



OFFERYNNAU STATUDOL
CYMRU

WELSH STATUTORY
INSTRUMENTS

2023 Rhif 678 (Cy. 100)

2023 No. 678 (W. 100)

AMAETHYDDIAETH, CYMRU

AGRICULTURE, WALES

Rheoliadau Ychwanegion Bwyd
Anifeiliaid (Ffurff Awdurdodiadau
Dros Dro) (Cyfansoddion
Cobalt(II)) (Cymru) 2023

The Feed Additives (Form of
Provisional Authorisations)
(Cobalt(II) Compounds) (Wales)
Regulations 2023

NODYN ESBONIADOL

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

Mae'r Rheoliadau hyn yn gwneud darpariaeth ynghylch awdurdodi dros dro, o ran Cymru, ychwanegion bwyd anifeiliaid penodol o dan Reoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid.

Mae rheoliad 3, ac Atodlenni 1 i 4, yn rhagnodi ffurfiau awdurdodiadau dros dro, o ran Cymru, pedwar ychwanegyn bwyd anifeiliaid.

- Mae Atodlen 1 yn cynnwys y ffurf awdurdodi dros dro ragnodedig ar gyfer cobalt(II) asetat tetrahydrad (rhif adnabod 3b301).
- Mae Atodlen 2 yn cynnwys y ffurf awdurdodi dros dro ragnodedig ar gyfer cobalt(II) carbonad (rhif adnabod 3b302).
- Mae Atodlen 3 yn cynnwys y ffurf awdurdodi dros dro ragnodedig ar gyfer cobalt(II) carbonad hydrocsid (2:3) monohydrad (rhif adnabod 3b303).
- Mae Atodlen 4 yn cynnwys y ffurf awdurdodi dros dro ragnodedig ar gyfer cobalt(II) sylffad heptahydrad (rhif adnabod 3b305).

Gellir cael rhagor o wybodaeth, gan gynnwys mewn perthynas ag unrhyw ddogfennaeth y cyfeirir ati yn yr Atodlenni, gan yr Asiantaeth Safonau Bwyd, Llawr 11, Tŷ Southgate, Stryd Wood, Caerdydd, CF10 1EW neu drwy anfon e-bost i regulated.products.wales@food.gov.uk.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations make provision as regards the provisional authorisation, in relation to Wales, of certain feed additives under Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition.

Regulation 3, and Schedules 1 to 4, prescribe the forms of the provisional authorisations, in relation to Wales, of four feed additives.

- Schedule 1 contains the prescribed form of provisional authorisation for cobalt(II) acetate tetrahydrate (identification number 3b301).
- Schedule 2 contains the prescribed form of provisional authorisation for cobalt(II) carbonate (identification number 3b302).
- Schedule 3 contains the prescribed form of provisional authorisation for cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303).
- Schedule 4 contains the prescribed form of provisional authorisation for cobalt(II) sulphate heptahydrate (identification number 3b305).

Further information, including in relation to any documentation referenced in the Schedules, can be obtained from the Food Standards Agency, 11th Floor, Southgate House, Wood Street, Cardiff, CF10 1EW or by writing to regulated.products.wales@food.gov.uk.

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

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

2023 Rhif 678 (Cy. 100)

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AMAETHYDDIAETH, CYMRU

AGRICULTURE, WALES

**Rheoliadau Ychwanegion Bwyd
Anifeiliaid (Ffurf Awdurdodiadau
Dros Dro) (Cyfansoddion
Cobalt(II)) (Cymru) 2023**

**The Feed Additives (Form of
Provisional Authorisations)
(Cobalt(II) Compounds) (Wales)
Regulations 2023**

Gwnaed 20 Mehefin 2023
Gosodwyd gerbron *Senedd*
Cymru 22 Mehefin 2023
Yn dod i rym 14 Gorffennaf 2023

Made 20 June 2023
Laid before Senedd Cymru 22 June 2023
Coming into force 14 July 2023

Mae Gweinidogion Cymru yn gwneud y Rheoliadau hyn drwy arfer y pwerau a roddir gan Erthyglau 15 a 18A(3)(b) o Reoliad (EC) Rhif 1831/2003 Senedd Ewrop a'r Cyngor ar ychwanegion sydd i'w defnyddio mewn maeth anifeiliaid(1).

The Welsh Ministers make these Regulations in exercise of the powers conferred by Articles 15 and 18A(3)(b) of Regulation (EC) No 1831/2003 of the European Parliament and of the Council on additives for use in animal nutrition(1).

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

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

Enwi, rhychwant, cymhwyso a dod i rym

Title, extent, application and coming into force

1.—(1) Enw'r Rheoliadau hyn yw Rheoliadau Ychwanegion Bwyd Anifeiliaid (Ffurf Awdurdodiadau Dros Dro) (Cyfansoddion Cobalt(II)) (Cymru) 2023.

