Asiantaeth Safonau Bwyd
food.gov.uk
Food Standards Agency

Dogfen Ymgynghori

Ymgynghoriad Ar Weithredu'r Rheoliad Rheolaethau Swyddogol

Tudalen Crynhoi'r Ymgynghoriad

Dyddiad lansio:	**Awst 28, 2019**	**Dyddiad cau:**	**9 Hydref 2019**

I bwy fydd yr ymgynghoriad hwn o ddiddordeb fwyaf?

- **Swyddogion gorfodi bwyd a bwyd anifeiliaid awdurdodau lleol ac awdurdodau iechyd porthladdoedd yn ogystal ag unrhyw gorff arall sy'n gyfrifol am ymgymryd rheolaethau swyddogol.**
- **Gweithredwyr busnesau bwyd sy'n mewnforio cynhyrchion bwyd a bwyd anifeiliaid i mewn i'r Undeb Ewropeaidd (UE).**
- **Gweithredwyr busnesau bwyd a gymeradwyir o dan Reoliad (CE) 853/2004.**

Beth yw pwnc yr ymgynghoriad hwn?

Bydd Rheoliad Rheolaethau Swyddogol (UE) 2017/625 (y Rheoliad) yn weithredol o 14 Rhagfyr 2019. Bydd yn uniongyrchol gymwys yng Nghymru ar 14 Rhagfyr 2019, os bydd y Deyrnas Unedig (DU):

- **yn parhau i fod yn rhan o'r UE**
- **neu wedi cytuno ar gyfnod gweithredu/cyfnod trosiannol gyda'r UE.**

Mae'r Rheoliad yn mynd i'r afael â rheolaethau swyddogol a gweithgareddau swyddogol eraill a gyflawnir i sicrhau y cymhwysir cyfraith bwyd a bwyd anifeiliaid, rheolau ar iechyd a lles anifeiliaid, iechyd planhigion a chynhyrchion diogelu planhigion.

Mae'r ymgynghoriad hwn yn canolbwyntio ar weithredu deddfwriaeth yng Nghymru er mwyn darparu ar gyfer arfer pwerau a gorfodi'r Rheoliad dim ond mewn perthynas â'r meysydd y mae gan yr Asiantaeth Safonau Bwyd (ASB) gyfrifoldeb drostynt o ran cyfraith bwyd a bwyd anifeiliaid ac iechyd a lles anifeiliaid.

Beth yw diben yr ymgynghoriad hwn?

Ceisio barn rhanddeiliaid mewn perthynas â:

- **Y ddeddfwriaeth gweithredu arfaethedig yng Nghymru i ddarparu ar gyfer arfer pwerau a gorfodi'r Rheoliad mewn perthynas â meysydd y mae gan yr ASB gyfrifoldeb drostynt o ran cyfraith bwyd a bwyd anifeiliaid ac iechyd a lles anifeiliaid.**
- **Mae ein hasesiad o'r effeithiau sy'n gysylltiedig â gweithredu'r ddeddfwriaeth yng Nghymru yn ymwneud â meysydd cyfrifoldeb yr ASB yn unig.**

Llawr 11 / 11th Floor
Tŷ Southgate / Southgate House
Wood Street
Caerdydd / Cardiff CF10 1EW

E: cymru@food.gov.uk / wales@food.gov.uk
Ffôn / Tel: 029 2067 8999

Dylid anfon ymatebion i'r ymgynghoriad hwn at:	
Elizabeth Hirst **Tîm Polisi Bwyd** **Asiantaeth Safonau Bwyd** **Ffôn: 02920 678940**	**Llawr 11, Tŷ Southgate** **Wood Street** **Caerdydd, CF10 1EW** **E-bost: Food.Policy.Wales@food.gov.uk**

Asesiad effaith wedi'i gynnwys?	**Oes x**	**Nac oes ☐**

Ymgynghoriad Ar Weithredu'r Rheoliad Rheolaethau Swyddogol

Manylion yr ymgynghoriad

Cyflwyniad

1. Cafodd Rheoliad (UE) 2017/625, a elwir yn Rheoliad Rheolaethau Swyddogol (y Rheoliad) ei fabwysiadu gan Senedd Ewrop a'r Cyngor Ewropeaidd ar 15 Mawrth 2017, a daeth i rym ar 27 Ebrill 2017. Serch hynny, y bwriad oedd cymhwyso rheolau newydd y Rheoliad yn raddol dros nifer o flynyddoedd gyda'r rhan fwyaf yn cael eu cymhwyso ar 14 Rhagfyr 2019. Mae tabl yn rhestru'r gwahanol ddyddiadau cymhwyso ar gael ar wefan y Comisiwn Ewropeaidd.[1]

2. Mae'r Rheoliad yn mynd i'r afael â rheolaethau swyddogol a gweithgareddau swyddogol eraill a gyflawnir i sicrhau y cymhwysir cyfraith bwyd a bwyd anifeiliaid, rheolau ar iechyd a lles anifeiliaid, iechyd planhigion a chynhyrchion diogelu planhigion. Mae'n diddymu ac yn cymryd lle Rheoliad (CE) 882/2004 ar reolaethau swyddogol a deddfwriaeth arall sydd ar hyn o bryd yn rheoli ac yn gorfodi rheolau ar hyd y gadwyn bwyd-amaeth. Nodir y ddeddfwriaeth hon yn Atodiad D.

3. Bu'r ASB yn ymgynghori â rhanddeiliaid yn ystod Trafodaethau'r UE ar effeithiau'r Rheoliad arfaethedig, gan gynnwys cwmpas estynedig y Rheoliad i integreiddio rheolaethau mewn perthynas ag iechyd planhigion a chynhyrchion diogelu planhigion â'r rheolaethau hynny yn ymwneud â bwyd, bwyd anifeiliaid, iechyd a lles anifeiliaid.[2]

4. Mae'r ymgynghoriad hwn yn canolbwyntio ar weithredu deddfwriaeth yng Nghymru i ddarparu ar gyfer arfer pwerau a gwaith gorfodi dim ond mewn perthynas â'r agweddau hynny o'r Rheoliad sy'n berthnasol o 14 Rhagfyr 2019, a dim ond mewn perthynas â meysydd y mae gan yr ASB gyfrifoldeb drostynt o ran cyfraith bwyd a bwyd anifeiliaid.

5. Ar 23 Mehefin 2016, cynhaliwyd refferendwm yr UE, a phleidleisiodd pobl y DU i ymadael. Bydd y DU yn parhau i fod yn Aelod-wladwriaeth hyd at y dyddiad ymadael ac felly, bydd Llywodraeth y DU yn parhau i drafod, gweithredu a chymhwyso deddfwriaeth yr UE.

6. Mae disgwyl y bydd y Rheoliad yn weithredol ar draws yr UE o 14 Rhagfyr 2019.[3] Mae'r ASB yn paratoi'r seiliau deddfwriaethol i weithredu'r Rheoliad os bydd y DU a'r UE yn cadarnhau Cytundeb Ymadael cyn diwedd mis Hydref. Byddai hynny'n golygu bod y DU yn dechrau ar gyfnod gweithredu. Bydd hi'n ofynnol yn ystod unrhyw gyfnod gweithredu i gadw at Reoliadau'r UE ar gyfer diogelwch a hylendid bwyd a bwyd anifeiliaid.

1 https://ec.europa.eu/food/sites/food/files/safety/docs/oc_application_timeline_20170407.pdf
2 https://webarchive.nationalarchives.gov.uk/20141204222847/http://www.food.gov.uk/news-updates/consultations/2013/officialcontrols-consult
3 https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:32017R0625

7. Os digwydd bod y DU yn ymadael â'r UE heb fargen, bydd yr ASB yn rhoi diweddariad pellach i randdeiliaid mewn perthynas â'r bwriad i weithredu'r Rheoliad.

Cynigion

8. Mae'r Rheoliad yn ddarn cyffredinol o ddeddfwriaeth sy'n pennu safonau gweithredol i awdurdodau cymwys arfer rheolaethau swyddogol a gweithgareddau swyddogol eraill ar draws yr UE. Bydd darpariaethau'r Rheoliad sy'n berthnasol o 14 Rhagfyr 2019 yn diddymu ac yn cymryd lle deddfwriaeth bresennol sy'n rhan annatod o weithgareddau rheoli swyddogol a gyflawnir gan yr ASB ac awdurdodau lleol yng Nghymru. Mae hyn yn cynnwys:
    - Rheoliad (CE) 882/2004 ynghylch rheolaethau swyddogol a gyflawnir i wirio cydymffurfiaeth â chyfraith bwyd a bwyd anifeiliaid, a
    - Rheoliad (CE) 854/2004 ar reolaethau swyddogol ar gynhyrchion sy'n dod o anifeiliaid ac a fwriedir i'w bwyta gan bobl.

9. Mae'r fframwaith cyfreithiol a grëwyd gan y Rheoliad yn galluogi Aelod-wladwriaethau i fod yn sicr bod yr awdurdodau cymwys mewn Aelod-wladwriaethau eraill yn cynnal rheolaethau mewn modd trylwyr a diduedd sy'n addas. Mae'r ddeddfwriaeth hefyd yn cwmpasu agweddau eraill ar y gadwyn bwyd-amaeth, fel rheolaethau mewnforio a labordai, yn ogystal â gwahanol nwyddau, fel anifeiliaid byw, planhigion a bwyd sy'n dod o anifeiliaid.

Agweddau allweddol ar gymhwyso'r Rheoliad sy'n berthnasol o 14 Rhagfyr 2019:

- **Dull rheoleiddio wedi'i gysoni a'i gydlynu at reolaethau swyddogol a chamau gorfodi ar hyd y gadwyn bwyd-amaeth;**
- **Gofynnol i awdurdodau cymwys (y sefydliadau hynny sy'n gyfrifol am drefnu neu arfer rheolaethau swyddogol) Aelod-wladwriaethau ddarparu rhagor o dryloywder ac atebolrwydd drwy gyhoeddi gwybodaeth am y sefydliad ac o ran arfer rheolaethau swyddogol;**
- **Rheolau mwy caeth ar dwyll yn rhoi mwy o ddiogelwch i ddefnyddwyr a bod o fudd i fusnesau sy'n cydymffurfio;**
- **Set gyffredin o reolau ar gyfer rheolaethau ar ffiniau gwledydd yr UE sy'n goresgyn y darnio cyfredol ac yn gwneud y system reoli yn llai beichus ar gyfer swyddogion gorfodi a busnesau;**
- **System gyfrifiadurol integredig i wella'r arfer o gyfnewid gwybodaeth rhwng Aelod-wladwriaethau am reolaethau swyddogol;**
- **Mwy o hyblygrwydd mewn perthynas ag achredu labordai swyddogol (h.y. cydnabyddiaeth ffurfiol o gymhwysedd yn eu maes);**
- **Bydd busnesau ac awdurdodau yn elwa ar leihau beichiau gweinyddol, prosesau mwy effeithlon a rheolaethau cryfach.**

10. Mae dadansoddiad manylach o'r newidiadau a ddaw i rym yn sgil y Rheoliad a'r ddeddfwriaeth drydyddol i'w weld yn **Atodiad D**.

11. Mae'r ASB yn bwriadu paratoi hyd at dri Offeryn Statudol (OS) er mwyn darparu pwerau a chapasiti gorfodi ar gyfer y Rheoliad a'i ddeddfwriaeth drydyddol yng Nghymru. Nid yw'r offerynnau statudol ar gael i'w cyhoeddi ar adeg yr ymgynghoriad hwn. Y bwriad yw y bydd yr offerynnau statudol newydd yn dilyn fframwaith yr offerynnau statudol presennol sy'n darparu pwerau gorfodi ar gyfer y rheoliad rheolaethau swyddogol cyfredol (Rheoliad UE (Rhif) 882/2004 a Rheoliad UE 854/2004).

Gorfodi a sancsiynau

12. Mae rhywfaint o dystiolaeth bod sancsiynau troseddol yn ffordd effeithiol o sicrhau cydymffurfiaeth â'r gyfraith bwyd a bwyd anifeiliaid yng Nghymru lle nad yw camau gorfodi eraill wedi llwyddo. Fodd bynnag, mewn perthynas â rhai methiannau i gydymffurfio sydd ag effeithiau cyfyngedig iawn i iechyd y cyhoedd, gall sancsiynau troseddol yn aml fod yn anghymesur gan osod beichiau diangen ar awdurdodau gorfodi a thanseilio effeithiolrwydd eu gwaith gorfodi. Yn rhan o'r gwaith datblygu polisi ar weithredu rheoliadau, bydd yr ASB yn ystyried p'un a yw'n fwy priodol darparu sancsiynau nad ydynt yn rhai troseddol am achosion o dorri rheolau sy'n bodloni'r meini prawf hyn.

Effeithiau

13. Mae Asesiad o Effaith yn cael ei ddarparu sy'n ceisio asesu'r newidiadau a ddaeth yn sgil y Rheoliadau domestig sy'n dod i mewn. Mae'n rhoi trosolwg o'r newidiadau a'r effeithiau disgwyliedig a ddaw yn sgil y ddeddfwriaeth Ewropeaidd a fydd yn uniongyrchol gymwys yng nghyd-destun y DU.

14. Mae asesiad yr ASB yn nodi ychydig iawn o effeithiau uniongyrchol ar fusnes yn sgil gweithredu'r Rheoliad yng Nghymru, ac nid yw'r effeithiau hynny a nodir yn cael eu hystyried yn arwyddocaol. Mae hyn yn bennaf oherwydd y newidiadau i egwyddorion cyffredinol y gwaith o gynnal rheolaethau swyddogol, y mae'r DU eisoes yn eu dilyn.

15. Mae'r ASB yn Lloegr ac yn Gogledd Iwerddon yn ymgynghori ar wahân ar eu priod ddeddfwriaeth genedlaethol, ac ar yr effeithiau a nodir yn yr asesiad effaith cyfunol hwn.

