyrchir drwy eplesu â *Corynebacterium stationis* (KCCM 10530) ac *Escherichia coli* K-12 (KFCC 11067) ($C_{10}H_{12}N_5Na_2O_8P$) • Rhif CAS: 5550-12-9[(1)] • Rhif EINECS: 226-914-1[(2)]
Dulliau dadansoddi[(3)]	I adnabod disodiwm 5'-gwanilad (GMP) yn yr ychwanegyn bwyd anifeiliaid: • Monograff "disodiwm 5'-gwanilad" FAO JECFA[(4)] I ganfod disodiwm 5'-gwanilad (GMP) yn yr ychwanegyn bwyd anifeiliaid, rhag-gymysgeddau cyflasu a dŵr: • Cromatograffaeth hylif perfformiad uchel a gyplysir â chanfod UV (HPLC-UV)
Rhywogaeth neu categori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[(5)]	Dim
Uchafswm cynnwys[(5)]	Dim
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Rhaid ymgorffori'r ychwanegyn yn y bwyd anifeiliaid ar ffurf rhag-gymysgedd.

	3. Rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label yr ychwanegyn: • Yn Saesneg: "Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides up to the same level per kg of complete feedingstuff with a moisture content of 12%: 50 mg". • Yn Gymraeg: "Yr uchafswm cynnwys a argymhellir o'r sylwedd actif pan y'i defnyddir ar ei ben ei hun neu mewn cyfuniad â riboniwcleotidau eraill hyd at yr un lefel fesul kg o fwyd anifeiliaid â chynnwys lleithder o 12%: 50 mg". 4. Rhaid i grŵp gweithredol, rhif adnabod, enw a swm ychwanegol y sylwedd actif gael eu nodi ar label y rhag-gymysgedd pan fyddai'r lefel defnydd ar label y rhag-gymysgedd yn golygu bod lefel y sylwedd actif (ar ei ben ei hun neu mewn cyfuniad â riboniwcleotidau eraill) mewn bwyd anifeiliaid cyflawn yn fwy na 50 mg/kg.

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

(2) Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C146A, 15.6.90, t.1.

(3) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2020)4619276 – 04/09/2020" a "JRC F.5/CvH/ZE /AS/Ares", ac a ddiweddarwyd ddiwethaf ar 16 Hydref 2020. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0085_en.

(4) Sefydliad Bwyd ac Amaeth y Cenhedloedd Unedig (FAO) Cydbwyllgor Arbenigol FAO/WHO ar Ychwanegion Bwyd (JECFA) - *Combined Compendium of Food Additive Specifications, "Disodium 5'-guanylate" Monograph 1* (2006). Cyhoeddwyd gan yr FAO ac a ddiweddarwyd ddiwethaf (fersiwn gwe) Awst 2011 (ISBN 92-5-105569-6). Ar gael yn: https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/detail/en/c/255

(5) Cynnwys disodiwm 5'-gwanilad (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 15

Rheoliad 3(1)

Awdurdodi paratoad o fwramidas (EC 3.2.1.17) a gynhyrchir drwy eplesu â *Trichoderma reesei* (DSM 32338) (rhif adnabod 4d16) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu

Mae'r paratoad o fwramidas (EC 3.2.1.17) a gynhyrchir drwy eplesu â *Trichoderma reesei* (DSM 32338) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion sootechnegol" ac i'r grŵp gweithredol "ychwanegion sootechnegol eraill", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	Mwramidas (EC 3.2.1.17)
Rhif adnabod	4d16
Deiliad yr awdurdodiad	DSM Nutritional Products Ltd
Categori ychwanegion	Ychwanegion sootechnegol
Grŵp gweithredol	Ychwanegion sootechnegol eraill
Cyfansoddiad yr ychwanegyn	Paratoadau solet a hylif o fwramidas (EC 3.2.1.17) a gynhyrchir drwy eplesu â *Trichoderma reesei* (DSM 32338) sydd ag isafswm actifedd ensym o 60,000 LSU(F)/g[(1)]
Nodweddiad y sylwedd(au) actif	Mwramidas (EC 3.2.1.17) a gynhyrchir drwy eplesu â *Trichoderma reesei* (DSM 32338) • Rhif CAS: 9001-63-2[(2)] • Rhif EINECS: 232-620-4[(3)] • Rhif EC (IUBMB): 3.2.1.17[(4)]
Dulliau dadansoddi[(5)]	I feintioli mwramidas yn yr ychwanegyn bwyd anifeiliaid, y rhag-gymysgeddau a'r bwyd anifeiliaid cyfansawdd: • Dull biobrawf ensym sy'n seiliedig ar fflworoleuedd sy'n pennu dadbolymeriad ensym wedi ei gataleiddio paratoad peptidoglycan â label fflworesin ar pH 6.0 a 30 °C.
Rhywogaeth neu gategori o anifail	Perchyll wedi eu diddyfnu
Oedran hynaf	Dim
Isafswm cynnwys[(6)]	50,000 LSU(F)/kg
Uchafswm cynnwys[(6)]	65,000 LSU(F)/kg
Darpariaethau eraill	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd.

[(1)] Diffinnir 1 LSU(F) fel swm yr ensym sy'n cynyddu fflworoleuedd peptidoglycan â label fflworescin 12.5 µg/ml y funud ar pH 6.0 a 30 ºC gan werth sy'n cyfateb i fflworoleuedd oddeutu 0.06 nmol isomer isothiocyanad fflworescin.

[(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, fel y'i cyhoeddwyd yn OJ Rhif C146A, 15.6.90, t.1.

[(4)] Rhif adnabod a ddyrannwyd gan yr Undeb Biocemeg a Bioleg Foleciwlaidd Rhyngwladol (IUBMB) https://iubmb.org.

[(5)] Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2018)811287 – 12/02/2018" a "JRC F.5/CvH/SB/AS/Ares" ac a ddiweddarwyd ddiwethaf ar 2 Mawrth 2018. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0046_en.

[(6)] Cynnwys mwramidas (LSU(F)/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%)

Awdurdodi paratoad ffytomenadion (fitamin K_1) (rhif adnabod 3a712) fel ychwanegyn bwyd anifeiliaid ar gyfer ceffylau

Mae'r paratoad o ffytomenadion (fitamin K_1) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "fitaminau, pro-fitaminau 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.

Yr ychwanegyn	Ffytomenadion neu fitamin K_1
Rhif adnabod	3a712
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Fitaminau, pro-fitaminau a sylweddau wedi eu diffinio'n dda yn gemegol sydd ag effaith debyg
Cyfansoddiad yr ychwanegyn	Cynhyrchir gan synthesis cemegol • Paratoad solet sy'n cynnwys o leiaf 4.2% o ffytomenadion (fitamin K_1)
Nodweddiad y sylwedd(au) actif	2-methyl-3-[(E-7R, 11R) -3,7,11,15-tetramethylhecsadec-2- enyl] naphthalen-1,4-dion (ffytomenadion) ($C_{31}H_{46}O_2$) • Rhif CAS: 84-80-0[(1)] • Rhif EINECS: 201-564-2[(2)] â'r elfennau a ganlyn: • E-ffytomenadion: isafswm o 75% • E-epocsiffytomenadion: Uchafswm o 4% • Cyfanswm purdeb isomerau E-ffytomenadion, E-epocsiffytomenadion a Z-ffytomenadion: 97% o leiaf
Dulliau dadansoddi[(3)]	I ganfod ffytomenadion (fitamin K_1) yn yr ychwanegyn bwyd anifeiliaid: • Cromatograffaeth hylif perfformiad uchel (HPLC) (Monograff yr European Pharmacopoeia 1036[(4)]) I ganfod ffytomenadion yn y paratoad ychwanegion ac mewn bwyd anifeiliaid cyflenwol: • Cromatograffaeth hylif perfformiad uchel â chanfod fflworoleuedd (HPLC-FLD) (BS EN 14148:2003[(5)])
Rhywogaeth neu gategori o anifail	Ceffylau
Oedran hynaf	Dim
Isafswm cynnwys[(6)]	Dim
Uchafswm cynnwys[(6)]	Dim
Darpariaethau eraill	Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd.

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

(2) Stocrestr Ewropeaidd o Sylweddau Masnachol Presennol, fel y'i cyhoeddwyd yn OJ Rhif C146A, 15.6.90, t.1.

(3) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2021)145311 – 07/01/2021" a "JRC F.5/CvH/SB /AS/Ares", ac a ddiweddarwyd ddiwethaf ar 17 Chwefror 2021. Ar gael yn https://joint-research-centre.ec.europa.eu/publications/fad-2020-0006_en.

(4) Monograff yr European Pharmacopoeia - Ph. Eur. 8.0 01 2014 Cyhoeddwyd ar-lein gan y Gyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd ar 1 Ionawr 2024. Ar gael yn: https://pheur.edqm.eu/home.

(5) O dan y cyfeirnod BS EN 14148:2003 "Foodstuffs. Determination of vitamin K1 by HPLC". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 25 Gorffennaf 2003 (ISBN 0 580 42317 4). Ar gael yn: https://knowledge.bsigroup.com.

(6) Cynnwys ffytomenadion (fitamin K_1) (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 17

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o gelad copr o analog hydrocsi o fethionin (rhif adnabod 3b410i (3b4.10 gynt)) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o gelad copr o analog hydrocsi o fethionin 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(**1**).