1.—(1) The title of these Regulations is the Feed Additives (Form of Provisional Authorisations) (Cobalt(II) Compounds) (Wales) Regulations 2023.

- (2) Mae'r Rheoliadau hyn—
- (a) yn rhychwantu Cymru a Lloegr;
 - (b) yn gymwys o ran Cymru;
 - (c) yn dod i rym ar 14 Gorffennaf 2023.

- (2) These Regulations—
- (a) extend to England and Wales;
 - (b) apply in relation to Wales;
 - (c) come into force on 14 July 2023.

(1) EUR 2003/1831, a ddiwygiwyd gan O.S. 2019/654, 2022/377 a 2022/1351. 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.

(2) EUR 2002/178, a ddiwygiwyd gan O.S. 2019/641; mae offerynnau diwygio eraill ond nid yw'r un ohonynt yn berthnasol. Diwygiwyd O.S. 2019/641 gan O.S. 2020/1504.

(1) EUR 2003/1831, amended by S.I. 2019/654, 2022/377 and 2022/1351. 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.

(2) EUR 2002/178, amended by S.I. 2019/641; there are other amending instruments but none is relevant. S.I. 2019/641 was amended by S.I. 2020/1504.

Dehongli

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

(2) Ym mharagraff (1)—

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

ystyr “Rheoliad 767/2009” (“*Regulation 767/2009*”) yw Rheoliad (EC) Rhif 767/2009 Senedd Ewrop a'r Cyngor ar roi bwyd anifeiliaid ar y farchnad a'i ddefnyddio(1).

Ffurf awdurdodiadau dros dro

3.—(1) Mae paragraffau (2) i (5) yn rhagnodi ffurfiau awdurdodiadau dros dro ar gyfer ychwanegion bwyd anifeiliaid penodol(2).

(2) Mae ffurf awdurdodi dros dro ragnodedig cobalt(II) asetad tetrahydrad (rhif adnabod 3b301) wedi ei nodi yn Atodlen 1.

(3) Mae ffurf awdurdodi dros dro ragnodedig cobalt(II) carbonad (rhif adnabod 3b302) wedi ei nodi yn Atodlen 2.

(4) Mae ffurf awdurdodi dros dro ragnodedig cobalt(II) carbonad hydrocsid (2:3) monohyrad (rhif adnabod 3b303) wedi ei nodi yn Atodlen 3.

(5) Mae ffurf awdurdodi dros dro ragnodedig cobalt(II) sylffad heptahyrad (rhif adnabod 3b305) wedi ei nodi yn Atodlen 4.

Interpretation

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

(2) In paragraph (1)—

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

“Regulation 767/2009” (“*Rheoliad 767/2009*”) means Regulation (EC) No 767/2009 of the European Parliament and of the Council on the placing on the market and use of feed(1).

Form of provisional authorisations

3.—(1) Paragraphs (2) to (5) prescribe the forms of provisional authorisations for certain feed additives(2).

(2) The prescribed form of provisional authorisation of cobalt(II) acetate tetrahydrate (identification number 3b301) is set out in Schedule 1.

(3) The prescribed form of provisional authorisation of cobalt(II) carbonate (identification number 3b302) is set out in Schedule 2.

(4) The prescribed form of provisional authorisation of cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303) is set out in Schedule 3.

(5) The prescribed form of provisional authorisation of cobalt(II) sulphate heptahydrate (identification number 3b305) is set out in Schedule 4.

Lynne Neagle

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

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

(1) EUR 2009/767, a ddiwygiwyd gan O.S. 2019/654; mae offeryn diwygio arall nad yw'n berthnasol i'r Rheoliadau hyn. Diwygiwyd O.S. 2019/654 gan O.S. 2020/1504.

(2) Cafodd yr ychwanegion bwyd anifeiliaid eu hawdurdodi dros dro, o ran Cymru, gan benderfyniad gweinyddol Gweinidogion Cymru dyddiedig 20 Mehefin 2023, yn unol ag Erthygl 15 o EUR 2003/1831.

(1) EUR 2009/767, amended by S.I. 2019/654; there is another amending instrument not relevant to these Regulations. S.I. 2019/654 was amended by S.I. 2020/1504.

(2) The feed additives were provisionally authorised, in relation to Wales, by administrative decision of the Welsh Ministers dated 20 June 2023, pursuant to Article 15 of EUR 2003/1831.

