Agenda – Y Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol

Lleoliad:
Ystafell Bwyllgora 1 – Y Senedd
Dyddiad: Dydd Llun, 3 Rhagfyr 2018
Amser: 14.30

I gael rhagor o wybodaeth cysylltwch a:
Gareth Williams
Clerc y Pwyllgor
0300 200 6362
SeneddMCD@cynulliad.cymru

1 Cyflwyniad, ymddiheuriadau, dirprwyon a datgan buddiannau

2 Offerynnau nad ydynt yn cynnwys materion i gyflwyno adroddiad arnynt o dan Reol Sefydlog 21.2 na 21.3

(Tudalennau 1 – 2)

CLA(5)-31-18 – Papur 1 – Offerynnau statudol sydd ag adroddiadau clir

Offerynnau'r Penderfyniad Negyddol

2.1 **SL(5)282 – Rheoliadau Cyfraniadau Ardrethu Annomestig (Cymru) (Diwygio) 2018**

2.2 **CLA283 – Gorchymyn Ardrethu Annomestig (Rhyddhad Ardrethi i Fusnesau Bach) (Cymru) (Diwygio) 2018**

3 Offerynnau nad ydynt yn cynnwys materion i gyflwyno adroddiad arnynt o dan Reol Sefydlog 21.2 na 21.3 ond sydd â goblygiadau o ganlyniad i ymadawiad y DU â'r UE

Offerynnau'r Penderfyniad Negyddol

3.1 **SL(5)281 – Rheoliadau Labelu Cig Eidion a Chig Llo (Cymru) (Diwygio) 2018**

(Tudalen 3)

CLA(5)-31-18 – Papur 2 – Adroddiad

4 Offerynnau Statudol sy'n gofyn am Ganiatâd yn unol â Rheol Sefydlog 30A - Ymadael yr UE

4.1 SICM(5)6 - Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019

(Tudalennau 4 - 38)

CLA(5)-27-18 - Papur 3 - Llythyr gan Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol

CLA(5)-27-18 - Papur 4 - Datganiad Ysgrifenedig Llywodraeth Cymru: Hysbysiad mewn perthynas ag Offerynnau Statudol a wneir gan Weinidogion y DU mewn meysydd datganoledig o dan Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 na chânt eu gosod gerbron y Cynulliad

CLA(5)-27-18 - Papur 5 - Memorandwm Cydsyniad Offeryn Statudol

CLA(5)-27-18 - Papur 6 - Rheoliadau

CLA(5)-27-18 - Papur 7 - Memorandwm Esboniadol

CLA(5)-31-18 - Papur 8 - Sylwebaeth

4.2 SICM(5)7 - Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019

(Tudalennau 39 - 69)

CLA(5)-27-18 - Papur 9 - Llythyr gan Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol

CLA(5)-27-18 - Papur 10 - Datganiad Ysgrifenedig Llywodraeth Cymru: Hysbysiad mewn perthynas ag Offerynnau Statudol a wneir gan Weinidogion y DU mewn meysydd datganoledig o dan Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 na chânt eu gosod gerbron y Cynulliad

CLA(5)-27-18 - Papur 11 - Memorandwm Cydsyniad Offeryn Statudol

CLA(5)-27-18 - Papur 12 - Rheoliadau

CLA(5)-27-18 - Papur 13 - Memorandwm Esboniadol

CLA(5)-31-18 - Papur 14 - Sylwebaeth

5 Datganiadau ysgrifenedig o dan Reol Sefydlog 30C

5.1 WS-30C(5)24 - Rheoliadau Trapiau Dal Coesau a Mewnforio Crwyn (Diwygio etc.) (Ymadael â'r UE) 2018

(Tudalennau 70 - 73)

CLA(5)-31-18 - Papur 15 - Datganiad

CLA(5)-31-18 - Papur 16 - Sylwebaeth

5.2 WS-30c(5)25 - Rheoliadau Anifeiliaid Ceffylaidd (Cofnodion, Adnabod a Symud) (Diwygio) (Ymadael â'r UE) 2018

(Tudalennau 74 - 77)

CLA(5)-31-18 - Papur 17 - Datganiad

CLA(5)-31-18 - Papur 18 - Sylwebaeth

5.3 WS-30C(5)26 - Rheoliadau Diogelwch ac Ansawdd Gwaed (Diwygiad) (Ymadael â'r UE) 2019

(Tudalennau 78 - 81)

CLA(5)-31-18 - Papur 19 - Datganiad

CLA(5)-31-18 - Papur 20 - Sylwebaeth

5.4 WS-30C(5)27 - Rheoliadau Cynhyrchion Organig (Diwygio) (Ymadael â'r UE) 2018

(Tudalennau 82 - 84)

CLA(5)-31-18 - Papur 21 - Datganiad

CLA(5)-31-18 - Papur 22 - Sylwebaeth

5.5 WS-30C(5)28 - Rheoliadau Dileu a Rheoli Afiechydon Milheintiol (Diwygio) (Ymadael â'r UE) 2018

(Tudalennau 85 - 88)

CLA(5)-31-18 - Papur 23 - Datganiad

CLA(5)-31-18 - Papur 24 - Sylwebaeth

5.6 **WS-30C(5)30 - Rheoliadau Rheolau Darpariaethau Cyffredin y Cronfeydd Strwythurol a Buddsoddi Ewropeaidd etc. (Diwygio etc.) (Ymadael â'r UE) 2018**

(Tudalennau 89 - 92)

CLA(5)-31-18 - Papur 25 - Datganiad

CLA(5)-31-18 - Papur 26 - Sylwebaeth

6 Papurau i'w nodi

6.1 **Llythyr gan y Llywydd ynghylch diwygio'r Cynulliad: cymhwysedd deddfwriaethol**

(Tudalennau 93 - 96)

CLA(5)-31-18 - Papur 27 - Llythyr gan y Llywydd

6.2 **Gohebiaeth rhwng Senedd y DU a Llywodraeth y DU ynghylch llif offerynnau o dan Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018**

(Tudalennau 97 - 104)

CLA(5)-31-18 - Papur 28 - Llythyr gan Gadeiryddion y Pwyllgor Gweithdrefnau, y Pwyllgor Offerynnau Statudol Ewropeaidd a Phwyllgor Tŷ'r Arglwyddi ar gyfer Craffu ar Is-ddeddfwriaeth at bob Adran ynghylch llif offerynnau o dan Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018

CLA(5)-31-18 - Papur 29 - Llythyr gan Arweinydd y Tŷ a Chris Heaton Harris AS, at y Pwyllgor Gweithdrefnau, y Pwyllgor Offerynnau Statudol Ewropeaidd a Phwyllgor Tŷ'r Arglwyddi ar gyfer Craffu ar Is-ddeddfwriaeth ynghylch llif offerynnau o dan Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018

6.3 **Llythyr gan Ysgrifennydd y Cabinet dros Gyllid: Y Fforwm Rhyngseneddol ar Brexit**

(Tudalennau 105 - 106)

CLA(5)-31-18 - Papur 30 - Llythyr gan Ysgrifennydd y Cabinet dros Gyllid: Y Fforwm Rhyngseneddol ar Brexit

7 Cynnig o dan Reol Sefydlog 17.42 i benderfynu gwahardd y cyhoedd o'r cyfarfod ar gyfer y mater a ganlyn:

8 Memorandwm Cydsyniad Deddfwriaethol: Bil Amaethyddiaeth y DU : Adroddiad Drafft

(Tudalennau 107 - 133)

CLA(5)-31-18 - Papur 31 - Adroddiad Drafft

9 Cynnig Cydsyniad Deddfwriaethol: Bil Gofal Iechyd (Trefniadau Rhyngwladol)

(Tudalennau 134 - 143)

CLA(5)-31-18 - Papur 32 - Papur briffio gan y Gwasanaeth Ymchwil

CLA(5)-31-18 - Papur 32 a - Memorandwm Cydsyniad Deddfwriaethol

10 Memorandwm Cydsyniad Deddfwriaethol: Bil Pysgodfeydd

(Tudalennau 144 - 155)

CLA(5)-31-18 - Papur 33 - Papur briffio gan y Gwasanaeth Ymchwil

CLA(5)-31-18 - Paper 33a - Memorandwm Cydsyniad Deddfwriaethol

11 Bil Deddfwriaeth: Dull craffu Cyfnod 1 (yn amodol ar gyflwyno'r Bil)

CLA(5)-31-18 - Papur 34 - Dull o graffu

CLA(5)-31-18 - Papur 35 - Papur briffio gan y Gwasanaeth Ymchwil - Crynodeb o'r ymatebion i ymgynghoriad Llywodraeth Cymru ar y Bil drafft

12 Blaenraglen Waith

Offerynnau Statudol sydd ag Adroddiadau Clir

03 Rhagfyr 2018

SL(5)282 – Rheoliadau Cyfraniadau Ardrethu Annomestig (Cymru) (Diwygio) 2018

Gweithdrefn: Negyddol

Mae'r Rheoliadau hyn, sy'n gymwys mewn perthynas â Chymru, yn diwygio Rheoliadau Cyfraniadau Ardrethu Annomestig (Cymru) (Diwygio) 1992 ("Rheoliadau 1992").

O dan Ran II o Atodlen 8 i Ddeddf Cyllid Llywodraeth Leol 1988, mae'n ofynnol i awdurdodau bilio (yng Nghymru, cynghorau sir a chynghorau bwrdeistref sirol) dalu symiau (a elwir yn gyfraniadau ardrethu annomestig) i Weinidogion Cymru. Mae Rheoliadau 1992 yn cynnwys rheolau ar gyfer cyfrifo'r cyfraniadau hynny ar gyfer awdurdodau bilio Cymru.

Mae'r Rheoliadau hyn yn diwygio Rheoliadau 1992 drwy roi Atodlen 4 newydd (Ffigurau Poblogaeth Oedolion), yn cynnwys ffigyrau poblogaeth oedolion wedi'u diweddaru ar gyfer pob awdurdod bilio, yn lle'r un bresennol.

Rhiant-Ddeddf: Deddf Cyllid Llywodraeth Leol 1988

Fe'u gwnaed ar: 15 Tachwedd 2018

Fe'u gosodwyd ar: 20 Tachwedd 2018

Yn dod i rym ar: 31 Rhagfyr 2018

SL(5)283 – Gorchymyn Ardrethu Annomestig (Rhyddhad Ardrethi i Fusnesau Bach) (Cymru) (Diwygio) 2018

Gweithdrefn: Negyddol

Mae Gorchymyn 2017 yn darparu ar gyfer cynllun rhyddhad ardrethi annomestig sy'n gymwys i gategorïau penodol o hereditamentau.

Mae'r Gorchymyn hwn yn cynyddu uchafswm y gwerth ardrethol ar gyfer hereditamentau sy'n bodloni'r amodau gofal plant a nodir yn Erthygl 8 o Orchymyn 2017 i £100,000.

Effaith y diwygiadau a wneir gan y Gorchymyn hwn yw eithrio pob hereditament sy'n bodloni'r amodau gofal plant a nodir yn Erthygl 8 o Orchymyn 2017 rhag talu ardrethi annomestig.

Rhiant-Ddeddf: Deddf Cyllid Llywodraeth Leol 1988

Fe'u gwnaed ar: 15 Tachwedd 2018

Fe'u gosodwyd ar: 20 Tachwedd 2018

Yn dod i rym ar: 19 Rhagfyr 2018

SL(5)281 - Rheoliadau Labelu Cig Eidion a Chig Llo (Cymru) (Diwygio) 2018

Cefndir a Diben

Gwneir y Rheoliadau hyn drwy arfer y pwerau sydd wedi'u cynnwys yn adran 2(2) o Ddeddf y Cymunedau Ewropeaidd 1972.

Mae'r Rheoliadau yn gwneud diwygiadau technegol i Reoliadau Labelu Cig Eidion a Chig Llo (Cymru) 2011 (OS 2011/991) i adlewyrchu darpariaethau yn Rheoliad (UE) Rhif 653/2014 Senedd Ewrop a'r Cyngor sy'n diwygio Rheoliad (EC) Rhif 1760 / 2000 o ran adnabod electronig o ran anifeiliaid buchol a labelu cig eidion.

Y weithdrefn

Negyddol.

Materion technegol: craffu

Ni nodir unrhyw bwyntiau i gyflwyno adroddiad arnynt o dan Reol Sefydlog 21.2 mewn perthynas â'r offeryn hwn.

Rhinweddau: craffu

Ni nodwyd unrhyw bwyntiau i gyflwyno adroddiad arnynt o dan Reol Sefydlog 21.3 mewn perthynas â'r offeryn hwn.

Y goblygiadau yn sgil gadael yr Undeb Ewropeaidd

Mae'r Rheoliadau hyn yn gweithredu rhwymedigaethau'r UE mewn perthynas â labelu bwyd, ac felly bydd y Rheoliadau hyn yn rhan o gyfraith yr UE a ddargedwir ar ôl y diwrnod ymadael.

Mae'r Cytundeb Rhynglywodraethol ar Fil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin yn nodi bod labelu bwyd yn faes polisi sy'n debygol o fod yn ddarostyngedig i reoliadau a wneir o dan adran 12 o Ddeddf yr UE (Ymadael) 2018. Felly, mae'r gyfraith sy'n dod o dan y Rheoliadau hyn yn debygol o fod yn faes o gyfraith yr UE sy'n cael ei rewi tra bod fframweithiau cyffredin yn cael eu rhoi ar waith.

Ymateb y Llywodraeth

Nid oes angen ymateb y llywodraeth.

Cynghorwyr Cyfreithiol
Y Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol
28 Tachwedd 2018

Vaughan Gething AC/AM
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol
Cabinet Secretary for Health and Social Services

Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: MA-L/VG/0675/18

Mick Antoniw AC
Cadeirydd
Y Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol
Cynulliad Cenedlaethol Cymru

22 Tachwedd 2018

Annwyl Mick,

Rwy'n ysgrifennu i'ch hysbysu fy mod wedi gosod dau Memorandwm Cydsyniad Offeryn Statudol yng Nghynulliad Cenedlaethol Cymru mewn perthynas â:

- **Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019, a**

- **Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019**

yn unol â'r gofyniad o dan Reol Sefydlog 30A (RhS30A).

Rwy'n ysgrifennu i roi gwybod ichi hefyd nad wyf, yn yr achos hwn yn bwriadu gosod cynnig i gynnal dadl arno ynglŷn â'r OS. Gwneuthum y penderfyniad hwnnw ar y sail bod yr OS wedi'i gyfyngu i wneud cywiriadau i'r diffygion yn y gyfraith a fydd yn codi o ganlyniad i ymadawiad y DU â'r UE. Mae darpariaethau'r OS yn rhai technegol, ac nid oes gwahaniaeth polisi rhwng Llywodraeth Cymru a Llywodraeth y DU yn yr achos hwn.

Mae RhS30A yn darparu y caiff unrhyw Aelod osod cynnig i gynnal dadl ar yr OS hwn. O ystyried cymaint o ddeddfwriaeth y mae'r Cynulliad yn ei ystyried, nid wyf yn credu y byddai cynnal dadl ar yr OS hwn yn ddefnydd cynhyrchiol o amser gwerthfawr yn y Cyfarfod Llawn ac ni fyddaf i fy hun yn mynd ati i ysgogi dadl o'r fath.

Yn gywir,

Vaughan Gething

Vaughan Gething AC/AM
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol
Cabinet Secretary for Health and Social Services

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1NA

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Gohebiaeth.Vaughan.Gething@llyw.cymru
Correspondence.Vaughan.Gething@gov.wales

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL	**Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019**
DYDDIAD	**22 Tachwedd 2018**
GAN	**Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019 ("y Rheoliadau")

Cyfraith [yr UE a ddargedwir] sy'n cael ei diwygio
Bydd y rheoliadau'n diwygio:

(a) Deddf Meinweoedd Dynol 2004
(b) Rheoliadau Deddf Meinweoedd Dynol 2004 (Cymeradwyaeth Foesegol, Eithriadau rhag Trwyddedu a Chyflenwi Gwybodaeth am Drawsblaniadau) 2006; a
(c) Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) 2007.

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu gymhwysedd gweithredol Gweinidogion Cymru
Mae'r OS yn rhoi pwerau i'r Ysgrifennydd Gwladol ac i Weinidogion Cymru mewn perthynas â rhai gofynion ansawdd, diogelwch a gofynion technegol yn ymwneud â rhoi meinweoedd. Nid oes effaith ar gymhwysedd deddfwriaethol y Cynulliad na chymhwysedd gweithredol Gweinidogion Cymru.

Byddai swyddogaethau a drosglwyddid i'r Ysgrifennydd Gwladol gyda chydsyniad yn golygu swyddogaethau Gweinidog y Goron at ddibenion Atodlen 7B i Ddeddf Llywodraeth Cymru 2006. Gallai hyn, felly, fod yn ystyriaeth berthnasol yng nghyd-destun cymhwysedd y Cynulliad i ddeddfu yn y meysydd hyn yn y dyfodol.

Diben y diwygiadau
Diben y diwygiadau hyn yw cywiro diffygion mewn deddfwriaeth sy'n ymwneud â meinweoedd dynol sy'n deillio o ymadawiad y DU â'r Undeb Ewropeaidd.

Mae Rheoliad 3 yn diwygio Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) 2007 i fewnosod adran newydd yn ymwneud â'r gallu i

olrhain, ansawdd a diogelwch mewnforion, hysbysu digwyddiadau ac adweithiau andwyol difrifol, ac amrywiol ofynion technegol. Mae'r rheoliad newydd yn datgan y caiff yr awdurdod priodol bennu'r gofynion yn y meysydd hyn. Diffinnir yr awdurdod priodol mewn perthynas â Chymru fel Gweinidogion Cymru neu'r Ysgrifennydd Gwladol yn gweithredu gyda chydsyniad Gweinidogion Cymru. Byddai'r rheoliadau hyn yn pennu'r gweithdrefnau ar gyfer sicrhau bod modd olrhain yr holl feinweoedd a chelloedd sy'n cael eu caffael, eu prosesu, eu storio neu eu dosbarthu yn y DU, yr holl ddata perthnasol sy'n dod i gysylltiad â'r meinweoedd a'r celloedd hynny, o'r rhoddwr i'r derbynnydd ac fel arall a gofynion technegol, gan gynnwys trwyddedu neu awdurdodi sefydliadau meinweoedd; systemau ansawdd; hyfforddiant; a meysydd eraill.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma:
http://www.legislation.gov.uk/ukdsi/2019/9780111174821/contents

Pam y rhoddwyd cydsyniad
Nid oes gwahaniaeth rhwng Llywodraeth Cymru a Llywodraeth y DU o ran y polisi ar gyfer y cywiriad. O ganlyniad, byddai gwneud OS ar wahân yng Nghymru ac yn Lloegr yn arwain at ddyblygu gwaith a chymhlethdod diangen i'r llyfr statud. Mae cydsynio i OS ar draws y DU yn sicrhau bod un fframwaith deddfwriaethol ar draws y DU sy'n hybu eglurder a hygyrchedd yn ystod y cyfnod hwn o newid. O dan yr amgylchiadau eithriadol hyn, mae Llywodraeth Cymru yn ystyried ei bod yn briodol i Lywodraeth y DU ddeddfu ar ein rhan yn yr achos hwn.

Mae Memorandwm Cydsyniad Offeryn Statudol hefyd wedi'i osod yn y Cynulliad Cenedlaethol mewn perthynas â'r diwygiadau i Ddeddf Meinweoedd Dynol 2004.

MEMORANDWM CYDSYNIAD OFFERYN STATUDOL

Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019

1. Gosodir y Memorandwm Cydsyniad Offeryn Statudol hwn o dan Reol Sefydlog ("RhS") 30A. Mae RhS 30A yn rhagnodi bod rhaid gosod Memorandwm Cydsyniad Offeryn Statudol, ac y ceir cyflwyno Cynnig Cydsyniad Offeryn Statudol, gerbron y Cynulliad Cenedlaethol os yw un o Offerynnau Statudol (OS) y DU yn gwneud darpariaeth mewn perthynas â Chymru sy'n diwygio deddfwriaeth sylfaenol sydd o fewn cymhwysedd deddfwriaethol y Cynulliad.

2. Cyflwynwyd Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019 gerbron Senedd y DU ar 19 Tachwedd 2018 ac mae'n cael ei osod gerbron y Cynulliad yn awr. Mae'r gorchymyn ar gael yn:

http://www.legislation.gov.uk/ukdsi/2019/9780111174821/contents

Crynodeb o'r Offeryn Statudol a'i nod

3. Nod yr OS yw cywiro diffygion mewn deddfwriaeth sy'n codi wrth i'r DU ymadael â'r Undeb Ewropeaidd, mewn perthynas ag ansawdd a diogelwch meinweoedd a chelloedd dynol.

4. Mae'r OS hwn yn gwneud cywiriadau technegol i Deddf Meinweoedd Dynol 2004. Mae gofyn gwneud y cywiriadau hyn er mwyn sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE.

Y ddarpariaeth berthnasol sydd i'w gwneud gan yr OS

5. Mae'r Rheoliadau hyn yn diwygio Deddf Meinweoedd Dynol 2004 sy'n gymwys i Gymru, Lloegr a Gogledd Iwerddon, i wneud mân ddiwygiad technegol i ddileu adran 46; pŵer i roi effaith i rwymedigaethau'r UE.

6. Mae Llywodraeth Cymru o'r farn fod y darpariaethau a ddisgrifir ym mharagraff 5 uchod o fewn cymhwysedd deddfwriaethol Cynulliad Cenedlaethol Cymru i'r graddau y maent yn ymwneud ag ansawdd a diogelwch meinweoedd a chelloedd dynol.

Pam y mae'n briodol i'r OS wneud y ddarpariaeth hon

7. Nid oes gwahaniaeth rhwng Llywodraeth Cymru a Llywodraeth y DU o ran y polisi ar gyfer y cywiriad. Felly, byddai gwneud OSau ar wahân yng Nghymru ac yn Lloegr yn arwain at ddyblygu gwaith a

chymhlethdod diangen i'r llyfr statud. Mae cydsynio i OS ar draws y DU yn sicrhau bod un fframwaith deddfwriaethol ar draws y DU sy'n hybu eglurder a hygyrchedd yn ystod y cyfnod hwn o newid. O dan yr amgylchiadau eithriadol hyn, mae Llywodraeth Cymru yn ystyried ei bod yn briodol i Lywodraeth y DU ddeddfu ar ein rhan yn yr achos hwn.