Yr ychwanegyn	Celad copr o analog hydrocsi o fethionin
Rhif adnabod	3b410i
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Cyfansoddion elfennau hybrin
Cyfansoddiad yr ychwanegyn	Celad copr o analog hydrocsi o fethionin ar ffurf solet sy'n cynnwys 16% o gopr o leiaf a'r cydrannau a ganlyn: • asid bwtanöig (2-hydrocsi-4-methylthio): 78% o leiaf • Nicel: Uchafswm o 20 ppm
Nodweddiad y sylwedd(au) actif	Celad copr o analog hydrocsi o fethionin ($Cu(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • Rhif CAS: 292140-30-8[(1)]
Dulliau dadansoddi[(2)]	I feintioli cynnwys analog hydrocsi o fethionin yn yr ychwanegyn bwyd anifeiliaid: • Titradaeth, titradiad potensiomedrig ar ôl adwaith lleihau ocsideiddio I feintioli cyfanswm y copr yn yr ychwanegyn bwyd anifeiliaid: • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[(3)] neu BS EN 15621:2017[(4)]); neu • Sbectrometreg amsugniad atomig (AAS) (BS EN ISO 6869:2001)[(5)] I feintioli cyfanswm y copr mewn rhag-gymysgeddau: • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[(3)] neu BS EN 15621:2017[(4)]); neu • Sbectrometreg amsugniad atomig (AAS) (BS EN ISO 6869:2001[(5)]); neu • Sbectrometreg màs â phlasma a gyplyswyd yn anwythol (ICP-MS) (BS EN 17053:2018[(6)])

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddu'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 349/2010 (EUR 2010/349). Mae EUR 2010/349 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

	I feintioli cyfanswm y copr mewn deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[3] neu BS EN 15621:2017[4]); neu • 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 neu BS EN ISO 6869:2001[5]); neu • Sbectrometreg màs â phlasma a gyplyswyd yn anwythol (ICP-MS) (BS EN 17053:2018[6])
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[7]	Dim
Uchafswm cynnwys[7]	Ar gyfer bucholion: • Cyn dechrau cnoi cil: 15mg/kg (cyfanswm) • Arall: 30mg/kg (cyfanswm) Ar gyfer defaid: • 15 mg/kg (cyfanswm) Ar gyfer geifr: • 35 mg/kg (cyfanswm) Ar gyfer perchyll: • Yn sugno ac wedi eu diddyfnu hyd at 4 wythnos ar ôl eu diddyfnu: 150 mg/kg (cyfanswm) • O'r 5ed wythnos hyd at 8 wythnos ar ôl diddyfnu: 100 mg/kg (cyfanswm) Ar gyfer cramenogion: • 50 mg/kg (cyfanswm) Ar gyfer pob rhywogaeth arall o anifail: • 25 mg/kg (cyfanswm)
Darpariaethau eraill	1. Rhaid ymgorffori'r ychwanegyn yn y bwyd anifeiliaid ar ffurf rhag-gymysgedd. 2. Ar gyfer bwyd anifeiliaid ar gyfer defaid, pan fo lefel y copr yn y bwyd anifeiliaid yn uwch na 10 mg/kg, rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label y bwyd anifeiliaid: • Yn Saesneg: "The level of copper in this feed may cause poisoning in certain breeds of sheep". • Yn Gymraeg: "Gall lefel y copr yn y bwyd anifeiliaid hwn achosi gwenwyno mewn rhai bridiau o ddefaid"; 3. Ar gyfer bwyd anifeiliaid ar gyfer bucholion ar ôl dechrau cnoi cil, pan fo lefel y copr yn y bwyd anifeiliaid yn llai nag 20 mg/kg, rhaid nodi'r canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar label y bwyd anifeiliaid: • Yn Saesneg: "The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur". • Yn Gymraeg: "Gall lefel y copr yn y bwyd anifeiliaid hwn achosi diffygion copr mewn gwartheg syn pori tir sydd â chynnwys uchel o folybdenwm neu sylffwr".

(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 "D08-FSQ(2007)D/29104" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0012_en.

(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 31 Awst 2017 (ISBN 978 0 580 94541 0). Ar gael yn: 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 yn: https://knowledge.bsigroup.com.

(5) 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 yn: https://knowledge.bsigroup.com.

(6) 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 (ISBN 978 0 580 94471 0). Ar gael yn: https://knowledge.bsigroup.com.

(7) Cynnwys copr (Cu) (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 18

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o gelad manganîs o analog hydrocsi o fethionin (rhif adnabod 3b510 (3b5.10 gynt)) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o gelad manganîs o analog hydrocsi o fethionin 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(**1**).

Yr ychwanegyn	Celad manganîs o analog hydrocsi o fethionin
Rhif adnabod	3b510
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Cyfansoddion elfennau hybrin
Cyfansoddiad yr ychwanegyn	Celad manganîs o analog hydrocsi o fethionin ar ffurf solet sy'n cynnwys 14% o fanganîs o leiaf a'r cydrannau a ganlyn: • asid bwtanöig (2-hydrocsi-4-methylthio): 76% o leiaf • Nicel: Uchafswm o 170 ppm
Nodweddiad y sylwedd(au) actif	Celad manganîs o analog hydrocsi o fethionin ($Mn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • Rhif CAS: 292140-29-5[1]
Dulliau dadansoddi[2]	I feintioli cynnwys analog hydrocsi o fethionin yn yr ychwanegyn bwyd anifeiliaid: • Titradaeth, titradiad potensiomedrig ar ôl adwaith lleihau ocsideiddio I feintioli cyfanswm y manganîs yn yr ychwanegyn bwyd anifeiliaid a'r rhag-gymysgeddau • Sbectrometreg amsugniad atomig (AAS) (BS EN ISO 6869:2001[3]); neu • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[4]), neu • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol ar ôl treulio drwy bwysedd (ICP-AES) (BS EN 15621:2017[5])

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddu'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 350/2010 (EUR 2010/350). Mae EUR 2010/350 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

	I feintioli cyfanswm y manganîs mewn deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • 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 neu BS EN ISO 6869:2001(3)), neu • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol, ICP-AES (BS EN 15510:2017(4)), neu • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol ar ôl treulio drwy bwysedd (ICP-AES) (BS EN 15621:2017(5))
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys(6)	Dim
Uchafswm cynnwys(6)	Ar gyfer pysgod: • 100 mg/kg (cyfanswm)
	Ar gyfer pob rhywogaeth arall o anifail: • 150 mg/kg (cyfanswm)
Darpariaethau eraill	1. Rhaid ymgorffori'r ychwanegyn yn y bwyd anifeiliaid ar ffurf rhag-gymysgedd. 2. Caniateir rhoi celad manganîs o analog hydrocsi o fethionin ar y farchnad a'i ddefnyddio fel ychwanegyn sy'n baratoad.

(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 "D08-FSQ(2007)D/29224" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0011_en.

(3) 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 yn: https://knowledge.bsigroup.com.

(4) 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 31 Awst 2017 (ISBN 978 0 580 94541 0). Ar gael yn: https://knowledge.bsigroup.com.

(5) 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 yn: https://knowledge.bsigroup.com.

(6) Cynnwys manganîs (Mn) (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 19

Rheoliad 3(1)

Adnewyddu awdurdodiad (ag addasiad) baratoad o gelad zinc o analog hydrocsi o fethionin (rhif adnabod 3b610 (3b6.10 gynt)) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail

Mae'r paratoad o gelad zinc o analog hydrocsi o fethionin 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(**1**).

Yr ychwanegyn	Celad zinc o analog hydrocsi o fethionin
Rhif adnabod	3b610
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion maethol
Grŵp gweithredol	Cyfansoddion elfennau hybrin
Cyfansoddiad yr ychwanegyn	Celad zinc o analog hydrocsi o fethionin ar ffurf solet sy'n cynnwys 17% o zinc o leiaf a'r cydrannau a ganlyn: • asid bwtanöig (2-hydrocsi-4-methylthio): 79% o leiaf • Nicel: Uchafswm o 1.7 ppm
Nodweddiad y sylwedd(au) actif	Celad zinc o analog hydrocsi o fethionin ($Zn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • Rhif CAS: 292140-29-5[1]
Dulliau dadansoddi[2]	I feintioli cynnwys analog hydrocsi o fethionin yn yr ychwanegyn bwyd anifeiliaid: • Titradaeth, titradiad potensiomedrig ar ôl adwaith lleihau ocsideiddio I feintioli cyfanswm y zinc yn yr ychwanegyn bwyd anifeiliaid: • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[3] neu BS EN 15621:2017[4]), neu • Sbectrometreg amsugniad atomig (AAS) (BS EN ISO 6869:2001[5]) I feintioli cyfanswm y zinc mewn rhag-gymysgeddau: • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[3] neu BS EN 15621:2017[4]), neu • Sbectrometreg amsugniad atomig (AAS) (BS EN ISO 6869:2001[5]), neu • Sbectrometreg màs â phlasma a gyplyswyd yn anwythol (ICP-MS) (BS EN 17053:2018[6])

(**1**) Mae'r awdurdodiad hwn yn cynnwys adnewyddu'r awdurdodiad a roddwyd o dan Reoliad y Comisiwn (EU) Rhif 335/2010 (EUR 2010/335). Mae EUR 2010/335 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.

	I feintioli cyfanswm y zinc mewn deunyddiau bwyd anifeiliaid a bwyd anifeiliaid cyfansawdd: • Sbectrometreg allyriant atomig â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017[3] neu BS EN 15621:2017[4]), neu • 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 neu BS EN ISO 6869:2001[5]), neu • Sbectrometreg màs â phlasma a gyplyswyd yn anwythol (ICP-MS) (BS EN 17053:2018[6])
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[7]	Dim
Uchafswm cynnwys[7]	Ar gyfer cathod: • 200 mg/kg (cyfanswm) Ar gyfer cŵn: • 200mg/kg (cyfanswm) Ar gyfer pysgod: • Rhywogaethau Salmonidau: 180mg/kg (cyfanswm) • Arall: 150mg/kg (cyfanswm) Ar gyfer amnewidion llaeth ar gyfer lloi: • 180 mg/kg (cyfanswm) Ar gyfer cwningod: • 150 mg/kg (cyfanswm) Ar gyfer *Suidae*: • Perchyll, hychod: 150mg/kg (cyfanswm) • Arall: 120mg/kg (cyfanswm) Ar gyfer pob rhywogaeth arall o anifail: • 120 mg/kg (cyfanswm)
Darpariaethau eraill	1. Rhaid ymgorffori'r ychwanegyn yn y bwyd anifeiliaid ar ffurf rhag-gymysgedd. 2. Caniateir rhoi celad zinc o analog hydrocsi o fethionin ar y farchnad a'i ddefnyddio fel ychwanegyn sy'n baratoad.

[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 "D08-FSQ(2007)D/29110" ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0010_en.

[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 31 Awst 2017 (ISBN 978 0 580 94541 0). Ar gael yn: 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 yn: https://knowledge.bsigroup.com.

[5] 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 yn: https://knowledge.bsigroup.com.

(6) 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 (ISBN 978 0 580 94471 0). Ar gael yn: https://knowledge.bsigroup.com.