Ffurf awdurdodi dros dro cobalt(II) asetad tetrahydrad (rhif adnabod 3b301) fel ychwanegyn bwyd anifeiliaid ar gyfer anifeiliaid cnoi cil sydd â rwmn gweithredol, equidae, lagomorffiaid, cnofilod, ymlusgiaid sy'n llysysyddion, a mamaliaid sw

Mae'r sylwedd cobalt(II) asetad tetrahydrad, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "cyfansoddion elfennau hybrin", wedi ei awdurdodi dros dro fel ychwanegyn mewn maeth anifeiliaid, yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	Cobalt(II) asetad tetrahydrad
<i>Rhif adnabod yr ychwanegyn</i>	3b301
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Cyfansoddion elfennau hybrin
<i>Cyfansoddiad yr ychwanegyn</i>	Cobalt(II) asetad tetrahydrad <ul style="list-style-type: none"> • Crisialau/gronigion, yn cynnwys isafswm o 23% o gobalt • Gronynnau < 50 µm: islaw 1%
<i>Nodweddiad y sylwedd(au) actif</i>	Cobalt(II) asetad tetrahydrad <ul style="list-style-type: none"> • $\text{Co}(\text{CH}_3\text{COO})_2 \times 4\text{H}_2\text{O}$ • Rhif CAS⁽¹⁾: 6147-53-1
<i>Dulliau dadansoddi</i> ⁽²⁾	I adnabod asetad yn yr ychwanegyn: <ul style="list-style-type: none"> • Monograff 20301 yr <i>European Pharmacopoeia</i>⁽³⁾
	Ar gyfer nodweddiad crisialograffig yr ychwanegyn: <ul style="list-style-type: none"> • Diffreithiant pelydr-X
	I ganfod cyfanswm y cobalt yn yr ychwanegyn, y rhag-gymysgeddau, y bwyd anifeiliaid cyfansawdd a'r deunyddiau bwyd anifeiliaid: <ul style="list-style-type: none"> • Sbectrometreg allyriant (atomig) optegol â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017⁽⁴⁾), neu • Sbectrometreg allyriant (atomig) optegol â phlasma a gyplyswyd yn anwythol (ICP-AES) ar ôl treulio drwy bwysedd (BS EN 15621:2017⁽⁵⁾)
	I ganfod dosbarthiad maint gronynnau: <ul style="list-style-type: none"> • Dadansoddiad maint gronynnau — dulliau diffreithiant laser (BS ISO 13320:2020⁽⁶⁾)
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Anifeiliaid cnoi cil sydd â rwmn gweithredol • Equidae • Lagomorffiaid • Cnofilod • Ymlusgiaid sy'n llysysyddion • Mamaliaid sw
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys</i> ⁽⁷⁾	Dim
<i>Uchafswm cynnwys</i> ⁽⁷⁾	1 (cyfanswm)
<i>Darpariaethau eraill</i>	1. Rhaid ymgorffori'r ychwanegyn mewn bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd.

	<p>2. Rhaid datgan ar labeli'r ychwanegyn a'r rhag-gymysgedd gyfanswm yr elfen (cobalt) sydd wedi ei chynnwys.</p> <p>3. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar labeli'r ychwanegyn a'r rhag-gymysgedd:</p> <ul style="list-style-type: none"> • Yn Saesneg: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." • Yn Gymraeg: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet." <p>4. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar gyfarwyddiadau defnyddio'r bwyd anifeiliaid cyfansawdd:</p> <ul style="list-style-type: none"> • Yn Saesneg: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." • Yn Gymraeg: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
<i>Dechrau'r cyfnod awdurdodi dros dro</i>	15 Gorffennaf 2023
<i>Diwedd y cyfnod awdurdodi dros dro</i>	Diwedd 14 Gorffennaf 2028

⁽¹⁾ CAS Registry Number® a neilltuwyd i'r sylwedd 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/PRO/ag/ARES(2012)214390" dyddiedig 24 Chwefror 2012, ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

⁽³⁾ Monograff 20301: 2.3.1 "Identification reactions of ions and functional groups". *European Pharmacopoeia*, Cyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd, 11eg argraffiad. Cyhoeddwyd Gorffennaf 2022 (ISBN 978 92 871 9105 2). Ar gael gan *European Pharmacopoeia Online* <https://pheur.edqm.eu/home>.

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

⁽⁶⁾ O dan y cyfeirnod BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Gorffennaf 2020 (ISBN 978 0 580 92329 6). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

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

Ffurf awdurdodi dros dro cobalt(II) carbonad (rhif adnabod 3b302) fel
ychwanegyn bwyd anifeiliaid ar gyfer anifeiliaid cnoi cil sydd â rwmn
gweithredol, equidae, lagomorffiaid, cnofilod, ymlusgiaid sy'n llysysyddion,
a mamaliaid sw