Vaughan Gething AC
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol

22 Tachwedd 2018

Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2019 No. XXX

EXITING THE EUROPEAN UNION

HUMAN TISSUE

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018(**a**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

PART 2

Amendment of primary legislation

Amendment of the Human Tissue Act 2004

2.—(1) The Human Tissue Act 2004(**b**) is amended as follows.

(2) Omit section 46 (power to give effect to EU obligations).

(3) In section 52 (orders and regulations)—

(**a**) 2018 c. 16.
(**b**) 2004 c. 30. Section 46 was amended by S.I. 2011/1043; amendments to section 52 are not relevant to these Regulations.

(a) in subsection (3) omit ", 46(1)";

(b) in subsection (4) for ", 33(3) or (7) or 46(1)" substitute "or 33(3) or (7)";

(c) in subsections (8) and (10) omit "section 46(1);".

PART 2

Amendment of subordinate legislation

Amendment of the Human Tissue (Quality and Safety for Human Application) Regulations 2007

3.—(1) The Human Tissue (Quality and Safety for Human Application) Regulations 2007(**a**) are amended as follows.

(2) Omit regulation 3(**b**) (designation of the competent authority).

(3) In regulation 4(**c**) (references to Directives), in the definition of "the third Directive", for "as amended by Commission Directive 2015/565/EU" substitute "as it had effect immediately before 29th April 2015 (the date on which the amendments made by Commission Directive 2015/565/EU came into force)".

(4) After regulation 4 (references to Directives), insert—

"**Modifications to the first, second, third and fourth Directives: general**

4A. For the purposes of these Regulations, the first, second, third and fourth Directives are to be read subject to the modifications set out in regulations 4B to 4E.

Modifications to the first Directive

4B.—(1) The modifications to the first Directive are as follows.

(2) Article 8 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(ii) for "on their territory" there were substituted "in the United Kingdom";

(iii) paragraphs 2, 3, 5 and 6 were omitted.

(3) Article 10(1) is to be read as if—

(a) for the reference to "the requirements referred to in Article 28(f)" there were substituted "the requirements referred to in paragraph 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) the reference to the competent authority or authorities were a reference to the Authority;

(c) for "an annual report on these activities" there were substituted "a report on these activities upon request";

(d) the words "This report shall be publicly accessible" were omitted.

(4) Article 14 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(**a**) S.I. 2007/1523, amended by S.I. 2018/335; there are other amending instruments but none is relevant.
(**b**) Regulation 3 was amended by S.I. 2018/335.
(**c**) Relevant amendments to regulation 4 were made by S.I. 2018/335.

(ii) for "within the scope of this Directive" there were substituted "in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 2, the reference to Member States were a reference to the Authority;

(c) in paragraph 3—

(i) the first reference to Member States were a reference to the Authority;

(ii) "in Member States" were omitted.

(5) Article 15 is to be read as if paragraphs 1, 2 and 4 were omitted.

(6) Article 19(5) is to be read as if the words ", in accordance with Article 8" were omitted.

(7) Article 20 is to be read as if, in paragraph 1, the reference to Article 28(h) were a reference to the requirements of Annex 2 of the third Directive listed in paragraph 14 of Schedule 2 to these Regulations.

(8) Article 21 is to be read as if—

(a) in paragraph 4, for "laid down in this Directive" there were substituted "of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 5—

(i) the first reference to Member States were a reference to the Authority;

(ii) the reference to a tissue establishment accredited, designated, authorised or licensed in accordance with Article 6 were a reference to a tissue establishment authorised or licensed in accordance with the provisions of the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006(**a**) or these Regulations;

(iii) for the words "Member States' legislation" there were substituted "legislation".

(9) Article 24 is to be read as if—

(a) in paragraph 2, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority.

(10) The Annex is to be read as if—

(a) in paragraph B.1, for "the legislation in force in Member States" there were substituted "the requirements of the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) paragraph B.2 were omitted.

Modifications to the second Directive

4C.—(1) The modifications to the second Directive are as follows.

(2) Article 2 is to be read as if, in paragraph 1, the reference to Member States were a reference to the Authority.

(3) Articles 3, 4 and 5 are to be read as if any reference to the competent authority or authorities were a reference to the Authority.

(4) Annex 1 is to be read as if, in the first paragraph, for "responsible person as defined in Article 17 of Directive 2004/23/EC" there were substituted "designated individual in

(**a**) 2006 asp 4.

accordance with regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(5) Annex 2 is to be read as if, in paragraph 2.1 the reference to the competent authority in the Member State were a reference to the Authority.

(6) Annex 3 is to be read as if, in paragraph 3.6, for "in force in Member States" there were substituted "of the Human Tissue (Quality and Safety for Human Application) Regulations 2007".

(7) Annex 4 is to be read as if—

(a) in paragraphs 1.1.1 and 1.2.1, the reference to an authorised person were to—

(i) the designated individual in accordance with regulations 11 and 12 of these Regulations, or

(ii) a person authorised to carry out the specified tasks by—

(aa) the designated individual, or

(bb) the Authority;

(b) in paragraph 1.1.1(a), for "Article 13 of Directive 2004/23/EC" there were substituted "the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph 1.4.4 the reference to the competent authority were a reference to the Authority.

Modifications to the third Directive

4D.—(1) The modifications to the third Directive are as follows.

(2) Annex 1 is to be read as if—

(a) in paragraph A.1—

(i) for "responsible person" there were substituted "designated individual";

(ii) for "as provided in Article 17 of Directive 2004/23/EC there were substituted "in accordance with the requirements of regulations 11(**a**) and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph A.4, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph C.6, for the words from "the requirements of Council" to the end there were substituted "the requirements of the Medical Devices Regulations 2002"(**b**);

(d) in paragraph D.1, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(e) in paragraph E.1, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(f) in paragraph E.8, the reference to the competent authority were a reference to the Authority.

(3) Annex 2 is to be read as if—

(**a**) Regulation 11 was amended by S.I. 2018/335.
(**b**) S.I. 2002/618.

(a) in the first paragraph the reference to the competent authority were a reference to the Authority;

(b) in paragraph A, for the words from "the tissues and cells must" to the end there were substituted "tissue establishment procedures must ensure that the licence conditions in paragraph 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 are met";

(c) in paragraph B.3, for the words from "the standards" to the end there were substituted "the requirements of paragraph 13 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(d) in paragraph B.8, the second sentence were omitted;

(e) in paragraph C.2, for "laid down in this Directive" there were substituted "of paragraph 14 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(f) in paragraphs C.4 and C.5, any reference to the responsible person as defined or specified in Article 17 of Directive 2004/23/EC were a reference to the designated individual in accordance with regulations 11 and 12 of these Regulations;

(g) in paragraph D.5, the reference to the competent authority were a reference to the Authority;

(h) in paragraph E.2(h), for "as set out in Articles 5 to 6" there were substituted "in accordance with paragraph 4 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007".

Modifications to the fourth Directive

4E.—(1) The modifications to the fourth Directive are as follows.

(2) The Directive is to be read as if references to a third country were references to any country other than the United Kingdom.

(3) Article 2 is to be read as if for "the Union", in each place where it occurs, there were substituted "the United Kingdom".

(4) Article 5(1) is to be read as if—

(a) for "laid down in Directive 2004/23/EC" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) the references to the competent authority or authorities were references to the Authority.

(5) Article 6 is to be read as if—

(a) in paragraph 2—

(i) the reference to the competent authority or authorities were a reference to the Authority;

(ii) the words from "The information laid out" to the end were omitted;

(b) in paragraph 3—

(i) the first reference to the competent authority or authorities were a reference to the Authority;

(ii) the reference to the competent authority or authorities in subparagraph (b) were a reference to the authority in the third country concerned responsible for regulating tissue establishments in that country.

(6) Article 7 is to be read as if—

(a) in paragraph 1—

(i) in the first subparagraph, for "the Union", in each place where it occurs, there were substituted "the United Kingdom";

(ii) for the second subparagraph, there were substituted "This requirement does not apply to one-off imports as defined in regulation 11(4C)(a) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 provided that the requirements in regulation 11(4B) of those regulations are met.";

(b) in paragraph 2, for "laid down in Directive 2004/23/EC" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph 3, the reference to the competent authority or authorities were a reference to the Authority;

(d) in paragraph 4, the reference to the competent authority or authorities were a reference to the Authority.

(7) Article 8(1) is to be read as if the word "annual" were omitted.

(8) Annex 1 is to be read as if—

(a) in paragraph A.4, for "TE compendium code" there were substituted "reference number previously allocated to the tissue establishment by the Authority";

(b) in paragraph B.4, the reference to the Responsible Person were a reference to the designated individual in accordance with regulations 11 and 12 of these Regulations;

(c) in paragraph C.2, the words "(where applicable, in accordance with the EU generic list)" were omitted;

(d) in paragraph F.3, the references to a third country competent authority or authorities were references to the authority in the third country responsible for regulating tissue establishments in that country.

(9) Annex 3 is to be read as if—

(a) in the first paragraph, the reference to the competent authority or authorities were a reference to the Authority;

(b) in paragraph A.1, for "as laid down in Directive 2004/23/EC" there were substituted "in accordance with regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph A.3, the words "applying the Single European Code," were omitted;

(d) in paragraph B.7, the reference to a third country competent authority or authorities were a reference to the authority in the third country responsible for regulating tissue establishments in that country.

(10) Annex 4 is to be read as if—

(a) in paragraph 1, for "laid down in Directive 2004/23/EC" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 4, the reference to a third country competent authority or authorities were a reference to the authority in the third country responsible for regulating tissue establishments in that country;

(c) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority;

(d) in paragraph 7, for "EU data protection rules" there were substituted "data protection legislation within the meaning of section 3(9) of the Data Protection Act 2018"(**a**);

(**a**) 2018 c.12.

(e) in paragraph 8, for the words from "requirements" to the end there were substituted "quality and safety standards required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007".".

(5) In regulation 5(**a**) (interpretation of other terms)—

(a) in paragraph (1)—

(i) after the definition of "the 2004 Act" insert—

"the Authority" means the Human Tissue Authority(**b**);";

(ii) for the definition of "third country", substitute—

""third country" means any country other than the United Kingdom;";

(iii) after the definition of "third party agreement" insert—

""tissue establishment" means a tissue bank or a unit of a hospital or another body which procures, tests, processes, preserves, stores or distributes human tissues and cells;";

"traceability" means the ability to—

(a) identify and locate tissues and cells during any step from procurement to use for human application and disposal;

(b) identify the donor and recipient of particular tissues and cells;

(c) identify any person who has carried out any activity in relation to particular tissues and cells; and

(d) identify and locate all relevant data relating to products and materials coming into contact with particular tissues and cells and which can affect their quality and safety.";

(b) for paragraph (4)(b), for the words from "is a reference to" to the end, substitute "is to be read as a reference to a requirement which that provision is expressed as requiring to be imposed (ignoring the fact that the Directives do not form part of domestic law)."

(6) In regulation 7(**c**) (licensing requirement), in paragraph (4) omit "for the purposes of Article 6(5) of the first Directive.".

(7) Omit regulation 7A(**d**) (import from the EEA and Gibraltar).

(8) In regulation 10(**e**) (breach of requirement to hold a licence or to act under a third party agreement)—

(a) omit paragraph (2A);

(b) in paragraph (3) for ", (2) or (2A)" substitute "or (2)".

(9) In regulation 11(**f**) (preconditions to grant of licence), for subparagraph (c) of paragraph (4B) substitute—

"(c) the applicant has provided the Authority with any information or documents as may be specified by the Authority for the purposes of demonstrating—

(i) traceability; and

(ii) that the import is a one-off import within the meaning of paragraph (4C)."

(10) In regulation 16(**g**) (directions: compliance with the first, second, third and fourth Directives)—

(a) in the heading, omit ":compliance with the first, second, third and fourth Directives";

(**a**) Relevant amendments to regulation 5 were made by S.I. 2018/335.
(**b**) The Human Tissue Authority was established by section 13(1) of the Human Tissue Act 2004 c.30.
(**c**) Regulation 7(4) was substituted by S.I. 2018/335.
(**d**) Regulation 7A was inserted by S.I. 2018/335.
(**e**) Regulation 10 was amended by S.I. 2018/335.
(**f**) Regulation 11 was amended by S.I. 2018/335.
(**g**) Regulation 16 was amended by S.I. 2018/335.

(b) in paragraphs (1) and (2), for "the first, second, third and fourth Directives" substitute "these Regulations";

(c) after paragraph (2), insert—

"(3) In this regulation, the references to securing compliance with these Regulations includes a reference to securing compatibility with the principles set out in Article 12 of the first Directive as modified by section 32(3B) of the 2004 Act.".

(11) In regulation 20(**a**) (duties of the Authority in relation to serious adverse events and reactions)—

(a) in paragraph (1) omit subparagraphs (c) and (d);

(b) omit paragraph (3).

(12) Omit regulation 20A(**b**) (duties of the Authority in relation to application of the Single European Code).

(13) Omit regulation 20B(**c**) (inspection of third country premises etc.).

(14) Omit regulation 20C(**d**) (third country premises and third country suppliers: report of inspections etc.).

(15) Omit regulation 21A(**e**) (inspection of documents to be held by an importing licence holder).

(16) Omit regulation 22A(**f**) (importing licence holders: requests for inspections).

(17) In regulation 27(**g**) (requirements when exercising power of inspection or search) omit paragraphs (4) and (5).

(18) In regulation 28(**h**) (enforcement) in subparagraph (1)(a), omit ", 21A".

(19) Before regulation 34 (but after the heading "General") (offences by bodies corporate) insert—

"**Powers to make regulations in relation to standards of quality and safety**

34ZA.—(1) The appropriate authority may by regulations make provision specifying requirements to be met for the purposes of ensuring traceability.

(2) The appropriate authority may by regulations make provision in relation to the notification of serious adverse events and reactions (whether to the Authority or such other person as may be specified in the regulations).

(3) The appropriate authority may by regulations make provision specifying requirements to be met for the purposes of verifying that standards of quality and safety equivalent to those required by these Regulations apply in relation to imports by tissue establishments of tissues and cells from third countries.

(4) The appropriate authority may by regulations prescribe technical requirements in relation to the following—

(i) the licensing or authorisation of tissue establishments;

(ii) the procurement of tissues or cells;

(iii) selection criteria for the donor of tissues or cells;

(iv) laboratory tests required for donors;

(v) procedures for the reception of tissues and cells at the tissue establishment;

(**a**) Regulation 20 was amended by S.I. 2018/335.
(**b**) Regulation 20A was inserted by S.I. 2018/335.
(**c**) Regulation 20B was inserted by S.I. 2018/335.
(**d**) Regulation 20C was inserted by S.I. 2018/335.
(**e**) Regulation 21A was inserted by S.I. 2018/335.
(**f**) Regulation 22A was inserted by S.I. 2018/335.
(**g**) Regulation 27 was amended by S.I. 2018/335.
(**h**) Regulation 28(1)(a) was amended by S.I. 2018/335.

(vi) the tissue and cell preparation process;

(vii) tissue and cell processing, storage and distribution;

(viii) the direct distribution to the recipient of specific tissues and cells.

(5) The provision that may be made in regulations under paragraphs (1) to (4) includes provision amending regulations 4A to 4E to modify, or further modify, the provisions of the second, third and fourth Directives as they apply by virtue of these Regulations.

(6) In this regulation—

"appropriate authority" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales—

(i) the Welsh Ministers; or

(ii) the Secretary of State acting with the consent of the Welsh Ministers;

(c) in relation to Scotland—

(i) the Scottish Ministers; or

(ii) the Secretary of State acting with the consent of the Scottish Ministers;

(d) in relation to Northern Ireland—

(i) the Department of Health in Northern Ireland; or

(ii) the Secretary of State acting with the consent of that Department;

(e) for the whole of the United Kingdom, the Secretary of State acting with the consent of the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland.

Scope and nature of powers

34ZB.—(1) Regulations made by the Secretary of State or the Welsh Ministers under regulation 34ZA are to be made by statutory instrument.

(2) For regulations made under regulation 34ZA by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**a**) (Scottish statutory instruments).

(3) Any power of the Department of Health in Northern Ireland to make regulations under regulation 34ZA is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**b**).

(4) Any power in regulation 34ZA to make regulations includes a power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.

Scrutiny of regulations

34ZC.—(1) A statutory instrument containing regulations made by the Secretary of State under regulation 34ZA may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

(2) A statutory instrument containing regulations made by the Welsh Ministers may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.

(**a**) 2010 asp 10.
(**b**) S.I. 1979/1573 (NI 12).

(3) Regulations made by the Scottish Ministers under regulation 34ZA are subject to the affirmative procedure (see section 29 of the Interpretation and Legislative Reform (Scotland) Act 2010).

(4) Regulations made under regulation 34ZA by the Department of Health in Northern Ireland may not be made unless a draft of the regulations has been laid before and approved by resolution of the Northern Ireland Assembly".

(20) In Schedule 1(**a**) (licences) in paragraph 5A for "in the form set out in Annex II to the fourth Directive" substitute "of authority in such form as the Authority considers appropriate".

(21) In Schedule 2(**b**) (directions for securing compliance with the first, second, third and fourth Directives)—

(a) for paragraph 1 substitute—

"**1.** Directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure, in relation to traceability, compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).";

(b) omit paragraph 1A;

(c) in paragraph 4, for the words from "are necessary" to the end substitute "the Authority considers appropriate";

(d) in paragraph 7, in subparagraph (b) for "the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive" substitute "the requirements of these Regulations in relation to notification of serious adverse reactions and notification of serious adverse events.".

PART 4

Transitional Provision

4.—(1) For a period of six months beginning with exit day the requirements of the provisions listed in paragraph (2) do not apply to—

(a) an import of tissues or cells into the United Kingdom from an EEA state or Gibraltar;

(b) an export of tissues or cells from the United Kingdom into an EEA state or Gibraltar,

provided that the Authority is satisfied that the import or, as the case may be, export meets the requirements of traceability and standards of quality and safety equivalent to those laid down in the Regulations.

(2) The provisions referred to in paragraph (1) are—

(a) regulation 11(4A) to (4C) of the Regulations.

(b) Schedule 2 to the Regulations.

(3) In this regulation—

(a) "the Regulations" means the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and

(b) the terms "the Authority", "cells", "tissue" and "traceability" have the same meanings as they have in the Regulations.

Signed by authority of the Secretary of State for Health and Social Care.

Name
Parliamentary Under-Secretary of State,
Address

(**a**) Paragraph 5A of Schedule 1 was inserted by S.I. 2018/335.
(**b**) Schedule 2 was amended by S.I. 2018/335.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers conferred by section 8(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (b), (c), (f) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to legislation concerning human tissue and cells intended for use in human application, including stem cells and cell lines grown outside the body. These Regulations do not apply to reproductive cells, embryos grown outside the human body, organs and blood. In particular, they amend legislation relating to technical requirements for the storage, procurement, testing, processing or distribution of tissues and cells into, and their export from, the United Kingdom. Part 2 amends primary legislation. Part 3 amends subordinate legislation and Part 4 makes transitional provision.

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

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£6.90

UK201811151012 11/2018 19585

http://www.legislation.gov.uk/id/ukdsi/2019/9780111174821

ISBN 978-0-11-117482-1

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EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2019;

THE HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) (EU EXIT) REGULATIONS 2019;

THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) (EU EXIT) REGULATIONS 2019

[2019] No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instruments

2.1 The three Statutory Instruments (SIs) on the safety of organs, tissues and cells, and reproductive cells (gametes and embryos) for treating patients are 'no deal' SIs. They have been developed as part of contingency planning and will be needed in the event that the United Kingdom (UK) leaves the European Union (EU) in March 2019 with no agreement in place; i.e. a 'no deal' scenario.

Withdrawal from the EU without a deal would mean that the law in this area will no longer work as it is intended to. This is because it contains a number of references that will no longer be appropriate, such as references to obligations that the UK is required to comply with as an EU Member State. Additionally, as the UK and EU Member States will consider each other to be third countries, amendments have been made to reflect this.

The SIs are being made under powers in the European Union (Withdrawal) Act 2018 (referred to here as the EU (Withdrawal) Act). There are three separate SIs:

- the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'Tissues and Cells SI';
- Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'HFE SI'; and
- the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'Organs SI'.

The SIs are being made on a UK-wide basis. The Tissues and Cells and Organs SIs are being made with the agreement of each of the Devolved Administrations (DAs) and the HFE SI is reserved to Westminster.

The SIs have been drafted separately as each amends different underlying legislation. The purpose of the SIs is to ensure that, in the unlikely scenario that the UK leaves the

EU with no deal, the law in this area will still function properly and the UK regulatory framework for the safety and quality of organs and tissues and cells (including reproductive cells) is maintained.

It is proposed that these SIs should be grouped and debated together.

Explanations

What did any relevant EU law do before exit day?

Donated human organs, tissues and cells are used in potentially life-saving or life changing treatments for patients. The UK regulatory frameworks set high standards of patient safety.

UK law in this area transposes the **EU Tissue and Cells Directives**[1] for tissues and cells (including reproductive cells) and the **EU Organ Donation Directives**[2] for organs.

These directives are collectively referred to in this memorandum as 'the Directives'.

The Directives introduced a range of quality and safety standards, aiming to safeguard patient safety. These include the following: -

- The procurement, testing, processing, and storage of tissues and cells (including reproductive cells);
- Organ and donor characterisation, which means information, including tissue typing tests, which must be collected so an organ can be matched with a suitable recipient;
- Traceability requirements in respect of organs for transplantation, tissues such as corneas or bone, stem cells and sperm, eggs and embryos (reproductive cells) for assisted reproduction; and
- Notification requirements in the event of serious adverse events or reactions which may impact the quality and safety of organs, tissue and cells (including reproductive cells).

Why is it being changed?

The amendments in these instruments are to ensure that the law on the quality and safety of organs, tissues and cells (including reproductive cells) will continue to function as intended after exit day. The UK and the EU will consider each other to be third countries if there is no deal on exit and the SIs redefine the term 'third country' to include EU countries and Gibraltar. As a result, licensed establishments will need to make administrative changes to continue to import organs, tissues and cells from EU countries and Gibraltar.