(7) Cynnwys zinc (Zn) (mg/kg o fwyd anifeiliaid cyflawn sydd â chynnwys lleithder o 12%).

ATODLEN 20

Rheoliad 3(1)

Awdurdodi paratoad o ffwmonisin esteras (EC 3.1.1.87) a gynhyrchir drwy eplesu â *Komagataella phaffii* (DSM 32159) (rhif adnabod 1m03i) fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail, i'w ddefnyddio mewn silwair yn seiliedig ar indrawn yn unig

Mae'r paratoad o ffwmonisin esteras (EC 3.1.1.87) a gynhyrchir drwy eplesu â *Komagataella phaffii* (DSM 32159) a bennir yn y tabl, sy'n perthyn i'r categori ychwanegion "ychwanegion technolegol" ac i'r grŵp gweithredol "sylweddau i leihau halogiad bwyd anifeiliaid gan fycotocsinau", wedi ei awdurdodi fel ychwanegyn mewn maeth anifeiliaid yn ddarostyngedig i'r amodau a nodir yn y tabl.

Yr ychwanegyn	Ffwmonisin esteras (EC 3.1.1.87)
Rhif adnabod	1m03i
Deiliad yr awdurdodiad	Dim
Categori ychwanegion	Ychwanegion technolegol
Grŵp gweithredol	Sylweddau i leihau halogiad bwyd anifeiliaid gan fycotocsinau
Cyfansoddiad yr ychwanegyn	Paratoad o ffwmonisin esteras (EC 3.1.1.87) a gynhyrchir drwy eplesu â *Komagataella phaffii* (DSM 32159) sydd ag isafswm actifedd ensym o 3000 U/g[(1)]
Nodweddiad y sylwedd(au) actif	Ffwmonisin esteras (EC 3.1.1.87) a gynhyrchir gan *Komagataella phaffii* (DSM 32159) • Rhif EC (IUBMB): 3.1.1.87[(2)]
Dulliau dadansoddi[(3)]	I ganfod actifedd ffwmonisin esteras: • Cromatograffaeth hylif perfformiad uchel wedi ei chyplysu â dull sbectrometreg màs tandem (HPLC-MS/MS) yn seiliedig ar feintioli'r asid tricarbalilig a ryddheir o weithred yr ensym ar ffwmonisin B^1 ar pH 8.0 a 30 ºC.
Rhywogaeth neu gategori o anifail	Pob rhywogaeth o anifail
Oedran hynaf	Dim
Isafswm cynnwys[(4)]	40 U/kg
Uchafswm cynnwys[(4)]	Dim
Darpariaethau eraill	1. Rhaid nodi'r amodau storio a'r sefydlogrwydd o ran trin â gwres yn y cyfarwyddiadau ar gyfer defnyddio'r ychwanegyn bwyd anifeiliaid a'r rhag-gymysgedd. 2. Mae'r ychwanegyn wedi ei awdurdodi i'w ddefnyddio mewn silwair yn seiliedig ar indrawn yn unig.

(1) 1 U yw'r actifedd ensymatig sy'n rhyddhau 1 µmol asid tricarbalilig y funud o 100 µM ffwmonisin B1 mewn 20 mM byffer Tris-Cl pH 8.0 gydag 0.1 mg/ml albwmin serwm buchol ar 30 ºC.

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

(3) Mae manylion y dulliau dadansoddi wedi eu nodi yn y ddogfen sydd â'r cyfeirnod "Ares(2017)2516958 – 17/05/2017" a "JRC F.5/CvH/MGH /AS/Ares", ac a ddiweddarwyd ddiwethaf ar 18 Mai 2017. Ar gael yn: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0005_en.

(4) Unedau actifedd/kg o ddeunydd ffres.

Dirymu

Rheoliad y Comisiwn (EC) Rhif 109/2007 ynghylch awdurdodi monensin sodiwm (Coxidin) fel ychwanegyn bwyd anifeiliaid(**1**)

Rheoliad y Comisiwn (UE) Rhif 333/2010 ynghylch awdurdodi defnydd newydd o *Bacillus subtilis* C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll wedi eu diddyfnu (deiliad yr awdurdodiad Asahi Calpis Wellness Co. Ltd, a gynrychiolir yn yr Undeb Ewropeaidd gan Pen & Tec Consulting S.L.U.)(**2**)

Rheoliad y Comisiwn (EU) Rhif 335/2010 sy'n ymwneud ag awdurdodi celad zinc o analog hydrocsi o fethionin fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**3**)

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 349/2010 sy'n ymwneud ag awdurdodi celad copr o analog hydrocsi o fethionin fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**4**)

Rheoliad y Comisiwn (EU) Rhif 350/2010 sy'n ymwneud ag awdurdodi celad manganîs o analog hydrocsi o fethionin fel ychwanegyn bwyd anifeiliaid ar gyfer pob rhywogaeth o anifail(**5**)

Rheoliad y Comisiwn (EU) Rhif 170/2011 ynghylch awdurdodi *Saccharomyces cerevisiae* MUCL 39885 fel ychwanegyn bwyd anifeiliaid ar gyfer perchyll (wedi eu diddyfnu) ac yn diwygio Rheoliad (EC) Rhif 1200/2005 (deiliad yr awdurdodiad Prosol SpA)(**6**)

Rheoliad y Comisiwn (EU) Rhif 184/2011 ynghylch awdurdodi *Bacillus subtilis* C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy, tyrcwn, mân rywogaethau adar ac adar addurniadol a hela eraill (deiliad yr awdurdodiad Asahi Calpis Wellness Co. Ltd, a gynrychiolir yn yr Undeb Ewropeaidd gan Pen & Tec Consulting S.L.U.)(**7**)

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 98/2012 ynghylch awdurdodi 6-ffytas (EC 3.1.3.26) a gynhyrchir gan *Pichia pastoris* (DSM 23036) fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a thyrcwn i'w pesgi, ieir a fegir ar gyfer dodwy, tyrcwn a fegir ar gyfer bridio, ieir dodwy, rhywogaethau eraill o adar i'w pesgi ac ar gyfer dodwy, perchyll i'w pesgi a hychod (deiliad yr awdurdodiad Huvepharma AD)(**8**)

Rheoliad Gweithredu'r Comisiwn (EU) Rhif 140/2012 sy'n ymwneud ag awdurdodi monensin sodiwm fel ychwanegyn bwyd anifeiliaid ar gyfer ieir a fegir ar gyfer dodwy (deiliad yr awdurdodiad Huvepharma NV Belgium(**9**)

Rheoliad Gweithredu'r Comisiwn (EU) 2019/893 ynghylch adnewyddu awdurdodiad *Bacillus subtilis* DSM 15544 fel ychwanegyn bwyd anifeiliaid ar gyfer ieir i'w pesgi ac yn diddymu Rheoliad (EC) Rhif

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(**1**) EUR 2007/109.
(**2**) EUR 2010/333. Gweler rheoliad 13 o'r Rheoliadau hyn am ddarpariaeth drosiannol. Diwygiwyd EUR 2010/333 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2020/146 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.
(**3**) EUR 2010/335. Gweler rheoliad 16 o'r Rheoliadau hyn am ddarpariaeth drosiannol. Diwygiwyd EUR 20140/335 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2016/1095 (EUR 2016/1095). Mae EUR 2016/1095 wedi ei ddiwygio gan reoliad 18 o'r Rheoliadau hyn
(**4**) EUR 2010/349. Gweler rheoliad 16 o'r Rheoliadau hyn am ddarpariaeth drosiannol. Diwygiwyd EUR 2010/349 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2018/1039 (EUR 2018/1039). Mae EUR 2018/1039 wedi ei ddiwygio gan reoliad 19 o'r Rheoliadau hyn.
(**5**) EUR 2010/350. Gweler rheoliad 16 o'r Rheoliadau hyn am ddarpariaeth drosiannol.
(**6**) EUR 2011/170.
(**7**) EUR 2011/184. Gweler rheoliad 13 o'r Rheoliadau hyn am ddarpariaeth drosiannol. Diwygiwyd EUR 2011/184 cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (diddymir EUR 2020/146 gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt).
(**8**) EUR 2012/98. Gweler rheoliad 12 o'r Rheoliadau hyn am ddarpariaeth drosiannol.
(**9**) EUR 2012/140.

1444/2006 (deiliad yr awdurdodiad Asahi Calpis Wellness Co. Ltd, a gynrychiolir yn yr Undeb Ewropeaidd gan Pen & Tec Consulting S.L.U.)(**1**)

Rheoliad Gweithredu'r Comisiwn (E) 2020/146 yn diwygio Rheoliad (EU) Rhif 333/2010, Rheoliad Gweithredu (EU) 2017/2312, Rheoliad Gweithredu (EU) 2018/1081, Rheoliad Gweithredu (EU) 2016/897, Rheoliad Gweithredu (EU) 2019/893 a Rheoliad (EU) Rhif 184/2011 ynghylch awdurdodi'r paratoad o *Bacillus subtilis* C-3102 (DSM 15544) fel ychwanegyn bwyd anifeiliaid(**2**)

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

(**1**) EUR 2019/893, a ddiwygiwyd cyn diwrnod cwblhau'r cyfnod gweithredu gan Reoliad Gweithredu'r Comisiwn (EU) 2020/146 (EUR 2020/146). Mae EUR 2020/146 wedi ei ddirymu gan reoliad 20 o'r Rheoliadau hyn, ac Atodlen 21 iddynt.
(**2**) EUR 2020/146.

SCHEDULES

SCHEDULE 1

Regulation 3(1)

Authorisation of a preparation of chromium chelate of DL-methionine (identification number GB4d0001) as a feed additive for dairy cows

The preparation of chromium chelate of DL-methionine specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "other zootechnical", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Chromium chelate of DL-methionine
Identification number	GB4d0001
Authorisation holder	Zinpro Animal Nutrition (Europe), Inc
Additive category	Zootechnical additives
Functional group	Other zootechnical
Additive composition	Solid preparation of chelates of chromium (Cr) with DL-methionine with the below components: • Calcium carbonate: 95.6% • Chromium-DL-Methionine: 3.4% • Vegetable oil: 1.0%
Characterisation of the active substance(s)	Chromium chelate of DL-methionine ($[CH_3S(CH_2)_2CH(NH_2)COO]_3$ Cr)
Analytical methods[(1)]	For the quantification of chromium in the feed additive: • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[(2)]) For the quantification of methionine in the feed additive: • Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) (BS EN ISO 13903:2005[(3)]) For proving the chelated structure of the feed additive: • Mid-infrared (IR) spectrometry together with the determination of the content of chromium and methionine in the feed additive
Species or category of animal	Dairy cows
Maximum age	None
Minimum content[(4)]	0.2 mg/kg
Maximum content[(4)]	0.5 mg/kg
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture

[(1)] Details of the analytical methods are set out in the document referenced "Ares(2019)6115119 - 03/10/2019" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 18 October 2019. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2018-0021_en.