Y Broses Ymgysylltu ac Ymgynghori

16. Ceisir barn rhanddeiliaid ar yr ymgynghoriad hwn ac Asesiad o Effaith cysylltiedig yr ASB. Yn arbennig, byddai'r ASB yn croesawu unrhyw dystiolaeth y gall rhanddeiliaid ei darparu tuag at hyn ac o'r herwydd rydym wedi darparu rhestr o gwestiynau isod:

Cwestiynau a ofynnir yn yr ymgynghoriad hwn

Esboniwch eich atebion cymaint ag y gallwch, a lle bo ar gael, dylech gynnwys tystiolaeth i gefnogi eich barn.

C1: A ydym ni wedi nodi'n briodol agweddau allweddol y broses o gymhwyso'r Rheoliad a fydd yn weithredol o 14 Rhagfyr 2019?

C2: A ydym ni wedi nodi'n briodol effeithiau'r newidiadau a fydd yn weithredol o 14 Rhagfyr 2019 yn ein Hasesiad o Effaith?

C3: A ydych chi'n cytuno â'r rhagdybiaethau a wneir yn ein Hasesiad o Effaith?

C4: Ydych chi'n ymwybodol o unrhyw effeithiau arwyddocaol eraill o'r newidiadau a fydd yn weithredol o 14 Rhagfyr 2019 nad ydym ni wedi'u nodi?

C5: Ydych chi'n ystyried y bydd y Rheoliadau yn effeithio ar gyfleoedd i ddefnyddio'r Gymraeg?

C6: Hoffem wybod eich barn ar effaith y rheoliadau arfaethedig ar y Gymraeg, yn arbennig yn ymwneud â:

i) chyfleoedd i bobl ddefnyddio'r Gymraeg

ii) trin y Gymraeg yr un mor ffafriol â'r Saesneg.

C7: Pa effeithiau ydych chi'n eu rhagweld? Sut ellir cynyddu effeithiau cadarnhaol, neu leihau effeithiau negyddol?

Cwestiynau a ofynnir yn yr Asesiad Effaith (Atodiad B)

Grwpiau yr effeithir arnynt

C.I: A yw'r rhestr gyfan o'r sectorau/grwpiau yr effeithir arnynt yn gynrychioliadol? Os ydych chi'n cytuno yn rhannol, neu os nad ydych chi'n cytuno, nodwch sectorau/grwpiau eraill yr effeithir arnynt y dylid hefyd eu hystyried a pham.

Costau:

C.II: Byddem ni'n croesawu tystiolaeth gan fusnesau yr effeithir arnynt ar y costau disgwyliedig i'w sefydliad pe byddai'r ASB yn gwirio cydymffurfiaeth naill ai drwy a) gasglu data o'r diwydiant neu b) drwy samplu.

C.III Byddem ni'n croesawu tystiolaeth ategol ar gyfanswm lefelau trwybwn lladd-dai a sefydliadau Trin Helgig capasiti isel, a dosbarthiad sefydliadau o'r fath mewn perthynas â'r trothwy blynyddol uchaf newydd. Byddem ni hefyd yn croesawu barn ar ein rhagdybiaeth y gall y gofyniad newydd arwain at gostau ychwanegol i fusnesau o'r fath ac i ba raddau y mae'r newid hwn yn debygol o effeithio arnynt.

C.IV: Byddem ni'n croesawu unrhyw dystiolaeth y gall rhanddeiliaid ei darparu mewn perthynas â nifer y gweithredwyr busnesau bwyd sy'n cynaeafu ecinodermiaid o ardaloedd di-ddosbarth.

C.V: Byddem ni'n croesawu barn, a lle bo modd dystiolaeth ategol, gan fusnesau yn y DU sy'n mewnforio un neu ragor o'r cynhyrchion sy'n ddarostyngedig i'r newidiadau uchod. Pa effaith ydych chi'n credu y bydd cysoni rheolaethau yn ei chael ar eich busnes?

C.VI: Byddem ni'n croesawu tystiolaeth gan randdeiliaid ac yn arbennig Awdurdodau Iechyd Porthladdoedd ar ba reolaethau sy'n cael eu cynnal ar hyn o bryd ar gig ymlusgiaid a phryfed a lle mae'r rheolaethau hyn yn cael eu harfer?

C.VII Byddem ni'n croesawu barn awdurdodau gorfodi ar ein rhagdybiaethau datganedig ar y gofynion hyfforddiant i gefnogi'r gwaith o gyflawni'r newidiadau a gyflwynir gan y Rheoliad? Nodwch fanylion unrhyw anghenion hyfforddi penodol rydych chi'n meddwl y bydd yn angenrheidiol.

C.VIII Wrth ofyn am dystiolaeth, byddem ni'n croesawu gwybodaeth am y newidiadau a/neu fesurau uwchraddio angenrheidiol y byddai'n ofynnol i rai Mannau Cyrraedd Dynodedig/Mannau Mewnforio Dynodedig ac Arolygfeydd Ffin eu gweithredu er mwyn cael ardystiad fel Mannau Rheoli ar y Ffin.

C.IX: Byddem ni'n croesawu sylwadau gan gynrychiolwyr Labordai Rheolaethau Swyddogol, neu awdurdodau lleol sydd ar hyn o bryd yn anfon/cael samplau o is-gontractau i/gan labordai eraill heb eu dynodi mewn Aelod-wladwriaethau eraill. Yn benodol, rydym ni'n gwahodd tystiolaeth ar yr effaith/effeithiau a allai godi yn sgil y newid hwn.

Buddion

C.X: A ydych chi'n cytuno y bydd dull rheoleiddio wedi'i gysoni a'i gydlynu tuag at reolaethau swyddogol yn cyflwyno unrhyw fuddion a/neu arbedion cost i'r diwydiant? Os ydych chi'n rhannol gytuno neu anghytuno â'r datganiad hwn, a wnewch chi roi tystiolaeth o ba fuddion (os o gwbl) rydych chi'n disgwyl eu gweld.

Q.XI: Byddem ni'n croesawu barn rhanddeiliaid ar unrhyw fuddion rydych chi'n eu rhagweld drwy weithredu'r Rheoliad. Lle bo'n bosibl, esboniwch eich barn a darparwch dystiolaeth fesuradwy.

C.XII: Nodwch a darparwch dystiolaeth lle bo'n bosibl, o unrhyw fudd rydych chi'n meddwl a ddaw i chi o'r newidiadau a amlinellir yn yr asesiad hwn.

17. Bydd yr ASB yn cyhoeddi adroddiad yn crynhoi'r ymatebion o fewn 3 mis i ddyddiad cau'r ymgynghoriad hwn.

Dogfennau perthnasol eraill

18. Mae dolen i'r Rheoliad wedi'i darparu er hwylustod. https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:02017R0625-20170407&from=EN

Ymatebion

19. **Mae angen ymatebion erbyn diwedd y dydd ar 3 Hydref 2019**. Yn eich ymateb, nodwch a ydych yn ymateb fel unigolyn neu ar ran sefydliad neu gwmni (gan gynnwys manylion unrhyw randdeiliaid y mae'ch sefydliad yn eu cynrychioli).

Ar ran yr ASB, hoffwn ddiolch yn fawr i chi am gymryd rhan yn yr ymgynghoriad cyhoeddus hwn.

Yn gywir,

Elizabeth Hirst
Tîm Polisi Bwyd
Asiantaeth Safonau Bwyd Cymru

Amgaeedig

Atodiad A: Gwybodaeth safonol am yr ymgynghoriad

Atodiad B: Asesiad Effaith

Atodiad C: Rhestr o bawb sydd â diddordeb

Atodiad D: Rhestr o newidiadau rhwng y ddeddfwriaeth bresennol a'r Rheoliad

Atodiad A: Gwybodaeth safonol am yr ymgynghoriad

Datgelu'r wybodaeth a ddarperir gennych

Efallai caiff yr wybodaeth a roddir mewn ymateb i'r ymgynghoriad hwn ei chyhoeddi i bartïon eraill neu ei datgelu yn unol â'r cyfundrefnau mynediad at wybodaeth (yn bennaf Deddf Rhyddid Gwybodaeth 2000, Deddf Diogelu Data 2018 a Rheoliadau Gwybodaeth Amgylcheddol 2004).

Os dymunwch i'r wybodaeth yr ydych yn ei rhoi gael ei thrin yn gyfrinachol, dylech fod yn ymwybodol bod yna God Ymarfer statudol o dan y Ddeddf Rhyddid Gwybodaeth y mae'n rhaid i awdurdodau cyhoeddus gydymffurfio ag ef. Mae'n ymdrin, ymhlith pethau eraill, â rhwymedigaethau cyfrinachedd.

O ystyried hyn, byddai'n ddefnyddiol pe gallech esbonio i ni pam eich bod yn ystyried yr wybodaeth a roddwyd gennych yn gyfrinachol. Os cawn gais i ddatgelu'r wybodaeth, byddwn yn ystyried eich esboniad yn llawn, ond ni allwn roi sicrwydd y gellir cadw cyfrinachedd dan bob amgylchiad.

Ni fydd unrhyw ymwadiad cyfrinachedd awtomatig a gynhyrchir gan eich system TG, ar ei ben ei hun, yn cael ei ystyried fel un sy'n rhwymo.

Yr ASB fydd 'Rheolydd' y data personol a ddarperir i ni.

Pam ein bod ni'n casglu eich data personol?

Mae eich data personol yn cael ei gasglu fel rhan hanfodol o'r broses ymgynghori, fel y gallwn gysylltu â chi ynglŷn â'ch ymateb ac at ddibenion ystadegol. Efallai hefyd y byddwn yn ei ddefnyddio i gysylltu â chi am faterion cysylltiedig.

Mae Deddf Diogelu Data 2018 yn datgan y gall yr ASB, fel adran o'r llywodraeth, brosesu data personol fel bo'r angen er mwyn cyflawni tasg sydd er budd y cyhoedd yn effeithiol h.y. ymgynghoriad.

Beth fyddwn ni'n ei wneud â'r wybodaeth?

Mae'r holl ddata personol rydym ni'n ei brosesu yn byw ar weinyddion o fewn yr Undeb Ewropeaidd. Mae ein gwasanaethau cwmwl wedi'u caffael drwy Gytundebau Fframwaith y Llywodraeth a'u hasesu yn erbyn egwyddorion cwmwl y Ganolfan Seiberddiogelwch Genedlaethol.
Nid oes gan drydydd partïon fynediad at eich data personol oni bai bod y gyfraith yn caniatáu iddynt wneud hynny. Bydd yr ASB weithiau'n rhannu data gydag adrannau eraill y llywodraeth, cyrff cyhoeddus a sefydliadau sy'n cyflawni swyddogaethau cyhoeddus i'w cynorthwyo i gyflawni eu dyletswyddau statudol, neu pan fydd er budd y cyhoedd.

Beth yw eich hawliau?

Mae gennych chi'r hawl i weld yr wybodaeth sydd gennym ni amdanoch chi drwy wneud cais ysgrifenedig i'r cyfeiriad e-bost isod. Os ydych chi ar unrhyw adeg o'r farn bod yr wybodaeth rydym ni'n ei phrosesu amdanoch chi yn anghywir, gallwch chi wneud cais i'w chywiro. Os hoffech chi wneud cwyn am y ffordd rydym ni wedi trin eich data personol, gallwch chi gysylltu â'n Swyddog Diogelu Data a fydd yn ymchwilio i'r mater.

Os nad ydych chi'n fodlon â'n hymateb neu os ydych chi o'r farn nad ydym yn prosesu eich data personol yn unol â'r gyfraith, fe allwch chi gwyno i Swyddfa'r Comisiynydd Gwybodaeth yn https://ico.org.uk/, neu drwy ffonio 0303 123 1113.

Ein Swyddog Diogelu Data yn yr ASB yw Arweinydd y Tîm Rheoli Gwybodaeth a Diogelwch. Gallwch chi gysylltu drwy anfon e-bost at: informationmanagement@foodstandards.gsi.gov.uk

Rhagor o wybodaeth

Os ydych chi angen y ddogfen hon mewn fformat sy'n haws i'w ddarllen, anfonwch fanylion at y cyswllt a enwir ar gyfer ymatebion i'r ymgynghoriad hwn a bydd eich cais yn cael ei ystyried.

Mae'r ymgynghoriad hwn wedi'i baratoi yn unol ag egwyddorion ymgynghori Llywodraeth Ei Mawrhydi[4].

[4] www.gov.uk/government/publications/consultation-principles-guidance

Atodiad B: Asesiad Effaith (*Saesneg yn unig*)

Title: The Official Control Regulations (OCR) **IA No: Food 0162** RPC Reference No: **Lead department or agency:** The Food Standards Agency **Other departments or agencies:**	Impact Assessment (IA) **Date: 23/08/19** **Stage:** Consultation **Source of intervention: Domestic** **Type of measure: Secondary legislation** **Contact for enquiries:** Elizabeth Hirst

Summary: Intervention and Options

Cost of Preferred (or more likely) Option (in 2016 prices)			
Total Net Present Social Value	**Business Net Present Value**	**Net cost to business per year**	**Business Impact Target Status**
-£0.3m	-£0.2m	£0.0m	Non qualifying provision

What is the problem under consideration? Why is government intervention necessary?

Regulation (EU) 2017/625 or the Official Control Regulations (OCR) addresses official controls and other official activities performed to ensure the application of food and feed law, rules on animal health and welfare, plant health and plant protection products. The OCR entered into force on 27 April 2017 and will apply in all European Union Member States from 14 December 2019. At this point the OCR will repeal and replace Regulation (EC) 882/2004 and Regulation (EC) 854/2004 on official controls and other legislation, which currently governs the control and enforcement of rules along the agri-food chain.

What are the policy objectives and the intended effects?

To provide the execution of powers and enforcement of the OCR and associated tertiary legislation. Implementation of national legislation will maintain the legal basis for official control activity in relation food and feed law and animal health and welfare. In doing so consumer protection will be maintained along with confidence in the UK agri-food chain.

What policy options have been considered, including any alternatives to regulation? Please justify preferred option (further details in Evidence Base)

Option 1: Implement national legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation. This is the preferred option.

Option 2: Do Nothing – Do not implement national legislation to provide for the execution of powers and enforcement of the OCR. This option does not fulfil UK or FSA statutory objectives and would undermine consumer protection. The option is therefore rejected.