The legislation being amended also contains a number of references that will no longer be appropriate once the UK withdraws from the EU, such as references to

[1] The requirements in the EU Tissue and Cells Directives have been implemented in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Fertilisation and Embryology Act 1990. The EU Tissue and Cells Directives are Directive 2004/23/EC and the Implementing Directives 2006/17/EC, 2006/86/EC, 2012/39/EU, (EU) 2015/565, (EU) 2015/566.

[2] The requirements in the EU Organ Donation Directives have been implemented in the Quality and Safety of Organs Intended for Transplantation Regulations 2012. The EU Organ Donation Directives are Directive 2010/53/EU and the Implementing Directive 2012/25/EU.

obligations which the UK must comply with as an EU Member State, and some references to the EU, the European Economic Area (EEA), the European Commission (the Commission) and EU law.

The Commission also has a number of powers under the Directives, to update technical requirements in line with scientific developments or if there is a health threat from a new disease. The Commission will no longer exercise these powers on the UK's behalf so the regulation making powers are being conferred on the Secretary of State (and where within devolved competence, the DAs) so the quality and safety standards can be updated following EU exit if they need to be.

What will it now do?

The amendments made by these instruments will ensure that the UK maintains the current quality and safety standards for organs, tissues and cells (including reproductive cells) after exit. Some organs, tissues and cells move between the UK and EU countries but numbers are relatively small, the amendments will allow this to continue after exit with minimal additional administration.

The detailed breakdown of the various types of changes which these instruments will bring about is included in section 7. They will make the following changes:

- Amend or omit references to EU/EEA/Member State.
- Revoke obligations on UK organisations and reciprocal arrangements between UK and EU organisations (referred to as competent authorities in the Directives) that will no longer be relevant to the UK.
- Confer relevant Commission powers to make regulations under the Tissue and Cells Directives and the Organ Donation Directives to the Secretary of State and, in relation to the Organs and Tissues and Cells SIs, the Devolved Administrations (all of which are detailed in paragraph 7.25).
- Set out updated requirements for licensing and written agreements to import tissues and cells from EEA states and Gibraltar to align these with existing requirements for countries outside the EEA and Gibraltar.
- In relation to the HFE and Tissues and Cells SIs, make transitional provisions so that imports of tissue and cells (including reproductive cells) from EEA states and Gibraltar may continue for a six-month period after exit day whilst licences and written agreements are put in place.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The HFE SI contains, at regulation 2(14), a new regulation making power for the Secretary of State to make regulations in relation to standards of quality and safety for reproductive cells. This power may be used to make amendments to the Human Fertilisation and Embryology Act 1990 within the scope of the regulation making power in the new section 42A of the Human Fertilisation and Embryology Act 1990, as inserted by regulation 2(14) of the HFE SI. The current standards of quality and safety are set out in the Human Fertilisation and Embryology Act 1990. The new regulation making power may be used to amend this Act to ensure that the current standards of quality and safety can be amended. The power is affirmative and any

Regulations proposing changes to existing provisions would be affirmative and subject to consultation.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of these instruments is the UK.

3.3 Legislative competence for the donation, processing and use in treatment of human reproductive cells (sperm, egg and embryos) is reserved to Westminster (i.e. legislation is dealt with by the Westminster Parliament). Competence in respect of all other human tissues and cells and organs is devolved.

4. Extent and Territorial Application

4.1 The territorial extent of these instruments is the UK.

4.2 The territorial application of these Regulations is set out in Section 3.2.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding Human Rights:

"In my view the provisions of The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The amendments in these instruments are needed to ensure that the law on the quality and safety of organs, tissues and cells (including reproductive cells) will continue to function after exit if the UK leaves the EU without a deal in place.

6.2 The relevant UK legislation is:

- The Human Tissue (Quality and Safety for Human Application) Regulations 2007;
- relevant amendments to the Human Tissue Act 2004 and the Human Fertilisation and Embryology Act 1990.
- the Quality and Safety of Organs Intended for Transplantation Regulations 2012); and
- the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007;

This legislation was made under powers conferred by section 2(2) of the European Communities Act 1972 in order to implement the Tissue and Cells Directives and the Organ Donation Directives (see paragraph 2.2 above for a full description of relevant EU law).

6.3 Section 2 of the EU (Withdrawal) Act saves EU-derived domestic legislation so that it continues to have effect in domestic law on and after exit day. The legislation in paragraph 6.2 will be preserved and is being amended pursuant to the power in Section 8 of the EU (Withdrawal) Act in order to function effectively after exit.

7. Policy background

7.1 An organ transplant can be life saving or life transforming and is often the only treatment option available for the patient concerned. Human tissues and cells are used in what can be life changing therapies, such as:

- stem cells used to treat blood cancers
- corneas to restore sight
- heart valves to treat heart conditions
- skin grafts to treat burns
- eggs and sperm to treat infertility

7.2 Other forms of tissue are much more generic in use, for example bone products used in operations and by dentists for fillings.

7.3 EU law sets the policy and legal framework in relation to the donation, retrieval, processing, storage, transport, import and export of organs, tissues and cells used for transplantation, as set out in paragraph 2.2.

7.4 These instruments are intended to ensure that UK law for the safety of organs, tissues and cells continues to apply effectively in the event of no deal. UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics that undertake licensable activities working in this area are regulated by:

- the Human Tissue Authority (HTA) for organs, tissues and cells other than reproductive tissues and cells; and
- the Human Fertilisation and Embryology Authority (HFEA) for reproductive tissues and cells.

7.5 UK licensed establishments will continue to work to the same safety standards in place before exit and the changes contained within the instruments are designed to make the necessary changes to reflect the status of the UK outside the EU.

7.6 At present some organs, tissues and cells move between the UK and EU countries, but also between the UK and non-EU countries (third countries). A small number of organs are shared with EU and non-EU countries, with less than 30 organs on average being imported or exported each year. Tissues and cells are imported from and exported to EEA/EU countries less often than they are imported and exported from and to countries outside the EEA/EU. The UK imports donated sperm, primarily from commercial sperm banks in the USA and Denmark.

What is being done and why?

7.7 As set out in Section 6, these instruments are being made so that the law in this area will continue to work as it is intended to after the UK leaves the EU.

Examples of the deficiencies addressed by these amendments are listed below.

EU obligations that will no longer be relevant or appropriate

7.8 In some cases, EU obligations are removed that will no longer be relevant or appropriate. For example, there are currently requirements on the HTA and the HFEA to report to the Commission and/or competent authorities of other Member States certain information submitted to them regarding serious adverse events and reactions that affect organs, tissues and cells used by UK establishments. The Tissues and Cells SI and the HFE SI remove this obligation as it is no longer appropriate.

7.9 Similarly, there is a requirement for the HTA to participate in a network of competent authorities established by the Commission and to co-ordinate UK input into the activities of that network. The Organs SI removes this requirement as it is no longer appropriate.

7.10 There is also an obligation under the EU Tissue and Cells Directives for EEA Member States to inspect third country premises at the request of another EEA Member State. As the UK will no longer be an EEA Member State after exit, there will no longer be an obligation on the HTA and the HFEA to inspect UK establishments on behalf of EEA Member States. These instruments therefore remove this obligation.

7.11 The current legislation, in relation to tissues and cells (including reproductive cells) requires tissue establishments to use the Single European Code (SEC) and the EU Coding Platform to facilitate the traceability of tissues and cells used to treat patients across the EU. The EU Coding Platform provides a list of all licensed establishments across the EU, the activities they are licensed for and the tissue and cells types they have been authorised by the competent authorities to work with. Competent authorities must ensure that entries for the establishments that they license are accurate and access to the platform is restricted to EEA countries. After exit day, the UK will be considered a third country under the Directives and UK tissue establishments will not use the SEC. The UK will not use the platform and there will be no need for the details for UK establishments to be added to the platform.

7.12 The obligation to use the SEC and associated obligations such as for the HTA and HFEA to update the details of UK licensed establishments on the platform has therefore been omitted in the Tissues and Cells SI and the HFE SI. UK licensed establishments were already using systems to ensure traceability from donor to recipient of tissues and cells before the introduction of the SEC, and in most cases the SEC was added to these existing systems. After exit, the UK licensed establishments will be able to use the traceability systems that were in place before the introduction of the SEC.

EU references which are redundant or inappropriate

7.13 There are a number of amendments being made by these instruments to take account of EU references which will be redundant or inaccurate. For example, the current law includes references to 'other Member States'. These references have been amended as they will not function correctly when the UK is no longer an EU Member State. Amendments have also been made to references to 'competent authority', to reflect that the Directives will not form part of domestic law after exit.

Exchange of organs, tissues and cells with EU countries as third countries

7.14 The Tissue and Cells Directives and the Organ Donation Directives allow for organ, tissue and cells exchange between EEA/EU Member States and third countries. In a no deal scenario, the UK and EEA/EU Member States will consider each other to be third countries and UK law has to be amended to reflect this change.

Import from EEA/EU countries

7.15 UK establishments will be able to continue to import organs, tissues and cells from establishments in EEA/EU states. As noted above, EEA/EU states will be considered as third countries by the UK and the UK will therefore extend the existing third country provisions to EU countries. For example, regulation 3 in the Tissues and Cells SI removes specific provision in relation to imports from the EEA and Gibraltar. This has been omitted as post exit the same requirements for imports will apply to all third countries.

7.16 Regulation 4 of the Tissues and Cells and the HFE SIs sets out that UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EEA states. This is to allow UK licensed establishments that import tissues and cells from EEA states to put in place new agreements or amend existing ones, to comply with the requirements in the legislation. This will also allow establishments sufficient time to apply for or amend existing import licences or authorisations.

7.17 The arrangement for accepting organs from third countries are less extensive for organs. NHS Blood and Transplant (NHSBT), the organisation responsible for organ donation and transplantation in the UK, and the HTA will work together to put any new agreements in place as needed to allow organ exchange to continue post-exit. UK transplant centres will not be affected by the fixes made by the Organs SI. There is therefore no need for a transitional period and NHSBT will be able to accept organs from EU countries from exit day provided that such organs can be traced from donor to recipient and meet quality and safety standards equivalent that required in UK law.

7.18 Information on export to EU countries is available in the technical notice published in August 2018: https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal

References to EU Directives in UK law

7.19 UK law[3] implements EU Directives in part by cross-referring to the Directives. After exit, some of these references will be retained in UK law. These instruments amend UK law to clarify that where there is a reference to a requirement of a directive in UK law, the requirement will still apply after exit in the same way it did prior to exit.

7.20 To ensure that such references function correctly after exit, it is necessary to modify how some of the articles and annexes in the Directives are to be read. For example, where a reference is made to "the competent authority or authorities" this will be read as a reference to the HFEA or HTA. In addition, where specific provisions have been implemented in UK law, instead of referring to the relevant articles in the Directives, amendments have been made to refer to the specific requirements in the relevant UK law.

[3] The Human Fertilisation and Embryology Act 1990 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007

Transfer of Commission Powers

7.21 Prior to exit day, any amendments to legislation in the field of organs, tissues and cells (including reproductive cells), have been made under section 2(2) of the European Communities Act 1972. After exit, the European Communities Act 1972 will be repealed. Similarly, the European Commission will no longer have any functions in respect of the UK.

7.22 As noted in paragraph 2.2, there are a range of powers currently held by the European Commission under the Tissue and Cells Directives and the Organ Donation Directives. These instruments insert into UK law[4] similar powers for the Secretary of State and where the matters fall within devolved competence, the DAs, to update legislation on organs, tissues and cells in response to, for example, emerging threats, changing safety and quality standards, and technological advances.

7.23 These updating powers are likely to have minimal impact on industry. Their purpose is to make sure that the UK is still able to make changes after we leave the EU, where needed.

Powers in the HFE SI and the Tissues and Cells SI

7.24 The Commission currently holds powers in Articles 8, 9, 11 and 28 of Directive 2004/23/EC to update technical requirements relating to tissues and cells (including reproductive cells), to prescribe traceability requirements and notification requirements in relation to serious adverse events and serious adverse reactions and to verify equivalent standards of safety and quality where tissues and cells (including reproductive cells) are imported from third countries.

7.25 In relation to tissues and cells (excluding reproductive cells) these powers are being conferred on the Secretary of State in relation to England and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in relation to Northern Ireland, the Department of Health).

7.26 Policy on reproductive cells is reserved to Westminster and so these powers are only being conferred on the Secretary of State.

7.27 The powers which will be conferred are contained in the new section 42A of the Human Fertilisation and Embryology Act 1990 (power to make regulations in relation to standards of quality and safety) and the new regulation 34ZA (power to make regulations in relation to standards of quality and safety) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

7.28 These provisions contain powers akin to the current Commission powers contained in Directive 2004/23/EC. Details of the powers being conferred and examples as to how these powers could be used are as follows: -

- The power to prescribe requirements to ensure traceability of tissues and cells (including reproductive cells).

[4] The Human Fertilisation and Embryology Act 1990, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Quality and Safety of Organs Intended for Transplantation Regulations 2012

This power could be used to introduce a UK national coding system for tissues and cells. The power could be used to make the use of the coding system a statutory obligation for tissue establishments and place duties on the two authorities in relation to the management of the coding system, and provide elements of it such as the product code, similar to the role the EU plays in the management of the Single European Code.

- The power to make provision in relation to the notification of serious adverse events and serious adverse reactions.

  This power could be used to specify that certain information that relates to a serious adverse incident is provided by tissue establishments or that information related to an incident is provided to another authority. For example, the HTA or HFEA may need to know if certain reagents were used in the preparation of tissue to which a patient suffered a severe adverse reaction, for the Medicines and Healthcare products Regulatory Agency (MHRA) to consider if the chemical should be prohibited from use with human material.

- The power to make provision specifying to requirements to be met for verifying equivalent standards of safety and quality in relation to imports of tissues and cells (including reproductive cells).

  This power could be used in the event of an outbreak of a serious infectious disease or a new infection that could be transmitted, through tissue transplantation, to the recipient, or adversely affect the development of a child conceived using gametes from an infected person. In such cases, the Secretary of State may wish to specify in regulations that tests specified by the UK Advisory Committee of the Safety of Blood, Tissues and Organs had been conducted by the third country exporting establishment and the tissues sent to the UK are certified as infection free.

- The power to prescribe technical requirements relating to tissue establishments.

  This power would be used to update the requirements related to the quality and safety of tissues and cells, in response to technical advances or the development of new therapies. For example, the power could be used to update the requirements that need to be met to demonstrate that a new technique used to process tissues or cells is safe and does not adversely affect the quality of the tissues or cells.

Powers in the Organs SI

7.29 The Commission currently holds a power in Article 24 of Directive 2010/53/EU to adopt delegated acts in order to supplement or amend the Annex to Directive 2010/53/EU (the Annex). The Annex contains the information requirements for organ and donor characterisation. As the European Commission will no longer have any functions in respect of the UK, in the event of a serious adverse event which presents a serious risk to human health, any delegated acts made by the Commission will not apply to the UK.

7.30 A similar power is therefore being conferred on the Secretary of State in relation to England and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also

be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in relation to Northern Ireland, the Department of Health).

7.31 As noted above, this power would be used to update organ and donor characterisation requirements to mitigate risk to human health, usually in response to an emerging disease outbreak. In such cases, the Secretary of State may wish to add additional requirements to characterise donors, such as additional tests.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 These instruments are being made using the power in section 8 of the EU (Withdrawal) Act in order to enable retained EU law to operate effectively following withdrawal of the United Kingdom from the European Union.

8.2 The Organs SI is also made under section 23(1) of the EU (Withdrawal) Act in order to make a consequential amendment to regulation 24 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012. This requires the Secretary of State to have regard to how the Organ Donation Directives have been implemented in EU member states when reviewing the regulations. This provision has no effect post exit in light of paragraph 9 of Schedule 8 of the EU (Withdrawal) Act.

8.3 As set out in paragraph 7.16, UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EU countries. This provision has been made under schedule 7, paragraph 21(b) of the EU (Withdrawal) Act.

8.4 In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 These Statutory Instruments do not involve consolidation and there are no plans to consolidate the Human Fertilisation and Embryology Act 1990 or the Human Tissue Act 2004 at this time.

10. Consultation outcome

10.1 The amendments introduced by these SIs are technical in nature and their purpose is to maintain the current UK regulatory framework for the safety and quality of organs and tissues and cells. There was therefore no public consultation. The changes in the SIs were discussed with the UK regulators, the HTA and HFEA, along with issues of operational implementation.

10.2 The proposed amendments have been discussed with the Scottish, Welsh and Northern Irish devolved administrations and their views have been taken into account in the drafting of these instruments. The Organs and Tissues and Cells SIs are being made on a UK wide basis with the agreement of the devolved administrations.

11. Guidance

11.1 Guidance for tissue establishments will be provided by the two UK competent authorities. For reproductive cells, guidance will be published by the HFEA. In respect of organs and all other human tissues and cells, guidance will be published by the HTA.

11.2 A technical notice was published in August 2018, setting out the actions organisations, businesses and members of the public should consider taking, to ensure continued access to and use of organs, tissues and cells, including reproductive cells, in the unlikely event that the UK leaves the EU in March 2019 with no agreement in place: https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal

11.3 NHSBT and the HTA will work together to put any new agreements in place as needed to allow organ exchange to continue post-exit. UK transplant centres will not be affected by the fixes made by the Organs SI.

11.4 UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EEA states.

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies.

12.2 An Impact Assessment has not been prepared for these instruments because the direct cost impact has been assessed as lower than the £5m threshold in any one year and the policy is not considered novel or contentious.

12.3 The instruments are intended to maintain the current regulatory framework so UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics will continue to work to the same standards that they did prior to exit. Some organs, tissues and cells move between the UK and EU countries. Numbers are relatively small and the amendments allow this to continue after exit.

12.4 The impact of these instruments on businesses will be low. The only key impacts are in relation to agreements that licensed establishments will need to put in place to be able to import tissues and cells from EU countries. Establishments that already hold an import licence to import tissues and cells from third countries will be able to use their existing written agreements with third country organisations as a template. There is no impact for organ transplant centres.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses. The SIs relate to quality, safety and traceability standards for patients and no exceptions would be applied to small businesses.

14. Monitoring & review

14.1 The SIs are intended to ensure that appropriate arrangements are in place for organs, tissues and cells to continue to be exchanged with EU countries and that quality and safety standards are maintained post exit. The effectiveness of the SIs in doing so will be regularly evaluated as part of a programme of accountability meetings between the Department of Health and Social Care and the HFEA and HTA.

14.2 As these instruments are made under the EU (Withdrawal) Act, no review clause is required.

15. Contact

15.1 Emma Wilbraham: (020) 7972 3013 or email: emma.wilbraham@dh.gsi.gov.uk can answer any queries regarding The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 and The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019.

Kim Hayes: (020) 7210 6339 or email: kim.hayes@dh.gsi.gov.uk can answer any queries regarding the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019.

15.2 Jeremy Mean at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Jackie Doyle-Price at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/ESIC
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 77	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9, and 23(1) or jointly exercising	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising clauses 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Sch 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 do no more than is appropriate".

1.2 This is the case because they do no more than amend legislation on organs, tissues and cells to correct deficiencies arising from the withdrawal of the United Kingdom from the European Union or to correct legislation on organs, tissues and cells where it would otherwise fail to operate effectively after the UK leaves the EU. This includes removing redundant provisions, amending references to obligations or reciprocal agreements that will no longer exist, and transferring appropriate Commission functions to the Secretary of State and the DAs (where within devolved competence). Further details, including examples of all the changes included in the instruments, are detailed in Section 7 of the main body of this explanatory memorandum.

2. Good reasons

2.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view there are good reasons for the provisions in these instruments, and I have concluded they are a reasonable course of action"

2.2 Following exit day, without amendments to the relevant legislation, policy on organs, tissues and cells would cease to function effectively. These instruments seek to remove or amend provisions in UK legislation and EU legislation saved by the EU (Withdrawal) Act 2018, in order to ensure that policy on organs, tissues and cells will continue to function at the same level as prior to exit. The instruments make a number of technical amendments, and provide the Secretary of State and DAs (where within devolved competence) with powers previously held by the EU Commission which will allow the Secretary of State and DAs to update legislation on organs, tissues and cells in in response to emerging threats, changing safety and quality standards, and technological advances. Further details, including examples of the amendments made and reasons for making them, are set out in section 7 of the main body of this explanatory memorandum.

3. Equalities

3.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement "The draft instruments do not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

3.2 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In relation to the draft instrument, I, Jackie Doyle-Price have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

3.3 This instrument will have no impact on equalities.

4. Explanations

4.1 The explanations statement has been made in paragraph 2.2 of the main body of this explanatory memorandum.

UK MINISTERS ACTING IN DEVOLVED AREAS

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019

Laid in UK Parliament: 19 November 2018

Sifting	
Subject to sifting in UK Parliament?	No
Procedure:	Draft Affirmative
Date of consideration by the House of Commons European Statutory Instruments Committee	N/A
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known
Date sifting period ends in UK Parliament	N/A
Written statement under SO 30C	Paper 4
SICM under SO 30A (because amends primary legislation)	Paper 5
Scrutiny procedure	
Outcome of sifting	N/A
Procedure	Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

These Regulations are proposed to be made by the UK Government pursuant to section 8(1) of, and paragraph 21(b) of Schedule 7 of the European Union (Withdrawal) Act 2018.

These Regulations make amendments to legislation concerning human tissue and cells intended for use in human application, including stem cells and cell lines grown outside the body. These Regulations do not apply to reproductive cells, embryos grown outside the human body, organs and blood.

In particular, they amend legislation relating to technical requirements for the storage, procurement, testing, processing or distribution of tissues and cells into, and their export from, These Regulations are proposed to be made by the UK Government pursuant to section 8(1) of, and paragraph 21(b) of Schedule 7 of the European Union (Withdrawal) Act 2018.

These Regulations make amendments to legislation concerning human tissue and cells intended
the United Kingdom. Part 2 amends primary legislation. Part 3 amends subordinate legislation and Part 4 makes transitional provision.
These Regulations form part of a suite of statutory instruments covering the safety of organs, tissues and cells and reproductive cells for treating patients. They are all 'no deal' SIs which have been developed as part of contingency planning and will be needed in the event that the UK leaves the EU with no agreement in place.