[(2)] 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 (ISBN 978 0 580 94471 0). Available at: https://knowledge.bsigroup.com.

(3) 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 at: https://knowledge.bsigroup.com.

(4) Content of chromium (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 2

Regulation 3(1)

Renewal of authorisation of a preparation of *Saccharomyces cerevisiae* (MUCL 39885) (identification number 4b1710) as a feed additive for weaned piglets, and its authorisation as a feed additive extending existing uses to cover all *Suidae* other than sows and suckling piglets, cats, and dogs

The preparation of *Saccharomyces cerevisiae* (MUCL 39885) 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**).

Additive	*Saccharomyces cerevisiae* (MUCL 39885)
Identification number	4b1710
Authorisation holder	Prosol S.p.A
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Solid preparation of *Saccharomyces cerevisiae* (MUCL 39885) containing a minimum of 1×10^9 colony forming units (CFU)/g
Characterisation of the active substance(s)	Viable cells of *Saccharomyces cerevisiae* (MUCL 39885)
Analytical methods(1)	For enumeration: • Pour plate method CGYE (chloramphenicol, glucose, yeast extract) agar (BS EN 15789:2021(2)) For identification of the yeast strain: • Polymerase chain reaction (PCR) method (DD CEN/TS 15790:2008(3))
Species or category of animal	• All *Suidae* other than suckling piglets or sows • Cats • Dogs
Maximum age	None
Minimum content(4)	For *Suidae*: • *Suidae* other than suckling piglets, sows and *Suidae* for reproduction purposes: 3×10^9 CFU/kg • *Suidae* for reproduction purposes other than sows: 6.4×10^9 CFU/kg For cats • 7×10^{10} CFU/kg For dogs: • 7×10^{10} CFU/kg
Maximum content(4)	None
Other provisions	The storage conditions must be indicated in the directions for use of the feed additive and premixtures

(1) Details of the analytical methods are set out in the document referenced "D06/FSQ/CVH/CMP/mdr/ARES (2010)58412", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0028_en.

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 170/2011 (EUR 2011/170). EUR 2011/170 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

(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 at: 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 the British Standards Institution on 31 January 2009 (ISBN 978 0 580 61806 2). Available at: https://knowledge.bsigroup.com.

(4) Colony forming units (CFU) of additive/kg complete feed with a moisture content of 12%.

SCHEDULE 3

Regulation 3(1)

Authorisation of a preparation of *Pediococcus acidilactici* (CNCM I-4622) (identification number 4d1712) as a feed additive for all animal species

The preparation of *Pediococcus acidilactici* (CNCM I-4622) specified in the table, belonging to the additive category "technological additives" and to the functional groups "acidity regulator" and "hygiene condition enhancer", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	*Pediococcus acidilactici* (CNCM I-4622)
Identification number	4d1712
Authorisation holder	None
Additive category	Technological additives
Functional group	• Acidity regulators • Hygiene condition enhancers
Additive composition	Solid preparation of *Pediococcus acidilactici* (CNCM I-4622) containing a minimum of 1×10^{10} colony forming units (CFU)/g
Characterisation of the active substance(s)	Viable cells of *Pediococcus acidilactici* (CNCM I-4622)
Analytical methods[(1)]	For enumeration (colony count) of the feed additive: • Spread plate method using MRS agar (BS EN 15786:2021[(2)]) For identification of the bacterial strain: • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	All animal species
Maximum age	None
Minimum content[(3)]	1×10^9 CFU/kg
Maximum content[(3)]	None
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. To be used only in mash compound feed intended for preparation of liquid feed on farm, or solid feed materials intended for preparation of liquid feed on farm. 3. If *Pediococcus acidilactici* (CNCM I-4622) 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: • Decoquinate • Diclazuril • Halofuginone • Nicarbazin • Robenidine

[(1)] Details of the analytical methods are set out in the document referenced "Ares(2014)1202206 - 16/04/2014" and "JRC.D.5/SFB/CvH/JO /mds/Ares", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2013-0031_en.

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

[(3)] Colony forming units (CFU) of additive/kg of complete feed with a moisture content of 12%.

SCHEDULE 4

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (carrier: perlite, calcium carbonate) (identification number 51701) as a feed additive for chickens for fattening, chickens reared for laying, and turkeys for fattening, and its authorisation as a feed additive extending existing uses to cover turkeys reared for breeding

The preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) 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**).

Additive	Monensin sodium
Identification number	51701
Authorisation holder	Huvepharma NV
Additive category	Coccidiostats and histomonostats
Functional group	None
Additive composition	Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) in powder form with the below components: • Monensin sodium technical substance: 250 g/kg containing: — Monensin A: 90% minimum — Monensin A + B: 95% minimum — Monensin C: 0.2 – 0.3% • Perlite: 150 – 200 g/kg • Calcium carbonate: 550 – 600 g/kg
Characterisation of the active substance(s)	Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419). • Monensin sodium A ($C_{36}H_{61}NaO_{11}$) • Monensin sodium B ($C_{35}H_{59}NaO_{11}$) • Monensin sodium C ($C_{37}H_{63}NaO_{11}$) • CAS number[(1)]: 22373-78-0
Analytical methods[(2)]	For the quantification of monensin in the feed additive, premixtures and compound feed: • Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) (BS EN ISO 14183:2008[(3)]) For the quantification of monensin sodium in chicken and turkey tissues: • Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods.

(**1**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EC) No 109/2007 (EUR 2007/109) and Commission Implementing Regulation (EU) No 140/2012 (EUR 2012/140). EUR 2007/109 and 2012/140 are revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Species or category of animal	• Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
Maximum age	For chickens for fattening: • None For chickens reared for laying: • 16 weeks For turkeys for fattening, turkeys reared for breeding: • 16 weeks
Minimum content(4)	For chickens for fattening; chickens reared for laying: • 100 mg/kg For turkeys for fattening; turkeys reared for breeding: • 60 mg/kg
Maximum content(4)	For chickens for fattening; chickens reared for laying: • 125 mg/kg For turkeys for fattening; turkeys reared for breeding: • 100 mg/kg
Maximum residue limits (MRLs) of monensin sodium in food of animal origin	For wet skin in combination with wet fat: • 25 µg/kg For wet liver; wet kidney; wet muscle: • 8 µg/kg
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. The feed additive must be incorporated into compound feed in the form of a premixture. 3. Monensin sodium must not be mixed with other coccidiostats. 4. The following must be stated, in English or in English and Welsh, in the directions for use: • In English: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances". • In Welsh: "Yn beryglus i geffylau. Mae'r bwyd anifeiliaid hwn yn cynnwys ionoffor. Dylid osgoi ei roi ar yr un pryd â tiamwlin, a dylid monitro ar gyfer adweithiau andwyol posibl wrth ei ddefnyddio gyda sylweddau meddygol eraill". 5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria* spp. A report containing the outcome of that programme must be submitted to the Welsh Ministers before the end of 19 December 2033.

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

(2) Details of the analytical methods are set out in the document referenced "Ares(2017)1087313 - 01/03/2017" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 27 April 2017. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en.

(3) Under reference BS EN ISO 14183:2008 "Animal feeding stuffs. Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivatization". Published by the

British Standards Institution on 24 January 2006 (ISBN 978 0 580 62955 6). Available at: https://knowledge.bsigroup.com.

(4) Content of monensin (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 5

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) (carrier: perlite, wheat bran) (identification number 51701) as a feed additive for chickens for fattening, and turkeys for fattening, and its authorisation as a feed additive extending existing uses to cover chickens reared for laying, and turkeys reared for breeding

The preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) 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**).

Additive	Monensin sodium
Identification number	51701
Authorisation holder	Huvepharma NV
Additive category	Coccidiostats and histomonostats
Functional group	None
Additive composition	Preparation of monensin sodium produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419) in powder form with the below components: • Monensin sodium technical substance: 250g/kg containing: — Monensin A: 90% minimum — Monensin A + B: 95% minimum — Monensin C: 0.2 – 0.3% • Perlite: 150 – 200 g/kg • Wheat bran: 550 – 600 g/kg
Characterisation of the active substance(s)	Monensin sodium technical substance produced by fermentation with *Streptomyces cinnamonensis* 28682 (NBIMCC 3419). • Monensin sodium A ($C_{36}H_{61}NaO_{11}$) • Monensin sodium B ($C_{35}H_{59}NaO_{11}$) • Monensin sodium C ($C_{37}H_{63}NaO_{11}$) • CAS number(2): 22373-78-0
Analytical methods(2)	For the quantification of monensin in the feed additive, premixtures and compound feed: • Reversed phase high performance liquid chromatography using post-column derivatisation coupled to spectrophotometric detection (RP-HPLC-PCD-UV-Vis) (BS EN ISO 14183:2008(3)) For the quantification of monensin sodium in chicken and turkey tissues: • Reversed phase high performance liquid chromatography coupled to a triple quadrupole mass spectrometer (RP-HPLC-MS/MS) or any equivalent methods.