Will the policy be reviewed? It **will/will not** be reviewed. **If applicable, set review date: Month/ Year**

Does implementation go beyond minimum EU requirements?		No		
Is this measure likely to impact on trade and investment?		No		
Are any of these organisations in scope?	**Micro** Yes	**Small** Yes	**Medium** Yes	**Large** Yes
What is the CO_2 equivalent change in greenhouse gas emissions? (Million tonnes CO_2 equivalent)		**Traded:**	**Non-traded:**	

I have read the Impact Assessment and I am satisfied that, given the available evidence, it represents a reasonable view of the likely costs, benefits and impact of the leading options.

Signed by the responsible
SELECT SIGNATORY: _____ Date: _____

Summary: Analysis & Evidence Policy Option 1

Description: Implement national legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation

FULL ECONOMIC ASSESSMENT

Price Base Year 2016	PV Base Year 2017	Time Period Years 10	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: -0.3

COSTS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	£0.3		£0.0	**£0.3**

Description and scale of key monetised costs by 'main affected groups'

One-off familiarisation costs are estimated to accumulate £0.1m for enforcement authorities and £0.2m for businesses.

Other key non-monetised costs by 'main affected groups'

New import requirements could be associated with compliance costs for importers of some products of high-risk food and feed. Selected approved establishments are expected to see some new requirements to verify their compliance with regards to hygiene controls. Enforcement Authorities, including PHAs, OCLs and the FSA, could see minor changes in their responsibility to deliver official controls, e.g. requirements for additional import checks and new data collection tasks.

BENEFITS (£m)	Total Transition (Constant Price)	Years	Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	n/a		n/a	**n/a**

Description and scale of key monetised benefits by 'main affected groups'

No benefits have been monetised.

Other key non-monetised benefits by 'main affected groups'

Industry should benefit from a harmonised and coherent regulatory approach to official controls and from a better targeting of risks. Importers of high-risk food and feed should also benefit from the harmonisation of entry documents which will reduce their administrative burden. We assume that Enforcement Authorities will benefit overall from a simplification and consolidation of the legislative framework.

Key assumptions/sensitivities/risks **Discount rate (%)** 3.5

There remains a high level of uncertainty around the implementation of the regulation in certain areas for which we were unable to monetise the impacts, in particular where tertiary legislation is affected.
The Impact Assessment is based on the assumption that the United Kingdom will be in an Implementation Period in December 2019 and that trade between the UK and the EU remains unchanged compared to the status quo if the OCR was implemented.

BUSINESS ASSESSMENT (Option 1)

Direct impact on business (Equivalent Annual) £m:			Score for Business Impact Target (qualifying provisions only) £m:
Costs: £0.02	Benefits: n/a	Net: £0.02	n/a

Summary: Analysis & Evidence Policy Option 2

Description: Do Nothing – Do not implement national legislation to provide for the execution of powers and enforcement of the OCR

FULL ECONOMIC ASSESSMENT

Price Base Year n/a	PV Base Year n/a	Time Period Years n/a	Net Benefit (Present Value (PV)) (£m)		
			Low: Optional	High: Optional	Best Estimate: n/a

COSTS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition)	Total Cost (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	n/a		n/a	**n/a**

Description and scale of key monetised costs by 'main affected groups'

n/a

Other key non-monetised costs by 'main affected groups'

n/a

BENEFITS (£m)	Total Transition (Constant Price) Years		Average Annual (excl. Transition) (Constant Price)	Total Benefit (Present Value)
Low	Optional		Optional	**Optional**
High	Optional		Optional	**Optional**
Best Estimate	n/a		n/a	**n/a**

Description and scale of key monetised benefits by 'main affected groups'

n/a

Other key non-monetised benefits by 'main affected groups'

n/a

Key assumptions/sensitivities/risks	n/a
Discount rate (%)	

The associated impacts of this option have not been assessed because of the disproportionate negative effects on public health and legal consequences that would be associated with this option.

BUSINESS ASSESSMENT (Option 2)

Direct impact on business (Equivalent Annual) £m:			**Score for Business Impact Target (qualifying provisions only) £m:**
Costs: n/a	**Benefits: n/a**	**Net: n/a**	n/a

Evidence Base (for summary sheets)

Problem under consideration

1. Regulation (EU) 2017/625, referred to as the Official Controls Regulation (OCR), is a directly applicable EU regulation and an overarching piece of legislation that sets operational standards for the performance of official controls and other official activities by competent authorities across the European Union.

2. The OCR entered into force on 27 April 2017, with the applicability of the new rules set to apply gradually over a number of years; with the main application taking effect on 14 December 2019. The OCR empowers the European Commission to adopt implementing acts and introduce delegated acts (tertiary legislation) to supplement the regulation.

3. When the OCR main application takes effect on 14 December 2019 it will give effect to applicable tertiary legislation and the new law will apply in all European Union Member States. It will also repeal and replace existing legislation integral to official control activities, including those carried out by the Food Standards Agency (FSA) and local authorities in England, Wales and Northern Ireland. This includes Regulation (EC) No 882/2004 regarding official controls performed to verify compliance with feed and food law, and Regulation (EC) No 854/2004 on official controls on products of animal origin intended for human consumption.

4. The legal framework created by the OCR allows members of the single market to be sure that the competent authorities in other Member States are conducting controls in a suitably rigorous and impartial fashion. The legislation cuts across aspects of the agri-food chain, such as import controls and laboratories, as well as different commodities, such as live animals, plants and food of animal origin.

5. The OCR is directly applicable in UK law in case of either an Article 50 extension or an Implementation Period. This means, in either of these scenarios, the Regulations that provide the UK basis for feed and food law official controls will no longer apply from 14 December 2019. New secondary legislation in England, Wales and Northern Ireland, is therefore required to repeal and replace current secondary legislation, to provide for the execution of powers and enforcement for the OCR and associated tertiary legislation that is currently being negotiated by Member States and the European Commission.

6. This Impact Assessment assesses the changes that will be brought about from 14 December by the proposed domestic secondary legislation in England, Wales and Northern Ireland that repeals, replaces and amends existing domestic secondary legislation and provides for the execution of powers and enforcement for the OCR and associated tertiary legislation. It also assesses the changes and expected impacts that the tertiary legislation will necessitate in the UK context[5].

7. Impacts are identified and assessed for England, Wales and Northern Ireland. Food Standards Scotland (FSS) are responsible for implementing these changes in Scotland and for assessing the impacts on Scotland.

8. It should be noted that the Impact Assessment covers all impacts and geographical areas for which FSA has full or partial policy responsibility. This ensures that FSA stakeholders receive a comprehensive overview of all impacts they might experience. Due to the broad scope of the OCR and the shared policy responsibilities between FSA and other government departments, especially DEFRA, some of these impacts might also be assessed by other departments.

[5] An Impact Assessment was produced to address the initial Commission proposal in 2013. Since then there have been significant changes to the legislation following European negotiations which necessitates a change in scope of the Impact Assessment. The 2013 IA can be accessed via https://www.reading.ac.uk/foodlaw/pdf/uk-13026-enforcement-consultation.pdf.

Rationale for intervention

9. Failing to provide for the execution of powers and enforcement in England, Wales and Northern Ireland, for the OCR, in the event the UK remains subject to directly applicable EU Regulations on 14 December 2019 (i.e. an implementation period or extension to Article 50) would present significant gaps to the legislative framework for the delivery of official controls.

10. UK enforcement authorities (such as the FSA and local authorities) carry out official controls at all stages of production, distribution, use, storage, transport, import and export of food and feed. The controls ensure that food and feed businesses are meeting their obligations to produce safe and wholesome food and feed and that unsafe products are removed from the market. Official controls are integral to protecting consumers' health and other interests and maintaining the integrity of the agri-food chain that provides consumer and business confidence as well as assurance to other Member States and 3rd countries, which is vital to trade.

11. When the main provisions of the OCR take effect on 14 December 2019, the OCR will repeal the European regulations that currently provide the legislative framework for UK official controls in relation to EU food and feed law. To maintain our legislative framework for EU food and feed law official controls the UK must provide for the execution of powers and enforcement of the OCR in domestic legislation. Failure to do so will undermine the effectiveness of official controls and therefore undermine consumer protection as well as confidence in the UK agri-food chain.

12. The FSA estimates that there are around a million cases of foodborne illness in the UK each year, generating an economic burden of treatment costs and loss of productivity in excess of £1 billion each year in resource and welfare costs for the UK[6]. A failure to introduce the required legislation to enforce official food and feed controls would undermine the effectiveness of official controls, likely leading to an increase in non-compliance and cases of foodborne disease, involving severe consequences for public health and costs to society.

13. Official controls also help maintain a level playing field for honest and diligent food and feed business operators, which is in the interest of industry as a whole. In particular, adherence to the principles contained within (or requirements of) the OCR will help the UK to demonstrate that food and feed produced and processed within the UK have been produced and handled in accordance with EU requirements. Consequently this will help to ensure continued confidence in the UK agri-food sector which contributed £121.7 billion (6.7%) to national Gross Value Added in 2017 and employs around 4.1 million people (14% of GB employment).[7] In terms of sales, the manufacture of food products remains the largest division within the whole UK manufacturing sector, contributing £71.8 billion (18.4%) of total UK manufacture in 2018[8], providing inputs for a multiple of secondary industries, including importing, exporting, processing, storage, distribution and retail. There is hence also a strong economic rationale for implementing the OCR and maintaining and strengthening confidence in food and feed produced in the UK.

Policy objective

[6] 2017/18 Annual Reports and Consolidated Accounts, p. 16. It should be noted that the FSA is currently updating the way it estimates the economic burden of foodborne illness. These figures are therefore preliminary and will be updated as soon as new evidence is available.

[7] Defra (2019): Food Statistics in your pocket: Summary (National Statistics, updated 8 April 2019): https://www.gov.uk/government/statistics/food-statistics-pocketbook.

[8] https://www.ons.gov.uk/businessindustryandtrade/manufacturingandproductionindustry/bulletins/ukmanufacturerssalesbyproductprodcom/2018provisionalresults#manufacturing-of-food-products-contributes-to-growth-in-2018.

14. The existing legal framework enables competent authorities to effectively enforce food and feed law. The statutory instruments to provide the execution of power and enforcement for the OCR will ensure sufficient national powers are in place to effectively enforce food and feed law and maintain the high level of consumer protection currently in place. The national legislation will also ensure that domestic law is up to date with the European Union acquis including the changes brought about by the provisions of the OCR on 14 December 2019.
15. Through the implementation of national legislation in England, Wales and Northern Ireland the FSA will repeal and replace current secondary legislation, to provide for the execution of powers and enforcement for the OCR and associated tertiary legislation currently under negotiation by Member States and the European Commission. Implementation of national legislation will maintain a strong legal basis for future official control activity in relation to food and feed law and animal health and welfare. It will also ensure that consumer protection is maintained and that confidence in the UK agri-food chain is maintained through the demonstration of the effectiveness of our regulatory control system including the legal basis for the execution of necessary powers and enforcement of official controls and other official activities.
16. The intention of the European Commission is to simplify and further harmonise control systems across the EU agri-food chain through the implementation of the OCR. The organisation of such controls is harmonised at an EU level to ensure a consistent high-level of consumer protection, provide confidence in the safety and standards of food produced in the EU or imported from third countries and provide for effective functioning of the internal market.

17. The new legislation builds upon and clarifies the existing risk-based approach towards the performance of official controls. The main intended effects identified by the Commission are summarised below:

- A harmonised and coherent regulatory approach to official controls and enforcement actions along the agri-food chain;
- Increased transparency and greater accountability required by Member States competent authorities through the publication of information about the organisation and performance of official controls;
- More stringent rules on fraud will provide greater consumer protection and benefit compliant businesses;
- A common set of rules for controls at EU borders that overcomes the current fragmentation and makes the control system less burdensome for enforcers and businesses;
- An integrated computerised system to improve the exchange of information between Member States on official controls;
- Greater flexibility in relation to the accreditation of official laboratories (i.e. formal recognition of competence in their field);
- Businesses and authorities will benefit from reduced administrative burdens, more efficient processes and strengthened controls.

Background

Delivery of Official Controls

18. The FSA is the Central Competent Authority (CCA) responsible for the delivery of official food and feed controls in England, Northern Ireland and Wales. In England and Wales the FSA is responsible for the delivery of dairy hygiene controls and official controls in approved meat premises, including meat hygiene requirements and regulations on the welfare of animals at slaughter. In Northern Ireland the Department of Agriculture, Environment and Rural Affairs (DAERA) carry out hygiene controls on behalf of the FSA in Northern Ireland in these premises.

The FSA is also responsible for the classification of shellfish production areas in England, Wales and Northern Ireland.

19. There are 387 Local authorities (LAs) in England, Northern Ireland and Wales delivering official food controls.[9] Of these, 149[10] LAs in England and 22 LAs in Wales have also been designated to deliver official feed controls for matters which are not within the remit of the Veterinary Medicines Directorate (VMD) or the Animal Plant and Health Agency (APHA). In Northern Ireland, the Department of Agriculture, Environment and Rural Affairs (DAERA) is responsible for delivery of all animal feed controls including veterinary medicines and regulating the use of specified materials in animal feed, including the ban on feeding animal proteins to ruminants and processed animal proteins to farmed animals.

20. In England, Wales and Northern Ireland the FSA is responsible for setting the standards and monitoring performance of the delivery of official controls for food and feed law. The FSA directs and maintains the consistency of delivery of food controls by local authorities through the Food Law Codes of Practice and associated Practice Guidance. For feed controls, in England and Wales the Feed Law Code of Practice and associated Practice Guidance and in Northern Ireland the Feed Law Enforcement Guidance document, issued to DAERA. The FSA also sets out the standards of performance for official control activity in FSA approved establishments through a published Manual for Official Controls (MOC) in England and Wales. In Northern Ireland, DAERA maintain and publish a parallel MOC which broadly reflects the content of the FSA MOC.