Legal Advisers agree with the statement laid by the Welsh Government dated 22 November 2018 regarding the effect of these Regulations.
The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.
Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

Legal Advisers have not identified any legal reason to seek a consent motion under Standing Order 30A.10 in relation to these Regulations.

Vaughan Gething AC/AM
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol
Cabinet Secretary for Health and Social Services

Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: MA-L/VG/0675/18

Mick Antoniw AC
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Y Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol
Cynulliad Cenedlaethol Cymru

22 Tachwedd 2018

Annwyl Mick,

Rwy'n ysgrifennu i'ch hysbysu fy mod wedi gosod dau Memorandwm Cydsyniad Offeryn Statudol yng Nghynulliad Cenedlaethol Cymru mewn perthynas â:

- **Rheoliadau Meinweoedd Dynol (Ansawdd a Diogelwch at Ddefnydd mewn Bodau Dynol) (Diwygio) (Ymadael â'r UE) 2019, a**

- **Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019**

yn unol â'r gofyniad o dan Reol Sefydlog 30A (RhS30A).

Rwy'n ysgrifennu i roi gwybod ichi hefyd nad wyf, yn yr achos hwn yn bwriadu gosod cynnig i gynnal dadl arno ynglŷn â'r OS. Gwneuthum y penderfyniad hwnnw ar y sail bod yr OS wedi'i gyfyngu i wneud cywiriadau i'r diffygion yn y gyfraith a fydd yn codi o ganlyniad i ymadawiad y DU â'r UE. Mae darpariaethau'r OS yn rhai technegol, ac nid oes gwahaniaeth polisi rhwng Llywodraeth Cymru a Llywodraeth y DU yn yr achos hwn.

Mae RhS30A yn darparu y caiff unrhyw Aelod osod cynnig i gynnal dadl ar yr OS hwn. O ystyried cymaint o ddeddfwriaeth y mae'r Cynulliad yn ei ystyried, nid wyf yn credu y byddai cynnal dadl ar yr OS hwn yn ddefnydd cynhyrchiol o amser gwerthfawr yn y Cyfarfod Llawn ac ni fyddaf i fy hun yn mynd ati i ysgogi dadl o'r fath.

Yn gywir,

Vaughan Gething

Vaughan Gething AC/AM
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol
Cabinet Secretary for Health and Social Services

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Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL	**Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019**
DYDDIAD	**22 Tachwedd 2018**
GAN	**Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019 ("y Rheoliadau")

Cyfraith [yr UE a ddargedwir] sy'n cael ei diwygio
Bydd y Rheoliadau'n diwygio:

(a) Deddf Meinweoedd Dynol 2004
(b) Rheoliadau Deddf Meinweoedd Dynol 2004 (Cymeradwyaeth Foesegol, Eithriadau rhag Trwyddedu a Chyflenwi Gwybodaeth am Drawsblaniadau) 2006; a
(c) Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu 2012.

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu gymhwysedd gweithredol Gweinidogion Cymru
Mae'r OS yn rhoi pwerau i'r Ysgrifennydd Gwladol ac i Weinidogion Cymru mewn perthynas â rhai gweithdrefnau yn ymwneud â rhoi meinweoedd. Nid oes effaith ar gymhwysedd deddfwriaethol y Cynulliad na chymhwysedd gweithredol Gweinidogion Cymru.

Byddai swyddogaethau a drosglwyddid i'r Ysgrifennydd Gwladol gyda chydsyniad yn golygu swyddogaethau Gweinidog y Goron at ddibenion Atodlen 7B i Ddeddf Llywodraeth Cymru 2006. Gallai hyn, felly, fod yn ystyriaeth berthnasol yng nghyd-destun cymhwysedd y Cynulliad i ddeddfu yn y meysydd hyn yn y dyfodol.

Diben y diwygiadau
Diben y diwygiadau hyn yw cywiro diffygion mewn deddfwriaeth rhoi organau sy'n deillio o ymadawiad y DU â'r Undeb Ewropeaidd.

Mae Rheoliad 3 yn diwygio Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu 2012 i fewnosod adran newydd mewn perthynas â'r gweithdrefnau ar gyfer trosglwyddo a chyfleu gwybodaeth am organau. Mae'r rheoliad newydd yn datgan y caiff yr awdurdod priodol ddiwygio'r setiau data yn y meysydd hyn trwy reoliadau. Diffinnir yr

awdurdod priodol mewn perthynas â Chymru fel Gweinidogion Cymru neu'r Ysgrifennydd Gwladol yn gweithredu gyda chydsyniad Gweinidogion Cymru.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma:
http://www.legislation.gov.uk/ukdsi/2019/9780111174807/contents

Pam y rhoddwyd cydsyniad
Nid oes gwahaniaeth rhwng Llywodraeth Cymru a Llywodraeth y DU o ran y polisi ar gyfer y cywiriad. O ganlyniad, byddai gwneud OS ar wahân yng Nghymru ac yn Lloegr yn arwain at ddyblygu gwaith a chymhlethdod diangen i'r llyfr statud. Mae cydsynio i OS ar draws y DU yn sicrhau bod un fframwaith deddfwriaethol ar draws y DU sy'n hybu eglurder a hygyrchedd yn ystod y cyfnod hwn o newid. O dan yr amgylchiadau eithriadol hyn, mae Llywodraeth Cymru yn ystyried ei bod yn briodol i Lywodraeth y DU ddeddfu ar ein rhan yn yr achos hwn.

Mae Memorandwm Cydsyniad Offeryn Statudol hefyd wedi'i osod yn y Cynulliad Cenedlaethol mewn perthynas â'r diwygiadau i Ddeddf Meinweoedd Dynol 2004.

MEMORANDWM CYDSYNIAD OFFERYN STATUDOL

Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019

1. Gosodir y Memorandwm Cydsyniad Offeryn Statudol hwn o dan Reol Sefydlog ("RhS") 30A. Mae RhS 30A yn rhagnodi bod rhaid gosod Memorandwm Cydsyniad Offeryn Statudol, ac y ceir cyflwyno Cynnig Cydsyniad Offeryn Statudol, gerbron y Cynulliad Cenedlaethol os yw un o Offerynnau Statudol (OS) y DU yn gwneud darpariaeth mewn perthynas â Chymru sy'n diwygio deddfwriaeth sylfaenol sydd o fewn cymhwysedd deddfwriaethol y Cynulliad.

2. Cyflwynwyd Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019 gerbron Senedd y DU ar 19 Tachwedd 2018 ac mae'n cael ei osod gerbron y Cynulliad yn awr. Mae'r gorchymyn ar gael yn:

http://www.legislation.gov.uk/ukdsi/2019/9780111174807/contents

Crynodeb o'r Offeryn Statudol a'i nod

3. Nod yr OS yw cywiro diffygion mewn deddfwriaeth sy'n codi wrth i'r DU ymadael â'r Undeb Ewropeaidd, mewn perthynas ag ansawdd a diogelwch organau y bwriedir iddynt gael eu trawsblannu.

4. Mae'r OS hwn yn gwneud cywiriadau technegol i Deddf Meinweoedd Dynol 2004. Mae gofyn gwneud y cywiriadau hyn er mwyn sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE.

Y ddarpariaeth berthnasol sydd i'w gwneud gan yr OS

5. Mae'r Rheoliadau hyn yn diwygio Deddf Meinweoedd Dynol 2004 i wneud mân ddiwygiad technegol i ddileu cyfeiriadau at y Cyfarwyddebau nad ydynt yn briodol bellach.

6. Mae Llywodraeth Cymru o'r farn fod y darpariaethau a ddisgrifir ym mharagraff 5 uchod o fewn cymhwysedd deddfwriaethol Cynulliad Cenedlaethol Cymru i'r graddau y maent yn ymwneud ag ansawdd a diogelwch organau y bwriedir iddynt gael eu trawsblannu.

Pam y mae'n briodol i'r OS wneud y ddarpariaeth hon

7. Nid oes gwahaniaeth rhwng Llywodraeth Cymru a Llywodraeth y DU o ran y polisi ar gyfer y cywiriad. Felly, byddai gwneud OSau ar wahân yng Nghymru ac yn Lloegr yn arwain at ddyblygu gwaith a chymhlethdod diangen i'r llyfr statud. Mae cydsynio i OS ar draws y DU yn sicrhau bod un fframwaith deddfwriaethol ar draws y DU sy'n hybu

eglurder a hygyrchedd yn ystod y cyfnod hwn o newid. O dan yr amgylchiadau eithriadol hyn, mae Llywodraeth Cymru yn ystyried ei bod yn briodol i Lywodraeth y DU ddeddfu ar ein rhan yn yr achos hwn.

Vaughan Gething AC
Ysgrifennydd y Cabinet dros Iechyd a Gwasanaethau Cymdeithasol

22 Tachwedd 2018

Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

D R A F T S T A T U T O R Y I N S T R U M E N T S

2019 No. 0000

EXITING THE EUROPEAN UNION

HUMAN TISSUE

The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019

Made - - - - 2019

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 23(1) of the European Union (Withdrawal) Act 2018(**a**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

PART 2

Amendment of primary legislation

Amendment of the Human Tissue Act 2004

2.—(1) Section 32 of the Human Tissue Act 2004(**b**) (prohibition of commercial dealings in human material for transplantation) is amended as follows.

(2) In subsection (3A)—

(**a**) 2018 c. 16.
(**b**) 2004 c. 30. Section 32 was amended by S.I. 2012/1501 and 2014/1459.

(a) for "could result in the United Kingdom being in breach of" substitute "would be incompatible with the principles set out in";

(b) at the end insert—

"and for the purposes of this subsection, those Articles of those Directives are to be read subject to the modifications set out in subsections (3B) and (3C).".

(3) After subsection (3A) insert—

"(3B) Article 12 of Directive 2004/23/EC(**a**) is to be read as if—

(a) in paragraph 1—

(i) for the first subparagraph there were substituted—

"Donations of tissues and cells shall be voluntary and unpaid.";

(ii) in the second subparagraph, the second sentence were omitted;

(iii) the third subparagraph were omitted;

(b) in paragraph 2, for the first subparagraph there were substituted—

"Any promotion and publicity activities in support of the donation of human tissues and cells shall comply with any directions of the Authority or any provision of any enactment which relates to such activities.";

(c) also in paragraph 2, in the second subparagraph—

(i) "Member States shall endeavour to ensure that" were omitted;

(ii) for "is" there were substituted "shall be".

(3C) Article 13 of Directive 2010/53/EU(**b**) is to be read as if—

(a) in paragraph 1—

(i) "Member States shall ensure that" were omitted; and

(ii) for "are" there were substituted "shall be".

(b) in paragraph 2, the second sentence were omitted;

(c) in paragraph 3—

(i) "Member States shall prohibit" were omitted; and

(ii) at the end there were inserted "shall be prohibited";

(d) in paragraph 4—

(i) "Member States shall ensure that" were omitted; and

(ii) for "is" there were substituted "shall be".".

PART 3

Amendment of subordinate legislation

Amendment of the Quality and Safety of Organs Intended for Transplantation Regulations 2012

3.—(1) The Quality and Safety of Organs Intended for Transplantation Regulations 2012(**c**) are amended as follows.

(2) In regulation 3 (interpretation)—

(a) the existing text becomes paragraph (1);

(b) in that paragraph (1)—

(**a**) OJ No L 102, 07.04.2004, p48.
(**b**) OJ No L 207, 06.08.2010, p14.
(**c**) S.I. 2012/1501, amended by S.I. 2014/1459 and 2015/1679.

(i) omit the definition of "the Directive";

(ii) omit the definition of "the Implementing Directive"(**a**);

(iii) after the definition of "procurement activity" insert—

""procurement organisation" means a healthcare establishment, a team or a unit of a hospital, a person, or any other body which undertakes or coordinates the procurement of organs, and is authorised to do so by the Authority;";

(c) after paragraph (1) insert—

"(2) In these Regulations, a reference to ensuring compliance with these Regulations includes a reference to ensuring compatibility with the principles set out in Article 13 of Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation as modified by section 32(3C) of the 2004 Act.".

(3) Omit regulation 4 (designation of the competent authority).

(4) In regulation 5 (licensing requirement), at the end insert—

"(6) Schedule 1A (which specifies information to be collected in certain circumstances for the purposes of paragraph 5 of Schedule 1) has effect.".

(5) In regulation 6(**b**) (application of the 2004 Act in relation to licences under Schedule 1), for "the Directive and the Implementing Directive", in each place where those words appear, substitute "these Regulations".

(6) In regulation 12(**c**) (guidance), in paragraph (1) for "the Directive and the Implementing Directive" substitute "these Regulations".

(7) In regulation 13(**d**) (framework and compliance with licensing conditions and directions), in paragraph (1) omit "in compliance with the Directive and the Implementing Directive".

(8) In regulation 18(**e**) (organs sent to or received from another country)—

(a) omit paragraphs (1), (1A) and (2);

(b) in paragraph (3) for "to, or received from, countries which are not in the European Union" substitute ", or received from, outside the United Kingdom";

(c) in paragraph (4) for "that are not in the European Union" substitute "outside the United Kingdom".

(9) Omit regulation 19 (European Union network of competent authorities).

(10) In regulation 24 (review) omit subsection (2).

(11) After regulation 24 insert—

"PART 5A

Power to amend data sets specified in Schedule 1A

Power for appropriate authority to amend Schedule 1A

24A.—(1) The appropriate authority may by regulations amend—

(a) the minimum data set specified in Part A of Schedule 1A (organ and donor characterisation) where the appropriate authority considers, on the basis of scientific evidence, that the amendment is justified by a serious risk to human health;

(**a**) The definition of "the Implementing Directive" was inserted by S.I. 2014/1459.
(**b**) Regulation 6 was amended by S.I. 2014/1459.
(**c**) Regulation 12 was amended by S.I. 2014/1459.
(**d**) Regulation 13 was amended by S.I. 2014/1459.
(**e**) Regulation 18 was amended by S.I. 2014/1459.

(b) the complementary data set specified in Part B of that Schedule where the appropriate authority considers, on the basis of scientific evidence, that it is appropriate to do so.

(2) In this regulation—

"appropriate authority" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales—

(i) the Welsh Ministers; or

(ii) the Secretary of State acting with the consent of the Welsh Ministers;

(c) in relation to Scotland—

(i) the Scottish Ministers; or

(ii) the Secretary of State acting with the consent of the Scottish Ministers;

(d) in relation to Northern Ireland—

(i) the Department of Health in Northern Ireland; or

(ii) the Secretary of State acting with the consent of that Department;

(e) for the whole of the United Kingdom, the Secretary of State acting with the consent of the Welsh Ministers, the Scottish Ministers and the Department for Health in Northern Ireland.

Scope and nature of powers

24B.—(1) Regulations made by the Secretary of State or the Welsh Ministers under regulation 24A are to be made by statutory instrument.

(2) For regulations made under regulation 24A by the Scottish Ministers see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**a**) (Scottish statutory instruments).

(3) Any power of the Department of Health in Northern Ireland to make regulations under regulation 24A is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**b**).

(4) Any power in regulation 24A to make regulations includes power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.

Scrutiny of regulations

24C.—(1) A statutory instrument containing regulations made by the Secretary of State under regulation 24A is subject to annulment in pursuance of a resolution of either House of Parliament.

(2) Regulations made under regulation 24A by the Scottish Ministers are subject to the negative procedure (see section 28 of the Interpretation and Legislative Reform (Scotland) Act 2010 (instruments subject to the negative procedure)).

(3) A statutory instrument containing regulations made by the Welsh Ministers under regulation 24A is subject to annulment in pursuance of a resolution of the National Assembly for Wales.

(4) Regulations made by the Department of Health in Northern Ireland under regulation 24A are subject to negative resolution within the meaning of section 41(6) of the

(**a**) 2010 asp 10.
(**b**) S.I. 1979/1573 (N.I. 12).

Interpretation Act (Northern Ireland) 1954(**a**) (definitions for parliamentary purposes) as if they were a statutory instrument within the meaning of that Act.".

(12) In Schedule 1 (licences)—

(a) in paragraph 3(a) omit "European Union,";

(b) in paragraph 5(b)—

(i) in paragraph (i), for "the Annex to the Directive" substitute "Schedule 1A";

(ii) in paragraph (ii), for the words from "the Annex" to the end substitute "Schedule 1A";

(c) in paragraph 7 for "the Annex to the Directive" substitute "Schedule 1A".

(13) After Schedule 1 insert—

"SCHEDULE 1A

Regulation 5

Organ and Donor Characterisation

PART A

Minimum data set

1. The information to be collected pursuant to paragraph 5(b)(i) of Schedule 1 for organ and donor characterisation is the following (the "minimum data set")—

(a) the establishment where the procurement takes place and other general data;

(b) type of donor;

(c) blood group;

(d) gender;

(e) cause of death;

(f) date of death;

(g) date of birth or estimated age;

(h) weight;

(i) height;

(j) past or present history of IV drug abuse;

(k) past or present history of malignant neoplasia;

(l) present history of other transmissible disease;

(m) HIV, HCV, HBV tests;

(n) basic information to evaluate the function of the donated organ.

PART B

Complementary data set

2. The information to be collected pursuant to paragraph 5(b)(ii) of Schedule 1 for organ and donor characterisation is the following (the "complementary data set")—

(**a**) 1954 c. 33.

General data

(a) Contact details of the procurement organisation and (if different) the establishment where the procurement takes place necessary for coordination, allocation and traceability of the organs from donors to recipients and vice versa.

Donor data

(b) Demographic and anthropometrical data required in order to guarantee an appropriate matching between the donor or organ and the recipient.

Donor medical history

(c) Medical history of the donor, in particular the conditions which might affect the suitability of the organs for transplantation and imply the risk of disease transmission.

Physical and clinical data

(d) Data from clinical examination which are necessary for the evaluation of the physiological maintenance of the potential donor as well as any finding revealing conditions which remained undetected during the examination of the donor's medical history and which might affect the suitability of the organs for transplantation or might imply the risk of disease transmission.

Laboratory parameters

(e) Data needed for the assessment of the functional characterisation of the organs and for the detection of potentially transmissible diseases and of possible contraindications with respect to organ donation.

Image tests

(f) Image explorations necessary for the assessment of the anatomical status of the organs for transplantation.

Therapy

(g) Treatments administered to the donor and relevant for the assessment of the functional status of the organs and the suitability for organ donation, in particular the use of antibiotics, inotropic support or transfusion therapy.".

(14) In Schedule 2 (directions of the Authority)—

(a) in paragraph 1, in sub-paragraph (e) omit "European Union,";

(b) omit paragraph 3(**a**).

Signed by authority of the Secretary of State for Health and Social Care.

Name
Parliamentary Under-Secretary of State,
Department of Health and Social Care

Address
Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in sections 8(1) and 23(1) of the European Union (Withdrawal) Act 2018 (c. 16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under section 8(2)(a), (f) and (g)) arising from the withdrawal of the UK from the European Union.

(**a**) Paragraph 3 was inserted by S.I. 2014/1459.

These Regulations make amendments to legislation in the field of procedures to be followed and information to be transmitted in connection with ensuring the quality and safety of organs intended for transplantation.

Part 2 amends primary legislation. Part 3 amends subordinate legislation, including to confer a power for the appropriate authority to make regulations in connection with the information to be collected concerning the characterisation of organs and donors.

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

Printed and published in the UK by The Stationery Office Limited under the authority and superintendence of Jeff James, Controller of Her Majesty's Stationery Office and Queen's Printer of Acts of Parliament.

£6.90

UK201811151011 11/2018 19585

http://www.legislation.gov.uk/id/ukdsi/2019/9780111174807

ISBN 978-0-11-117480-7

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EXPLANATORY MEMORANDUM TO

THE HUMAN TISSUE (QUALITY AND SAFETY FOR HUMAN APPLICATION) (AMENDMENT) (EU EXIT) REGULATIONS 2019;

THE HUMAN FERTILISATION AND EMBRYOLOGY (AMENDMENT) (EU EXIT) REGULATIONS 2019;

THE QUALITY AND SAFETY OF ORGANS INTENDED FOR TRANSPLANTATION (AMENDMENT) (EU EXIT) REGULATIONS 2019

[2019] No. [XXXX]

1. Introduction

1.1 This explanatory memorandum has been prepared by the Department of Health and Social Care and is laid before Parliament by Command of Her Majesty.

1.2 This memorandum contains information for the Joint Committee on Statutory Instruments.

2. Purpose of the instruments

2.1 The three Statutory Instruments (SIs) on the safety of organs, tissues and cells, and reproductive cells (gametes and embryos) for treating patients are 'no deal' SIs. They have been developed as part of contingency planning and will be needed in the event that the United Kingdom (UK) leaves the European Union (EU) in March 2019 with no agreement in place; i.e. a 'no deal' scenario.

Withdrawal from the EU without a deal would mean that the law in this area will no longer work as it is intended to. This is because it contains a number of references that will no longer be appropriate, such as references to obligations that the UK is required to comply with as an EU Member State. Additionally, as the UK and EU Member States will consider each other to be third countries, amendments have been made to reflect this.

The SIs are being made under powers in the European Union (Withdrawal) Act 2018 (referred to here as the EU (Withdrawal) Act). There are three separate SIs:

- the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'Tissues and Cells SI';
- Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'HFE SI'; and
- the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 – referred to here as the 'Organs SI'.

The SIs are being made on a UK-wide basis. The Tissues and Cells and Organs SIs are being made with the agreement of each of the Devolved Administrations (DAs) and the HFE SI is reserved to Westminster.

The SIs have been drafted separately as each amends different underlying legislation. The purpose of the SIs is to ensure that, in the unlikely scenario that the UK leaves the

EU with no deal, the law in this area will still function properly and the UK regulatory framework for the safety and quality of organs and tissues and cells (including reproductive cells) is maintained.

It is proposed that these SIs should be grouped and debated together.

Explanations

What did any relevant EU law do before exit day?

Donated human organs, tissues and cells are used in potentially life-saving or life changing treatments for patients. The UK regulatory frameworks set high standards of patient safety.

UK law in this area transposes the **EU Tissue and Cells Directives**[1] for tissues and cells (including reproductive cells) and the **EU Organ Donation Directives**[2] for organs.

These directives are collectively referred to in this memorandum as 'the Directives'.