(**1**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Regulation (EC) No 109/2007 (EUR 2007/109). EUR 2007/109 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Species or category of animal	• Chickens for fattening • Chickens reared for laying • Turkeys for fattening • Turkeys reared for breeding
Maximum age	For chickens for fattening: • None For chickens reared for laying: • 16 weeks For turkeys for fattening; turkeys reared for breeding: • 16 weeks
Minimum content(4)	For chickens for fattening; chickens reared for laying: • 100 mg/kg For turkeys for fattening; turkeys reared for breeding: • 60 mg/kg
Maximum content(4)	For chickens for fattening; chickens reared for laying: • 125 mg/kg For turkeys for fattening; turkeys reared for breeding: • 100 mg/kg
Maximum residue limits (MRLs) of monensin sodium in food of animal origin	For wet skin in combination with wet fat: • 25 µg/kg For wet liver; wet kidney; wet muscle: • 8 µg/kg
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. The feed additive must be incorporated into compound feed in the form of a premixture. 3. Monensin sodium must not be mixed with other coccidiostats. 4. The following must be stated, in English or in English and Welsh, in the directions for use: • In English: "Dangerous for equines. This feed contains an ionophore. Avoid simultaneous administration with tiamulin and monitor for possible adverse reactions when used concurrently with other medicinal substances". • In Welsh: "Yn beryglus i geffylau. Mae'r bwyd anifeiliaid hwn yn cynnwys ionoffor. Dylid osgoi ei roi ar yr un pryd â thiamwlin, a dylid monitro ar gyfer adweithiau andwyol posibl wrth ei ddefnyddio gyda sylweddau meddygol eraill". 5. A post-market monitoring programme must be carried out by the holder of the authorisation for resistance to bacteria and *Eimeria* spp. A report containing the outcome of that programme must be submitted to the Welsh Ministers before the end of 19 December 2033.

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

(2) Details of the analytical methods are set out in the document referenced "Ares(2017)1087313 - 01/03/2017" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 27 April 2017. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0009_en.

(3) Under reference BS EN ISO 14183:2008 "Animal feeding stuffs. Determination of monensin, narasin and salinomycin contents. Liquid chromatographic method using post-column derivatization". Published by the

British Standards Institution on 24 January 2006 (ISBN 978 0 580 62955 6). Available at: https://knowledge.bsigroup.com.

(4) Content of monensin (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 6

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (formerly *Komagataella pastoris*) (DSM 23036) (identification number 4a16) as a feed additive for chickens for fattening, chickens reared for laying, laying hens, turkeys for fattening, turkeys reared for breeding, other avian species for fattening and laying, sows, pigs for fattening and weaned piglets, and its authorisation as a feed additive extending existing uses to cover all avian species and all *Suidae*

The preparation of 6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "digestibility enhancers", is authorised as an additive in animal nutrition subject to the conditions set out in the table(**1**).

Additive	6-phytase (EC 3.1.3.26)
Identification number	4a16
Authorisation holder	Huvepharma NV
Additive category	Zootechnical additives
Functional group	Digestibility enhancers
Additive composition	Preparation of 6–phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) having a minimum enzyme activity of: • 4,000 OTU/g(1) in solid form • 8,000 OTU/g in liquid form
Characterisation of the active substance(s)	6-phytase (EC 3.1.3.26) produced by fermentation with *Komagataella phaffii* (DSM 23036) • CAS number(2): 9001-89-2 • EC (IUBMB) number(3): 3.1.3.26
Analytical methods(4)	For the quantification of phytase activity in the feed additive, premixtures and compound feed: • Colorimetric method based on the quantification of the inorganic phosphate released by the enzyme from the sodium phytate
Species or category of animal	• All avian species • All *Suidae*
Maximum age	None
Minimum content(5)	For avian species: • All avian species other than turkeys: 125 OTU/kg • Turkeys: 250 OTU/kg For *Suidae*: • All *Suidae* other than piglets: 125 OTU/kg • Piglets: 250 OTU/kg
Maximum content(5)	None

(**1**) This authorisation contains a renewal (with modification) of the authorisation granted under Commission Implementing Regulation (EC) No 98/2012 (EUR 2012/98). EUR 2012/98 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

(1) OptiPhos technical units (phytase activity): 1 OTU is the amount of enzyme that catalyses the release of 1 μmol of inorganic phosphate per minute from 5.1 mM sodium phytate in pH 5.5 citrate buffer at 37ºC, measured as the blue P-molybdate complex colour at 820 nm

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

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

(4) Details of the analytical methods are set out in the document referenced "Ares(2016)5971303 - 17/10/2016" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 17 November 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2016-0019_en.

(5) Content of 6-phytase (EC 3.1.3.26) (units of activity (OTU)/kg of complete feed with a moisture content of 12%).

SCHEDULE 7

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of *Bacillus velezensis* (formerly *Bacillus subtilis*) (DSM 15544) (identification number 4b1820) as a feed additive for weaned piglets, chickens reared for laying, turkeys, minor avian species, ornamental birds and game birds; consolidation of existing authorised uses for laying hens and chickens for fattening; and its authorisation as a feed additive extending existing uses to cover all avian species

The preparation of *Bacillus velezensis* (DSM 15544) 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**).

Additive	*Bacillus velezensis* (DSM 15544)
Identification number	4b1820
Authorisation holder	Asahi Biocycle Co., Ltd
Additive category	Zootechnical additives
Functional group	Gut flora stabilisers
Additive composition	Solid preparation of *Bacillus velezensis* (DSM 15544) containing a minimum of 1×10^{10} colony forming units (CFU)/g
Characterisation of the active substance(s)	Viable spores of *Bacillus velezensis* (DSM 15544)
Analytical methods(1)	For enumeration (colony count) of the feed additive: • Spread plate method using tryptone soya agar in all target matrices (BS EN 15784:2021(2)) For identification of the feed additive • Pulsed-field gel electrophoresis (PFGE)
Species or category of animal	• Weaned piglets • All avian species
Maximum age	None
Minimum content(3)	3×10^8 CFU/kg
Maximum content(3)	None
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

(1) Details of the analytical methods are set out in the document referenced "D08/FSQ/CVH/CMP/mds/ARES (2009)347415" and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2009-0013_en.

(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 at: https://knowledge.bsigroup.com.

(3) Colony forming units (CFU)/kg of complete feed with a moisture content of 12%.

(**1**) This authorisation contains a renewal of the authorisations granted under Commission Regulation (EU) No 333/2010 (EUR 2010/333) and Commission Regulation (EU) No 184/2011 (EUR 2011/184) and consolidates authorisations for categories of avian species granted under Commission Implementing Regulations (EU) 2016/897 (EUR 2016/897) and 2019/893 (EUR 2019/893). EUR 2016/897 is amended by regulation 4 of these Regulations. EUR 2010/333, 2011/184 and 2019/893 are revoked by regulation 20 of, and Schedule 21 to, these Regulations.

SCHEDULE 8

Regulation 3(1)

Authorisation of a preparation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) (identification number 3c352i) as a feed additive for all animal species

The preparation of L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	L-histidine monohydrochloride monohydrate
Identification number	3c352i
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	L-histidine monohydrochloride monohydrate with a purity criteria not less than 98% as a powder with the following components: • Moisture: 1% maximum • Histidine: 72% minimum • Histamine: 100ppm maximum
Characterisation of the active substance(s)	L-histidine monohydrochloride monohydrate produced by fermentation with *Escherichia coli* K-12 (KCCM 80212) ($C_6H_{12}ClN_3O_3$) • CAS number: 5934-29-2[(1)] • EINECS number: 611-821-4[(2)]
Analytical methods[(3)]	For the quantification of histidine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) (BS EN ISO 13903:2005[(4)]), or • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) For the quantification of histidine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled to post-column derivatisation and photometric detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed(**1**) - Annex 3, F) For the quantification of histamine in the feed additive: • High performance liquid chromatography coupled with photometric detection (HPLC-UV) (BS EN ISO 13903:2005[(4)])
Species or category of animal	All animal species
Maximum age	None
Minimum content[(5)]	None
Maximum content[(5)]	None

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

Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. L-histidine monohydrochloride monohydrate may be placed on the market and used as an additive consisting of a preparation. 3. The histidine content must be stated on the labelling of the additive and premixture. 4. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-histidine monohydrochloride monohydrate shall be limited to the nutritional requirements of the target animal, which depend on the species, the physiological state of the animal, the performance level, the environmental conditions, the level of other amino acids in the diet and the level of essential trace elements such as copper and zinc". • In Welsh: "Rhaid i'r ychwanegiad â L-histidin monohydroclorid monohydrad fod yn gyfyngedig i ofynion maethol yr anifail targed, sy'n dibynnu ar y rhywogaeth, cyflwr ffisiolegol yr anifail, lefel perfformiad, yr amodau amgylcheddol, lefel asidau amino eraill yn y diet a lefel elfennau hybrin hanfodol fel copor a zinc". 5.The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air(6).

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

(2) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(3) Details of the analytical methods are set out in the document referenced "Ares(2020)3718494 – 14/07/2020" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0016_en.

(4) 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 at: https://knowledge.bsigroup.com.

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

(6) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by the European Food Safety Authority (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia (Ph. Eur.): Supplement 6.6 (official January 1, 2010), Bacterial Endotoxins (reference 01/2010:20614).

SCHEDULE 9

Regulation 3(1)

Authorisation of a preparation of L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) (identification number 3c440i) as a feed additive for all animal species

The preparation of L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	L-tryptophan
Identification number	3c440i
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	L-tryptophan with a purity criteria on a dry matter basis not less than 98% as a powder with the following components: • Moisture content: 1% maximum • 1,1'-ethylidene-bis-L-tryptophan: 10 mg/kg maximum
Characterisation of the active substance(s)	L-tryptophan produced by fermentation with *Escherichia coli* (KCCM 80210) ($C_{11}H_{12}N_2O_2$) • CAS number: 73-22-3(1) • EINECS number: 200-795-6(2)
Analytical methods(3)	For the identification of L-tryptophan in the feed additive: • Food Chemical Codex "L-tryptophan monograph"(4) For the determination of tryptophan in the feed additive and premixtures: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) (BS EN ISO 13904:2016(5)) For the determination of tryptophan in feed materials and compound feed: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, G)
Species or category of animal	All animal species
Maximum age	None
Minimum content(6)	None
Maximum content(6)	None
Other provisions	1. L-tryptophan must be rumen protected when administered to ruminants. 2. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-tryptophan shall take into account all essential and conditionally essential amino acids in order to avoid imbalances". • In Welsh: "Rhaid i'r atchwanegiad ag L-tryptophan ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd". 3. The endotoxin content of the additive and its dusting potential must ensure a maximal endotoxin exposure of 1600 IU endotoxins/m^3 air(7).

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

(2) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(3) Details of the analytical methods are set out in the document referenced "Ares(2020)7146784 – 27/11/2020" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 19 December 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-0038_en.