Impact of the OCR

21. The OCR is part of a wider initiative to simplify EU legislation to establish a more integrated approach to official controls in all areas across the agri-food chain to ensure consistency across the legislation. The new OCR expands the scope of the official controls legislation to include official controls on animal health (including aquaculture), plant health, Plant Reproductive Material (PRM) and plant protection products in addition to food and feed and animal welfare. This includes the 'Animal Health Law' (Regulation 2016/429) and the Plant Health Law (Regulation 2016/2031).

22. The OCR also empowers the creation of tertiary legislation ('implementing acts' and 'delegated acts') which allow the European Commission to create further detailed rules in specific areas. The majority of this tertiary legislation so far, which has been under development since 2017, has addressed import controls and conditions. New rules have also been published regarding hygiene inspection for products of animal origin This tertiary legislation will also apply from 14 December 2019.

23. Though the OCR entered into force on the 27 April 2017, the applicability of the new rules was set to apply gradually over several years; with the main application taking effect 14 December 2019. In the event the UK remains subject to directly applicable EU Regulations on 14 December 2019 (i.e. an implementation period or extension to Article 50) the new rules will fully apply and the current legislative framework for food and feed law official control will be repealed.

24. This impact assessment assumes that the domestic legislation will be implemented fully in December 2019. It focuses solely on the changes in relation to the aspects of the OCR that apply from 14 December 2019, and only in relation to the FSA areas of

[9] Annual report on local authority food law enforcement 2017/18, http://www.reading.ac.uk/foodlaw/pdf/2018-FSA-LAEMS-2017-18.pdf

[10] This figure refers to the number of local authorities as at 1st April 2019. Source: FSA Animal Feed Enforcement Return 2019/20.

responsibility for food and feed law and animal health and welfare. In this space the new OCR introduces reforms in certain areas but does not deviate significantly from the existing legal architecture and general approach to official controls. Separate legislation is being prepared by Defra for their areas of responsibility and the impacts assessed accordingly.

25. In the event the UK leaves without a deal the FSA will update stakeholders further in relation to the proposed implementation of the OCR. We will also consult further on any proposals to align national legislation with the OCR, including an updated assessment of the impacts.

General Changes to the Delivery of Official Controls

26. The OCR will introduce changes across a number of policy areas. However, for the most part it is expected that these changes will result in relatively few impacts, as they relate to the overarching principles of conducting official controls to which the UK is already aligned. The key changes identified by the FSA in relation to the main provisions of the OCR that apply from 14 December 2019 are set out below.

27. Further impacts, associated with provisions laid down in the tertiary European legislation, which sets out in further detail how official controls should be carried out, are also identified and assessed.

Other official activities

28. Article 2 of the OCR introduces a new definition of 'other official activities', which includes activities performed by competent authorities (CAs) or delegated bodies other than official controls. For example, enforcement measures and/or remedial actions following non-compliance; management of lists of registered/approved food and feed business operators or the issuance of official certificates. The OCR sets out rules necessary to ensure that such activities are properly and effectively performed. Our assessment is that the FSA Food and Feed Law Codes of Practice, and associated Practice Guidance, likewise, the FSA Manual for Official Controls, already acknowledge and align with the OCR requirements in respect of the way these activities are carried out by CAs in England, Wales and Northern Ireland. We therefore do not expect any incremental impact associated with this change.

Risk-based controls

29. The general risk-based approach of existing legislation and current practice, detailed in Article 9 of the OCR, is maintained. However, a new provision strengthens the fight against fraud along the agri-food chain by clarifying that CAs are required to carry out regular risk-based official controls, directed at identifying fraudulent and deceptive practices.

30. Our assessment is that the FSA Food and Feed Law Codes of Practice, and associated Practice Guidance already acknowledge and have regard to food fraud as part of the food and animal feed law risk rating schemes. Likewise, the FSA Manual for Official Controls also identify the need to have regard to fraudulent practices during routine audits. We do not expect any change to the frequency or number of official controls as a result of this new provision.

31. Furthermore, there is now a requirement on competent authorities that the penalties associated with fraud convictions must represent the economic advantage gained by the perpetrator as a result of that fraudulent action. Such penalties are already available for fraudulent activities prosecuted in the UK through the Proceeds of Crime Act 2002. We therefore do not expect any incremental impact from this change.

Transparency requirements

28. Transparency requirements for competent authorities are clarified in Article 11 of the

OCR by identifying the minimum level of information which must be made public and at what frequency. Competent authorities are required to provide FBOs with copies of reports where non-compliance has been detected as well as where compliance has been achieved. New provisions regulate the delegation of specific tasks relating to 'other official activities' and the conditions to be met for delegating certain official tasks.

29. Our assessment is that the current practice in England, Wales and Northern Ireland already meets these requirements. We therefore do not expect any incremental impact from this change.

Sampling

30. Articles 35 and 36 of the OCR relating to 'second expert opinion' and 'sampling of animals and goods offered for sale by means of distance communication' provide greater clarity to enforcers that a sample ordered on-line by the CA without identifying themselves can be validly used for the purposes of an official control. While also making provision that they need to inform the operator that such a sample has been taken and, where appropriate, is being analysed in the context of an official control.

31. Our assessment is that this provision of notification already exists in UK law. We therefore do not expect any incremental impact from this change.

Official Controls for products of animal origin

32. Article 18 of the OCR creates specific rules on official controls and for action taken by the competent authorities in relation to the production of products of animal origin intended for human consumption. This Article derives from the now revoked Regulation 854/2004 and provides the legal basis for the work of the FSA in establishments or areas where products of animal origin for human consumption are produced or processed. The implementing and delegated acts made under Article 18(7) and Article 18(8) establish detailed rules in this area. Our analysis of the OCR requirements indicates that OAs can continue provide assistance to OVs in undertaking ante-mortem and post mortem inspection. The impact of these changes is analysed in further detail below.

Import controls

33. Articles 43 – 77, 90, 126 -128 and Article 134 of the OCR are revised rules regarding import controls and import conditions on animals and goods arriving in the European Union from third countries. These changes are intended to create a common framework for all goods covered by the OCR across the agri-food chain. Central to this project is the re-designation of all existing specialised border facilities, such as Designated Points of Entry (DPEs) and Border Inspection Posts (BIPs) as Border Control Posts (BCPs). Furthermore, existing entry documents, such as the Common Entry Document (CED) for high-risk food not of animal origin and the Common Veterinary Entry Document (CVED) for products of animal origin, will be amalgamated as Common Health Entry Documents (CHEDs). These systemic changes will be underpinned by a new Information Management System for Official Controls (IMSOC). This platform will link existing systems, such as RASFF and TRACES, rather than replacing any elements of the Commission's computational architecture.

34. Although the groundwork for this new common framework for imports is established in the OCR, the legislation itself provides the power to make detailed implementing tertiary legislation. Since 2017 these rules have been negotiated between European Union Member States and the European Commission. The UK has participated fully in this process. As these detailed rules establish, to a much greater extent, the shape of the new regime, their impact is examined below in greater, individual detail.

National Reference Laboratories (NRLs) & Official Control Laboratories (OCLs)

35. National Reference Laboratories (NRLs) & official control laboratories (OCLs) will see

minor changes to the responsibilities placed upon them (Articles 34, 38, 40, 42, 92, 94, 100 & 101). The changes for NRLs have in fact applied since April 2018. Changes to the responsibilities of OCLs (applicable from December 2019) will mean that competent authorities are required to have closer contact with the laboratories and greater oversight of delegated laboratories. The main issue in this area is a legislative change which means that a laboratory can only send a sample to a laboratory in another member state if the second laboratory has been designated an official laboratory in the receiving member state. The impact of this change has been assessed in further detail in the appraisal section.

Cross-border incidents

36. Articles 102 – 108 of the OCR subjects CAs to tighter rules and more formalised processes for interacting with authorities in other Member States when responding to cross-border incidents. For example, CAs must set out within ten days their intentions regarding notifications from other Member States.

37. Our assessment is that the UK already consistently complies with these requirements. We therefore do not expect any incremental impact.

Financing of Official Controls

38. The OCR also expands upon the European Union's existing legal basis for the financing of official controls. This includes, in particular at Article 85, a greater emphasis on transparency.

39. The FSA does not anticipate introducing any changes now or immediately after 14 December 2019. Further stakeholder engagement will take place in due course.

Tertiary Legislation: UK Integrated Multi-Annual National Control Plan (MANCP) – Annual Report

40. It is a European Commission requirement that all member states have a national control plan. The purpose of this plan is to ensure that effective systems are in place for monitoring and enforcing feed and food law, animal health and animal welfare rules, and plant health law. Progress on implementation is continually monitored and annual reports are prepared and submitted to the European Commission.

41. In order to ensure the uniform presentation of annual reports, the OCR provides for implementing acts to adopt and update as necessary standard model forms to be used for annual submission of the information. The EU have now finalised and published these model forms under Commission Implementing Regulation (EU) 2019/723. This requirement applies from 14 December 2019, however, the first annual report against the new template is not required until August 2021. We do not expect any incremental impact associated with this requirement.

Tertiary Legislation: Hygiene controls on products of animal origin (POAO) for human consumption

42. Article 7 of Regulation (EU) 2019/624 places maximum thresholds limiting the use of official auxiliaries (OA) carrying out post-mortem inspection (PMI) at what are now referred to as low-capacity slaughterhouses and low-capacity game handling establishments (GHE) based on maximum number of animals slaughtered annually. The Regulation also permits this level to be raised where the total national production of the low-capacity facilities which take advantage of the increased threshold do not exceed 5 percent of the total market for the species concerned.

43. Currently PMI can be undertaken in slaughterhouses and GHEs which do not operate continually throughout the working week by OAs, without an official veterinarian (OV) being present, following a risk-assessment by the competent authority.

44. The FSA will look to make use of the provision within Article 7 of Regulation (EU)

2019/624 to maximise the use of OAs at low-capacity slaughterhouses and low-capacity GHEs on a risk-basis.

45. Article 36 of Regulation (EU) 2019/627 includes a new requirement for CAs to verify food business operator compliance with campylobacter process hygiene criterion (PHC) as set out in Regulation (EU) No 2073/2005 on microbiological criteria of foodstuffs, which applies only to slaughterhouses where the approved activity is broiler production.

46. The Regulation provides two options for how the competent authority can undertake its verification, sampling or collection of industry data:

    - The first option is for official sampling using the same method and sampling area as food business operators. At least 49 random samples shall be taken in each slaughterhouse each year. This number of samples may be reduced in small slaughterhouses based on a risk evaluation.
    - The second option is to collect information on the total number of samples and the number with more than 1,000 cfu/g taken by food business operators in accordance with Article 5 of Regulation (EC) 2073/2005 and take samples only where it is considered necessary.

47. The FSA currently considers option 2 to be the preferred policy option but no decision has yet been taken and proposals will be discussed with industry stakeholders before any final decision is taken.

48. From the implementation of the OCR on 14 December 2019, echinoderms will no longer be permitted to be harvested from unclassified areas. This will create an impact on LAs and the FSA as any FBOs that harvest echinoderms from unclassified areas will require the area to be classified in accordance with the Regulation 2019/627 or else cease harvesting.

49. Article 61 of Regulation (EU) 2019/627 specifies that sampling frequency for toxin analysis in live bivalve molluscs shall be weekly. The provision for less frequent monitoring, through a risk assessment, still applies. This is more stringent than the current sampling frequency carried out in England, Wales and Northern Ireland. A Risk Assessment has been carried out to consider the appropriateness of the current regimes and consideration of the evidence in relation to the new requirements is still under review. The FSA will consult further with stakeholders, including an assessment of the impacts, once our analysis is complete.

50. The OCR also changes some existing requirements in the following areas of official controls on POAO:

    - Ante-mortem inspection allowed to take place at the holding of provenance for all species and not limited to poultry and lagomorphs.
    - There is the capacity for delayed post mortem inspection for up to 24 hours in low capacity slaughterhouses and game handling establishments.
    - It is possible for authorities to introduce less supervision of on-line checks of poultry and lagomorphs when certain criteria are met by the food business operator in accordance with Article 25.
    - The age at which post-mortem inspection of bovine animals can be carried out without incision has been lifted from six weeks to eight months reducing risks of cross-contamination and retaining the value of meat, a higher percentage of which will remain intact.
    - There are reduced post mortem requirements for cattle which are from herds that are certified by the competent authority as being ‘free’ of cysticercosis.

- There is provision, based on a risk assessment (only on a temporary and non-recurring basis) to permit continued harvesting of live bivalve molluscs when health standards have not been met in Class A areas, without the closure or reclassification as long as the area and all approved establishments are under a single competent authority and are subject to appropriate restrictive measure.

Tertiary Legislation: Import Controls & Conditions

51. The new OCR and its tertiary legislation are intended to streamline, modernise and harmonise rules regarding the import of animals and goods into the European Union. Responsibility for the delivery of official controls on imported food and feed in England, Wales and Northern Ireland is shared between ministerial departments (such as Defra) and the FSA. Port Health Authorities and Local Authorities (at designated airport points of entry) deliver veterinary controls on products of animal origin arriving from third countries on behalf of the ministerial departments, although these controls have a public health element and therefore a significant degree of FSA interest. Port Health Authorities and Local Authorities (at designated airport points of entry) also perform controls on high-risk foods not of animal origin (FNAO) on behalf of the FSA.

52. Legislative responsibility for the policies which underpin the import controls regime is also shared between the FSA and Defra. This includes legislation which determines the rules and criteria for the performance of controls, as well as import conditions which must be met before goods can enter the European Union. Tertiary legislation empowered by the OCR updates existing rules in the area of import conditions for products of animal origin intended for human consumption in the European Union.

53. Given the division of responsibility in this area between competent authorities, this impact assessment addresses the two aspects of the legislation for which the FSA can be understood to have primary legislative responsibility: controls on high-risk FNAO and import conditions for products of animal origin for human consumption. It is also necessary to examine the impact that the Commission's new Integrated Management System for Official Controls (IMSOC) will have on the general performance of import controls.

54. Although negotiations have been ongoing since 2017, legislation in some areas is yet to be finalised or published. This is clearly set out below where relevant.