The Directives introduced a range of quality and safety standards, aiming to safeguard patient safety. These include the following: -

- The procurement, testing, processing, and storage of tissues and cells (including reproductive cells);
- Organ and donor characterisation, which means information, including tissue typing tests, which must be collected so an organ can be matched with a suitable recipient;
- Traceability requirements in respect of organs for transplantation, tissues such as corneas or bone, stem cells and sperm, eggs and embryos (reproductive cells) for assisted reproduction; and
- Notification requirements in the event of serious adverse events or reactions which may impact the quality and safety of organs, tissue and cells (including reproductive cells).

Why is it being changed?

The amendments in these instruments are to ensure that the law on the quality and safety of organs, tissues and cells (including reproductive cells) will continue to function as intended after exit day. The UK and the EU will consider each other to be third countries if there is no deal on exit and the SIs redefine the term 'third country' to include EU countries and Gibraltar. As a result, licensed establishments will need to make administrative changes to continue to import organs, tissues and cells from EU countries and Gibraltar.

The legislation being amended also contains a number of references that will no longer be appropriate once the UK withdraws from the EU, such as references to

[1] The requirements in the EU Tissue and Cells Directives have been implemented in the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Human Fertilisation and Embryology Act 1990. The EU Tissue and Cells Directives are Directive 2004/23/EC and the Implementing Directives 2006/17/EC, 2006/86/EC, 2012/39/EU, (EU) 2015/565, (EU) 2015/566.

[2] The requirements in the EU Organ Donation Directives have been implemented in the Quality and Safety of Organs Intended for Transplantation Regulations 2012. The EU Organ Donation Directives are Directive 2010/53/EU and the Implementing Directive 2012/25/EU.

obligations which the UK must comply with as an EU Member State, and some references to the EU, the European Economic Area (EEA), the European Commission (the Commission) and EU law.

The Commission also has a number of powers under the Directives, to update technical requirements in line with scientific developments or if there is a health threat from a new disease. The Commission will no longer exercise these powers on the UK's behalf so the regulation making powers are being conferred on the Secretary of State (and where within devolved competence, the DAs) so the quality and safety standards can be updated following EU exit if they need to be.

What will it now do?

The amendments made by these instruments will ensure that the UK maintains the current quality and safety standards for organs, tissues and cells (including reproductive cells) after exit. Some organs, tissues and cells move between the UK and EU countries but numbers are relatively small, the amendments will allow this to continue after exit with minimal additional administration.

The detailed breakdown of the various types of changes which these instruments will bring about is included in section 7. They will make the following changes:

- Amend or omit references to EU/EEA/Member State.
- Revoke obligations on UK organisations and reciprocal arrangements between UK and EU organisations (referred to as competent authorities in the Directives) that will no longer be relevant to the UK.
- Confer relevant Commission powers to make regulations under the Tissue and Cells Directives and the Organ Donation Directives to the Secretary of State and, in relation to the Organs and Tissues and Cells SIs, the Devolved Administrations (all of which are detailed in paragraph 7.25).
- Set out updated requirements for licensing and written agreements to import tissues and cells from EEA states and Gibraltar to align these with existing requirements for countries outside the EEA and Gibraltar.
- In relation to the HFE and Tissues and Cells SIs, make transitional provisions so that imports of tissue and cells (including reproductive cells) from EEA states and Gibraltar may continue for a six-month period after exit day whilst licences and written agreements are put in place.

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

3.1 The HFE SI contains, at regulation 2(14), a new regulation making power for the Secretary of State to make regulations in relation to standards of quality and safety for reproductive cells. This power may be used to make amendments to the Human Fertilisation and Embryology Act 1990 within the scope of the regulation making power in the new section 42A of the Human Fertilisation and Embryology Act 1990, as inserted by regulation 2(14) of the HFE SI. The current standards of quality and safety are set out in the Human Fertilisation and Embryology Act 1990. The new regulation making power may be used to amend this Act to ensure that the current standards of quality and safety can be amended. The power is affirmative and any

Regulations proposing changes to existing provisions would be affirmative and subject to consultation.

Matters relevant to Standing Orders Nos. 83P and 83T of the Standing Orders of the House of Commons relating to Public Business (English Votes for English Laws)

3.2 The territorial application of these instruments is the UK.

3.3 Legislative competence for the donation, processing and use in treatment of human reproductive cells (sperm, egg and embryos) is reserved to Westminster (i.e. legislation is dealt with by the Westminster Parliament). Competence in respect of all other human tissues and cells and organs is devolved.

4. Extent and Territorial Application

4.1 The territorial extent of these instruments is the UK.

4.2 The territorial application of these Regulations is set out in Section 3.2.

5. European Convention on Human Rights

5.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding Human Rights:

"In my view the provisions of The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 are compatible with the Convention rights."

6. Legislative Context

6.1 The amendments in these instruments are needed to ensure that the law on the quality and safety of organs, tissues and cells (including reproductive cells) will continue to function after exit if the UK leaves the EU without a deal in place.

6.2 The relevant UK legislation is:

- The Human Tissue (Quality and Safety for Human Application) Regulations 2007;
- relevant amendments to the Human Tissue Act 2004 and the Human Fertilisation and Embryology Act 1990.
- the Quality and Safety of Organs Intended for Transplantation Regulations 2012); and
- the Human Fertilisation and Embryology (Quality and Safety) Regulations 2007;

This legislation was made under powers conferred by section 2(2) of the European Communities Act 1972 in order to implement the Tissue and Cells Directives and the Organ Donation Directives (see paragraph 2.2 above for a full description of relevant EU law).

6.3 Section 2 of the EU (Withdrawal) Act saves EU-derived domestic legislation so that it continues to have effect in domestic law on and after exit day. The legislation in paragraph 6.2 will be preserved and is being amended pursuant to the power in Section 8 of the EU (Withdrawal) Act in order to function effectively after exit.

7. Policy background

7.1 An organ transplant can be life saving or life transforming and is often the only treatment option available for the patient concerned. Human tissues and cells are used in what can be life changing therapies, such as:

- stem cells used to treat blood cancers
- corneas to restore sight
- heart valves to treat heart conditions
- skin grafts to treat burns
- eggs and sperm to treat infertility

7.2 Other forms of tissue are much more generic in use, for example bone products used in operations and by dentists for fillings.

7.3 EU law sets the policy and legal framework in relation to the donation, retrieval, processing, storage, transport, import and export of organs, tissues and cells used for transplantation, as set out in paragraph 2.2.

7.4 These instruments are intended to ensure that UK law for the safety of organs, tissues and cells continues to apply effectively in the event of no deal. UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics that undertake licensable activities working in this area are regulated by:

- the Human Tissue Authority (HTA) for organs, tissues and cells other than reproductive tissues and cells; and
- the Human Fertilisation and Embryology Authority (HFEA) for reproductive tissues and cells.

7.5 UK licensed establishments will continue to work to the same safety standards in place before exit and the changes contained within the instruments are designed to make the necessary changes to reflect the status of the UK outside the EU.

7.6 At present some organs, tissues and cells move between the UK and EU countries, but also between the UK and non-EU countries (third countries). A small number of organs are shared with EU and non-EU countries, with less than 30 organs on average being imported or exported each year. Tissues and cells are imported from and exported to EEA/EU countries less often than they are imported and exported from and to countries outside the EEA/EU. The UK imports donated sperm, primarily from commercial sperm banks in the USA and Denmark.

What is being done and why?

7.7 As set out in Section 6, these instruments are being made so that the law in this area will continue to work as it is intended to after the UK leaves the EU.

Examples of the deficiencies addressed by these amendments are listed below.

EU obligations that will no longer be relevant or appropriate

7.8 In some cases, EU obligations are removed that will no longer be relevant or appropriate. For example, there are currently requirements on the HTA and the HFEA to report to the Commission and/or competent authorities of other Member States certain information submitted to them regarding serious adverse events and reactions that affect organs, tissues and cells used by UK establishments. The Tissues and Cells SI and the HFE SI remove this obligation as it is no longer appropriate.

7.9 Similarly, there is a requirement for the HTA to participate in a network of competent authorities established by the Commission and to co-ordinate UK input into the activities of that network. The Organs SI removes this requirement as it is no longer appropriate.

7.10 There is also an obligation under the EU Tissue and Cells Directives for EEA Member States to inspect third country premises at the request of another EEA Member State. As the UK will no longer be an EEA Member State after exit, there will no longer be an obligation on the HTA and the HFEA to inspect UK establishments on behalf of EEA Member States. These instruments therefore remove this obligation.

7.11 The current legislation, in relation to tissues and cells (including reproductive cells) requires tissue establishments to use the Single European Code (SEC) and the EU Coding Platform to facilitate the traceability of tissues and cells used to treat patients across the EU. The EU Coding Platform provides a list of all licensed establishments across the EU, the activities they are licensed for and the tissue and cells types they have been authorised by the competent authorities to work with. Competent authorities must ensure that entries for the establishments that they license are accurate and access to the platform is restricted to EEA countries. After exit day, the UK will be considered a third country under the Directives and UK tissue establishments will not use the SEC. The UK will not use the platform and there will be no need for the details for UK establishments to be added to the platform.

7.12 The obligation to use the SEC and associated obligations such as for the HTA and HFEA to update the details of UK licensed establishments on the platform has therefore been omitted in the Tissues and Cells SI and the HFE SI. UK licensed establishments were already using systems to ensure traceability from donor to recipient of tissues and cells before the introduction of the SEC, and in most cases the SEC was added to these existing systems. After exit, the UK licensed establishments will be able to use the traceability systems that were in place before the introduction of the SEC.

EU references which are redundant or inappropriate

7.13 There are a number of amendments being made by these instruments to take account of EU references which will be redundant or inaccurate. For example, the current law includes references to 'other Member States'. These references have been amended as they will not function correctly when the UK is no longer an EU Member State. Amendments have also been made to references to 'competent authority', to reflect that the Directives will not form part of domestic law after exit.

Exchange of organs, tissues and cells with EU countries as third countries

7.14 The Tissue and Cells Directives and the Organ Donation Directives allow for organ, tissue and cells exchange between EEA/EU Member States and third countries. In a no deal scenario, the UK and EEA/EU Member States will consider each other to be third countries and UK law has to be amended to reflect this change.

Import from EEA/EU countries

7.15 UK establishments will be able to continue to import organs, tissues and cells from establishments in EEA/EU states. As noted above, EEA/EU states will be considered as third countries by the UK and the UK will therefore extend the existing third country provisions to EU countries. For example, regulation 3 in the Tissues and Cells SI removes specific provision in relation to imports from the EEA and Gibraltar. This has been omitted as post exit the same requirements for imports will apply to all third countries.

7.16 Regulation 4 of the Tissues and Cells and the HFE SIs sets out that UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EEA states. This is to allow UK licensed establishments that import tissues and cells from EEA states to put in place new agreements or amend existing ones, to comply with the requirements in the legislation. This will also allow establishments sufficient time to apply for or amend existing import licences or authorisations.

7.17 The arrangement for accepting organs from third countries are less extensive for organs. NHS Blood and Transplant (NHSBT), the organisation responsible for organ donation and transplantation in the UK, and the HTA will work together to put any new agreements in place as needed to allow organ exchange to continue post-exit. UK transplant centres will not be affected by the fixes made by the Organs SI. There is therefore no need for a transitional period and NHSBT will be able to accept organs from EU countries from exit day provided that such organs can be traced from donor to recipient and meet quality and safety standards equivalent that required in UK law.

7.18 Information on export to EU countries is available in the technical notice published in August 2018: https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal

References to EU Directives in UK law

7.19 UK law[3] implements EU Directives in part by cross-referring to the Directives. After exit, some of these references will be retained in UK law. These instruments amend UK law to clarify that where there is a reference to a requirement of a directive in UK law, the requirement will still apply after exit in the same way it did prior to exit.

7.20 To ensure that such references function correctly after exit, it is necessary to modify how some of the articles and annexes in the Directives are to be read. For example, where a reference is made to "the competent authority or authorities" this will be read as a reference to the HFEA or HTA. In addition, where specific provisions have been implemented in UK law, instead of referring to the relevant articles in the Directives, amendments have been made to refer to the specific requirements in the relevant UK law.

[3] The Human Fertilisation and Embryology Act 1990 and the Human Tissue (Quality and Safety for Human Application) Regulations 2007

Transfer of Commission Powers

7.21 Prior to exit day, any amendments to legislation in the field of organs, tissues and cells (including reproductive cells), have been made under section 2(2) of the European Communities Act 1972. After exit, the European Communities Act 1972 will be repealed. Similarly, the European Commission will no longer have any functions in respect of the UK.

7.22 As noted in paragraph 2.2, there are a range of powers currently held by the European Commission under the Tissue and Cells Directives and the Organ Donation Directives. These instruments insert into UK law[4] similar powers for the Secretary of State and where the matters fall within devolved competence, the DAs, to update legislation on organs, tissues and cells in response to, for example, emerging threats, changing safety and quality standards, and technological advances.

7.23 These updating powers are likely to have minimal impact on industry. Their purpose is to make sure that the UK is still able to make changes after we leave the EU, where needed.

Powers in the HFE SI and the Tissues and Cells SI

7.24 The Commission currently holds powers in Articles 8, 9, 11 and 28 of Directive 2004/23/EC to update technical requirements relating to tissues and cells (including reproductive cells), to prescribe traceability requirements and notification requirements in relation to serious adverse events and serious adverse reactions and to verify equivalent standards of safety and quality where tissues and cells (including reproductive cells) are imported from third countries.

7.25 In relation to tissues and cells (excluding reproductive cells) these powers are being conferred on the Secretary of State in relation to England and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in relation to Northern Ireland, the Department of Health).

7.26 Policy on reproductive cells is reserved to Westminster and so these powers are only being conferred on the Secretary of State.

7.27 The powers which will be conferred are contained in the new section 42A of the Human Fertilisation and Embryology Act 1990 (power to make regulations in relation to standards of quality and safety) and the new regulation 34ZA (power to make regulations in relation to standards of quality and safety) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

7.28 These provisions contain powers akin to the current Commission powers contained in Directive 2004/23/EC. Details of the powers being conferred and examples as to how these powers could be used are as follows: -

- The power to prescribe requirements to ensure traceability of tissues and cells (including reproductive cells).

[4] The Human Fertilisation and Embryology Act 1990, the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and the Quality and Safety of Organs Intended for Transplantation Regulations 2012

This power could be used to introduce a UK national coding system for tissues and cells. The power could be used to make the use of the coding system a statutory obligation for tissue establishments and place duties on the two authorities in relation to the management of the coding system, and provide elements of it such as the product code, similar to the role the EU plays in the management of the Single European Code.

- The power to make provision in relation to the notification of serious adverse events and serious adverse reactions.

  This power could be used to specify that certain information that relates to a serious adverse incident is provided by tissue establishments or that information related to an incident is provided to another authority. For example, the HTA or HFEA may need to know if certain reagents were used in the preparation of tissue to which a patient suffered a severe adverse reaction, for the Medicines and Healthcare products Regulatory Agency (MHRA) to consider if the chemical should be prohibited from use with human material.

- The power to make provision specifying to requirements to be met for verifying equivalent standards of safety and quality in relation to imports of tissues and cells (including reproductive cells).

  This power could be used in the event of an outbreak of a serious infectious disease or a new infection that could be transmitted, through tissue transplantation, to the recipient, or adversely affect the development of a child conceived using gametes from an infected person. In such cases, the Secretary of State may wish to specify in regulations that tests specified by the UK Advisory Committee of the Safety of Blood, Tissues and Organs had been conducted by the third country exporting establishment and the tissues sent to the UK are certified as infection free.

- The power to prescribe technical requirements relating to tissue establishments.

  This power would be used to update the requirements related to the quality and safety of tissues and cells, in response to technical advances or the development of new therapies. For example, the power could be used to update the requirements that need to be met to demonstrate that a new technique used to process tissues or cells is safe and does not adversely affect the quality of the tissues or cells.

Powers in the Organs SI

7.29 The Commission currently holds a power in Article 24 of Directive 2010/53/EU to adopt delegated acts in order to supplement or amend the Annex to Directive 2010/53/EU (the Annex). The Annex contains the information requirements for organ and donor characterisation. As the European Commission will no longer have any functions in respect of the UK, in the event of a serious adverse event which presents a serious risk to human health, any delegated acts made by the Commission will not apply to the UK.

7.30 A similar power is therefore being conferred on the Secretary of State in relation to England and on the appropriate devolved minister in relation to Wales and Scotland and on the Department of Health in Northern Ireland. The Secretary of State will also

be able to make UK wide regulations, or regulations for a part of the UK, with the consent of the appropriate devolved ministers (or in relation to Northern Ireland, the Department of Health).

7.31 As noted above, this power would be used to update organ and donor characterisation requirements to mitigate risk to human health, usually in response to an emerging disease outbreak. In such cases, the Secretary of State may wish to add additional requirements to characterise donors, such as additional tests.

8. European Union (Withdrawal) Act/Withdrawal of the United Kingdom from the European Union

8.1 These instruments are being made using the power in section 8 of the EU (Withdrawal) Act in order to enable retained EU law to operate effectively following withdrawal of the United Kingdom from the European Union.

8.2 The Organs SI is also made under section 23(1) of the EU (Withdrawal) Act in order to make a consequential amendment to regulation 24 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012. This requires the Secretary of State to have regard to how the Organ Donation Directives have been implemented in EU member states when reviewing the regulations. This provision has no effect post exit in light of paragraph 9 of Schedule 8 of the EU (Withdrawal) Act.

8.3 As set out in paragraph 7.16, UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EU countries. This provision has been made under schedule 7, paragraph 21(b) of the EU (Withdrawal) Act.

8.4 In accordance with the requirements of that Act the Minister has made the relevant statements as detailed in Part 2 of the Annex to this Explanatory Memorandum.

9. Consolidation

9.1 These Statutory Instruments do not involve consolidation and there are no plans to consolidate the Human Fertilisation and Embryology Act 1990 or the Human Tissue Act 2004 at this time.

10. Consultation outcome

10.1 The amendments introduced by these SIs are technical in nature and their purpose is to maintain the current UK regulatory framework for the safety and quality of organs and tissues and cells. There was therefore no public consultation. The changes in the SIs were discussed with the UK regulators, the HTA and HFEA, along with issues of operational implementation.

10.2 The proposed amendments have been discussed with the Scottish, Welsh and Northern Irish devolved administrations and their views have been taken into account in the drafting of these instruments. The Organs and Tissues and Cells SIs are being made on a UK wide basis with the agreement of the devolved administrations.

11. Guidance

11.1 Guidance for tissue establishments will be provided by the two UK competent authorities. For reproductive cells, guidance will be published by the HFEA. In respect of organs and all other human tissues and cells, guidance will be published by the HTA.

11.2 A technical notice was published in August 2018, setting out the actions organisations, businesses and members of the public should consider taking, to ensure continued access to and use of organs, tissues and cells, including reproductive cells, in the unlikely event that the UK leaves the EU in March 2019 with no agreement in place: https://www.gov.uk/government/publications/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal/quality-and-safety-of-organs-tissues-and-cells-if-theres-no-brexit-deal

11.3 NHSBT and the HTA will work together to put any new agreements in place as needed to allow organ exchange to continue post-exit. UK transplant centres will not be affected by the fixes made by the Organs SI.

11.4 UK establishments will have a transitional period of six months to comply with the requirements to import tissues and cells from EEA states.

12. Impact

12.1 There is no significant impact on business, charities or voluntary bodies.

12.2 An Impact Assessment has not been prepared for these instruments because the direct cost impact has been assessed as lower than the £5m threshold in any one year and the policy is not considered novel or contentious.

12.3 The instruments are intended to maintain the current regulatory framework so UK organisations such as hospitals, stem cell laboratories, tissue banks and fertility clinics will continue to work to the same standards that they did prior to exit. Some organs, tissues and cells move between the UK and EU countries. Numbers are relatively small and the amendments allow this to continue after exit.

12.4 The impact of these instruments on businesses will be low. The only key impacts are in relation to agreements that licensed establishments will need to put in place to be able to import tissues and cells from EU countries. Establishments that already hold an import licence to import tissues and cells from third countries will be able to use their existing written agreements with third country organisations as a template. There is no impact for organ transplant centres.

13. Regulating small business

13.1 The legislation applies to activities that are undertaken by small businesses. The SIs relate to quality, safety and traceability standards for patients and no exceptions would be applied to small businesses.

14. Monitoring & review

14.1 The SIs are intended to ensure that appropriate arrangements are in place for organs, tissues and cells to continue to be exchanged with EU countries and that quality and safety standards are maintained post exit. The effectiveness of the SIs in doing so will be regularly evaluated as part of a programme of accountability meetings between the Department of Health and Social Care and the HFEA and HTA.

14.2 As these instruments are made under the EU (Withdrawal) Act, no review clause is required.

15. Contact

15.1 Emma Wilbraham: (020) 7972 3013 or email: emma.wilbraham@dh.gsi.gov.uk can answer any queries regarding The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 and The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019.

Kim Hayes: (020) 7210 6339 or email: kim.hayes@dh.gsi.gov.uk can answer any queries regarding the Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019.

15.2 Jeremy Mean at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

15.3 Jackie Doyle-Price at the Department of Health and Social Care can confirm that this Explanatory Memorandum meets the required standard.

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

This table sets out the statements that may be required under the 2018 Act.