(4) Food Chemicals Codex (FCC), 13th edition (Method: FCC L-tryptophan monograph published). Published by the United States Pharmacopeial Convention on 1 March 2022 (ISSN 2153-1455). Available at: https://www.foodchemicalscodex.org.

(5) Under reference BS EN ISO 13904:2016 "Animal feeding stuffs. Determination of tryptophan content". Published by the British Standards Institution on 31 March 2016 (ISBN 978 0 580 84452 2). Available at: https://knowledge.bsigroup.com.

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

(7) Exposure calculated based on the endotoxin level and the dusting potential of the additive according to the method used by the European Food Safety Agency (EFSA Journal 2015;13(2):4015); analytical method: European Pharmacopoeia (Ph. Eur.): Supplement 6.6 (official January 1, 2010), Bacterial Endotoxins (reference 01/2010:20614).

SCHEDULE 10

Regulation 3(1)

Authorisation of a preparation of L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) (identification number 3c324i) as a feed additive for all animal species

The preparation of L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	L-lysine sulphate
Identification number	3c324i
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	Granulated preparation of L-lysine sulphate with a minimum of 52% L-lysine, a maximum of 24% sulphate and a maximum moisture content of 4%
Characterisation of the active substance(s)	L-lysine sulphate produced by fermentation with *Corynebacterium glutamicum* (KCCM 80227) ($C_{12}H_{28}N_4O_4 \cdot H_2SO_4$) • CAS Number: 60343-69-3(1)
Analytical methods(2)	For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013(3)) For the identification of sulphate in the feed additive: • European Pharmacopoeia Monograph 20301(4) For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS - Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013(3))
Species or category of animal	All animal species
Maximum age	None
Minimum content(5)	None
Maximum content(5)	10,000 mg/kg
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. The L-lysine content must be stated on the labelling of the additive. 3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-lysine should take into

	account all essential and conditionally essential amino acids in order to avoid imbalances". • In Welsh: "Dylai'r atchwanegiad ag L-lysin ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

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

(2) Details of the analytical methods are set out in the document referenced "Ares(2021)2533252 – 14/04/2021" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 2 July 2021. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2020-00820085_en

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

(4) European Pharmacopoeia monograph – Ph. Eur. 6.0, 01/2008:20301: "Identification reactions of ions and functional groups – sulphates". Published online by the European Directorate for the Quality of Medicines and Healthcare. Available at: https://pheur.edqm.eu/home.

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

SCHEDULE 11

Regulation 3(1)

Authorisation of the substance butylated hydroxyanisole (identification number 1b320) as a feed additive for cats

The substance butylated hydroxyanisole (identification number 1b320) specified in the table, belonging to the additive category "technological additives" and to the functional group "antioxidants", is authorised as an additive in animal nutrition subject to the conditions set out in the table(**1**).

Additive	Butylated hydroxyanisole
Identification number	1b320
Authorisation holder	None
Additive category	Technological additives
Functional group	Antioxidants
Additive composition	Butylated hydroxyanisole with a minimum content of 98.5% in a waxy solid form
Characterisation of the active substance(s)	Butylated hydroxyanisole containing a mixture of 2-tert-butyl-4-hydroxyanisole and a minimum of 85% 3-tert-butyl-4-hydroxyanisole ($C_{11}H_{16}O_2$) • CAS number: 25013-16-5[(1)]
Analytical methods[(2)]	For the quantification of butylated hydroxyanisole in feed additives: • Gas chromatography coupled to flame ionization detection (GC-FID) (Food Chemicals Codex 7th edition method[(3)]) For the quantification of butylated hydroxyanisole in premixtures and compound feed: • Reversed phase high performance liquid chromatography coupled to ultraviolet-diode-array detection (RP-HPLC-UV-DAD, 285 nm)
Species or category of animal	Cats
Maximum age	None
Minimum content[(4)]	None
Maximum content[(4)]	150 mg/kg
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. Butylated hydroxyanisole is authorised to be used in combination with butylated hydroxytoluene up to a maximum combined content of 150 mg/kg of complete feed.

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

[(2)] Details of the analytical methods are set out in the document referenced "JRC.D.5/CvH/SB/ag/ARES(2012)40826", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2010-0132_en.

(**1**) This Schedule contains a new authorisation of a substance that is currently on the market as an 'existing product' under Article 10 of EUR 2003/1831. Prior to implementation period completion day, an application was submitted to the European Commission, pursuant to Article 10(2) of Regulation (EC) No 1831/2003, for the re-evaluation of butylated hydroxyanisole (BHA) as a feed additive for all animal species. The applicant later withdrew the application with regard to cats. BHA was re-evaluated and was subsequently authorised as a feed additive for all species except cats under Commission Implementing Regulation (EU) 2020/1399 (EUR 2020/1399). As a feed additive for cats, the authorisation of BHA as an 'existing product' under Article 10 of EUR 2003/1831 is withdrawn by regulation 8 of these Regulations, but see regulation 15 for transitional provision.

(3) Food Chemicals Codex (FCC), 7th edition (Method: BHA-FCC V1 monograph _ published). Published by the United States Pharmacopeial Convention on 1 March 2010. Available at: https://www.foodchemicalscodex.org.

(4) Content of butylated hydroxyanisole (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 12

Regulation 3(1)

Authorisation of a preparation of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c320) as a feed additive for all animal species

The preparation of L-lysine base (liquid) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	L-lysine base (liquid)
Identification number	3c320
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	Aqueous solution with a minimum of 50% L-lysine
Characterisation of the active substance(s)	L-lysine base (liquid) ($NH_2(CH_2)CH(NH_2)COOH$) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183). • CAS number: 56-87-1[(1)]
Analytical methods[(2)]	For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(3)]) For quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(3)]), or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 - Annex 3, F)
Species or category of animal	All animal species
Maximum age	None
Minimum content[(4)]	None
Maximum content[(4)]	None
Other provisions	1. The L-lysine content must be stated on the labelling of the additive. 2. The additive may be used via water for drinking.

	3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: “The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances”. • In Welsh: “Dylai’r atchwanegiad ag L-lysin, yn arbennig drwy ddŵr i’w yfed, ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd”.

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

(2) Details of the analytical methods are set out in the document referenced “Ares(2019)7003671 - 12/11/2019” and “JRC F.5/CvH/SB/AS/Ares”, and last updated on 27 January 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en.

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

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

SCHEDULE 13

Regulation 3(1)

Authorisation of the substance L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) (identification number 3c322ii) as a feed additive for all animal species

The substance L-lysine monohydrochloride (technically pure) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) specified in the table, belonging to the additive category "nutritional additives" and to the functional group "amino acids, their salts and analogues", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	L-lysine monohydrochloride (technically pure)
Identification number	3c322ii
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Amino acids, their salts and analogues
Additive composition	Powder of L-lysine monohydrochloride with a minimum of 78% L-lysine and a maximum moisture content of 1.5%
Characterisation of the active substance(s)	L-lysine monohydrochloride (technically pure) ($NH_2(CH_2)_4CH(NH_2)COOH$) produced by fermentation with *Corynebacterium glutamicum* (KCCM 80183) • CAS number: 657-27-2[(1)]
Analytical methods[(2)]	For the identification of L-lysine monohydrochloride in the feed additive: • Food Chemicals Codex "L-lysine monohydrochloride monograph"[(3)] For the quantification of lysine in the feed additive and premixtures containing more than 10% lysine: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(4)]) For the quantification of lysine in premixtures, feed materials and compound feed: • Ion-exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for the official control of feed - Annex 3, F) For the quantification of lysine in water: • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS/FLD) (BS EN ISO 17180:2013[(4)]), or • Ion exchange chromatography coupled with post-column derivatisation and optical detection (IEC-VIS) (Commission Regulation (EC) No 152/2009 - Annex 3, F)
Species or category of animal	All animal species
Maximum age	None
Minimum content	None
Maximum content	None
Other provisions	1. The L-lysine content must be stated on the labelling of the additive. 2. The additive may be used via water for drinking.

	3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture: • In English: "The supplementation with L-lysine, in particular via water for drinking, should take into account all essential and conditionally essential amino acids in order to avoid imbalances". • In Welsh: "Dylai'r atchwanegiad ag L-lysin, yn arbennig drwy ddŵr i'w yfed, ystyried yr holl asidau amino hanfodol ac amodol hanfodol er mwyn osgoi anghydbwysedd".

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

(2) Details of the analytical methods are set out in the document referenced "Ares(2019)7003671 - 12/11/2019" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 27 January 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-00160028_en.

(3) Food Chemicals Codex (FCC), 13th edition (Method: FCC L-lysine monohydrochloride monograph published). Published by the United States Pharmacopeial Convention on 1 March 2022 (ISSN 2153-1455). Available at: https://www.foodchemicalscodex.org/.

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

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

SCHEDULE 14

Regulation 3(1)

Authorisation of the substance disodium 5’-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) (identification number 2b627i) as a feed additive for all animal species

The substance disodium 5’-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) specified in the table, belonging to the additive category “sensory additives” and to the functional group “flavouring compounds”, is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Disodium 5’-guanylate
Identification number	2b627i
Authorisation holder	None
Additive category	Sensory additives
Functional group	Flavouring compounds
Additive composition	Powder of disodium 5’-guanylate with a minimum purity criteria of 97%.
Characterisation of the active substance(s)	Hydrated form of disodium 5’-guanylate (GMP) produced by fermentation with *Corynebacterium stationis* (KCCM 10530) and *Escherichia coli* K-12 (KFCC 11067) ($C_{10}H_{12}N_5Na_2O_8P$) • CAS number: 5550-12-9(1) • EINECS number: 226-914-1(2)
Analytical methods(3)	For the identification of disodium 5'-guanylate (GMP) in the feed additive: • FAO JECFA monograph "disodium 5'-guanylate"(4) For the determination of disodium 5'-guanylate (GMP) in the feed additive, flavouring premixtures and water: • High performance liquid chromatography coupled to UV detection (HPLC-UV)
Species or category of animal	All animal species
Maximum age	None
Minimum content(5)	None
Maximum content(5)	None
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. The additive must be incorporated into the feed in the form of a premixture. 3. The following must be stated, in English or in English and Welsh, on the labelling of the additive: • In English: “Recommended maximum content of the active substance when used alone or in combination with other ribonucleotides up to the same level per kg of complete feedingstuff with a moisture content of 12%: 50 mg”. • In Welsh: “Yr uchafswm cynnwys a argymhellir o’r sylwedd actif pan y’i defnyddir ar ei ben ei hun neu mewn cyfuniad â riboniwcleotidau eraill hyd at yr un lefel fesul kg o fwyd anifeiliaid â chynnwys lleithder o 12%: 50 mg”.