Mae'r sylwedd cobalt(II) carbonad, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "cyfansoddion elfennau hybrin", wedi ei awdurdodi dros dro fel ychwanegyn mewn maeth anifeiliaid, yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	Cobalt(II) carbonad
<i>Rhif adnabod yr ychwanegyn</i>	3b302
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Cyfansoddion elfennau hybrin
<i>Cyfansoddiad yr ychwanegyn</i>	<p>Cobalt(II) carbonad</p> <ul style="list-style-type: none"> • Powdr, yn cynnwys isafswm o 46% o gobalt • Cobalt carbonad: isafswm o 75% • Cobalt hydrocsid: 3% - 15% • Dŵr: uchafswm o 6% • Gronynnau < 11 µm: islaw 90%
<i>Nodweddiad y sylwedd(au) actif</i>	<p>Cobalt(II) carbonad</p> <ul style="list-style-type: none"> • CoCO₃ • Rhif CAS⁽¹⁾: 513-79-1
<i>Dulliau dadansoddi⁽²⁾</i>	I adnabod carbonad yn yr ychwanegyn: <ul style="list-style-type: none"> • Monograff 20301 yr <i>European Pharmacopoeia</i>⁽³⁾
	Ar gyfer nodweddiad crisialograffig yr ychwanegyn: <ul style="list-style-type: none"> • Diffreithiant pelydr-X
	I ganfod cyfanswm y cobalt yn yr ychwanegyn, y rhag-gymysgeddau, y bwyd anifeiliaid cyfansawdd a'r deunyddiau bwyd anifeiliaid: <ul style="list-style-type: none"> • Sbectrometreg allyriant (atomig) optegol â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017⁽⁴⁾), neu • Sbectrometreg allyriant (atomig) optegol â phlasma a gyplyswyd yn anwythol (ICP-AES) ar ôl treulio drwy bwysedd (BS EN 15621:2017⁽⁵⁾)
	I ganfod dosbarthiad maint gronynnau: <ul style="list-style-type: none"> • Dadansoddiad maint gronynnau — dulliau diffreithiant laser (BS ISO 13320:2020⁽⁶⁾)
<i>Rhywogaeth neu categori o anifail</i>	<ul style="list-style-type: none"> • Anifeiliaid cnoi cil sydd â rwmn gweithredol • Equidae • Lagomorffiaid • Cnofilod • Ymlusgiaid sy'n llysysyddion • Mamaliaid sw
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁷⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁷⁾</i>	1 (cyfanswm)

<i>Darpariaethau eraill</i>	1. Rhaid ymgorffori'r ychwanegyn mewn bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd. Rhaid rhoi'r bwyd anifeiliaid cyfansawdd hwn ar y farchnad ar ffurf nad yw'n bowdr.
	2. Rhaid datgan ar labeli'r ychwanegyn a'r rhag-gymysgedd gyfanswm yr elfen (cobalt) sydd wedi ei chynnwys.
	3. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar labeli'r ychwanegyn a'r rhag-gymysgedd: <ul style="list-style-type: none"> • Yn Saesneg: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." • Yn Gymraeg: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet."
	4. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar gyfarwyddiadau defnyddio'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Yn Saesneg: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." • Yn Gymraeg: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
<i>Dechrau'r cyfnod awdurdodi dros dro</i>	15 Gorffennaf 2023
<i>Diwedd y cyfnod awdurdodi dros dro</i>	Diwedd 14 Gorffennaf 2028

(1) CAS Registry Number® a neilltuwyd i'r sylwedd 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/PRO/ag/ARES(2012)214390" dyddiedig 24 Chwefror 2012, ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograff 20301: 2.3.1 "Identification reactions of ions and functional groups". *European Pharmacopoeia*, Cyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd, 11eg argraffiad. Cyhoeddwyd Gorffennaf 2022 (ISBN 978 92 871 9105 2). Ar gael gan *European Pharmacopoeia Online* <https://pheur.edqm.eu/home>.

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

(6) O dan y cyfeirnod BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Gorffennaf 2020 (ISBN 978 0 580 92329 6). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

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

Ffurf awdurdodi dros dro cobalt(II) carbonad hydrocsid (2:3) monohydrad (rhif adnabod 3b303) fel ychwanegyn bwyd anifeiliaid ar gyfer anifeiliaid cnoi cil sydd â rwmn gweithredol, equidae, lagomorffiaid, cnofilod, ymlusgiaid sy'n llysysyddion, a mamaliaid sw