Statement	Where the requirement sits	To whom it applies	What it requires
Sifting	Paragraphs 3(3), 3(7) and 17(3) and 17(7) of Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) to make a Negative SI	Explain why the instrument should be subject to the negative procedure and, if applicable, why they disagree with the recommendation(s) of the SLSC/ESIC
Appropriate-ness	Sub-paragraph (2) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	A statement that the SI does no more than is appropriate.
Good Reasons	Sub-paragraph (3) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain the good reasons for making the instrument and that what is being done is a reasonable course of action.
Equalities	Sub-paragraphs (4) and (5) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2	Explain what, if any, amendment, repeals or revocations are being made to the Equalities Acts 2006 and 2010 and legislation made under them. State that the Minister has had due regard to the need to eliminate discrimination and other conduct prohibited under the Equality Act 2010.
Explanations	Sub-paragraph (6) of paragraph 28, Schedule 77	Ministers of the Crown exercising clauses 8(1), 9 and 23(1) or jointly exercising powers in Schedule 2 In addition to the statutory obligation the Government has made a political commitment to include these statements alongside all EUWA SIs	Explain the instrument, identify the relevant law before exit day, explain the instrument's effect on retained EU law and give information about the purpose of the instrument, e.g., whether minor or technical changes only are intended to the EU retained law.
Criminal offences	Sub-paragraphs (3) and (7) of paragraph 28, Schedule 7	Ministers of the Crown exercising clauses 8(1), 9, and 23(1) or jointly exercising	Set out the 'good reasons' for creating a criminal offence, and the penalty attached.

		powers in Schedule 2 to create a criminal offence	
Sub-delegation	Paragraph 30, Schedule 7	Ministers of the Crown exercising clauses 10(1), 12 and part 1 of Schedule 4 to create a legislative power exercisable not by a Minister of the Crown or a Devolved Authority by Statutory Instrument.	State why it is appropriate to create such a sub-delegated power.
Urgency	Paragraph 34, Schedule 7	Ministers of the Crown using the urgent procedure in paragraphs 4 or 14, Sch 7.	Statement of the reasons for the Minister's opinion that the SI is urgent.
Explanations where amending regulations under 2(2) ECA 1972	Paragraph 13, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement explaining the good reasons for modifying the instrument made under s.2(2) ECA, identifying the relevant law before exit day, and explaining the instrument's effect on retained EU law.
Scrutiny statement where amending regulations under 2(2) ECA 1972	Paragraph 16, Schedule 8	Anybody making an SI after exit day under powers outside the European Union (Withdrawal) Act 2018 which modifies subordinate legislation made under s.2(2) ECA	Statement setting out: a) the steps which the relevant authority has taken to make the draft instrument published in accordance with paragraph 16(2), Schedule 8 available to each House of Parliament, b) containing information about the relevant authority's response to— (i) any recommendations made by a committee of either House of Parliament about the published draft instrument, and (ii) any other representations made to the relevant authority about the published draft instrument, and, c) containing any other information that the relevant authority considers appropriate in relation to the scrutiny of the instrument or draft instrument which is to be laid.

Part 2

Statements required when using enabling powers under the European Union (Withdrawal) 2018 Act

1. Appropriateness statement

1.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019; Human Fertilisation and Embryology (Amendment) (EU Exit) Regulations 2019 and the Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 do no more than is appropriate".

1.2 This is the case because they do no more than amend legislation on organs, tissues and cells to correct deficiencies arising from the withdrawal of the United Kingdom from the European Union or to correct legislation on organs, tissues and cells where it would otherwise fail to operate effectively after the UK leaves the EU. This includes removing redundant provisions, amending references to obligations or reciprocal agreements that will no longer exist, and transferring appropriate Commission functions to the Secretary of State and the DAs (where within devolved competence). Further details, including examples of all the changes included in the instruments, are detailed in Section 7 of the main body of this explanatory memorandum.

2. Good reasons

2.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In my view there are good reasons for the provisions in these instruments, and I have concluded they are a reasonable course of action"

2.2 Following exit day, without amendments to the relevant legislation, policy on organs, tissues and cells would cease to function effectively. These instruments seek to remove or amend provisions in UK legislation and EU legislation saved by the EU (Withdrawal) Act 2018, in order to ensure that policy on organs, tissues and cells will continue to function at the same level as prior to exit. The instruments make a number of technical amendments, and provide the Secretary of State and DAs (where within devolved competence) with powers previously held by the EU Commission which will allow the Secretary of State and DAs to update legislation on organs, tissues and cells in in response to emerging threats, changing safety and quality standards, and technological advances. Further details, including examples of the amendments made and reasons for making them, are set out in section 7 of the main body of this explanatory memorandum.

3. Equalities

3.1 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement "The draft instruments do not amend, repeal or revoke a provision or provisions in the Equality Act 2006 or the Equality Act 2010 or subordinate legislation made under those Acts.

3.2 The Parliamentary Under Secretary of State (Mental Health, Inequalities and Suicide Prevention) Jackie Doyle-Price MP has made the following statement regarding use of legislative powers in the European Union (Withdrawal) Act 2018:

> "In relation to the draft instrument, I, Jackie Doyle-Price have had due regard to the need to eliminate discrimination, harassment, victimisation and any other conduct that is prohibited by or under the Equality Act 2010."

3.3 This instrument will have no impact on equalities.

4. Explanations

4.1 The explanations statement has been made in paragraph 2.2 of the main body of this explanatory memorandum.

GWEINIDOGION Y DU SY'N GWEITHIO MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu (Diwygio) (Ymadael â'r UE) 2019

Dyddiad gosod yn Senedd y DU: 19 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Na fydd
Gweithdrefn:	Cadarnhaol drafft
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Amherthnasol
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	Amherthnasol
Datganiad ysgrifenedig o dan Reol Sefydlog 30C	Papur 11
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Papur 10
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Cadarnhaol drafft
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau hyn gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8(1), a pharagraff 21(b) o Atodlen 7 i Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 er mwyn galluogi cyfraith yr UE a ddargedwir i weithredu'n effeithiol ar ôl i'r Deyrnas Unedig ymadael â'r Undeb Ewropeaidd.

Caiff y Rheoliadau hyn hefyd eu gwneud o dan adran 23(1) o Ddeddf yr Undeb Ewropeaidd (Ymadael) er mwyn gwneud diwygiad canlyniadol i reoliad 24 o Reoliadau Ansawdd a Diogelwch Organau y Bwriedir eu Trawsblannu 2012. Mae hyn yn ei gwneud yn ofynnol i'r Ysgrifennydd Gwladol ystyried sut y mae'r Cyfarwyddebau Rhoi Organau wedi'u gweithredu yn aelod-wladwriaethau'r UE wrth adolygu'r rheoliadau.

Diben y rheoliadau hyn yw gwneud diwygiadau i gywiro diffygion mewn deddfwriaeth sy'n ymwneud â rhoi organau ac sy'n deillio o ymadawiad y DU â'r Undeb Ewropeaidd.

Mae'r Rheoliadau yn caniatáu i'r Ysgrifennydd Gwladol a/neu Weinidogion Cymru (o fewn cymhwysedd datganoledig) sydd â phwerau a ddaliwyd yn flaenorol gan Gomisiwn yr UE i ddiweddaru deddfwriaeth ar organau mewn ymateb i fygythiadau sy'n dod i'r amlwg a safonau diogelwch ac ansawdd sy'n newid.

Mae'r Rheoliadau hyn yn rhan o gyfres o offerynnau statudol sy'n ymwneud â diogelwch organau, meinweoedd a chelloedd a chelloedd atgenhedlu ar gyfer trin cleifion. Maent i gyd yn Offerynnau Statudol 'dim bargen' sydd wedi'u datblygu fel rhan o gynlluniau wrth gefn ac y bydd eu hangen os bydd y DU yn ymadael â'r UE heb gytundeb ar waith.
Mae'r Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 22 Tachwedd 2018 ynghylch effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol i'r Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r Rheoliadau hyn yn creu polisi newydd mewn meysydd datganoledig.
Nid yw'r Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 y Memorandwm ar Fil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Nid yw'r Cynghorwyr Cyfreithiol wedi nodi unrhyw reswm cyfreithiol i geisio cynnig cydsyniad o dan Reol Sefydlog 30A.10 mewn perthynas â'r Rheoliadau hyn.

Eitem 5.1

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL	**Rheoliadau Trapiau Dal Coesau a Mewnforion Crwyn (Diwygio etc.) (Ymadael â'r UE) 2018**
DYDDIAD	**22 Tachwedd 2018**
GAN	**Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Trapiau Dal Coesau a Mewnforion Crwyn (Diwygio etc.) (Ymadael â'r UE) 2018
Cyfraith [yr UE a ddargedwir] sy'n cael ei diwygio

- Rheoliad y Cyngor (EEC) Rhif 3254/91
- Penderfyniad y Cyngor 97/602
- Rheoliad y Comisiwn (EC) Rhif 35/97

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu ar gymhwysedd gweithredol Gweinidogion Cymru
O ran Trapiau Dal Coesau a Mewnforion Crwyn, bydd y diwygiadau sy'n ymwneud â gweithredadwyedd yn ymdrin â rhai materion datganoledig (gwaharddiad ar ddefnyddio trapiau dal coesau) a rhai materion a gedwir yn ôl (gwaharddiad ar fewnforio crwyn).

Diben y diwygiadau
Diben yr OS hwn (y weithdrefn negyddol), i'w gyflwyno gan Adran yr Amgylchedd, Bwyd a Materion Gwledig (DEFRA), fydd gweithredu'r addasiadau hynny sy'n angenrheidiol ar draws y DU er mwyn i ddeddfwriaeth yr UE barhau i weithredu'n effeithiol mewn perthynas â gwahardd trapiau dal coesau a chyflwyno i'r DU grwyn rhywogaethau penodol o anifeiliaid gwyllt, a nwyddau wedi'u gweithgynhyrchu ohonynt, sy'n tarddu o wledydd sy'n eu dal drwy gyfrwng trapiau dal coesau neu ddulliau trapio nad ydynt yn bodloni safonau trapio rhyngwladol heb greulondeb.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-leghold-trap-and-pelt-imports-amendment-etc-eu-exit-regulations-2018

Pam y rhoddwyd cydsyniad
Rhoddwyd cydsyniad i Lywodraeth y DU wneud y cywiriadau hyn o ran, ac ar ran, Cymru am resymau'n ymwneud ag effeithlonrwydd, hwylustod ac oherwydd natur dechnegol y

diwygiadau. Mae'r diwygiadau wedi cael eu hystyried yn llawn; ac nid oes unrhyw wahaniaeth o ran polisi. Diben y diwygiadau hyn yw sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE. Mae hyn yn unol â'r egwyddorion ar gyfer cywiro y cytunwyd arnynt ym mis Mai gan Is-bwyllgor y Cabinet ar Bontio Ewropeaidd.

GWEINIDOGION Y DU YN GWEITHREDU MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Trapiau Dal Coesau a Mewnforion Crwyn (Diwygio etc.) (Ymadael â'r UE) 2018

Dyddiad gosod yn Senedd y DU: 21 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Bydd
Gweithdrefn:	Negyddol arfaethedig
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	wythnos yn dechrau 3 Rhagfyr 2018
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	6 Rhagfyr 2018
Datganiad ysgrifenedig o dan Reol Sefydlog 30C:	Papur 15
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Dim angen
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Negyddol neu Gadarnhaol
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau hyn gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8(1) o Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 (y Ddeddf), a pharagraff 21(b) o Atodlen 7 i'r Ddeddf.

Gwaharddodd Rheoliad y Cyngor (EEC) 3254/91 y defnydd o drapiau dal coesau yn yr Undeb Ewropeaidd a chyflwyno i mewn i'r UE fewnforion crwyn a nwyddau a weithgynhyrchir o rywogaethau anifeiliaid gwyllt penodol sy'n deillio o wledydd sy'n eu dal gyda thrapiau dal coesau neu ddulliau trapio nad ydynt yn cyrraedd safonau rhyngwladol rhwydo heb greulondeb.

Mae'r Rheoliadau hyn yn diwygio Rheoliad y Cyngor (EEC) 3254/91 a dau ddarn o ddeddfwriaeth gysylltiedig (Rheoliad y Comisiwn (EC) Rhif 35/97 a

Phenderfyniad y Cyngor (EC) Rhif 97/602) i sicrhau eu gweithrediad yn dilyn ymadawiad y DU â'r UE. Mae'r Rheoliadau hefyd yn dirymu Rheoliad cysylltiedig 1771/94 y Comisiwn a Phenderfyniadau 98/188 / EC y Comisiwn a 98/596.

Yn dilyn ymadawiad y DU â'r UE, bydd Rheoliad y Cyngor (EEC) 3254/91 (fel y'i diwygiwyd) yn gwahardd defnyddio trapiau dal coesau yn y DU a chyflwyno i mewn i'r DU (oni bai o Aelod-wladwriaethau'r UE) fewnforion crwyn, a nwyddau a weithgynhyrchir sy'n cynnwys crwyn, o rywogaethau anifeiliaid gwyllt penodol oni bai fod y crwyn yn deillio o wlad gymeradwy neu sy'n dod o anifeiliaid a gafodd eu magu'n gaeth. Nid yw dulliau rheoli mewnforio crwyn yn cael eu gosod ar Aelod-wladwriaethau'r UE gan y Rheoliadau hyn er mwyn osgoi newid polisi ac ehangu cylch gwaith Rheoliad y Cyngor (EEC) 3254/91 i gwmpasu gwledydd nad ydynt yn cael eu cynnwys ar hyn o bryd.

Mae Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 22 Tachwedd 2018 ynghylch effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol i'r Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r Rheoliadau hyn yn rhoi polisi newydd ar waith mewn meysydd datganoledig.

Nid yw Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 o'r Memorandwm ar Fil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Nid yw'r Cynghorwyr Cyfreithiol wedi nodi rheswm cyfreithiol i geisio cynnig cydsyniad o dan Reol Sefydlog 30A.10 mewn perthynas â'r Rheoliadau hyn.

Eitem 5.2

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL **Rheoliadau Anifeiliaid Ceffylaidd (Cofnodion, Adnabod a Symud) (Diwygio) (Ymadael â'r UE) 2018**

DYDDIAD **22 Tachwedd 2018**

GAN **Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Anifeiliaid Ceffylaidd (Cofnodion, Adnabod a Symud) (Diwygio) (Ymadael â'r UE) 2018

Cyfraith [yr UE a ddargedwir] sy'n cael ei diwygio

- Rheoliad Gweithredu'r Comisiwn (EU) 2015/262 dyddiedig 17 Chwefror 2015 sy'n gosod rheolau yn unol â Chyfarwyddebau'r Cyngor 90/427/EEC a 2009/156/EC mewn perthynas â'r dulliau ar gyfer adnabod equidae ("Y Rheoliad ar Basbortau Ceffylau")
- Penderfyniad 92/353/EEC dyddiedig 11 Mehefin 1992 sy'n gosod y meini prawf ar gyfer cymeradwyo neu gydnabod sefydliadau a chymdeithasu sy'n cadw neu'n sefydlu llyfrau gre ar gyfer equidae cofrestredig
- Penderfyniad y Comisiwn 92/216/EEC dyddiedig 26 Mawrth 1992 ar gasglu data yn ymwneud â chystadlaethau ar gyfer equidae fel y cyfeirir atynt yn Erthygl 4(2) o Gyfarwyddeb y Cyngor 90/428/EEC
- Penderfyniad y Comisiwn 92/354/EEC dyddiedig 11 Mehefin 1992 sy'n gosod rheolau penodol ar gyfer sicrhau cydlyniant rhwng sefydliadau a chymdeithasau sy'n cadw neu'n sefydlu llyfrau gre ar gyfer equidae cofrestredig
- Cytundeb ar yr Ardal Economaidd Ewropeaidd 2018/424, fel y'i diwygiwyd gan Benderfyniad Cyd-bwyllgor yr Ardal Economaidd Ewropeaidd Rhif 166/2016

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu ar gymhwysedd gweithredol Gweinidogion Cymru
Mae adnabod anifeiliaid o deulu'r ceffyl yn swyddogaeth ddatganoledig

Diben y diwygiadau
Diben yr OS hwn (y weithdrefn negyddol), i'w gyflwyno gan Adran yr Amgylchedd, Bwyd a Materion Gwledig (DEFRA), fydd gweithredu'r addasiadau hynny sy'n angenrheidiol ar draws y DU er mwyn i Reoliadau'r UE ynghylch adnabod ceffylau barhau i fod yn gymwys. Bydd yn sicrhau y bydd rheolau adnabod a fydd yn gyfwerth â'r rheini yn Rheoliad (EU)

2015/262 yn gallu parhau i weithio ar draws y DU unwaith y bydd y DU wedi ymadael â'r UE.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-equine-identification-england-amendment-eu-exit-regulations-2018

Pam y rhoddwyd cydsyniad

Rhoddwyd cydsyniad i Lywodraeth y DU wneud y cywiriadau hyn o ran, ac ar ran, Cymru am resymau'n ymwneud ag effeithlonrwydd, hwylustod ac oherwydd natur dechnegol y diwygiadau. Mae'r diwygiadau wedi cael eu hystyried yn llawn; ac nid oes unrhyw wahaniaeth o ran polisi. Diben y diwygiadau hyn yw sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE. Mae hyn yn unol â'r egwyddorion ar gyfer cywiro y cytunwyd arnynt ym mis Mai gan Is-bwyllgor y Cabinet ar Bontio Ewropeaidd.

GWEINIDOGION Y DU YN GWEITHREDU MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Anifeiliaid Ceffylaidd (Cofnodion, Adnabod a Symud) (Diwygio) (Ymadael â'r UE) 2018

Dyddiad gosod yn Senedd y DU: 20 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Bydd
Gweithdrefn:	Negyddol arfaethedig
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	wythnos yn dechrau 3 Rhagfyr 2018
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	5 Rhagfyr 2018
Datganiad ysgrifenedig o dan Reol Sefydlog 30C:	Papur 17
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Dim angen
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Negyddol neu Gadarnhaol
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau hyn gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8 o Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018 (y Ddeddf Ymadael), a pharagraff 21 o Atodlen 7 i'r Ddeddf honno.

Gwneir y Rheoliadau hyn i fynd i'r afael â'r ffaith nad yw cyfraith yr UE a ddargedwir yn gweithredu'n effeithiol a hefyd â diffygion eraill sy'n deillio o'r Deyrnas Unedig yn ymadael â'r Undeb Ewropeaidd.

Mae'r Rheoliadau hyn yn diwygio deddfwriaeth yr UE ym maes adnabod anifeiliaid o deulu'r ceffyl, a oedd, cyn i'r Deyrnas Unedig ymadael â'r UE, yn effeithio'n uniongyrchol ar y Deyrnas Unedig ac a gaiff ei dargadw yn rhinwedd y Ddeddf Ymadael.

Bydd y Rheoliadau hyn yn sicrhau bod anifeiliaid o deulu'r ceffyl yn parhau i gael eu hadnabod drwy gyfrwng un ddogfen a fydd yn para drwy gydol oes yr anifail, gan gynnal safonau uchel o ran bioddiogelwch, symudiadau anifeiliaid o deulu'r ceffyl, diogelwch a lles bwyd. Bydd y Rheoliadau'n helpu i sicrhau bod anifeiliaid o deulu'r ceffyl y DU yn parhau i allu teithio mor ddidrafferth â phosibl i'r Undeb Ewropeaidd ac oddi yno.
Mae'r Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 22 Tachwedd 2018 am effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol sy'n mynd gyda'r Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r Rheoliadau hyn yn rhoi polisi newydd ar waith mewn meysydd datganoledig.

Nid yw Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 o'r Memorandwm sy'n mynd gyda Bil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Eitem 5.3

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL **Rheoliadau Diogelwch ac Ansawdd Gwaed (Diwygio) (Ymadael â'r UE) 2019**

DYDDIAD **22 Tachwedd 2018**

GAN **Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Diogelwch ac Ansawdd Gwaed (Diwygio) (Ymadael â'r UE) 2019 ("y Rheoliadau")

Cyfraith [yr UE a ddargedwir] sy'n cael ei diwygio

Bydd y rheoliadau'n diwygio:

- Rheoliadau Diogelwch ac Ansawdd Gwaed 2005

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu gymhwysedd gweithredol Gweinidogion Cymru
Mae'r OS yn rhoi pwerau i'r Ysgrifennydd Gwladol ac i Weinidogion Cymru mewn perthynas â rhai safonau ansawdd a diogelwch a gofynion technegol yn ymwneud â chasglu, profi, prosesu, storio a dosbarthu gwaed a chydrannau gwaed. Nid oes effaith ar gymhwysedd deddfwriaethol y Cynulliad na chymhwysedd gweithredol Gweinidogion Cymru.

Byddai swyddogaethau a drosglwyddid i'r Ysgrifennydd Gwladol gyda chydsyniad yn golygu swyddogaethau Gweinidog y Goron at ddibenion Atodlen 7B i Ddeddf Llywodraeth Cymru 2006. Gallai hyn, felly, fod yn ystyriaeth berthnasol yng nghyd-destun cymhwysedd y Cynulliad i ddeddfu yn y meysydd hyn yn y dyfodol.

Diben y diwygiadau
Diben y diwygiadau yw cywiro diffygion mewn deddfwriaeth sy'n deillio o ymadawiad y DU â'r Undeb Ewropeaidd yn ymwneud ag Ansawdd a Diogelwch Gwaed.

Mae rheoliad 13 yn diwygio Rheoliadau Diogelwch ac Ansawdd Gwaed 2005 i fewnosod adran newydd ynghylch darpariaethau mewn perthynas â phennu safonau a gofynion mewn perthynas â gwaed a chydrannau gwaed sy'n cael eu casglu a'u profi at ddibenion trallwyso awtologaidd gan gynnwys sefydlu safonau a manylebau am system ansawdd i'w chyflawni gan sefydliad gwaed; safonau ansawdd a diogelwch ar gyfer casglu, profi, prosesu, storio a

dosbarthu gwaed a chydrannau gwaed; gofynion olrhain; hysbysu adweithiau a digwyddiadau andwyol difrifol eraill; ac amrywiol ofynion technegol eraill.

Mae'r rheoliad newydd yn datgan y caiff yr awdurdod priodol wneud darpariaethau yn y meysydd hyn trwy reoliadau. Diffinnir yr awdurdod priodol mewn perthynas â Chymru fel Gweinidogion Cymru neu'r Ysgrifennydd Gwladol yn gweithredu gyda chydsyniad Gweinidogion Cymru.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma:
http://www.legislation.gov.uk/ukdsi/2019/9780111174814/contents

Pam y rhoddwyd cydsyniad
Nid oes gwahaniaeth rhwng ymagwedd Llywodraeth Cymru a Llywodraeth y DU ar y polisi i'w gywiro. O ganlyniad, byddai gwneud OS ar wahân yng Nghymru ac yn Lloegr yn arwain at ddyblygu gwaith a chymhlethdod diangen i'r llyfr statud. Mae cydsynio i OS ar draws y DU yn sicrhau bod un fframwaith deddfwriaethol ar draws y DU sy'n hybu eglurder a hygyrchedd yn ystod y cyfnod hwn o newid. O dan yr amgylchiadau eithriadol hyn, mae Llywodraeth Cymru yn ystyried ei bod yn briodol i Lywodraeth y DU ddeddfu ar ein rhan yn yr achos hwn.