	4. The functional group, identification number, name and added amount of the active substance must be indicated on the label of the premixture where the use level on the label of the premixture would result in the level of active substance (alone or in combination with other ribonucleotides) in complete feed exceeding 50 mg/kg.

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

(2) European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

(3) Details of the analytical methods are set out in the document referenced "Ares(2020)4619276 – 04/09/2020" and "JRC F.5/CvH/ZE/AS/Ares", and last updated on 16 October 2020. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2019-0085_en.

(4) Food and Agriculture Organisation of the United Nations (FAO) Joint FAO/WHO Expert Committee on Food Additives (JECFA) - Combined Compendium of Food Additive Specifications, "Disodium 5'-guanylate" Monograph 1 (2006). Published by the FAO and last updated (Web version) August 2011 (ISBN 92-5-105569-6). Available at: https://www.fao.org/food/food-safety-quality/scientific-advice/jecfa/jecfa-additives/detail/en/c/255

(5) Content of disodium 5'-guanylate (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 15

Regulation 3(1)

Authorisation of a preparation of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) (identification number 4d16) as a feed additive for weaned piglets

The preparation of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) specified in the table, belonging to the additive category "zootechnical additives" and to the functional group "other zootechnical additives", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Muramidase (EC 3.2.1.17)
Identification number	4d16
Authorisation holder	DSM Nutritional Products Ltd
Additive category	Zootechnical additives
Functional group	Other zootechnical additives
Additive composition	Solid and liquid preparations of muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) having a minimum enzyme activity of 60,000 LSU(F)/g[(1)]
Characterisation of the active substance(s)	Muramidase (EC 3.2.1.17) produced by fermentation with *Trichoderma reesei* (DSM 32338) • CAS number: 9001-63-2[(2)] • EINECS number: 232-620-4[(3)] • EC (IUBMB) number: 3.2.1.17[(4)]
Analytical methods[(5)]	For the quantification of muramidase in the feed additive, premixtures and compound feed: • Fluorescence-based enzyme assay method that determines the enzyme-catalysed depolymerisation of a fluorescein-labelled peptidoglycan preparation at pH 6.0 and 30 °C.
Species or category of animal	Weaned piglets
Maximum age	None
Minimum content[(6)]	50,000 LSU(F)/kg
Maximum content[(6)]	65,000 LSU(F)/kg
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

[(1)] 1 LSU(F) is defined as the amount of enzyme that increases the fluorescence of 12.5 µg/ml fluorescein-labelled peptidoglycan per minute at pH 6.0 and 30 ºC by a value that corresponds to the fluorescence of approximately 0.06 nmol fluorescein isothiocyanate isomer.

[(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, as published in OJ No C146A, 15.6.90, p.1.

[(4)] Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) https://iubmb.org.

[(5)] Details of the analytical methods are set out in the document referenced "Ares(2018)811287 - 12/02/2018" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 2 March 2018. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0046_en.

[(6)] Content of muramidase (LSU(F)/kg of complete feed with a moisture content of 12%)

SCHEDULE 16

Regulation 3(1)

Authorisation of a preparation of phytomenadione (vitamin K_1) (identification number 3a712) as a feed additive for horses

The preparation of phytomenadione (vitamin K_1) specified in the table, belonging to the additive category "nutritional additives" and to the functional group "vitamins, pro-vitamins and chemically well-defined substances having a similar effect", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Phytomenadione or vitamin K_1
Identification number	3a712
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Vitamins, pro-vitamins and chemically well-defined substances having similar effect
Additive composition	Produced by chemical synthesis • Solid preparation containing a minimum of 4.2% of phytomenadione (vitamin K_1)
Characterisation of the active substance(s)	2-methyl-3-[(E-7R,11R)-3,7,11,15-tetramethylhexadec-2- enyl] naphthalene-1,4-dione (phytomenadione) ($C_{31}H_{46}O_2$) • CAS number: 84-80-0[(1)] • EINECS number: 201-564-2[(2)] with the following components: • E-phytomenadione: 75% minimum • E-epoxyphytomenadione: 4% maximum • Total purity of E-phytomenadione, E-epoxyphytomenadione and Z-phytomenadione isomers: 97% minimum
Analytical methods[(3)]	For the determination of phytomenadione (vitamin K_1) in the feed additive: • High performance liquid chromatography (HPLC) (European Pharmacopoeia monograph 1036[(4)]) For the determination of phytomenadione in the additive preparation and in complimentary feed: • High performance liquid chromatography with fluorescence detection (HPLC-FLD) (BS EN 14148:2003[(5)])
Species or category of animal	Horses
Maximum age	None
Minimum content[(6)]	None
Maximum content[(6)]	None
Other provisions	The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture.

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

[(2)] European Inventory of Existing Commercial Substances, as published in OJ No C146A, 15.6.90, p.1.

[(3)] Details of the analytical methods are set out in the document referenced "Ares(2021)145311 – 07/01/2021" and "JRC F.5/CvH/SB/AS/Ares", and last updated on 17 February 2021. Available at https://joint-research-centre.ec.europa.eu/publications/fad-2020-0006_en.

(4) European Pharmacopoeia monograph - Ph. Eur. 8.0, 01/2014:1036. Published online by the European Directorate for the Quality of Medicines and Healthcare on 1 January 2024. Available at: https://pheur.edqm.eu/home.

(5) Under reference BS EN 14148:2003 “Foodstuffs. Determination of vitamin K1 by HPLC”. Published by the British Standards Institution on 25 July 2003 (ISBN 0 580 42317 4). Available at: https://knowledge.bsigroup.com.

(6) Content of phytomenadione (vitamin K_1) (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 17

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of copper chelate of hydroxy analogue of methionine (identification number 3b410i (formerly 3b4.10)) as a feed additive for all animal species

The preparation of copper chelate of hydroxy analogue of methionine 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(**1**).

Additive	Copper chelate of hydroxy analogue of methionine
Identification number	3b410i
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Copper chelate of hydroxy analogue of methionine in solid form containing a minimum of 16% copper and the following components: • (2-hydroxy-4-methylthio) butanoic acid: 78% minimum • Nickel: 20 ppm maximum
Characterisation of the active substance(s)	Copper chelate of hydroxy analogue of methionine ($Cu(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • CAS number: 292140-30-8[(1)]
Analytical methods[(2)]	For the quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For the quantification of total copper in the feed additive: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(3)] or BS EN 15621:2017[(4)]); or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001)[(5)] For the quantification of total copper in premixtures: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(3)] or BS EN 15621:2017[(4)]); or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(5)]); or • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[(6)])

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 349/2010 (EUR 2010/349). EUR 2010/349 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

	For the quantification of total copper in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[3] or BS EN 15621:2017[4]); or • Atomic absorption spectrometry (AAS) (Commission Regulation (EC) No 152/2009 laying down the methods of sampling and analysis for official control of feed - Annex 4, C or BS EN ISO 6869:2001[5]); or • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[6])
Species or category of animal	All animal species
Maximum age	None
Minimum content[7]	None
Maximum content[7]	For bovines: • Before the start of rumination: 15 mg/kg (total) • Other: 30 mg/kg (total) For ovines: • 15 mg/kg (total) For caprines: • 35 mg/kg (total) For piglets: • Suckling and weaned up 4 weeks after weaning:150 mg/kg (total) • From 5th week up to 8 weeks after weaning: 100 mg/kg (total) For crustaceans: • 50 mg/kg (total) For all other animal species: • 25 mg/kg (total)
Other provisions	1. The additive must be incorporated into feed in the form of a premixture. 2. For feed for sheep, where the level of copper in the feed exceeds 10 mg/kg, the following must be stated, in English or in English and Welsh, on the labelling of the feed: • In English: "The level of copper in this feed may cause poisoning in certain breeds of sheep". • In Welsh: "Gall lefel y copr yn y bwyd anifeiliaid hwn achosi gwenwyno mewn rhai bridiau o ddefaid". 3. For feed for bovines after the start of rumination, where the level of copper in the feed is less than 20 mg/kg, the following must be stated, in English or in English and Welsh, on the labelling of the feed: • In English: "The level of copper in this feed may cause copper deficiencies in cattle grazing pastures with high contents of molybdenum or sulphur". • In Welsh: "Gall lefel y copr yn y bwyd anifeiliaid hwn achosi diffygion copr mewn gwartheg syn pori tir sydd â chynnwys uchel o folybdenwm neu sylffwr".

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

(2) Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29104", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0012_en.

(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 31 August 2017 (ISBN 978 0 580 94541 0). Available at: 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 at: https://knowledge.bsigroup.com.

(5) 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 at: https://knowledge.bsigroup.com.

(6) 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 (ISBN 978 0 580 94471 0). Available at: https://knowledge.bsigroup.com.

(7) Content of copper (Cu) (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 18

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of manganese chelate of hydroxy analogue of methionine (identification number 3b510 (formerly 3b5.10)) as a feed additive for all animal species

The preparation of manganese chelate of hydroxy analogue of methionine 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(**1**).

Additive	Manganese chelate of hydroxy analogue of methionine
Identification number	3b510
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Manganese chelate of hydroxy analogue of methionine in solid form containing a minimum of 14% manganese and the following components: • (2-hydroxy-4-methylthio) butanoic acid: 76% minimum • Nickel: 170 ppm maximum
Characterisation of the active substance(s)	Manganese chelate of hydroxy analogue of methionine ($Mn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • CAS number: 292140-29-5[(1)]
Analytical methods[(2)]	For the quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For the quantification of total manganese in the feed additive and premixtures • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(3)]), or • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(4)]), or • Inductively coupled plasma atomic emission spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[(5)]) For the quantification of total manganese in feed materials and compound feed: • 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 or BS EN ISO 6869:2001[(3)]), or • Inductively coupled plasma atomic emission spectrometry, ICP-AES (BS EN 15510:2017[(4)]), or • Inductively coupled plasma atomic emission spectrometry after pressure digestion (ICP-AES) (BS EN 15621:2017[(5)])

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 350/2010 (EUR 2010/350). EUR 2010/350 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

Species or category of animal	All animal species
Maximum age	None
Minimum content(6)	None
Maximum content(6)	For fish: • 100 mg/kg (total) For all other animal species: • 150 mg/kg (total)
Other provisions	1. The additive must be incorporated into feed in the form of a premixture. 2. Manganese chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation.