Import controls on high-risk FNAO

55. Certain foods are subject to a higher level of import controls as a result of the elevated risk they are deemed to pose to consumers. Specified commodities from specified countries are subject to physical inspection and laboratory sampling at a rate agreed by Member States on a biannual basis. This system is currently based on Regulation (EC) 882/2004 and Regulation (EU) 669/2009. Rules in this area are replaced by the relevant provisions of the OCR and an as yet unpublished Implementing Regulation. It is foreseen that evidence-based frequency rates will be agreed at a committee of Member States at regular intervals. This would allow for a more transparent and efficient review of risks and for a swifter revision of these measures. As the fundamental mechanics of the system will remain the same, no further impact beyond existing practice is expected in this area in the short-term; current sampling frequencies would remain unchanged unless new evidence suggests that the level of risk has changed e.g. the product may be de-listed or subject to a higher frequency of checking or enhanced controls.

56. Existing border control facilities for the control of high-risk FNAO are currently classified as Designated Points of Entry (DPEs). As the OCR unifies all border control facilities under the definition Border Control Posts (BCPs) these facilities will now be required to meet the standards established in Regulation (EU) 2019/1014. These rules go beyond existing standards as set out in Regulation (EU) 669/2009. As a result, the operators of these BCPs will be required to ensure that their facilities are compliant with the new

legislation.

57. Detailed rules regarding how competent authorities should deal with transit and transhipment of goods entering the European Union have also been developed. This legislation, to be made under Article 51(1)(a) of the OCR, has, however, not yet been published. The rules, as currently drafted, build on existing processes but have introduced an increased degree of flexibility for Member States in most instances. For example, there are some proposed changes to the minimum time in port requirements and the Commission is proposing no checks at the BCP of first arrival on animal products which are destined to third countries when consignments are staying on the same means of transport for onward travel to the BCP of destination. As a result of the limited nature of these changes, no costs beyond familiarisation costs for operators or competent authorities are foreseen.

58. Regulation (EU) 2019/1013 establishes that the operator responsible for a consignment of high-risk food and feed not of animal origin arriving in the European Union must be notified at least one working day prior to the expected arrival of the consignment. This is consistent with many of the existing requirements which also require notification one day prior to the expected arrival except for POAO which must be notified 'in advance'. In certain scenarios, where there are 'logistical constraints', for example a short journey, this can be reduced to four hours at the discretion of the competent authorities of the BCP. As such minimal additional impacts are anticipated as a result of this new legislation, on operators or competent authorities.

59. A draft regulation is also under development which would allow for the performance of identity and physical checks on high-risk FNAO to be performed at an inland control point, away from the immediate point of entry for the commodity. This inland control point would be required to meet the same criteria as an inspection centre at a BCP. A process for permitting and management of the transfer of goods would also be established, to ensure the traceability of potentially high-risk foods. As this is flexibility available to the operators of BCPs it does not create potential impacts but could be used in the future to allow for the establishment of more inspection facilities at lower costs. These would require suitable legal designation and approval. Current rules which allow for the onward movement of consignments of high-risk FNAO pending the results of laboratory testing have also been retained.

60. The basic act of the OCR establishes that existing formats of certification will be unified as Common Health Entry Documents (CHEDs). The contents of these categories will vary according to the relevant commodity. The current format of the Common Entry Document (CED), used for consignments of high-risk FNAO, will become the CHED-D. This will require some familiarisation costs for operators and competent authorities alike. The FSA is currently undergoing an internal piece of work to better understand the details of the proposed changes to entry documents and the potential impacts on importers beyond familiarisation costs.

61. Legislation is also yet to be finalised regarding certain derogations for border controls. For example, legislation regarding derogations for the designation of BCPs (such as instances where facilities can be situated away from an entry point in to the Union). As these rules create the potential for derogations and flexibilities, no immediate significant impact is foreseen.

Import Conditions for POAO for human consumption

62. Regulation (EC) No 853/2004 establishes that all products of animal origin imported into the European Union must come from a listed third country. This requirement has not been applied fully in the EU since its inception and has been subject to recurrent transitional measures. Legislation, empowered by the OCR, has been made in order to effectively enforce this requirement and to further harmonise import conditions for POAO and some

other high-risk goods across the European Union. Regulation (EU) 2019/625 creates an overarching framework for the reformed import conditions regime. This is supplemented by Regulation (EU) 2019/626, as regards third country listing, and Regulation (EU) 2019/628, as regards certification.

63. The most significant new element of this package of legislation is the increased scope of goods which will be subject to certain forms of harmonised import conditions for the first time. These changes will affect the movement of reptile meat, insects and products derived from insects, composite products, raw materials for the production of gelatine and collagen, sprouts for human consumption and fats and greaves.

64. Regulation 2019/625reforms to the way composite products are controlled. All composite products (with some exceptions) will need to be channelled through BCPs and there will be a move away from a percentage approach to temperature control requirements. The Regulation will not take effect until April 2021, and as such is not included in the appraisal section.

65. Reptile meat is currently imported in the United Kingdom from third countries under national rules. It is still subject to official controls at Border Inspection Posts. The new rules will require imports of reptile meat to derive from an approved third country, as set out in Regulation (EU) 2019/626. As of December 2019 this list will include only Switzerland, Botswana, Vietnam, South Africa and Zimbabwe. These consignments must also arrive with a model health certificate as established in Annex III Part XII of Regulation (EU) 2019/628, which clearly sets out that the products have been produced in line with the relevant European hygiene legislation. This requirement for a model health certificate is subject to a transitional period until 13 March 2020, allowing time for familiarisation and preparation. Regardless, this introduction of harmonised paperwork may create further work for Port Health Authorities and operators involved with the trade of reptile meat for human consumption. Operators in third countries will require the services of an official veterinarian to sign certificates prior to export.

66. Food consisting of, isolated from or produced from insects or their parts will also now be subject to harmonised import conditions in a similar fashion to reptile meat. This will involve the introduction of a third country list established in Regulation (EU) 2019/626 and a certificate in Regulation 2019/628 Annex III Part XIII. In terms of third country listing, this is dependent upon the prior approval of exporting countries or regions in line with novel foods legislation, Regulation (EU) 2015/2283 and Regulation (EU) 2017/2470. Equally this may create a greater administrative burden on Port Health Authorities and new regulatory requirements on operators.

67. Regulation (EU) 2019/625 also establishes a framework of new risk-based rules on importing composite products from third countries based on shelf stability and composition. These measures, however, will not apply until April 2021. As such their impact will not be assessed at this time.

68. Raw materials for the production of gelatine and collagen are also subject to a slight change in the legislation. The new rules provide that raw materials, intended for the production of gelatine and collagen, referred to in point 4(a), Chapter I of Sections XIV and XV, Annex III to Regulation (EC) No 853/2004, for import into the European Union must be obtained from listed slaughterhouses, game-handling establishments, cutting plants and establishments handling fishery products. Existing rules state that raw materials for the production of gelatine and collagen must derive from a listed third country (as set out in Regulation (EU) 2016/759) and originate from a registered or approved establishment. Although at present there exists an approved list of establishments for *treated* raw material for the production of gelatine and collagen, Regulation (EU) 2019/625 sets out that this requirement will be expanded to such raw materials. As these goods are already subject to certification and veterinary controls, this means that the impact on Port Health Authorities will be limited. However, this could

potentially have an impact on the movement of goods from third countries and could affect operators adversely as a result of short-term trade disruption.

69. Sprouts and seeds intended for human consumption produced within the European Union are currently subject to heightened rules as a result of the risk they pose to spread foodborne illnesses. In addition, sprouts and seeds imported into the European Union from third countries must be accompanied by a health certificate, as set out in Regulation (EU) 211/2013. As a result of Regulation (EU) 2019/625, sprouts falling under specific CN codes will be required to derive from a listed establishment in a third country which is approved in accordance with the requirements of Article 2 of Regulation (EU) 210/2013 and Regulation (EU) 852/2004. This means that third country establishments producing sprouts are subject to equivalent legislation as those within the European Union. The model health certificate for sprouts is also reformatted and is now published in Annex 3 Part 15 of Regulation (EU) 2019/628. While this could, in theory necessitate some familiarisation costs for Port Health Authorities and operators, it is understood that this is primarily an inland control.

70. Rendered fats and greaves are currently required to derive from an approved establishment in any third country. Regulation (EU) 2019/626, however, requires these products in future to derive from third countries authorised for the import of meat products into the Union in accordance with point (b)(i) of Article 3 of Decision 2007/777/EC.

71. Regulation (EU) 2019/626 will introduce a list for products of animal origin not otherwise covered by the regulations. This will provide greater clarity than is currently the case under Article 6 of Regulation (EC) No. 853/2004. It is not foreseen yet what this will encompass, but we do not anticipate that this will have a significant impact.

72. Regulation (EU) 2019/628 also creates a new format for the model health certificate required for specific goods. Although this format will only be introduced for goods for which the previous certificates had a legal basis pursuant to Regulation (EC) No. 882/2004, it is anticipated that the new format will eventually be extended to all commodities. This new format will incur familiarisation costs for operators and Port Health Authorities alike.

73. Regulation (EU) 2019/628 also creates new rules for the issuance of replacement certificates at Article 6. It is anticipated that these will also result in familiarisation costs.

Tertiary Legislation: IMSOC

74. The IMSOC will act as a unifying platform for existing EU system such as TRACES, RASFF, Administrative Assistance and Cooperation and the Food Fraud Network. The legal basis for the IMSOC and how it will function will be further expanded upon in an Implementing Regulation empowered under Article 134 of the OCR.

75. Operators and competent authorities will be required to familiarise themselves with the new platform and its interface. However, it is anticipated that in the long run the new system will create efficiency savings for businesses and authorities alike.

GROUPS AFFECTED

76. The following groups will be affected by the proposed changes.

Food and Feed Business Operators

77. As the current landscape and the general performance of official controls under the OCR remains substantially the same for FSA policy areas, for the majority of food and feed industry stakeholders there will be no requirement to familiarise themselves with the requirements of the Regulation.

78. However, where the OCR necessitates changes to the tertiary legislation, selected Food and Feed Business Operators will need to familiarise themselves with the changes and comply with new requirements. Selected FSA Approved Establishments, which are subject to official hygiene controls performed for the verification of compliance, will be affected by new tertiary requirements. These include businesses in the following sub-sectors:

a. Slaughterhouses
b. Cutting Plants
c. Fish Auctions
d. Wholesale fish markets, factory vessel and freezer vessels
e. Game Handling Establishments
f. Operators of vessels catching and handling live bivalve molluscs, shell fish and fishery products
g. Milk and Colostrum Production Holdings

79. In addition, we assume that all UK importers of high-risk food and feed will be affected by new import requirements and changes to border procedures.

80. We have identified the following number of affected food and feed business operators (FBOs) across England, Wales and Northern Ireland. To note, total figures may be subject to rounding.

Table 1: Affected food and feed business operators (FBOs)

FBO	England	Wales	NI	Total
Approved Establishments[11]	1,676	150	89	**1,915**
Importers of high-risk food and feed[12]	2,812	32	99	**2,944**

Enforcement Authorities

81. The OCR primarily addresses the responsibilities of Member States' CCA and their designated enforcement authorities who carry out official controls to check that business operators comply with the relevant law.

82. Local Authorities, as CAs, which deliver official regulatory controls across food and feed will have to familiarise themselves with the new requirements. Similarly, Port Health Authorities (PHAs), as CAs, for the delivery of official regulatory controls with regards to

[11] A list of all approved establishments is available at: https://data.food.gov.uk/catalog/datasets/1e61736a-2a1a-4c6a-b8b1-e45912ebc8e3

[12] The number of importers has been extracted from TRACES (https://ec.europa.eu/food/animals/traces_en). Regional splits were calculated using the proportion of importers recorded in the LAEMS annual report (https://signin.riams.org/connect/revision/msy26/Environmental-Health/LAEMS-Annual-report-2017-2018).

imports of POAO and high-risk FNAO will be affected by the new requirements.

83. Operational staff from FSA (in England and Wales) and DAERA (in Northern Ireland) will be affected by changes to the delivery of official controls in relation to meat hygiene, which are directly undertaken by FSA and DAERA operational staff respectively. In addition, selected FSA staff will be required to familiarise themselves with the proposed changes and acquire sufficient expertise to provide guidance and training to stakeholders.

84. Official Control Laboratories (OCLs) are designated by CAs for the purpose of analysing samples taken during official controls and for food and feed enforcement. They will see minor changes to the responsibilities placed upon them, requiring them to have closer contact with the laboratories and greater oversight of delegated laboratories.

85. We have identified the following number of affected enforcement authorities across England, Wales and Northern Ireland.

Table 2: Number of affected enforcement authorities by country

Competent / enforcement authority	England	Wales	NI	Total
Local Authorities (LAs)[13]	354	22	11	**387**
Port Health Authorities (PHAs)[14]	25	0	2	**27**
Official Control Laboratories[15]	14	5	4	**23**
FSA Field Operations (no. of managers)[16]	28		N/a	**28**
DAERA Operations (no. of managers)[17]	N/a		5	**5**

Consumers

86. Consumers are not directly affected by the OCR, although a more integrated and simplified approach to controls across the EU should in theory lead to improved consumer protection and increase consumer confidence in food and feed produced within the EU and imported third countries. Harmonisation of official controls will provide reassurance to consumers on the functioning of control systems and increase their ability to make informed choices.

87. These indirect impacts on consumers have not been further assessed in the cost-benefit section which follows.

Q.I: Is the total list of identified affected sectors / groups representative? If you partly agree or do not agree please identify other sectors / affected groups that should also be considered and provide reasons for your suggestion.

[13] Annual report on local authority food law enforcement 2017/18, https://signin.riams.org/connect/revision/msy26/Environmental-Health/LAEMS-Annual-report-2017-2018

[14] This analysis only concerns PHAs that are classed as either DPE/DPI/BIP (https://www.food.gov.uk/business-guidance/port-designations *and* https://www.gov.uk/government/publications/uk-border-inspection-posts-contact-details/live-animals-and-animal-products-border-inspection-posts-bip-in-the-uk)

[15] https://www.food.gov.uk/about-us/official-feed-and-food-control-laboratories

[16] Figures based on internal intelligence.