Mae'r sylwedd cobalt(II) carbonad hydrocsid (2:3) monohydrad, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "cyfansoddion elfennau hybrin", wedi ei awdurdodi dros dro fel ychwanegyn mewn maeth anifeiliaid, yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	Cobalt(II) carbonad hydrocsid (2:3) monohydrad
<i>Rhif adnabod yr ychwanegyn</i>	3b303
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Cyfansoddion elfennau hybrin
<i>Cyfansoddiad yr ychwanegyn</i>	Cobalt(II) carbonad hydrocsid (2:3) monohydrad <ul style="list-style-type: none"> • Powdr, yn cynnwys isafswm o 50% o gobalt • Gronynnau < 50 µm: islaw 98%
<i>Nodweddiad y sylwedd(au) actif</i>	Cobalt(II) carbonad hydrocsid (2:3) monohydrad <ul style="list-style-type: none"> • $2\text{CoCO}_3 \times 3\text{Co(OH)}_2 \times \text{H}_2\text{O}$ • Rhif CAS⁽¹⁾: 51839-24-8
<i>Dulliau dadansoddi⁽²⁾</i>	I adnabod carbonad yn yr ychwanegyn: <ul style="list-style-type: none"> • Monograff 20301 yr <i>European Pharmacopoeia</i>⁽³⁾
	Ar gyfer nodweddiad crisialograffig yr ychwanegyn: <ul style="list-style-type: none"> • Diffreithiant pelydr-X
	I ganfod cyfanswm y cobalt yn yr ychwanegyn, y rhag-gymysgeddau, y bwyd anifeiliaid cyfansawdd a'r deunyddiau bwyd anifeiliaid: <ul style="list-style-type: none"> • Sbectrometreg allyriant (atomig) optegol â phlasma a gyglyswyd yn anwythol (ICP-AES) (BS EN 15510:2017⁽⁴⁾), neu • Sbectrometreg allyriant (atomig) optegol â phlasma a gyglyswyd yn anwythol (ICP-AES) ar ôl treulio drwy bwysedd (BS EN 15621:2017⁽⁵⁾)
	I ganfod dosbarthiad maint gronynnau: <ul style="list-style-type: none"> • Dadansoddiad maint gronynnau — dulliau diffreithiant laser (BS ISO 13320:2020⁽⁶⁾)
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Anifeiliaid cnoi cil sydd â rwmn gweithredol • Equidae • Lagomorffiaid • Cnofilod • Ymlusgiaid sy'n llysysyddion • Mamaliaid sw
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁷⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁷⁾</i>	1 (cyfanswm)
<i>Darpariaethau eraill</i>	1. Rhaid ymgorffori'r ychwanegyn mewn bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd. Rhaid rhoi'r bwyd anifeiliaid cyfansawdd hwn ar y farchnad ar ffurf nad yw'n bowdr.

	<p>2. Rhaid datgan ar labeli'r ychwanegyn a'r rhag-gymysgedd gyfanswm yr elfen (cobalt) sydd wedi ei chynnwys.</p> <p>3. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar labeli'r ychwanegyn a'r rhag-gymysgedd:</p> <ul style="list-style-type: none"> • Yn Saesneg: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." • Yn Gymraeg: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet." <p>4. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar gyfarwyddiadau defnyddio'r bwyd anifeiliaid cyfansawdd:</p> <ul style="list-style-type: none"> • Yn Saesneg: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." • Yn Gymraeg: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
<i>Dechrau'r cyfnod awdurdodi dros dro</i>	15 Gorffennaf 2023
<i>Diwedd y cyfnod awdurdodi dros dro</i>	Diwedd 14 Gorffennaf 2028

(1) CAS Registry Number® a neilltuwyd i'r sylwedd 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/PRO/ag/ARES(2012)214390" dyddiedig 24 Chwefror 2012, ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograff 20301: 2.3.1 "Identification reactions of ions and functional groups". *European Pharmacopoeia*, Cyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd, 11eg argraffiad. Cyhoeddwyd Gorffennaf 2022 (ISBN 978 92 871 9105 2). Ar gael gan *European Pharmacopoeia Online* <https://pheur.edqm.eu/home>.

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

(6) O dan y cyfeirnod BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Gorffennaf 2020 (ISBN 978 0 580 92329 6). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

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

Ffurf awdurdodi dros dro cobalt(II) sylffad heptahydrad (rhif adnabod 3b305) fel ychwanegyn bwyd anifeiliaid ar gyfer anifeiliaid cnoi cil sydd â rwmen gweithredol, equidae, lagomorffiaid, cnofilod, ymlusgiaid sy'n llysysyddion, a mamaliaid sw

Mae'r sylwedd cobalt(II) sylffad heptahydrad, sy'n perthyn i'r categori ychwanegion "ychwanegion maethol" ac i'r grŵp gweithredol "cyfansoddion elfennau hybrin", wedi ei awdurdodi dros dro fel ychwanegyn mewn maeth anifeiliaid, yn ddarostyngedig i'r amodau a nodir yn y tabl.