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

(2) Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29224", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0011_en.

(3) 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 at: https://knowledge.bsigroup.com.

(4) 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 31 August 2017 (ISBN 978 0 580 94541 0). Available at: https://knowledge.bsigroup.com.

(5) 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 at: https://knowledge.bsigroup.com.

(6) Content of manganese (Mn) (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 19

Regulation 3(1)

Renewal of authorisation (with modification) of a preparation of zinc chelate of hydroxy analogue of methionine (identification number 3b610 (formerly 3b6.10)) as a feed additive for all animal species

The preparation of zinc chelate of hydroxy analogue of methionine 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(**1**).

Additive	Zinc chelate of hydroxy analogue of methionine
Identification number	3b610
Authorisation holder	None
Additive category	Nutritional additives
Functional group	Compounds of trace elements
Additive composition	Zinc chelate of hydroxy analogue of methionine in solid form containing a minimum of 17% zinc and the following components. • (2-hydroxy-4-methylthio) butanoic acid: 79% minimum • Nickel: 1.7 ppm maximum
Characterisation of the active substance(s)	Zinc chelate of hydroxy analogue of methionine ($Zn(CH_3S(CH_2)_2\text{-}CH(OH)\text{-}COO)_2$) • CAS number: 292140-29-5[(1)]
Analytical methods[(2)]	For the quantification of the hydroxy analogue of methionine content in the feed additive: • Titrimetry, potentiometric titration after oxidation reduction reaction For the quantification of total zinc in the feed additive: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(3)] or BS EN 15621:2017[(4)]), or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(5)]) For the quantification of total zinc in premixtures: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[(3)] or BS EN 15621:2017[(4)]), or • Atomic absorption spectrometry (AAS) (BS EN ISO 6869:2001[(5)]), or • Inductively coupled plasma mass spectrometry (ICP-MS) (BS EN 17053:2018[(6)])

(**1**) This authorisation contains a renewal of the authorisation granted under Commission Regulation (EU) No 335/2010 (EUR 2010/335). EUR 2010/335 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.

	For the quantification of total zinc in feed materials and compound feed: • Inductively coupled plasma atomic emission spectrometry (ICP-AES) (BS EN 15510:2017[3] or BS EN 15621:2017[4]), or • 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 or BS EN ISO 6869:2001[5]), or • Inductively coupled plasma mass spectrometry ICP-MS (BS EN 17053:2018[6])
Species or category of animal	All animal species
Maximum age	None
Minimum content[7]	None
Maximum content[7]	For cats: • 200 mg/kg (total) For dogs: • 200mg/kg (total) For fish: • Salmonids: 180 mg/kg (total) • Other: 150 mg/kg (total) For milk replacers for calves: • 180 mg/kg (total) For rabbits: • 150 mg/kg (total) For *Suidae*: • Piglets, sows: 150 mg/kg (total) • Other: 120 mg/kg (total) For all other animal species: • 120 mg/kg (total)
Other provisions	1. The additive must be incorporated into feed in the form of a premixture. 2. Zinc chelate of hydroxy analogue of methionine may be placed on the market and used as an additive consisting of a preparation.

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

[2] Details of the analytical methods are set out in the document referenced "D08-FSQ(2007)D/29110", and last updated on 6 June 2016. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2007-0010_en.

[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 31 August 2017 (ISBN 978 0 580 94541 0). Available at: 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 at: https://knowledge.bsigroup.com.

[5] 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 at: https://knowledge.bsigroup.com.

[6] 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 (ISBN 978 0 580 94471 0). Available at: https://knowledge.bsigroup.com.

(7) Content of zinc (Zn) (mg/kg of complete feed with a moisture content of 12%).

SCHEDULE 20

Regulation 3(1)

Authorisation of a preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) (identification number 1m03i) as a feed additive for all animal species, for use only in maize-based silages

The preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) specified in the table, belonging to the additive category "technological additives" and to the functional group "substances for reduction of the contamination of feed by mycotoxins", is authorised as an additive in animal nutrition subject to the conditions set out in the table.

Additive	Fumonisin esterase (EC 3.1.1.87)
Identification number	1m03i
Authorisation holder	None
Additive category	Technological additives
Functional group	Substances for reduction of the contamination of feed by mycotoxins
Additive composition	Preparation of fumonisin esterase (EC 3.1.1.87) produced by fermentation with *Komagataella phaffii* (DSM 32159) having a minimum enzyme activity of 3000 U/g[(1)]
Characterisation of the active substance(s)	Fumonisin esterase (EC 3.1.1.87) produced by *Komagataella phaffii* (DSM 32159) • EC (IUBMB) Number: 3.1.1.87[(2)]
Analytical methods[(3)]	For the determination of fumonisin esterase activity: • High performance liquid chromatography coupled with a tandem mass spectrometry (HPLC-MS/MS) method based on the quantification of the tricarballylic acid released from the action of the enzyme on fumonisin B_1 at pH 8.0 and 30 ºC.
Species or category of animal	All animal species
Maximum age	None
Minimum content[(4)]	40 U/kg
Maximum content[(4)]	None
Other provisions	1. The storage conditions and stability to heat treatment must be stated in the directions for use of the feed additive and premixture. 2. The additive is authorised for use only in maize-based silages.

[(1)] 1 U is the enzymatic activity that releases 1 µmol tricarballylic acid per minute from 100 µM fumonisin B1 in 20 mM Tris-Cl buffer pH 8.0 with 0.1 mg/ml bovine serum albumin at 30 ºC.

[(2)] Identification number allocated by the International Union of Biochemistry and Molecular Biology (IUBMB) https://iubmb.org.

[(3)] Details of the analytical methods are set out in the document referenced "Ares(2017)2516958 - 17/05/2017" and "JRC F.5/CvH/MGH /mds/Ares", and last updated on 18 May 2017. Available at: https://joint-research-centre.ec.europa.eu/publications/fad-2017-0005_en.

[(4)] Units of activity/kg of fresh material.

SCHEDULE 21

Regulation 20

Revocations

Commission Regulation (EC) No 109/2007 concerning the authorisation of monensin sodium (Coxidin) as a feed additive(**1**)

Commission Regulation (EU) No 333/2010 concerning the authorisation of a new use of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for weaned piglets (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**2**)

Commission Regulation (EU) No 335/2010 concerning the authorisation of zinc chelate of hydroxy analogue of methionine as a feed additive for all animal species(**3**)

Commission Regulation (EU) No 349/2010 concerning the authorisation of copper chelate of hydroxy analogue of methionine as a feed additive for all animal species(**4**)

Commission Regulation (EU) No 350/2010 concerning the authorisation of manganese chelate of hydroxy analogue of methionine as a feed additive for all animal species(**5**)

Commission Regulation (EU) No 170/2011 concerning the authorisation of *Saccharomyces cerevisiae* MUCL 39885 as a feed additive for piglets (weaned) and amending Regulation (EC) No 1200/2005 (holder of authorisation Prosol SpA)(**6**)

Commission Regulation (EU) No 184/2011 concerning the authorisation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive for chickens reared for laying, turkeys, minor avian species and other ornamental and game birds (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**7**)

Commission Implementing Regulation (EU) No 98/2012 concerning the authorisation of 6-phytase (EC 3.1.3.26) produced by *Pichia pastoris* (DSM 23036) as a feed additive for chickens and turkeys for fattening, chickens reared for laying, turkeys reared for breeding, laying hens, other avian species for fattening and laying, weaned piglets, pigs for fattening and sows (holder of authorisation Huvepharma AD)(**8**)

Commission Implementing Regulation (EU) No 140/2012 concerning the authorisation of monensin sodium as a feed additive for chickens reared for laying (holder of authorisation Huvepharma NV Belgium)(**9**)

Commission Implementing Regulation (EU) 2019/893 concerning the renewal of the authorisation of *Bacillus subtilis* DSM 15544 as a feed additive for chickens for fattening and repealing Regulation (EC)

(**1**) EUR 2007/109.
(**2**) EUR 2010/333. See regulation 13 of these Regulations for transitional provision. EUR 2010/333 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.
(**3**) EUR 2010/335. See regulation 16 of these Regulations for transitional provision. EUR 2010/335 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2016/1095 (EUR 2016/1095). EUR 2016/1095 is amended by regulation 18 of these Regulations.
(**4**) EUR 2010/349. See regulation 16 of these Regulations for transitional provision. EUR 2010/349 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2018/1039 (EUR 2018/1039). EUR 2018/1039 is amended by regulation 19 of these Regulations.
(**5**) EUR 2010/350. See regulation 16 of these Regulations for transitional provision.
(**6**) EUR 2011/170.
(**7**) EUR 2011/184. See regulation 13 of these Regulations for transitional provision. EUR 2011/184 was amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.
(**8**) EUR 2012/98. See regulation 12 of these Regulations for transitional provision.
(**9**) EUR 2012/140.

No 1444/2006 (holder of authorisation Asahi Calpis Wellness Co. Ltd, represented in the European Union by Pen & Tec Consulting S.L.U.)(**1**)

Commission Implementing Regulation (EU) 2020/146 amending Regulation (EU) No 333/2010, Implementing Regulation (EU) 2017/2312, Implementing Regulation (EU) 2018/1081, Implementing Regulation (EU) 2016/897, Implementing Regulation (EU) 2019/893 and Regulation (EU) No 184/2011 concerning the authorisations of the preparation of *Bacillus subtilis* C-3102 (DSM 15544) as a feed additive(**2**)

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(**1**) EUR 2019/893, amended prior to implementation period completion day by Commission Implementing Regulation (EU) 2020/146 (EUR 2020/146). EUR 2020/146 is revoked by regulation 20 of, and Schedule 21 to, these Regulations.
(**2**) EUR 2020/146.