[17] Five regional managers in DAERA (four meat and one dairy) require familiarisation, based on internal intelligence.

POLICY OPTIONS

Two policy options have been identified:

Baseline: Status Quo

88. This is the baseline option against which all other options have been assessed. It reflects the status quo, i.e. a situation in which there were no incremental changes to the current legislation.

89. It should be noted that this is not a realistic option as the OCR has already been published in April 2017 and will be directly applicable in the UK from 14 December 2019 in an Article 50 extension or transition period. The baseline solely serves the purpose to quantify the expected impacts of all policy options against a consistent baseline.

Option 1: Implement national legislation to provide for the execution of powers and enforcement of the OCR and associated tertiary legislation.

90. Take appropriate action to fully implement the provisions of the OCR into UK law. This would require making legislation to enable the delivery of the requirements.

91. This is the preferred option.

Option 2: Do Nothing – Do not implement national legislation to provide for the execution of powers and enforcement of the OCR.

92. Regulation 2017/625 (OCR) will repeal the current legislation on official controls. If the new legislation is not implemented prior to the current legislation being revoked, the UK would have no legal framework to enforce official controls and therefore the UK would be unable to demonstrate that it can meet one of its primary objectives which is to protect human health.

93. The OCR is directly applicable European legislation, so failure to put in place the measures needed to implement could lead to the European Union bringing infraction proceedings against the UK. This policy option is rejected.

94. The associated impacts of this option have not been further assessed because of the disproportionate negative effects on public health and legal consequences that would be associated with this option.

OPTION APPRAISAL

Baseline: Status Quo

COSTS & BENEFITS

95. This is the baseline against which all other options have been assessed. There are no incremental costs and benefits associated with this option.

Option 1: Implement Regulation 2017/625 - OCR

COSTS & BENEFITS

96. The cost benefit analysis that follows assesses a range of different costs and benefits that we expect under option 2. These are:

    - **Familiarisation costs:** one-off / transitional costs for all affected stakeholders to acquaint themselves with the new requirements of the legislation. This ensures a smooth transition between the two regimes. Figures are presented in current prices.
    - **Non-monetised costs:** potential outcomes from the legislation where it is currently not possible to quantify their impact. Where we are unable to quantify expected impacts, we have explained in detail why the required data is not available and how we seek to substantiate the assessment and our understanding going forward.

97. All quantified costs and benefits in this section are estimated in current prices and measured over a 10-year appraisal period. This appraisal period was deemed appropriate as all monetised costs and benefits are transitional in nature. All total costs and benefits highlighted throughout are rounded to the nearest '000 to aid interpretation.

98. To ensure consistency in our calculations we have adopted an established method based on the Standard Cost Model (SCM) Approach published by BEIS. Where we have used wage rate data we have taken hourly wage rates from the 2018 Annual Survey of Hours and Earnings (ASHE)18, using the median rate of pay. Furthermore, when using wage rate data we have uplifted rates to account for overheads by 30%, in line with The Green Book[19] guidance.

COSTS

Food and Feed Business Operators

99. As outlined above, the substance of OCR 2017/625 largely repeals and replaces much of the existing legislation governing official controls of food and feed. Most businesses will not experience any material changes in the way official controls take place and/or are currently delivered. We understand that the main affected sectors will be:

    - Importers (including freight handlers) of high-risk food not of animal origin (FNAO) and products of animal origin (POAO) for human consumption; and
    - Selected FSA Approved Establishments which are subject to official hygiene controls performed for the verification of compliance. We understand that only the following approved establishments will be affected:
        - Slaughterhouses

[18] https://www.ons.gov.uk/employmentandlabourmarket/peopleinwork/earningsandworkinghours/datasets/ashe1997to2015selectedestimates

[19] https://www.gov.uk/government/publications/the-green-book-appraisal-and-evaluation-in-central-governent

- Cutting Plants
- Fish Auctions
- Wholesale fish markets, factory vessel and freezer vessels
- Game Handling Establishments
- Operators of vessels catching and handling live bivalve molluscs, shell fish and fishery products
- Milk and Colostrum Production Holdings

Familiarisation

100. Importers of high-risk FNAO and POAO (including Freight Handlers) will have to familiarise themselves with the new legislation as it affects the streamlining of new systems and formatting requirements. According to TRACES, there were 2,944 unique UK-based importers of high-risk FNAO or POAO who submitted either a CED or CVED in 2018 (see Table 1). This can be regarded as the minimum number of UK businesses that need to familiarise themselves with the proposed legislation as they will be directly affected by changes to official entry documents. We assume that one manager from each importing business will spend one hour reading the guidance, and another hour disseminating to staff and key stakeholders. Following the SCM approach, we multiply the wage rate with the number of importing businesses to calculate the total familiarisation costs. This generates a total cost of familiarisation to importers of £133,000 which is equivalent to £45.29 per importer[20].

101. Selected FSA Approved Establishments will also have to familiarise themselves with the legislation. These FBOs are subject to official controls for verification purposes and may be impacted by the new requirements for OV attendance and campylobacter sampling. They may also be affected by the additional flexibilities that the OCR introduces. As of May 2019, there were 1,915 applicable Approved Establishments operating across England, Wales and Northern Ireland which are expected to be affected by the new legislation (see Table 1). We assume that one manager from each establishment will dedicate one hour reading the guidance and another disseminating it to staff and key stakeholders. This implies a total one-off cost to affected Approved Establishments of £58,000 or £30.51, on average, per establishment[21].

102. At the aggregate level, we estimate the total familiarisation cost to industry to be £192,000. This is equivalent to £39.47 per business.

103. As outlined above, this estimate is based on the assumption that the majority of food and feed industry stakeholders will not need to familiarise themselves with the requirements of the regulation for those areas where the FSA has policy responsibility.

104. It should be noted that Defra takes a different approach to familiarisation costs, in line with Defra's broader policy remit. Where there is an overlap between affected Defra stakeholders and affected FSA stakeholders, familiarisation costs for such businesses (of up to £192,000) might therefore be double counted.

Changes to the delivery of Official Controls

General performance of Official Controls

105. In terms of the secondary legislation, the current landscape and the general performance of official controls under the OCR remains substantially the same. Editorial changes will

[20] Based on the median wage rate for *Managers and directors in transport and distribution* (Code 1161), ASHE (2018), table 14.6a.
[21] Based on the median wage rate for *Managers and proprietors in agriculture and horticulture* (Code 1211) and *Managers and proprietors in forestry, fishing and related services* (Code 1213), ASHE (2018), table 14.6a.

be made to the FSA Food and Feed Law Codes of Practice, and associated Practice Guidance, the Feed Law Enforcement Guidance document (Northern Ireland) and Manual for Official Controls, which will require familiarisation by local authorities, FSA and DAERA staff performing official controls and other official activities. This will be captured by a separate impact assessment at a later date.

106. The legislation requires competent authorities to verify the correct implementation by operators of broiler slaughterhouses, of the *Campylobacter* process hygiene criterion (PHC). As of May 2019, there were 63 FSA approved slaughterhouses where the approved activity was broiler production, in England, Wales and Northern Ireland. Collection of sampling data would require FBOs to supply data in a form that permits it to be centrally collated by the FSA. As affected slaughterhouses have existing requirements to test for campylobacter, this additional burden on industry is anticipated to be marginal; the majority of costs will fall on the FSA, as the CCA. Once the FSA clarifies its preferred policy position, a supporting piece of analysis will be completed which will estimate both the cost to industry and the FSA of the preferred verification option.

Q.II: We would welcome evidence from affected businesses on the expected costs on their establishment if the FSA were to verify compliance by either a) collecting industry data or b) by sampling.

107. The introduction of maximum annual throughput thresholds at low capacity slaughterhouses and GMEs will potentially have an impact on the required presence of OVs conducting PMIs at these establishments. It is expected that some affected slaughterhouses and GHEs will exceed threshold levels that have been set, requiring establishments to replace OAs with OVs. However, the FSA would look to maximise the threshold applicable to these establishments, in line with the total national production provision outlined in Regulation 2019/624, as explained in paragraph 44. Where this is not possible then extra OV presence required at affected establishments would generate an additional cost to these businesses due to OVs rate of pay being higher than that of OAs. An OV's charge rate is approximately 30% higher than that of an OA/inspector, before any applicable discount.[22]

108. Assessing the total throughput levels of low capacity slaughterhouses and GHEs, as well as allocating individual establishments above or below the maximum annual threshold constitutes a substantial piece of work. Internal engagement and discussions with the OCR Delivery Working Group have begun, in part, to better understand if centrally held data can provide additional understanding in this area.

Q.III: We would welcome supporting evidence on the total throughput levels of low capacity slaughterhouses and Game Handling Establishments, and the distribution of such establishments in relation to the new maximum annual threshold. We would also welcome views on our assumption that the new requirement may result in additional costs on such businesses and the degree to which this change is likely to impact them.

109. From the implementation of the OCR on 14 December 2019, echinoderms will no longer be permitted to be harvested from unclassified areas. As the number of potential FBOs harvesting echinoderms from unclassified areas is unknown, we are currently unable to assess the impact of the change being introduced. In addition, it is understood that the inclusion of 'Holothuroidea' was a drafting error and it is not yet known when this error will be corrected.

[22] Based on 2019/20 Charge Rates to Food Business Operators (https://www.food.gov.uk/sites/default/files/media/document/official-controls-charging-guidance-201920.pdf), Annex A

Q.IV: We would welcome any evidence stakeholders are able to provide in relation to the number of food business operators that currently harvest echinoderms from unclassified areas.

New import requirements

110. On balance, we anticipate a marginal overall increase in official controls for imported POAO or high-risk FNAO products. The legislation outlines harmonised controls, for the first time, for imports of reptile meat, insects and products derived from insects, raw materials for the production of gelatine and collagen, sprouts for human consumption and fats and greaves. Previously, enforcement of these commodities was at the discretion of MSs.

111. Increased import controls are associated with a corresponding rise in compliance costs for the importer. Potential costs include charges and time spent for approval processing, relevant certificates and Sanitary and Phytosanitary checks at the border as well as potential disruption to the supply chain if new import routes have to be established. Robust evidence on the scale of these costs is scarce and highly product specific.

112. In addition, the FSA understands that some of the affected products are already subject to border checks under the current operating regime which will mitigate the tangible impact of a formal harmonisation of controls. We are currently engaging with port officials to understand the practical changes to border procedures and the likelihood of trade disruption in more detail.

113. While we are unable to monetise the costs associated with the new import requirements at this stage, it should be noted that the number of affected consignments is likely to be very small. In particular, we understand that there are currently no imports of reptile meat for human consumption from third countries. Furthermore, the estimated import volume of sprouts for human consumption and rendered animal fats and greaves in 2018 accumulated at most 20,000 tonnes, which is equivalent to less than one percent of all UK food and drink imports from third countries in that year[23].

114. Under OCR 2017/625 IMSOC, as well as other criteria, will determine the level of sampling which has to take place for each high-risk commodity. The system seeks to create a unified platform for existing EU systems, including TRACES, rather than replacing the computational architecture. It is understood that initially, changes in frequencies will still be determined by an EU committee that will meet at regular intervals; we anticipate that IMSOC will influence decisions once enforced. The assumption, under our current understanding, is that IMSOC may automatically change frequencies as IMSOC is implemented further into EU processes. These rates will be based on levels of compliance meaning we could see a decrease or an increase in the number of samples required to be taken. As such, it is intrinsically difficult to quantify what the cost will be for business or understand the potential shift in magnitude at the macro level.

115. However, it is assumed that from the outset current rates and frequency of sampling will remain constant. The FSA supports these changes in principle. However, we realise that we will have to work with industry to ensure compliant trade is not disrupted.

Q.V: We would welcome views, and where possible supporting evidence, from business importing one or more of the products subject to the above changes. What impact do you believe the harmonising of controls will have on your business?

[23] Import volumes of affected products are based on HMRC UK Trade Info data. It should be noted that we are unable to quantify the import volume of insects and products derived from insects due to a lack of suitable trade statistics.

Q.VI: We would welcome evidence from stakeholders, and in particular PHAs, on the number of controls on reptile meat and insects currently performed.

Total costs to Food Business Operators

116. As preparations to implement the OCR are currently in their infancy, the FSA is unable to monetise any of the expected impacts on FBOs beyond one-off familiarisation costs. As such, the total monetised cost to industry is estimated to be £192,000 over a ten-year appraisal period, as reflected in paragraph 102.

117. As internal workstreams progress on the specific additional requirements placed on industry, across all identified policy areas, we will seek to update this analysis to deliver a more thorough representation. We welcome any intelligence from industry stakeholders that can assist in gaining a better understanding of the general impacts and associated costs and benefits.

Enforcement Authorities

118. The 'basic act' of the OCR, Regulation (EU) 2017/625, will make changes across a number of policy areas. However, for the most part these changes will create relatively few impacts for enforcement authorities. Where there are impacts, they will predominantly affect CAs and delegated delivery bodies that perform official controls across a range of areas.

119. In order to perform and deliver statutory obligations, we have identified the number of applicable enforcement authorities across England, Wales and Northern Ireland.

Familiarisation

120. Local Authorities, as CAs, which deliver official regulatory controls across food and feed will have to familiarise themselves with the new requirements. This should enable a smooth transition between the two regimes. We anticipate that one Environmental Health Officer (EHO) and one Trading Standards Officer (TSO) employed at each of the 387 Local Authorities across England, Wales and Northern Ireland will spend one hour reading the new SIs and other provisions, as required by the OCR, and two hours disseminating it to staff via the appropriate channels. We estimate this one-off cost as £132.99 per LA, or £51,000 in total[24].