GWEINIDOGION Y DU YN GWEITHREDU MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Diogelwch ac Ansawdd Gwaed (Diwygio) (Ymadael â'r UE) 2019

Dyddiad gosod yn Senedd y DU: 20 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Na fydd
Gweithdrefn:	Cadarnhaol drafft
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	3 Rhagfyr 2018
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	5 Rhagfyr 2018
Datganiad ysgrifenedig o dan Reol Sefydlog 30C:	Papur 19
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Dim angen
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Negyddol neu Gadarnhaol
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8 Deddf yr Undeb Ewropeaidd (Ymadael) 2018.

Mae'r Rheoliadau hyn yn cael eu gwneud er mwyn mynd i'r afael â methiannau cyfraith yr UE a ddargedwir i weithredu'n effeithiol a diffygion eraill sy'n deillio o'r Deyrnas Unedig yn ymadael â'r Undeb Ewropeaidd.

Mae'r Rheoliadau hyn yn diwygio Rheoliadau Diogelwch ac Ansawdd Gwaed 2005 (OS 2005/50) i sicrhau y bydd deddfwriaeth diogelwch ac ansawdd gwaed yn parhau i weithredu ar ôl y diwrnod ymadael.
Mae'r Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 22 Tachwedd 2018 ynghylch effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol i'r Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r Rheoliadau hyn yn creu polisi newydd mewn meysydd datganoledig. Nid yw'r Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 y Memorandwm ar Fil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Nid yw'r Cynghorwyr Cyfreithiol wedi nodi unrhyw reswm cyfreithiol i geisio cynnig cydsyniad o dan Reol Sefydlog 30A.10 mewn perthynas â'r Rheoliadau hyn.

Eitem 5.4

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL	**Rheoliadau Cynhyrchion Organig (Diwygio) (Ymadael â'r UE) 2018**
DYDDIAD	**23 Tachwedd 2018**
GAN	**Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Cynhyrchion Organig (Diwygio) (Ymadael â'r UE) 2018

Y gyfraith sy'n cael ei diwygio
Y ddeddfwriaeth a gaiff ei diwygio gan y rheoliadau hyn yw Rheoliadau Cynhyrchion Organig 2009.

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu gymhwysedd gweithredol Gweinidogion Cymru
Mae'r offeryn statudol hwn yn cynnwys darpariaethau mewn meysydd lle y mae cymhwysedd wedi ei ddatganoli.

Diben y diwygiadau
Mae Rheoliadau Cynhyrchion Organig (Diwygio) (Ymadael â'r UE) 2018 yn gwneud diwygiadau i ddeddfwriaeth, sy'n rhoi pwerau i weinyddu a gorfodi deddfwriaeth yr UE a ddargedwir mewn perthynas â rheolau labelu a chynhyrchu organig, a hynny er mwyn ei bod yn parhau'n weithredol ar ôl i'r DU ymadael â'r UE.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-organic-products-amendment-eu-exit-regulations-2018

Pam y rhoddwyd cydsyniad
Rhoddwyd cydsyniad i Lywodraeth y DU wneud y cywiriadau hyn o ran ac ar ran Cymru, am resymau'n ymwneud ag effeithlonrwydd, hwylustod ac oherwydd natur dechnegol y diwygiadau. Mae'r diwygiadau wedi cael eu hystyried yn llawn; ac nid oes unrhyw wahaniaeth o ran polisi. Diben y diwygiadau hyn yw sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE. Mae hyn yn unol â'r egwyddorion ar gyfer cywiro y cytunwyd arnynt ym mis Mai gan Is-bwyllgor y Cabinet ar Bontio Ewropeaidd.

GWEINIDOGION Y DU YN GWEITHREDU MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Cynhyrchion Organig (Diwygio) (Ymadael â'r UE) 2018

Dyddiad gosod yn Senedd y DU: 20 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Bydd
Gweithdrefn:	Negyddol arfaethedig
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Anhybys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	wythnos yn dechrau 3 Rhagfyr 2018
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	5 Rhagfyr 2018
Datganiad ysgrifenedig o dan Reol Sefydlog 30C:	Papur 21
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Dim angen
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Negyddol neu Gadarnhaol
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau hyn gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8(1) o Ddeddf yr Undeb Ewropeaidd (Ymadael).

Mae'r Rheoliadau hyn yn diwygio is-ddeddfwriaeth sy'n ymwneud â chynhyrchion organig (Rheoliadau Cynhyrchion Organig 2009), gan fynd i'r afael â methiant deddfwriaeth ddomestig a hefyd â diffygion eraill sy'n deillio o benderfyniad y Deyrnas Unedig i ymadael â'r Undeb Ewropeaidd. Mae Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 23 Tachwedd 2018 am effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol ar y Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r

Rheoliadau hyn yn rhoi polisi newydd ar waith mewn meysydd datganoledig.

Nid yw Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 o'r Memorandwm sy'n mynd gyda Bil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Nid yw'r Cynghorwyr Cyfreithiol wedi nodi unrhyw reswm cyfreithiol i geisio cynnig cydsyniad o dan Reol Sefydlog 30A.10 mewn perthynas â'r Rheoliadau hyn.

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG
GAN
LYWODRAETH CYMRU

TEITL **Rheoliadau Dileu a Rheoli Afiechydon Milheintiol (Diwygio) (Ymadael â'r UE) 2018**

DYDDIAD **23 Tachwedd 2018**

GAN **Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Dileu a Rheoli Afiechydon Milheintiol (Diwygio) (Ymadael â'r UE) 2018

Cyfraith yr UE a ddargedwir sy'n cael ei diwygio neu ei dirymu gan y Rheoliadau hyn yw:

- Penderfyniad gan y Comisiwn 2003/644/EC a sefydlodd warantau ychwanegol o safbwynt salmonela ar gyfer llwythi o ddofednod bridio a chywion diwrnod oed i'r Ffindir a Sweden i'w cyflwyno i heidiau o ddofednod bridio neu heidiau o ddofednod cynhyrchu;
- Rheoliad (EC) Rhif 2160/2003 ynghylch rheoli salmonela a chyfryngau milheintiol eraill penodedig a gludir mewn bwyd;
- Penderfyniad gan y Comisiwn 2004/235/EC yn sefydlu gwarantau ychwanegol ynghylch salmonela ar gyfer llwythi o ieir dodwy i'r Ffindir a Sweden;
- Penderfyniad gan y Comisiwn 2004/665/EC ynghylch astudiaeth sylfaenol ynghylch nifer yr achosion o salmonela mewn heidiau dodwy o *Gallus gallus;*
- Rheoliad gan y Comisiwn (EC) Rhif 1177/2006 yn gweithredu Rheoliad (EC) Rhif 2160/2003 Senedd Ewrop a'r Cyngor ynghylch gofynion ar gyfer defnyddio dulliau rheoli penodol yn y fframwaith o'r rhaglenni rheoli cenedlaethol i reoli salmonela mewn dofednod;
- Rheoliad gan y Comisiwn (EU) Rhif 200/2010 yn gweithredu Rheoliad (EC) Rhif 2160/2003 Senedd Ewrop a'r Cyngor ynghylch targed gan yr Undeb i leihau nifer yr achosion o seroteipiau *Salmonela* mewn heidiau bridio llawndwf o *Gallus gallus;*
- Rheoliad gan y Comisiwn (EU) Rhif 517/2011 yn gweithredu Rheoliad (EC) Rhif 2160/2003 Senedd Ewrop a'r Cyngor ynghylch targed gan yr Undeb i leihau nifer yr achosion o rai seroteipiau *Salmonela* mewn ieir dodwy o *Gallus gallus;*
- Rheoliad gan y Comisiwn (EU) Rhif 200/2012 ynghylch targed gan yr Undeb i leihau nifer yr achosion o *Salmonella entertidis* a *Salmonella typhimurium* mewn heidau o ieir bwyta;
- Rheoliad gan y Comisiwn (EU) Rhif 1190/2012 ynghylch targed gan yr Undeb i leihau *Salmonella Entertidis* a *Salmonella Typhimurium* mewn heidiau o dyrcwn;

- Penderfyniad Gweithredu gan y Comisiwn 2013/652/EU ynghylch monitro ac adrodd ar ymwrthedd i gyffuriau mewn bacteria milheintiol a chydfwytaol.

Maent hefyd yn diwygio Cytundeb yr AEE.

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu gymhwysedd gweithredol Gweinidogion Cymru
Mae'r offeryn statudol hwn yn cynnwys darpariaethau mewn meysydd lle y mae cymhwysedd wedi ei ddatganoli.

O safbwynt Rheoliadau Dileu a Rheoli Afiechydon Milheintiol (Diwygio) (Ymadael â'r UE) 2018, mae tair swyddogaeth wedi'u trosglwyddo sy'n golygu mai dim ond yr Ysgrifennydd Gwladol all eu harfer (mewn un achos dim ond gyda chydsyniad yr Awdurdodau Datganoledig mewn perthynas â thiriogaethau datganoledig).

Byddai swyddogaethau a drosglwyddir i'r Ysgrifennydd Gwladol â chydsyniad yn gyfystyr â swyddogaethau un o Weinidogion y Goron at ddibenion Atodlen 7B i Ddeddf Llywodraeth Cymru 2006. Gallai Bil Cynulliad yn y dyfodol yn ceisio gwaredu neu addasu'r swyddogaethau hyn sbarduno gofyniad i ymgynghori â Llywodraeth y DU.

Diben y diwygiadau
Diben y diwygiadau yw gwneud rhai o'r diwygiadau sy'n angenrheidiol er mwyn sicrhau bod deddfwriaeth sy'n diogelu iechyd y cyhoedd rhag clefyd milheintiol ac yn benodol rhag salmonela yn parhau'n weithredol ar ôl i'r DU ymadael â'r UE.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-zoonotic-disease-eradication-and-control-amendment-eu-exit-regulations-2018

Pam y rhoddwyd cydsyniad
Rhoddwyd cydsyniad i Lywodraeth y DU wneud y cywiriadau hyn o ran ac ar ran Cymru, am resymau'n ymwneud ag effeithlonrwydd, hwylustod ac oherwydd natur dechnegol y diwygiadau. Mae'r diwygiadau wedi cael eu hystyried yn llawn; ac nid oes unrhyw wahaniaeth o ran polisi. Diben y diwygiadau hyn yw sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE. Mae hyn yn unol â'r egwyddorion ar gyfer cywiro y cytunwyd arnynt ym mis Mai gan Is-bwyllgor y Cabinet ar Bontio Ewropeaidd.

GWEINIDOGION Y DU YN GWEITHREDU MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Dileu a Rheoli Milheintiau (Diwygio) (Ymadael â'r UE) 2018

Dyddiad gosod yn Senedd y DU: 20 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Bydd
Gweithdrefn:	Negyddol arfaethedig
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	wythnos yn dechrau 3 Rhagfyr 2018
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	5 Rhagfyr 2018
Datganiad ysgrifenedig o dan Reol Sefydlog 30C:	Papur 23
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Dim angen
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Negyddol neu Gadarnhaol
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau hyn gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8(1) o Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018, a pharagraff 21(b) o Atodlen 7 i'r Ddeddf honno.

Mae Rheoliadau Dileu a Rheoli Milheintiau (Newidiad) (Ymadael â'r UE) 2018 yn diwygio ac, i raddau llai, yn dirymu cyfraith yr UE a ddargedwir sy'n diogelu iechyd dynol rhag milheintiau (salmonela'n benodol) er mwyn iddi barhau i fod yn weithredol wedi i'r DU ymadael â'r EU. Heintiau sy'n gallu trosglwyddo o anifeiliaid i bobl yw milheintiau.

Bwriedir i'r mân newidiadau technegol a wneir gan yr offeryn sicrhau bod cyfraith yr UE a ddargedwir yn parhau i weithredu'n effeithiol. Mae'r newidiadau'n cynnwys dileu neu ddiwygio unrhyw gyfeiriad at sefydliadau'r UE fel "labordai cyfeirio Cymunedol" a'r "Comisiwn" na

fyddant yn berthnasol ar ôl i'r DU ymadael. Bydd y trefniadau presennol ar gyfer mewnforio dofednod byw ac wyau deor o'r UE yn parhau ar ôl i'r DU ymadael.

Mae deddfwriaeth bresennol yr UE yn cynnwys mesurau rheoli sy'n diogelu iechyd y cyhoedd rhag milheintiau, a salmonela'n benodol. Mae Llywodraeth y DU wedi dweud ei bod yn dymuno cadw'r safonau diogelu iechyd hynny ar ôl ymadael â'r UE ac mae'n diwygio deddfwriaeth yr UE a ddargedwir at y diben hwn.

Mae Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 23 Tachwedd 2018 am effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol sy'n mynd gyda'r Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r Rheoliadau hyn yn rhoi polisi newydd ar waith mewn meysydd datganoledig.

Nid yw Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 o'r Memorandwm sy'n mynd gyda'r Bil Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Nid yw'r Cynghorwyr Cyfreithiol wedi nodi unrhyw reswm cyfreithiol i geisio cynnig cydsyniad o dan Reol Sefydlog 30A.10 mewn perthynas â'r Rheoliadau hyn.

Llywodraeth Cymru
Welsh Government

DATGANIAD YSGRIFENEDIG GAN LYWODRAETH CYMRU

TEITL	**Rheoliadau Rheolau Darpariaethau Cyffredin y Cronfeydd Strwythurol a Buddsoddi Ewropeaidd etc. (Diwygio etc.) (Ymadael â'r UE) 2018**
DYDDIAD	**26 Tachwedd 2018**
GAN	**Julie James AC, Arweinydd y Tŷ a'r Prif Chwip**

Rheoliadau Rheolau Darpariaethau Cyffredin y Cronfeydd Strwythurol a Buddsoddi Ewropeaidd etc. (Diwygio etc.) (Ymadael â'r UE) 2018

Y Gyfraith sy'n cael ei diwygio

Mae'r offerynnau a ganlyn yn cael eu diwygio:

- Rheoliad Dirprwyedig y Comisiwn (EU) Rhif 480/2014;
- Rheoliad Gweithredu'r Comisiwn (EU) 215/2014;
- Rheoliad Dirprwyedig y Comisiwn (EU) Rhif 240/2014;
- Rheoliad Gweithredu'r Comisiwn (EU) Rhif 821/2014;
- Rheoliad Gweithredu'r Comisiwn (EU) Rhif 964/2014;
- Rheoliad Dirprwyedig y Comisiwn (EU) Rhif 2015/1076; a
- Rheoliad Dirprwyedig y Comisiwn (EU) Rhif 2015/1516).

Mae'r offerynnau a ganlyn yn cael eu dirymu:

- Rheoliad Gweithredu'r Comisiwn (EU) Rhif 184/2014;
- Rheoliad Gweithredu'r Comisiwn (EU) Rhif 1011/2014; a
- Phenderfyniad Gweithredu'r Comisiwn (EU) Rhif 2014/660.

Unrhyw effaith y gall yr OS ei chael ar gymhwysedd deddfwriaethol y Cynulliad a/neu gymhwysedd gweithredol Gweinidogion Cymru

Mae swyddogaethau mewn perthynas â gweinyddu'r polisi amaethyddol cyffredin wedi'u trosglwyddo gan yr offeryn hwn i'r graddau y maent yn arferadwy gan Weinidogion Cymru yn unig.

Diben y diwygiadau

Mae'r offeryn hwn yn mynd i'r afael â methiannau cyfraith yr UE sydd wedi'i dargadw i weithredu'n effeithiol a hefyd â diffygion eraill sy'n deillio o'r ffaith bod y DU yn ymadael â'r UE. Mae'n ymdrin â chywiriadau sy'n dechnegol o ran eu natur ac nad ydynt yn gwneud unrhyw newidiadau polisi arwyddocaol. Mae'r cywiriadau hyn, yn hytrach, yn addasu

Rheoliadau'r UE sydd wedi'u dargadw i gynnwys telerau (cytunedig) newydd i sicrhau y bydd rhaglenni Cronfa Amaethyddol Ewrop ar gyfer Datblygu Gwledig (EAFRD) a Chronfa'r Môr a Physgodfeydd Ewrop (EMFF) yr UE sydd eisoes yn bodoli yn parhau i gael eu cyllido am weddill rhaglen 2014 i 2020, os na fydd cytundeb o ran Brexit. Yr OS hwn yw ail Offeryn Statudol cywiro'r DU sydd wedi'i gynnwys yn rhan o'r pecyn ehangach i gywiro'r Polisi Amaethyddol Cyffredin.

Mae'r OS a'r Memorandwm Esboniadol sy'n mynd gydag ef, ac sy'n nodi effaith pob un o'r diwygiadau, ar gael yma: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-european-structural-and-investment-funds-common-provisions-rules-etc-amendment-etc-eu-exit-regulations-2018

Pam y rhoddwyd cydsyniad

Rhoddwyd cydsyniad i Lywodraeth y DU wneud y cywiriadau hyn o ran, ac ar ran, Cymru am resymau'n ymwneud ag effeithlonrwydd, hwylustod ac oherwydd natur dechnegol y diwygiadau. Mae'r diwygiadau wedi cael eu hystyried yn llawn; ac nid oes unrhyw wahaniaeth o ran polisi. Diben y diwygiadau hyn yw sicrhau bod y llyfr statud yn parhau i weithio ar ôl i'r DU ymadael â'r UE. Mae hyn yn unol â'r egwyddorion ar gyfer cywiro y cytunwyd arnynt ym mis Mai gan Is-bwyllgor y Cabinet ar Bontio Ewropeaidd.

GWEINIDOGION Y DU YN GWEITHREDU MEWN MEYSYDD DATGANOLEDIG

Rheoliadau Rheolau Darpariaethau Cyffredin y Cronfeydd Strwythurol a Buddsoddi Ewropeaidd etc. (Diwygio etc.) (Ymadael â'r UE) 2018

Dyddiad gosod yn Senedd y DU: 21 Tachwedd 2018

Sifftio	
A fydd angen eu sifftio yn Senedd y DU?	Bydd
Gweithdrefn:	Negyddol arfaethedig
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Ewropeaidd Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	wythnos yn dechrau 3 Rhagfyr 2018
Y dyddiad y daw'r cyfnod sifftio i ben yn Senedd y DU	6 Rhagfyr 2018
Datganiad ysgrifenedig o dan Reol Sefydlog 30C:	Papur 25
Memorandwm Cydsyniad Offeryn Statudol o dan Reol Sefydlog 30A (oherwydd ei fod yn diwygio deddfwriaeth sylfaenol)	Dim angen
Gweithdrefn graffu	
Canlyniad y broses sifftio	Anhysbys
Y weithdrefn	Negyddol neu Gadarnhaol
Dyddiad trafod gan y Cyd-bwyllgor ar Offerynnau Statudol	Anhysbys
Dyddiad trafod gan Bwyllgor Offerynnau Statudol Tŷ'r Cyffredin	Anhysbys
Dyddiad trafod gan Bwyllgor Craffu ar Is-ddeddfwriaeth Tŷ'r Arglwyddi	Anhysbys

Sylwadau

Bwriedir i'r Rheoliadau hyn gael eu gwneud gan Lywodraeth y DU yn unol ag adran 8(1) o Ddeddf yr Undeb Ewropeaidd (Ymadael) 2018, a pharagraff 21(b) o Atodlen 7 i'r Ddeddf honno.

Mae'r offeryn hwn yn mynd i'r afael â'r ffaith nad yw cyfraith yr UE sydd wedi'i dargadw yn gweithredu'n effeithiol a hefyd â diffygion eraill sy'n deillio o ymadawiad y DU â'r UE. Mae'n ymdrin â chywiriadau sy'n dechnegol o ran eu natur ac nad ydynt yn gwneud unrhyw newidiadau polisi arwyddocaol.
Mae'r cywiriadau hyn, yn hytrach, yn addasu Rheoliadau'r UE sydd wedi'u dargadw i gynnwys telerau (cytunedig) newydd i sicrhau y bydd rhaglenni Cronfa Amaethyddol Ewrop ar gyfer Datblygu Gwledig (EAFRD) a Chronfa'r Môr a Physgodfeydd Ewrop (EMFF) yr UE sydd eisoes yn bodoli

yn parhau i gael eu cyllido am weddill rhaglen 2014 i 2020, os na fydd cytundeb o ran Brexit. Yr OS hwn yw ail Offeryn Statudol cywiro'r DU sydd wedi'i gynnwys yn rhan o'r pecyn ehangach i gywiro'r Polisi Amaethyddol Cyffredin.

Mae Cynghorwyr Cyfreithiol yn cytuno â'r datganiad a osodwyd gan Lywodraeth Cymru dyddiedig 26 Tachwedd 2018 am effaith y Rheoliadau hyn.

Mae'r crynodeb uchod a chynnwys y Memorandwm Esboniadol ar y Rheoliadau hyn yn cadarnhau eu heffaith ac i ba raddau y byddai'r Rheoliadau hyn yn rhoi polisi newydd ar waith mewn meysydd datganoledig.

Nid yw Cynghorwyr Cyfreithiol yn ystyried bod unrhyw faterion arwyddocaol yn codi o dan baragraff 8 o'r Memorandwm sy'n mynd gyda Bil yr Undeb Ewropeaidd (Ymadael) a Sefydlu Fframweithiau Cyffredin mewn perthynas â'r Rheoliadau hyn.

Nid yw'r Cynghorwyr Cyfreithiol wedi nodi unrhyw reswm cyfreithiol i geisio cynnig cydsyniad o dan Reol Sefydlog 30A.10 mewn perthynas â'r Rheoliadau hyn.

Elin Jones AC, Llywydd
Cynulliad Cenedlaethol Cymru
Elin Jones AM, Presiding Officer
National Assembly for Wales

Mick Antoniw AC
Cadeirydd
Y Pwyllgor Materion Cyfansoddiadol a Deddfwriaethol
Cynulliad Cenedlaethol Cymru
Bae Caerdydd
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Eich cyf:
Ein cyf: EJ/HF

27 Tachwedd 2018

Annwyl Mick

Diwygio'r Cynulliad: cymhwysedd deddfwriaethol

Fel y gwyddoch, mae Comisiwn y Cynulliad yn arwain gwaith ar ran y sefydliad i ystyried sut y gellid defnyddio'r pwerau sydd wedi'u datganoli o dan Ddeddf Cymru 2017 o ran trefniadau etholiadol, i greu deddfwrfa fwy effeithiol, hygyrch ac amrywiol, os ceir consensws gwleidyddol digonol ar gyfer diwygio etholiadol. Mae hyn yn cynnwys ystyried cymhwysedd deddfwriaethol y Cynulliad. Rwy'n ysgrifennu atoch i roi gwybod ichi am yr ohebiaeth rhyngof fi ac Ysgrifennydd Gwladol Cymru mewn perthynas â'r materion hyn.