<i>Yr ychwanegyn</i>	Cobalt(II) sylffad heptahydrad
<i>Rhif adnabod yr ychwanegyn</i>	3b305
<i>Deiliad yr awdurdodiad</i>	Dim un wedi ei bennu
<i>Categori ychwanegion</i>	Ychwanegion maethol
<i>Grŵp gweithredol</i>	Cyfansoddion elfennau hybrin
<i>Cyfansoddiad yr ychwanegyn</i>	Cobalt(II) sylffad heptahydrad <ul style="list-style-type: none"> • Powdr, yn cynnwys isafswm o 20% o gobalt • Gronynnau < 50 µm: islaw 95%
<i>Nodweddiad y sylwedd(au) actif</i>	Cobalt(II) sylffad heptahydrad <ul style="list-style-type: none"> • CoSO₄ × 7H₂O • Rhif CAS⁽¹⁾: 10026-24-1
<i>Dulliau dadansoddi⁽²⁾</i>	I adnabod sylffad yn yr ychwanegyn: <ul style="list-style-type: none"> • Monograff 20301 yr <i>European Pharmacopoeia</i>⁽³⁾
	Ar gyfer nodweddiad crisialograffig yr ychwanegyn: <ul style="list-style-type: none"> • Diffreithiant pelydr-X
	I ganfod cyfanswm y cobalt yn yr ychwanegyn, y rhag-gymysgeddau, y bwyd anifeiliaid cyfansawdd a'r deunyddiau bwyd anifeiliaid: <ul style="list-style-type: none"> • Sbectrometreg allyriant (atomig) optegol â phlasma a gyplyswyd yn anwythol (ICP-AES) (BS EN 15510:2017⁽⁴⁾), neu • Sbectrometreg allyriant (atomig) optegol â phlasma a gyplyswyd yn anwythol (ICP-AES) ar ôl treulio drwy bwysedd (BS EN 15621:2017⁽⁵⁾)
	I ganfod dosbarthiad maint gronynnau: <ul style="list-style-type: none"> • Dadansoddiad maint gronynnau — dulliau diffreithiant laser (BS ISO 13320:2020⁽⁶⁾)
<i>Rhywogaeth neu gategori o anifail</i>	<ul style="list-style-type: none"> • Anifeiliaid cnoi cil sydd â rwmen gweithredol • Equidae • Lagomorffiaid • Cnofilod • Ymlusgiaid sy'n llysysyddion • Mamaliaid sw
<i>Oedran hynaf</i>	Dim
<i>Isafswm cynnwys⁽⁷⁾</i>	Dim
<i>Uchafswm cynnwys⁽⁷⁾</i>	1 (cyfanswm)
<i>Darpariaethau eraill</i>	1. Rhaid ymgorffori'r ychwanegyn mewn bwyd anifeiliaid cyfansawdd ar ffurf rhag-gymysgedd. Rhaid rhoi'r bwyd anifeiliaid cyfansawdd hwn ar y farchnad ar ffurf nad yw'n bowdr.

	2. Rhaid datgan ar labeli'r ychwanegyn a'r rhag-gymysgedd gyfanswm yr elfen (cobalt) sydd wedi ei chynnwys.
	3. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar labeli'r ychwanegyn a'r rhag-gymysgedd: <ul style="list-style-type: none"> • Yn Saesneg: "It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account." • Yn Gymraeg: "Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet."
	4. Rhaid datgan y canlynol, yn Saesneg neu yn Gymraeg a Saesneg, ar gyfarwyddiadau defnyddio'r bwyd anifeiliaid cyfansawdd: <ul style="list-style-type: none"> • Yn Saesneg: "Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken." • Yn Gymraeg: "Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol."
<i>Dechrau'r cyfnod awdurdodi dros dro</i>	15 Gorffennaf 2023
<i>Diwedd y cyfnod awdurdodi dros dro</i>	Diwedd 14 Gorffennaf 2028

(1) CAS Registry Number® a neilltuwyd i'r sylwedd 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/PRO/ag/ARES(2012)214390" dyddiedig 24 Chwefror 2012, ac a ddiweddarwyd ddiwethaf ar 6 Mehefin 2016. Mae'r ddogfen hon ar gael ar y cyfeiriad a ganlyn: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograff 20301: 2.3.1 "Identification reactions of ions and functional groups". *European Pharmacopoeia*, Cyfarwyddiaeth Ewropeaidd ar gyfer Ansawdd Meddyginiaethau a Gofal Iechyd, 11eg argraffiad. Cyhoeddwyd Gorffennaf 2022 (ISBN 978 92 871 9105 2). Ar gael gan *European Pharmacopoeia Online* <https://pheur.edqm.eu/home>.

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

(6) O dan y cyfeirnod BS ISO 13320:2020 "Particle size analysis. Laser diffraction methods". Cyhoeddwyd gan y Sefydliad Safonau Prydeinig ar 31 Gorffennaf 2020 (ISBN 978 0 580 92329 6). Ar gael gan y Sefydliad Safonau Prydeinig <https://knowledge.bsigroup.com>.

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

SCHEDULE 1

Regulation 3(2)

Form of provisional authorisation of cobalt(II) acetate tetrahydrate (identification number 3b301) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) acetate tetrahydrate, belonging to the additive category “nutritional additives” and to the functional group “compounds of trace elements”, is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

<i>Additive</i>	Cobalt(II) acetate tetrahydrate
<i>Identification number of the additive</i>	3b301
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	Cobalt(II) acetate tetrahydrate <ul style="list-style-type: none"> • Crystals/granules, containing a minimum of 23% cobalt • Particles < 50 µm: below 1%
<i>Characterisation of the active substance(s)</i>	Cobalt(II) acetate tetrahydrate <ul style="list-style-type: none"> • $\text{Co}(\text{CH}_3\text{COO})_2 \times 4\text{H}_2\text{O}$ • CAS number⁽¹⁾: 6147-53-1
<i>Analytical methods</i> ⁽²⁾	For the identification of acetate in the additive: <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽³⁾
	For the crystallographic characterisation of the additive: <ul style="list-style-type: none"> • X-ray diffraction
	For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	For determination of particle size distribution: <ul style="list-style-type: none"> • Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Ruminants with a functional rumen • Equidae • Lagomorphs • Rodents • Herbivore reptiles • Zoo mammals
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	None
<i>Maximum content</i> ⁽⁷⁾	1 (total)
<i>Other provisions</i>	1. The additive must be incorporated into compound feed in the form of a premixture.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.