121. Port Health Authorities (PHAs), as CAs, deliver official regulatory controls with regards to imports of POAO and high-risk FNAO will have to familiarise themselves with the new requirements. Across England and Northern Ireland[25] there are 27 PHAs, including only: existing Designated Points of Entry (DPEs) and Designated Points of Import (DPIs) for high-risk FNAO and Designated Border Inspection Posts (BIPs) for POAO products.[26] The number of enforcement agents at each PHA will vary in accordance with the volume of trade received, however each PHA will have a team containing a mix of EHOs, TSOs and Port Health Officers (PHOs), amongst other professions.[27] As the EHOs and TSOs are employed by the respective LA we have chosen not to include them within calculating PHA-specific familiarisation costs, to avoid double counting. We anticipate that one PHO per PHA will spend one hour reading the necessary guidance and two hours disseminating it to staff and notifying main stakeholders via appropriate channels. This one-off cost is estimated to be £67.55 per PHA or £2,000 in total[28].

122. Official Control Laboratories (OCLs) are designated by CAs for the purpose of analysing samples taken during official controls and for food and feed enforcement purposes. The analysis of official control samples is carried out in OCLs by official control scientists. As National Reference Laboratories (NRLs) are already familiar with the new changes only OCLs will be required to familiarise themselves. Across England, Wales and Northern Ireland there are 23 OCLs (see Table 2). Anticipating that one professional scientist at each laboratory will spend one hour reading the legislation and one hour disseminating it to staff we estimate a cost of need to each OCL of £50.18, or £1,000 in total.[29]

123. As the CCA, the FSA will be required to hold expert in-house knowledge of the IMSOC system, both in terms of its content and interface but also in its practical applications. It is believed that one FTE employee will familiarise themselves with the IMSOC system until

[24] Based on the median wage rate for *Inspectors of standards and regulations* (Code 3565) and *Environmental health professionals* (Code 2463), ASHE (2018), table 14.6a.
[25] There are no DPEs/DPIs/BIPs in Wales.
[26] Under OCR 2017/625 DPEs, DPIs and BIPs will be reclassified as Border Control Posts (BCPs). Refer to par. 75 for potential associated costs for this reclassification with regards to requirements in infrastructure upgrades.
[27] Including auxiliary support staff, technical officers and business support officers, for example.
[28] Based on the median wage rate for *Health and safety officers* (Code 3567), ASHE (2018), table 14.6a.
[29] Based on the median wage rate for *Biological scientists and biochemists* (Code 2112), ASHE (2018), table 14.6a.

such point they can be deemed an 'expert'. This is in order to provide support in its wider implementation and also in an advisory capacity to affected policy teams.[30] Assuming a SEO grade employee will become the in-house expert, and adopting a central estimate of 24 hours (3 full working days) to become fully versed with the IMSOC system, this one-off cost in productive time lost is estimated to be £1,000.[31]

124. All field operation managers involved in the delivery of official controls in relation to meat hygiene will have to familiarise themselves with the new requirements. As the substance of many of the new provisions do not change the performance of official controls; instead providing nuanced revisions in how they are delivered, it is understood that only field operational managers will have to read the guidance and disseminate it as they see fit. Headcount data identifies 28 field operational managers operating across England and Wales. Assuming, as a central estimate, that each field manager is a Grade 7 employee, we anticipate that each manager will spend one hour reading the guidance and two hours disseminating to. This generates a cost estimate of £127.07 per manager, or £4,000 in total.[32]

125. In NI, 5 field operations managers will be required to familiarise themselves with the new requirements. Assuming that each field manager is a Grade 7 employee, we anticipate that each manager will also be required to spend one hour reading the guidance and two hours disseminating it relevant colleagues, including Meat Health Inspectors and other key stakeholders. The cost of this is estimated at £205.92 per manager, or £1,000 in total.[33]

Training

126. Authorised officers[34] at each PHA will require additional training to effectively enforce the new legislation. We expect that on average four authorised officers from each of the 27 PHAs (108 in total) will be required to go on a 1.5 day training course. This one-off cost, in productive time lost, is estimated to cost each PHA £1,080.77, or £29,000 in total.

127. Enforcement Authorities will require training and guidance in order to use IMSOC effectively. As the new system will enable a unified platform for existing EU systems, including TRACES, it is understood that the Commission will run a focussed session at a UK venue for enforcement officers and key stakeholder groups. Central estimates suggest that each PHA will require 2 attendees (54 in total) and that the FSA will require 6 attendees. This one-off cost, in productive time lost, is estimated to cost £11,000 in total.

128. Those authorised officers trained in IMSOC will be required to cascade training to other officers, including auxiliary support assistants at each port. They will also be required to support industry during implementation by providing in/formal training and guidance to freight handling agents, importers and associated third-country partners. Over a period of one month, from IMSOCs initial inception, it is assumed that one authorised officer at each PHA will spend a full day per week on training stakeholders, responding to general queries and providing guidance. On average, this will cost each PHA £720.51, or £19,000 in total.

129. It should be noted that the above estimates are based on assumptions around potential training requirements and delivery. These assumptions reflect our current understanding and could be subject to change.

[30] Imports Surveillance and Incidents will require advice on the day-to-day functioning of the system, e.g data searches and inputting. Also, Strategy and Surveillance will require a general overview of its overall functions.
[31] Based on FSA average salary for FY 2018/19.
[32] Based on FSA average salary for FY 2018/19.
[33] Based on DAERA chargeout rates.
[34] Including OVs, EHOs and TSOs.

Q.VII: We welcome enforcement authority views on our stated assumptions for training requirements to support delivery of the changes introduced by the OCR. Please provide details of any specific training needs you think will be necessary.

Changes to the delivery of Official Controls

General performance of Official Controls

130. The secondary legislation necessary to provide for the execution of powers and enforcement for the OCR makes no significant changes which would impact on the frequency or number of inland official food and feed controls undertaken by enforcement authorities. Rather it seeks to clarify and enhance current provisions for example by introducing more stringent rules on fraud and provide greater transparency and accountability required by CAs through the publication of information about the organisation and performance of official controls. Such requirements are already being met in the UK.

Campylobacter sampling in broiler slaughterhouses

131. The legislation requires CAs to verify that broiler slaughterhouses have correctly implemented the *Campylobacter* PHC. As explained above, no policy decision has yet been taken as to how the FSA will undertake the verification. If the FSA decides to collect and analyse industry data, this will likely have cost implications to the FSA, as the CCA. Additional administrative resource would be required to create and maintain a framework that centrally gathers and analyses data. This would enable the FSA to monitor compliance at the individual FBO level and on a national scale. Once the FSA clarifies its preferred policy position, a supporting piece of analysis will be completed which will estimate both the cost to industry and the FSA of the preferred verification option.

New imports requirements

132. The Official Control Regulation 2017/625 rebadges DPE/Is and BIPs as Border Controls Posts, or BCPs. BCPs will need to meet specific minimum requirements as laid down in the legislation. Many of the existing DPE and DPI minimum requirements remain in place, but other, new requirements have now been introduced. Any new facilities that wish to become a BCP, once the Regulation has taken effect, will need to fully meet the new requirements and go through the necessary approval process. The changes may therefore affect Port Operators, Port Health and Local Authorities with responsibilities for DPE/Is and BIPs and/or existing BIP/DPE/DPI operators. There may be some work required to ensure that existing facilities meet the new requirements. The financial implications are currently unknown. However, the FSA is drawing up a document which will help to check and verify existing facilities against the new BCP requirements along with a self-assessment checklist, also detailing the new requirements. A letter is planned to be sent to DPEs, along with this checklist in August and Port Health will subsequently be invited to workshops to assist with understanding the new requirements and implementing a plan if changes are required to existing facilities.

Q.VIII: We would welcome information from existing specialised border facilities (DPE/Is and BIPs) on what necessary changes and/or upgrades are required in order to obtain certification as a Border Control Post.

133. New products covered by the legislation, such as insects and reptile meat, will in future be required to be derived from approved third-countries. Raw materials for the production of gelatine and collagen, sprouts for human consumption and fats and grieves will have to be derived from approved establishments in third-countries. Under harmonising legislation across these commodities, new controls could result in additional administrative requirements; increasing the burden of work on PHAs. For example, consignments of reptile meat products will be required to arrive with model health certificates, for PHAs to assess and sanction. As trade in these commodities is expected to remain low, any increase in administrative burden for enforcement authorities is expected to be relatively muted; and might further be offset by general simplifications of administrative procedures.

Official Veterinarian resource requirements

134. As outlined in paragraph 42ff, additional OV resource may be required at low capacity slaughterhouses and GMEs for PMI. Additional costs of OV presence will fall on the affected individual establishment, although there may be some associated administrative costs to the CCA. Any such additional cost is expected to be marginal as resource activity costs (in this case switching OAs for OVs) would be included in the direct cost element of the hourly rates charged to industry.

Funding of analyses carried out by OCLs

135. It is known that there are UK OCLs that currently sub-contract samples for analysis to partner laboratories in other member states (where the partner laboratory is not officially designated as an OCL in that MS) and these may also receive, and subsequently sub-contract samples from other UK OCLs. As explained in paragraph 35, such sub-contracting of samples to other MS would not be permissible under the changes to the OCR which could have a financial impact on OCLs. Alternative arrangements are being explored for the affected laboratories such that any new situation may not have any incremental impact.

136. We are currently unable to quantify this impact as it would have to be calculated on a case-by-case basis where it is known exactly what tests and how many samples are being sub-contracted. The impact of such increased costs of sub-contracting the analysis of samples will be dependent on finding suitable alternative sources for analysis, either by an alternative UK laboratory, another MS OCL or a commercial alternative. Depending on options, this could have an associated cost for LAs, as the primary funders of OCLs. However, alternative arrangements are being explored for the affected laboratories such that any new situation may not have any incremental impact.

Q.IX: We would welcome views from Official Control Labs representatives, or LAs that currently send/receive sub-contracts samples to/from other non-designated laboratories in other Member States. Specifically, we invite evidence on the impact(s) that may arise from this change.

Total costs to Enforcement Authorities

137. We are only able to monetise the one-off familiarisation costs (including familiarisation and associated training requirements) to enforcement bodies with regards to the new SIs and provisions included within OCR 2017/625. The total identified transitional costs are £119,000.

138. It should be noted that, where there is an overlap between affected Enforcement Authorities between Defra and FSA, familiarisation costs (of up to £119,000) might be double counted.

Total costs

139. The total costs associated with Policy Option 1 over a 10-year appraisal period are £311,000 with a Net Present Value (NPV) of £311,000. Industry will assume 62% of total costs imposed as a result of this policy, with enforcement agencies assuming the remaining 38%. As such the Equivalent Annual Net Direct Cost to Business (EANDCB) is £22,000. Benefits were not monetised, therefore the total net cost over the 10-year appraisal period is £311,000.

BENEFITS

Food and Feed Business Operators

Simplified legislative framework

140. Overall, industry should benefit from a harmonised and coherent regulatory approach to official controls and enforcement actions along the agri-food chain, and from a better targeting of risks.

141. In particular import controls would be streamlined and adjusted to actual risk levels in the long-term. It is expected that the harmonisation of entry documents and the establishment of a comprehensive management system, IMSOC, will reduce the administrative burden for importers of high-risk food and feed. As CAs and business operators have not yet had the opportunity to test early versions of IMSOC, it is difficult at this time to estimate the extent of these changes. IMSOC aims to provide numerous benefits. The harmonisation of documents will create a familiar and consistent format, making it easier and more accessible for importers and stakeholders to use. IMSOC will allow competent authorities access to various relevant data/intelligence by interlinking a variety of current systems used for imported products. The intended long-term risk-based adjustments to levels of controls aims to make more efficient use of resource, with the aim of shifting resource as levels of risk change. These adjustments aim to allow changes of frequencies to occur quicker as data and information is analysed on an ongoing basis.

142. Closer cooperation among CAs would improve the overall effectiveness of delivery of official controls, reducing duplication, increasing consistency and ensuring non-compliance is dealt with in a timely manner.

Q.X: Do you agree that a harmonised and coherent regulatory approach to official controls will deliver any benefits and/or cost savings to industry? We would welcome evidence on what benefits (if any) you expect to be delivered.

Additional changes (POAO official controls)

143. The impact of changing some existing requirements on official controls of POAO should enable certain FBOs to generate cost savings across their operations. As the changes will depend on the take up by FBOs, as well as a high level of uncertainty surrounding the future delivery process, it is not possible to estimate the potential cost savings at present. The ability for an FBO to apply these changes depends on a confirmatory risk assessment by the CA which could limit application at some establishments.

Q.XI: We would welcome views from industry stakeholders on any benefits you foresee from the implementation of the OCR. Where possible, please explain your views and provide quantifiable evidence.

Enforcement Authorities

Reduced administrative burden

144. We do not expect any substantial benefits for enforcement authorities. While they could benefit, overall, from a simplification and consolidation of the legislative framework, we are unable to substantiate this due to a high level of uncertainty surrounding the future delivery process.

Q.XII: We would welcome views from PHAs and LAs on any benefits you foresee from the implementation of the OCR. Where possible, please explain your views and provide quantifiable evidence.

TOTAL NET COST

145. The total costs associated with Policy Option 1 over a 10-year appraisal period are £311,000 with a Net Present Value (NPV) of £311,000. Industry will assume 62% of total costs imposed as a result of this policy, with enforcement agencies assuming the remaining 38%. As such the Equivalent Annual Net Direct Cost to Business (EANDCB) is £22,000.

146. Benefits were not monetised, therefore the total net cost over the 10-year appraisal period is £311,000.

Wider considerations

Risks and assumptions

147. A summary of key risks and assumptions underpinning the assessment is provided below:

- All impacts have been assessed to the best of our knowledge and ability to date. However, and as outlined in the sections above, there remains a high level of uncertainty around the implementation of the regulation in certain areas, in particular where tertiary legislation is affected. We have been unable to monetise any recurring costs to industry or enforcement bodies, which over time could deliver a larger impact. As such, the exact impacts are therefore likely to differ from the monetised impacts described in this assessment.
- We have only assessed the impacts of the necessary domestic secondary legislation and those pieces of tertiary legislation which have already been negotiated. All impacts of legislation that is still being negotiated by the Commission and that will be implemented after December 2019, has been excluded. This Impact Assessment can therefore not draw a full picture of the impacts that the OCR will ultimately have for FSA stakeholders as a whole.
- The Impact Assessment is based on the assumption that the United Kingdom will be in an Implementation Period in December 2019 and that trade between the UK and the EU remains unchanged compared to the status quo if the OCR was implemented. The consequences of a non-negotiated Exit have not been considered in the assessment.