Fel y cyhoeddais mewn Datganiad Ysgrifenedig i'r Cynulliad ym mis Gorffennaf 2018, rwy'n hyderus, ar sail y sgyrsiau a gefais hyd yma a'r ymateb i'r ymgynghoriad cyhoeddus a gynhaliodd Comisiwn y Cynulliad, sef Creu Senedd i Gymru, fod digon o gefnogaeth i argymhelliad y Panel Arbenigol y dylid cynyddu nifer yr Aelodau. Fodd bynnag, nid oes consensws ymysg y pleidiau gwleidyddol ynghylch y system bleidleisio y dylid ei defnyddio i ethol y sefydliad hwnnw wedi iddo gynyddu o ran maint. Mae'n amlwg bod angen rhagor o amser i drafod sut y

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dylid ethol Aelodau a sut y dylid sicrhau mwy o amrywiaeth ymysg cynrychiolwyr etholedig yng Nghymru.

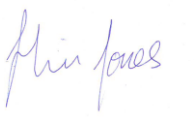
Tra bo'r trafodaethau hyn yn mynd rhagddynt, mae Comisiwn y Cynulliad yn ystyried sut y gellid bwrw ymlaen ag argymhellion y Panel Arbenigol ar gyfer diwygio trefniadau etholiadol y Cynulliad, os bydd consensws gwleidyddol i wneud hynny. Mae hyn yn cynnwys argymhellion y Panel ar gyfer mesurau i sicrhau mwy o amrywiaeth ymysg cynrychiolwyr etholedig yng Nghymru.

Fel y gwyddoch, mae'r Swyddfa Gymreig yn bwriadu cyflwyno Gorchymyn Adran 109 yr hydref hwn, a hynny'n bennaf i ymdrin â materion sy'n codi mewn perthynas â gadael yr Undeb Ewropeaidd. Mae swyddogion Comisiwn y Cynulliad wedi cynnal sgyrsiau cychwynnol â swyddogion y Swyddfa Gymreig i ystyried a fyddai'r Gorchymyn hwn, neu Orchymyn Adran 109 dilynol, yn gallu cynnig dull deddfwriaethol addas o roi diffiniad clir o gymhwysedd deddfwriaethol y Cynulliad o safbwynt materion o fewn cwmpas y gwaith o ddiwygio'r Cynulliad.

Un mater i'w ystyried yw'r modd y gallai cyfle cyfartal, fel mater a gedwir yn ôl, gyfyngu'n anfwriadol ar allu'r Cynulliad i ddeddfu mewn perthynas â materion etholiadol. Amgaeaf gopi o lythyr at Ysgrifennydd Gwladol Cymru yn ymwneud â'r mater hwn. Byddai cadarnhad ynghylch cymhwysedd y Cynulliad yn hyn o beth drwy Orchymyn o dan Adran 109 yn rhoi eglurhad llawn ynghylch datganoli cymhwysedd deddfwriaethol dros drefniadau etholiadol y Cynulliad. Byddai eglurhad o'r fath yn galluogi'r Cynulliad ei hun i benderfynu a yw'n dymuno ymateb i argymhellion y Panel Arbenigol, a sut y dylid gwneud hynny.

Os hoffech drafod y mater hwn, byddwn yn hapus i wneud hynny.

Yn gywir



Elin Jones

Y Llywydd

Elin Jones AC, Llywydd
Cynulliad Cenedlaethol Cymru
Elin Jones AM, Presiding Officer
National Assembly for Wales

Y Gwir Anrhydeddus Alun Cairns AS
Ysgrifennydd Gwladol Cymru

27 Tachwedd 2018

Annwyl Alun

Cyfle cyfartal a threfniadau etholiadol y Cynulliad

Mae Deddf Cymru 2017 yn datganoli pwerau i'r Cynulliad dros ei etholiadau ei hun, a daeth y pwerau hyn i rym ym mis Ebrill 2018. Byddwch yn ymwybodol fy mod yn arwain cynigion i ddiwygio'r Cynulliad a'i drefniadau etholiadol, gan gynnwys ystyried amrywiaeth ymhlith cynrychiolwyr.

Rwyf wedi cael ar ddeall y gallai 'Cyfle cyfartal,' fel mater a gedwir yn ôl, gyfyngu'n anfwriadol ar allu'r Cynulliad i ddeddfu mewn perthynas â materion etholiadol. Felly, byddai'n dda gennym gael clywed eich barn ynghylch y dull y gellid cadarnhau cymhwysedd deddfwriaethol y Cynulliad yn hyn o beth, a'r amserlen ar gyfer cadarnhad o'r fath.

Ym mis Rhagfyr 2017, argymhellodd y Panel Arbenigol ar Ddiwygio Etholiadol y Cynulliad y dylid cynyddu nifer yr Aelodau i rhwng 80 a 90. I gynyddu maint y ddeddfwrfa, rhaid newid y modd y caiff Aelodau eu hethol. Argymhellodd y Panel y dylai'r newid hwn gynnwys mesurau i gefnogi a hybu proses o ethol deddfwrfa sy'n adlewyrchu'n agosach amrywiaeth y bobl a'r cymunedau y mae'n eu gwasanaethu. Gallai mesurau o'r fath gynnwys integreiddio cwota rhywedd yn y system etholiadol, cyflwyno gofynion deddfwriaethol i bleidiau gwleidyddol gyhoeddi data dienw ar amrywiaeth eu hymgeiswyr.

Pe bai Comisiwn y Cynulliad yn penderfynu deddfu i'r perwyl a nodir uchod, fe fydd angen i'r Comisiwn archwilio sut y gellid bwrw ymlaen gyda'r argymhellion perthnasol.

Mae paragraff 187 o Atodlen 7A i Ddeddf Llywodraeth Cymru 2006 yn nodi bod cyfle cyfartal yn fater a gedwir yn ôl, er bod hyn yn cynnwys nifer o eithriadau.

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Y diffiniad o gyfle cyfartal ym mharagraff 187 yw: "the prevention, elimination or regulation of discrimination". Diben unrhyw ddeddfwriaeth y byddai'r Comisiwn y Cynulliad yn ei chyflwyno i roi argymhellion y Panel Arbenigol ar waith fyddai sicrhau mwy o amrywiaeth ymysg cynrychiolwyr etholedig drwy sicrhau mwy o gydbwysedd rhwng y rhywiau yn achos ymgeiswyr etholiadol. Ni fyddai hyn yn ymwneud â'r swyddogaethau a bennir yn y diffiniad o gyfle cyfartal ym mharagraff 187.

Mae'n amlwg, felly, o ran y prawf 'diben ac effaith', y byddai'n rhesymol dadlau nad yw ceisio sicrhau cydbwysedd rhwng y rhywiau yn y Cynulliad yn fater a gedwir yn ôl. Fodd bynnag, nid oes eithriad penodol ar hyn o bryd ar gyfer etholiadau'r Cynulliad. Byddai cadarnhad bod y cymal ar gyfleoedd cyfartal wedi'i gadw nôl drwy Orchymyn o dan Adran 109 yn cael gwared ar unrhyw amheuaeth yn hyn o beth, ac yn rhoi eglurhad llawn ynghylch datganoli cymhwysedd deddfwriaethol dros drefniadau etholiadol y Cynulliad. Byddai eglurhad o'r fath yn galluogi'r Cynulliad ei hun i benderfynu a yw'n dymuno ymateb i argymhellion y Panel Arbenigol, a sut y dylid gwneud hynny.

Rwy'n croesawu'r modd y mae eich swyddogion wedi bod yn barod i ymgysylltu â swyddogion Comisiwn y Cynulliad yn ystod y trafodaethau cychwynnol ar y materion hyn. Edrychaf ymlaen at glywed eich sylwadau, gan gynnwys yr amserlen ar gyfer cyflwyno unrhyw Orchymyn o dan Adran 109 er mwyn llywio trafodaethau trawsbleidiol ar ddiwygio etholiadol.

Yn gywir

Elin JonesY Llywydd

Croesewir gohebiaeth yn Gymraeg neu'n Saesneg.
We welcome correspondence in Welsh or English.

cc Y Gwir Anrhydeddus Carwyn Jones AC, Prif Weinidog

HOUSE OF LORDS
Secondary Legislation Scrutiny Committee

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1 November 2018

To all Ministers with departmental responsibility for secondary legislation

Flow and volume of secondary legislation

We are writing this joint letter in our capacity as Chairmen of the House of Lords Secondary Legislation Scrutiny Committee (SLSC) and its sub-committees, the House of Commons European Statutory Instruments Committee (ESIC) and the House of Commons Procedure Committee. As you know, the SLSC and ESIC are charged with considering all proposed negative instruments laid under the European Union (Withdrawal) Act 2018. In addition, the SLSC considers all negative and affirmative instruments whether laid under the Withdrawal Act or other Acts of Parliament, as well as treaties laid under the Constitutional Reform and Governance Act 2010.

The Government have said on a number of occasions that they anticipate that the decision to withdraw from Europe would give rise to 800 to 1,000 instruments. Of those Brexit-related instruments, a significant proportion would be "proposed negative instruments" laid under provisions of the European Union (Withdrawal) Act 2018 ("the Withdrawal Act") which provide for a choice between the affirmative and negative resolution procedure.

From an early stage, when it became clear that the decision to leave the European Union would result in a large number of additional statutory instruments, committees in the Lords and the Commons have pressed the Government to ensure that the flow of instruments should be as even as possible and to keep Parliament informed about anticipated numbers. The SLSC, in evidence to the House of Commons Procedure Committee, for example, urged the Government to ensure "proper management of the flow of instruments …, offering advance information about the planned flow". The House of Commons Procedure Committee, in its report on the scrutiny of delegated legislation under the Withdrawal Act, said: "We expect the [PBL Committee] to take an active role in managing the flow of secondary legislation under the Act. The Government must ensure a steady even flow of instruments for scrutiny for the Parliamentary process to work effectively."

Whilst both Houses have made every effort to ensure that they are well-placed to undertake the scrutiny work resulting from the decision to withdraw from the EU, we are disappointed to observe that, so far, the flow of both Brexit-related statutory instruments and of proposed negative instruments has been very slow to start. We note that the Hansard Society has recently suggested that only 9% of Brexit-related instruments have been laid before Parliament. Bearing in mind the deadline to which we are working, it is vital that our Committees and the Houses more generally are given more information about what we can expect in the coming months. To this end, we would be grateful if you would provide answers to the following questions. We are writing to all departments and would like responses from each department so that we can, ourselves, piece together the Whitehall-wide picture.

Questions

1. How many Brexit-related statutory instruments in total remain to be laid by your department, and under which Acts of Parliament?

2. With regard to your department, for each of the months from November 2018 to March 2019:

   (a) how many statutory instruments subject to the negative procedure (excluding *proposed* negative instruments) and how many statutory instruments subject to the affirmative procedure will be laid before Parliament?

   (b) what proportion of those instruments are Brexit-related instruments and are therefore included in the Government's estimate of 800 to 1,000 Brexit-related instruments?

   (c) how many proposed negative instruments will be laid before Parliament?

   (d) how many treaties under CRAG will be laid before Parliament?

3. Is the underlying assumption of those figures deal (with an implementation period) or "no deal"? How would they change if the assumption were reversed?

4. When does the department think it can lay the last proposed negative instruments before Parliament, allowing enough time to schedule a debate should the committees recommend upgrades to the affirmative procedure?

5. Does the department expect to use the "urgent cases" procedure under the Withdrawal Act?

In addition, please can you provide your departmental planning document setting out which statutory instruments – whether Brexit-related only or all statutory instruments – are to be laid and when.

The Committees are anxious to receive this information as soon as possible. We would be grateful if you could reply by **Friday 16 November**, to the email addresses provided below. We may decide to publish your response.

Yours sincerely

The Rt Hon. The Lord Trefgarne
Chairman
SLSC and of Sub-Committee A of the SLSC
House of Lords
hlseclegscrutiny@parliament.uk

The Rt Hon. The Lord Cunningham of Felling DL
Chairman
Sub-Committee B of the SLSC
House of Lords
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Rt Hon. Sir Patrick McLoughlin MP
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Mr Charles Walker OBE MP
Chair
Procedure Committee
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Office of the Leader of the House of Commons

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Leader of the House of Commons
70 Whitehall
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Department for Exiting the European Union

Chris Heaton-Harris MP
Parliamentary Under Secretary of State for Exiting the European Union
9 Downing Street
SW1A 2AG

Mr Charles Walker OBE MP
Chair, Procedure Committee
House of Commons
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Rt Hon Sir Patrick McLoughlin MP
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The Rt Hon. the Lord Trefgarne
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The Rt Hon. the Lord Cunningham of Felling DL
Chairman, Secondary Legislation Scrutiny Committee
Sub-Committee B
House of Lords
London
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19 November 2018

Dear Charles, Sir Patrick, Lord Trefgarne and Lord Cunningham,

FLOW AND VOLUME OF SECONDARY LEGISLATION

Thank you for your letter to Departmental SI Ministers of 1 November asking for further information on the remaining EU exit SIs we are expecting to lay between now and the end of March next year. We are responding on their behalf.

We agree that the laying of EU exit SIs has accelerated rapidly from a low base. However, as there are many parts to the process in Government and Parliament, it has been useful to allow the system to be tested without huge pressure. We welcome the constructive discussions we have had with you and your Committees, and have been happy to go beyond what is usually expected by providing a forecast of the likely number of SIs, broken down by month, and indicating the departments that will be laying the most SIs.

We hope this has helped your Committees to plan your work better whilst ensuring Parliament has more clarity on when it can expect to scrutinise exit SIs. We want to provide further assurances and assist in your Committees' planning. We have therefore set out at Annex A an indication of the likely percentage of EU exit SIs each department expects to lay. We hope that this information, taken alongside that previously provided (including on the number of SIs expected to be laid each month, which we re-attach in Annex B) provides you with a sufficient forward look to enable you to plan your resources.

We want to be as helpful as possible to the Committees and we have gone further than any previous Government in being open and transparent about our plans regarding secondary legislation.

Flow of Brexit SIs

As Chris Heaton-Harris outlined in his letter of 25 October, the number of EU exit SIs being laid started to increase significantly from 1 November onward, and progress has already been made. As of 16 November 138 SIs have been laid since Royal Assent of the EU (Withdrawal) Act - 56 were laid in October alone. 87 proposed negatives have so far been

laid for consideration by the Sifting Committees and we expect around 146 more negatives under the EU (Withdrawal) Act to be laid ahead of exit day. 42 affirmative SIs have been laid of which 37 are under the EU (Withdrawal) Act or a combination of that Act and other powers. The final number of affirmatives will of course depend on the sifting recommendations.

Ever since we published the white paper for what became the EU (Withdrawal) Act in January 2017, we have indicated we expect that the total number of Brexit SIs needed before exit day to be between 800-1,000. As Chris Heaton-Harris noted in his letter of 25 October, we have been clear that this total would likely fluctuate and could only be an indicative figure as departmental plans were finalised and negotiations progressed. This figure has continued to become clearer as policy decisions have crystalised, other exit-related primary legislation has received Royal Assent, and legal drafting finalised, which is why we now expect the total number of EU exit SIs we need will be fewer than 800. We now expect the total number to be up to 700, although again this may fluctuate.

The Government has always said that the objective is to ensure a functioning statute book. To do this, SIs necessary for exit day have been prioritised, and other SIs with less time pressure will be laid later in the process to enable a manageable flow and allow the necessary scrutiny by Parliament.

Departments quite rightly continue to refine the drafting and policy content of each SI and, in some cases, have combined measures to form coherent packages and/or to aid public understanding. Furthermore, around a quarter of statutory instruments will legislate on behalf of the devolved administrations adding another layer of complexity. This all impacts the number of SIs and the departmental breakdown. For these reasons, providing a reliable department-by-department month-by-month snapshot would be misleading. But we hope that you will find the detail provided at Annex A useful to understand the likely percentage breakdown of the total number of SIs we expect each department to lay.

Your letter also asked about ‘business as usual’ SIs. In the months between now and exit day We are very confident that the volume of non-EU exit SIs will be much lower than in comparable months in previous sessions. As the SLSC noted in its interim report on the work of that Committee in this session so far, the number of routine SIs laid before Parliament has remained at a relatively low level.

The number of treaties to be laid under the Constitutional Reform and Governance Act 2010 will be determined by the wider EU exit scenario. In the unlikely event of no deal, we will seek to put a number of successor international agreements with third countries in place by the end of March 2019 to replace EU international treaties and ensure continuity. In a deal scenario, our existing EU international agreements would continue to apply and so we would seek to bring successor treaties into force for the end of the Implementation Period.

Parliamentary scrutiny

You asked in your letter about the secondary legislation required for a deal scenario and a no deal scenario. The majority of EU exit SIs will be needed for a no deal scenario as well as for a deal at the end of the implementation period. Once the withdrawal agreement is legislated for, the SIs that are currently being laid under the EU (Withdrawal) Act will be deferred, amended or revoked by the Withdrawal Agreement Bill, ready for the end of an implementation period rather than for exit day.

Proper parliamentary scrutiny is a vital part of our democracy and the Government is keen to ensure Parliament has sufficient time to scrutinise these important pieces of legislation. We

do not plan to use the urgent procedure under the EU (Withdrawal) Act. This power is there as a very last resort.

We will continue to work closely with you and your Committees at both Ministerial and official levels and we will write to you again with a further update before the end of the year.

I am copying this letter to the other Business Managers and all SI Ministers.

RT HON ANDREA LEADSOM MP
LEADER OF THE HOUSE OF COMMONS

CHRIS HEATON-HARRIS MP
PARLIAMENTARY UNDER SECRETARY OF STATE FOR EXITING THE EUROPEAN UNION

Annex A

Department	Percentage of Brexit SIs
BEIS	10-15%
CO	up to 5%
DCMS	0-5%
DEFRA	15-20%
DExEU	up to 5%
DfE	up to 5%
DfT	10-15%
DHSC	up to 5%
DIT	up to 5%
DWP	up to 5%
FCO	up to 5%
FSA	up to 5%
HMRC	10-15%
HMT	10-15%
HO	up to 5%
MHCLG	up to 5%
MOJ	up to 5%
Other	up to 5%

ANNEX B

Projected flow of SIs provided in letter from Chris Heaton-Harris of 25 October 2018:

- 50-100 SIs, of which 55% are likely to be negative under the EUWA in October;
- 150-200 SIs, of which 55% are likely to be negative under the EUWA in November;
- 100-150 SIs, of which 35% are likely to be negative under the EUWA in December;
- 100-150 SIs, of which 25% are likely to be negative under the EUWA in January;
- 10-50 SIs, of which 20% are likely to be negative under the EUWA in February;
- 10-50 SIs, of which 30% are likely to be negative under the EUWA in March.

Mark Drakeford AC/AM
Ysgrifennydd y Cabinet dros Gyllid
Cabinet Secretary for Finance

Llywodraeth Cymru
Welsh Government

Eich cyf/Your ref
Ein cyf/Our ref

Mick Antoniw AM, Chair of the Constitutional and Legislative Affairs Committee
David Rees AM, Chair of the External Affairs and Additional Legislation Committee
National Assembly for Wales

29 November 2018

Dear both,

Thank you for copying to me your letter of 29 October, sent on behalf of the Interparliamentary Forum on Brexit to the Chancellor of the Duchy of Lancaster.

I welcome the Forum's interest in the relations between governments across the UK. The Welsh Government has been in the vanguard of calls for reform of intergovernmental relations; we set these out in 'Brexit and Devolution', which we published almost 18 months ago, and which itself built on positions outlined initially in 'Securing Wales' Future'. I believe our ideas are gaining traction: there is a growing recognition that we need a different way of working, because the current structures are not capable of bearing the weight EU withdrawal is placing upon them.

Our position in these matters is very much aligned with those expressed by a number of committees in recent years, as summarised in the annex to your letter, and I am able to assure you that we are taking careful note of the findings of these committees. Indeed, one of the first products undertaken as part of the IGR review was a review of the evidence from external commentators, including parliamentarians and academics, about the current state of intergovernmental relations, and recommendations for reform.

The need for reform is further demonstrated by our recent experiences in respect of the Ministerial Forum for EU negotiations. We welcomed the creation of the Forum, which is a sub-group of the JMC (EN) and a useful addition to the intergovernmental machinery, with the aim of allowing the views of the Devolved Administrations to feed into the negotiations process.

However, the quality of engagement in that Forum has been below expectations. Whilst some fruitful discussions have now been held on specific topics like cooperative accords, engagement on major elements of the negotiations has been unsatisfactory.

We remain disappointed and frustrated by the lack of meaningful engagement more widely. We were not shown or provided the detail of the draft Withdrawal Agreement or the political declaration before it was published, despite the fact that the UK Government cannot speak for the whole UK on many of the issues covered – many are in areas within the devolved competence of Welsh Ministers and the National Assembly for Wales.

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It nevertheless remains essential that we present the Welsh Government's position at every opportunity. We fully expect to be involved in the detailed negotiations with the EU on the future economic partnership on matters within our devolved competence, and have made clear that we believe the model used to prepare for Council negotiations on fisheries in particular is one we should build upon to make sure the views of the devolved administrations are incorporated into the UK negotiating position.

The Welsh Government is keen to see the development of inter-parliamentary relationships through initiatives such as the Forum, and whilst these relationships are a matter for the Assembly and the other legislatures, we would be willing to participate in work to facilitate their development.

I am copying this letter to the Chancellor of the Duchy of Lancaster, and the Cabinet Secretary for Government Business and Constitutional Relations at the Scottish Government.

Best wishes,

Mark Drakeford AC/AM
Ysgrifennydd y Cabinet dros Gyllid
Cabinet Secretary for Finance

Mae cyfyngiadau ar y ddogfen hon

Mae cyfyngiadau ar y ddogfen hon

Mae cyfyngiadau ar y ddogfen hon

Mae cyfyngiadau ar y ddogfen hon

Mae cyfyngiadau ar y ddogfen hon