	<p>3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • In English: “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account.” • In Welsh: “Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet.”
	<p>4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed:</p> <ul style="list-style-type: none"> • In English: “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.” • In Welsh: “Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol.”
<i>Start of provisional authorisation period</i>	15 July 2023
<i>End of provisional authorisation period</i>	End of 14 July 2028

(1) CAS Registry Number® assigned to this substance 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/FSQ/CvH/PRO/ag/ARES(2012)214390” dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograph 20301: 2.3.1. “Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.

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

(6) Under reference BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

SCHEDULE 2

Regulation 3(3)

Form of provisional authorisation of cobalt(II) carbonate (identification number 3b302) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) carbonate, belonging to the additive category “nutritional additives” and to the functional group “compounds of trace elements”, is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

<i>Additive</i>	Cobalt(II) carbonate
<i>Identification number of the additive</i>	3b302
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	<p>Cobalt(II) carbonate</p> <ul style="list-style-type: none"> • Powder, containing a minimum of 46% cobalt • Cobalt carbonate: minimum 75% • Cobalt hydroxide: 3% - 15% • Water: maximum 6% • Particles < 11 µm: below 90%
<i>Characterisation of the active substance(s)</i>	<p>Cobalt(II) carbonate</p> <ul style="list-style-type: none"> • CoCO₃ • CAS number⁽¹⁾: 513-79-1
<i>Analytical methods</i> ⁽²⁾	For the identification of carbonate in the additive: <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽³⁾
	For the crystallographic characterisation of the additive: <ul style="list-style-type: none"> • X-ray diffraction
	For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	For determination of particle size distribution: <ul style="list-style-type: none"> • Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Ruminants with a functional rumen • Equidae • Lagomorphs • Rodents • Herbivore reptiles • Zoo mammals
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	None
<i>Maximum content</i> ⁽⁷⁾	1 (total)
<i>Other provisions</i>	1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.

	<p>2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.</p> <p>3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • In English: “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account.” • In Welsh: “Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet.” <p>4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed:</p> <ul style="list-style-type: none"> • In English: “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.” • In Welsh: “Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol.”
<i>Start of provisional authorisation period</i>	15 July 2023
<i>End of provisional authorisation period</i>	End of 14 July 2028

(1) CAS Registry Number® assigned to this substance 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/FSQ/CvH/PRO/ag/ARES(2012)214390” dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograph 20301: 2.3.1. “Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.

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

(6) Under reference BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

SCHEDULE 3

Regulation 3(4)

Form of provisional authorisation of cobalt(II) carbonate hydroxide (2:3) monohydrate (identification number 3b303) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) carbonate hydroxide (2:3) monohydrate, belonging to the additive category “nutritional additives” and to the functional group “compounds of trace elements”, is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

<i>Additive</i>	Cobalt(II) carbonate hydroxide (2:3) monohydrate
<i>Identification number of the additive</i>	3b303
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	<p>Cobalt(II) carbonate hydroxide (2:3) monohydrate</p> <ul style="list-style-type: none"> • Powder, containing a minimum of 50% cobalt • Particles < 50 µm: below 98%
<i>Characterisation of the active substance(s)</i>	<p>Cobalt(II) carbonate hydroxide (2:3) monohydrate</p> <ul style="list-style-type: none"> • $2\text{CoCO}_3 \times 3\text{Co}(\text{OH})_2 \times \text{H}_2\text{O}$ • CAS number⁽¹⁾: 51839-24-8
<i>Analytical methods</i> ⁽²⁾	<p>For the identification of carbonate in the additive:</p> <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽³⁾
	<p>For the crystallographic characterisation of the additive:</p> <ul style="list-style-type: none"> • X-ray diffraction
	<p>For the determination of total cobalt in the additive, premixtures, compound feed and feed materials:</p> <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	<p>For determination of particle size distribution:</p> <ul style="list-style-type: none"> • Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Ruminants with a functional rumen • Equidae • Lagomorphs • Rodents • Herbivore reptiles • Zoo mammals
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	None
<i>Maximum content</i> ⁽⁷⁾	1 (total)
<i>Other provisions</i>	1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.

	<p>3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • In English: “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account.” • In Welsh: “Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet.”
	<p>4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed:</p> <ul style="list-style-type: none"> • In English: “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.” • In Welsh: “Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol.”
<i>Start of provisional authorisation period</i>	15 July 2023
<i>End of provisional authorisation period</i>	End of 14 July 2028

(1) CAS Registry Number® assigned to this substance 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/FSQ/CvH/PRO/ag/ARES(2012)214390” dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograph 20301: 2.3.1. “Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.

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

(6) Under reference BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

SCHEDULE 4

Regulation 3(5)

Form of provisional authorisation of cobalt(II) sulphate heptahydrate (identification number 3b305) as a feed additive for ruminants with a functional rumen, equidae, lagomorphs, rodents, herbivore reptiles, and zoo mammals

The substance cobalt(II) sulphate heptahydrate, belonging to the additive category “nutritional additives” and to the functional group “compounds of trace elements”, is provisionally authorised as an additive in animal nutrition, subject to the conditions set out in the table.

<i>Additive</i>	Cobalt(II) sulphate heptahydrate
<i>Identification number of the additive</i>	3b305
<i>Authorisation holder</i>	None specified
<i>Additive category</i>	Nutritional additives
<i>Functional group</i>	Compounds of trace elements
<i>Additive composition</i>	<p>Cobalt(II) sulphate heptahydrate</p> <ul style="list-style-type: none"> • Powder, containing a minimum of 20% cobalt • Particles < 50 µm: below 95%
<i>Characterisation of the active substance(s)</i>	<p>Cobalt(II) sulphate heptahydrate</p> <ul style="list-style-type: none"> • $\text{CoSO}_4 \times 7\text{H}_2\text{O}$ • CAS number⁽¹⁾: 10026-24-1
<i>Analytical methods</i> ⁽²⁾	For the identification of sulphate in the additive: <ul style="list-style-type: none"> • European Pharmacopoeia monograph 20301⁽³⁾
	For the crystallographic characterisation of the additive: <ul style="list-style-type: none"> • X-ray diffraction
	For the determination of total cobalt in the additive, premixtures, compound feed and feed materials: <ul style="list-style-type: none"> • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) (BS EN 15510:2017⁽⁴⁾), or • Inductively coupled plasma optical (atomic) emission spectrometry (ICP-AES) after pressure digestion (BS EN 15621:2017⁽⁵⁾)
	For determination of particle size distribution: <ul style="list-style-type: none"> • Particle size analysis — Laser diffraction methods (BS ISO 13320:2020⁽⁶⁾)
<i>Species or category of animal</i>	<ul style="list-style-type: none"> • Ruminants with a functional rumen • Equidae • Lagomorphs • Rodents • Herbivore reptiles • Zoo mammals
<i>Maximum age</i>	None
<i>Minimum content</i> ⁽⁷⁾	None
<i>Maximum content</i> ⁽⁷⁾	1 (total)
<i>Other provisions</i>	1. The additive must be incorporated into compound feed in the form of a premixture. This compound feed must be placed on the market in a non-powder form.
	2. The total element (cobalt) content must be stated on the labelling of the additive and premixture.

	<p>3. The following must be stated, in English or in English and Welsh, on the labelling of the additive and premixture:</p> <ul style="list-style-type: none"> • In English: “It is recommended to limit the supplementation with cobalt to 0.3 mg/kg in complete feed. In this context, the risk for cobalt deficiency due to local conditions and the specific composition of the diet should be taken into account.” • In Welsh: “Argymhellir cyfyngu ar atchwanegu â chobalt i 0.3 mg/kg mewn bwyd anifeiliaid cyflawn. Yn y cyd-destun hwn, dylid ystyried y risg o ddiffyg cobalt oherwydd amodau lleol a chyfansoddiad penodol y deiet.”
	<p>4. The following must be stated, in English or in English and Welsh, on the instructions of use of the compound feed:</p> <ul style="list-style-type: none"> • In English: “Protective measures to avoid exposure with cobalt by inhalation or by dermal route should be taken.” • In Welsh: “Dylid cymryd mesurau diogelu i osgoi dod i gysylltiad â chobalt drwy fewnanadlu neu drwy lwybr croenol.”
<i>Start of provisional authorisation period</i>	15 July 2023
<i>End of provisional authorisation period</i>	End of 14 July 2028

(1) CAS Registry Number® assigned to this substance 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/FSQ/CvH/PRO/ag/ARES(2012)214390” dated 24 February 2012, and last updated on 6 June 2016. This document is available at the following address: https://joint-research-centre.ec.europa.eu/publications/fad-cobalt-group_en.

(3) Monograph 20301: 2.3.1. “Identification reactions of ions and functional groups”. European Pharmacopoeia, European Directorate for the Quality of Medicines and Healthcare, 11th edition. Published July 2022 (ISBN 978 92 871 9105 2). Available from European Pharmacopoeia Online <https://pheur.edqm.eu/home>.

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(6) Under reference BS ISO 13320:2020 “Particle size analysis. Laser diffraction methods”. Published by the British Standards Institution on 31 July 2020 (ISBN 978 0 580 92329 6). Available from the British Standards Institution <https://knowledge.bsigroup.com>.

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

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