Small and Micro Business Assessment (SaMBA)

148. EU legislation generally applies to food and feed businesses regardless of size, as requirements are intended to be risk based to reflect the activities undertaken. It is estimated that there were approximately 170,000 micro businesses and 40,000 small businesses registered in the agri-food sector in 2018, which together represents more than 95% of all food and feed businesses in the UK[35]. It is therefore not feasible to exempt those businesses from the OCR in general as this would fail to achieve the intended effect of reducing risks to consumer health. The negative consequences of an increased risk for public health would be disproportionate to the additional compliance costs to small and micro businesses.

149. The FSA estimates that there are currently a million cases of foodborne disease per year. With an estimated cost per case (in terms of financial losses as well as pain and suffering) of nearly £1,000, even a small hypothetical increase of cases of foodborne disease of 1% could be associated with a societal cost of nearly £10m. The associated costs of severe food incidents exceed these costs by a multiple, with the costs of BSE and Foot and Mouth Disease to the UK economy estimated to exceed several billion pounds.[36] In comparison, the estimated costs to industry in this assessment accumulate £192,000.

150. That said, the FSA makes every effort to minimise the burden on small and micro businesses and pays attention to impacts on them. The FSA appreciates that micro and small businesses might find it more difficult to familiarise themselves with new import processes. To mitigate for such disproportionate effects, the FSA is planning to provide

[35] Based on ONS' Inter Departmental Business Register (IDBR), all businesses registered in SIC Codes 10,11,46,47 and 56.

[36] DTZ Pieda Consulting (1998): *The Impact of BSE on the UK Economy*; and DEFRA/DCMS (2002). *Economic cost of foot and mouth disease in the UK: a joint working paper*.

additional support, detailed guidance and training to Port Health Officers to ensure they can assist micro and small importers in their familiarisation process.

151. The proposed amendments should therefore not have any disproportionate negative impact on small and micro businesses. If anything, a more streamlined and harmonised controls regime across the EU might benefit micro and small businesses because they will be regulated in a proportionate and consistent way according to their business activities across the agri-food chain.

Trade Implications

152. Implementing the OCR could have implications for trade of high-risk food and feed products with third countries as a result of new requirements and changes to existing border procedures.

153. The OCR aims to integrate and harmonise rules across sectors. Assuming the new legislation is successful in reducing the administrative burden on importers, this could facilitate trade with third countries and contribute to lower food prices, as 20% of food consumed in the UK currently originates in third countries.[37]

154. Adherence with the OCR will also enable the UK to demonstrate that food and feed produced and processed within the UK have been produced and handled in accordance with EU requirements. This will help to validate that food and feed is safe and fit for purpose and can stimulate demand for imports from the UK. The UK exports £22bn worth of food, feed and drink annually, 40% of which are exported to third countries.[38] Maintaining and strengthening confidence in UK produce is therefore likely to benefit the UK industry.

155. While the OCR also proposes to introduce some new regulatory requirements for imports of selected products into the Union, including reptile meat, insects for human consumption and rendered animal fats and greaves, trade volumes of the affected products are very small relative to the UK's total import volumes.

156. We are engaging with industry stakeholders and other government departments to understand these implications in further detail. However, as trade flows are dependent on a variety of different factors and complex to model, we will not be able to assess the net impact on trade.

[37] Defra (2019): Food Statistics in your pocket: Summary (National Statistics, updated 8 April 2019): https://www.gov.uk/government/statistics/food-statistics-pocketbook.
[38] Defra (2017): Agriculture in the United Kingdom 2017, https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/741062/AUK-2017-18sep18.pdf, chapter 13

Atodiad C: Rhestr o bawb sydd â diddordeb (*Saesneg yn unig*)

Agriculture and Horticulture Development Board
British Soft Drinks Asssociation
CH Foods
Chartered Trading Standards Institute in Wales
Dunbia
FAWL Farm Assured Welsh Livestock
Federation of Small Businesses
Food and Drink Federation Cymru
Food Technology Centre
FUW (Farmers Union of Wales)
HCC (Hybu Cig Cymru) (Meat Promotion Wales)
Horeb Food Centre
Menai Mussels
Minton Treharne & Davies
National Sheep Association Wales
NFMFT (National Federation of Meat and Food Traders)
NFU Cymru
NSA National Sheep Association
Provision Trade Federation
Royal Welsh Agricultural Society
SAGB (Shellfish Association of Great Britain)
Seafish
Trading Standards
Welsh Fishermans Association
WLBP Welsh Lamb and Beef Producers
Zero to Five, Cardiff Met

Atodiad D: Rhestr o newidiadau rhwng y ddeddfwriaeth bresennol a'r Rheoliad (*Saesneg yn unig*)

The table below outlines the OCR changes identified by the FSA to delivery/practice taking affect from 14 December 2019. The changes identified outline the regulatory provisions that need to be provided for in domestic secondary legislation in the event that the UK leaves the EU with an implementation period.

Current legislation	Current requirements	Provision under OCR/tertiary legislation	Change to delivery/practice
Commission implementing Regulation on uniform practical arrangements of multi annual control plans and annual reports by Member States on the presence of contaminants in food			Under negotiation
Regulation 2016/6 imposing special conditions governing the import of feed and food originating in or consigned from Japan following the accident at the Fukushima nuclear power station	Article 9 Prior notification 1.Feed and food business operators or their representatives shall give prior notification of the arrival of each consignment of products referred to in Article 5(1). 2.For the purpose of prior notification, feed and food business operators or their representatives shall complete: (a) for products of non-animal origin: Part I of the common entry document (CED) referred to in point (a) of Article 3 of Regulation (EC) No 669/2009, taking into account the notes for guidance for the CED laid down in Annex II to that Regulation; for the purpose of this	Prior notification rules are laid down in Regulation 2019/1013. The legislation containing the Common Veterinary Entry Document (CVED) and Common Entry Document (CED) is being amended as a result of the publication of the OCR. It is likely that CEDs will be replaced with a CHED D with the	No substantive changes to delivery/practice Current legislation needs to be amended to refer to definitions in the OCR. No changes to delivery/practice. Current legislation to be amended to: Replace ‘Common Health Entry Document (CHED-D) as provided for in [**DN:** appropriate reference to the EU legislation that will replace Regulation (EC) No. 669/2009, when it is published in the Official Journal]’.

	Regulation, Box I.13 of the CED can contain more than one commodity code; (b) for fish and fishery products: the common veterinary entry document (CVED) set out in Annex III to Commission Regulation (EC) No 136/2004(1). The respective document shall be transmitted to the competent authority at the designated point of entry or border inspection post, at least two working days prior to the physical arrival of the consignment.	introduction of the yet-to-be published tertiary legislation replacing Regulation (EC) No. 669/2009. Common Veterinary Entry Document (CVED) as provided for in Article 2 of Commission Regulation (EC) No 136/2004 but this will be replaced by a 'Common Health Entry Document (CHED-P) with the introduction of the yet-to-be published tertiary legislation replacing Regulation (EC) No. 136/2004.	Replace 'Common Veterinary Entry Document' with 'Common Health Entry Document'
Commission Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC, as amended by Commission Decision 2013/287/EU	**Article 2 (Definitions)** For the purposes of this Decision, the definitions laid down in Articles 2 and 3 of Regulation (EC) No 178/2002, Article 2 of Regulation (EC) No 882/2004 of the European Parliament and of the Council of 29 April 2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules and Article 3(b) and (c) of Commission Regulation (EC) No 669/2009 on	Article 3 (Definitions) of OCR Relevant provisions of yet-to-be published tertiary legislation replacing Regulation (EC) No. 669/2009	No substantive changes to delivery/practice. Current legislation needs to be amended to refer to definitions in the OCR. No changes to delivery/practice. Current legislation to be amended to: • Replace 'Article 2 of Regulation 882/2004 with: 'Article 3 of Commission Regulation 2017/625'

	increased controls on imports of certain feed and food of non-animal origin shall apply.		• Replace 'Article 3 (b) and (c) of Regulation (EC) No. 669/2009' with: '[**DN:** Insert appropriate reference to EU legislation that will replace Regulation (EC) No. 669/2009, when it is published in the Official Journal]'
	Article 3 (Prior notification) 1. Feed and food business operators or their representatives shall give adequate prior notification of the estimated date and time of the physical arrival of the consignment and of the nature of the consignment to the competent authorities at the Border Inspection Post or at the Designated Point of Entry as appropriate. Operators shall also indicate the designation of the product as to whether it is food or feed. 2. For that purpose, they shall complete the relevant parts of the common entry document (CED) referred to in Annex II to Regulation (EC) No 669/2009, or the common veterinary entry document (CVED), as provided for in Article 2 of Commission Regulation (EC) No 136/2004 (*), and transmit that document to the competent authority at the Border Inspection Post or at the Designated Point of Entry as appropriate, at least one	**Article 3 (Definitions)** Article 3(38): Definition of 'border control post' Note: Under OCR 'border inspection posts' (BIPs), 'designated points of entry' (DPEs), 'points of entry' and 'first points of introduction' will collectively be known as 'border control posts'. Article 56 (Common Health Entry Document (CHED))	No substantive changes to delivery/practice. Current legislation needs to be amended to refer only to 'border control posts'. Current legislation to be amended to: • Replace 'Border Inspection Post or at the Designated Point of Entry as appropriate' with: 'Border Control Post' as defined in Article 3(38) of Regulation (EU) 2017/625 No substantive changes to delivery/practice other than the overarching need for the competent authority to complete the relevant new type of common entry document provided for by the OCR and yet-to-be published tertiary legislation.

	working day prior to the physical arrival of the consignment.	Relevant provisions of yet-to-be published tertiary legislation replacing Regulation (EC) No. 669/2009.	Current legislation to be amended to: • Replace 'Common Entry Document (CED) referred to in Annex II to Regulation (EC) No 669/2009' with: 'Common Health Entry Document (CHED-D) as provided for in [DN: appropriate reference to the EU legislation that will replace Regulation (EC) No. 669/2009, when it is published in the Official Journal]'. • Replace 'Common Veterinary Entry Document (CVED) as provided for in Article 2 of Commission Regulation (EC) No 136/2004' with: 'Common Health Entry Document (CHED-P) as provided for in [DN: insert appropriate reference to the EU legislation that will replace Regulation (EC) No. 136/2004, when it is published in the Official Journal]'.
Commission Decision 2011/884/EU *on emergency measures regarding unauthorised genetically modified rice in rice products originating*	**Article 2(1)** "Article 2 of Regulation (EC) No 882/2004"	ANNEX V - CORRELATION TABLES REFERRED TO IN ARTICLE 146(2) **[Repeals]**	According to Annex V, replace with: "Article 3 of Regulation (EU) 2017/625"

from China and repealing Decision 2008/289/EC		1. Regulation (EC) No 882/2004	
Commission Decision 2011/884/EU *on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC*	**Article 2(1)** **&** **Article 3(2)** "Article 3 (b) and (c) of Regulation (EC) No. 669/2009"	If becomes relevant - Insert appropriate reference to EU legislation that will replace Regulation (EC) No. 669/2009, when it is published in the Official Journal	Not yet known
Commission Decision 2011/884/EU *on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC*	**Article 3(1) & Article 3(2)** Where mentioned "Border Inspection Post or at the Designated Point of Entry"	Would seem to have been renamed as "Border Control Post" as defined in Articles 3(38) and 47(1) of Regulation (EU) 2017/625	Could potentially insert its definition as "Border Control Posts" at Article 2(2)(f) of retained 2011/884/EC and replace wording.
Commission Decision 2011/884/EU *on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC*	all instances of common entry document 'CED'	Replace with common health entry document 'CHED-D' Provided by appropriate reference to the EU legislation that will replace Regulation (EC) No. 669/2009, when it is published in the Official Journal	Although not part of OCR – there is the possible expectation to be replaced into 'Common Health Entry Document' 'CHED-D'
Commission Decision 2011/884/EU *on emergency measures regarding unauthorised genetically modified rice in rice products originating from China and repealing Decision 2008/289/EC*	all instances of 'common veterinary entry document' 'CVED' as provided for in Article 2 of Commission Regulation (EC) No 136/2004	Replace with 'CHED-PP' Provided by appropriate reference to the EU legislation that will replace Regulation (EC) No.	Although not part of OCR – expected to be replaced into 'Common Health Entry Document for Plants, Plant Products and Plant propagating material' 'CHED-PP'

		669/2009, when it is published in the Official Journal	
Regulation (EC) No 1829/2003 *of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*	**<u>ANNEX - Paragraph 3(b) + Paragraph 4</u>** "Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004 " & **<u>Article 32 of EU regulation:</u>** Community reference laboratory The Community reference laboratory and its duties and tasks shall be those referred to in the Annex. National reference laboratories may be established in accordance with the procedure referred to in Article 35(2). Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the tasks of the Community reference laboratory and the European Network of GMO laboratories mentioned in the Annex. The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods.	ANNEX V - CORRELATION TABLES REFERRED TO IN ARTICLE 146(2) **<u>[Repeals]</u>** 1. Regulation (EC) No 882/2004 & **<u>Article 93(5)</u>** By way of derogation from paragraphs 1 and 2 of this Article, the laboratories referred to in the first paragraph of Article 32 of Regulation (EC) No 1829/2003 and the first paragraph of the Article 21 of Regulation (EC) No 1831/2003 shall be the European Union reference laboratories having the responsibilities and performing the tasks referred to in	Not required & This includes all mention of 'Community' in Community Reference Lab for OCR changes into "European Union Reference Lab" Reference laboratory 1. The appropriate authority may appoint a reference laboratory to perform the duties and tasks set out in the Annex. 2. Applicants for authorisation of genetically modified food and feed shall contribute to supporting the costs of the duties and tasks of the reference laboratory. 3. The contributions from applicants shall not exceed the costs incurred in carrying out the validation of detection methods. 4. The appropriate authority may prescribe— (a) measures for implementing this Article and the Annex; and

	Detailed rules for implementing this Article and the Annex may be adopted in accordance with the regulatory procedure referred to in Article 35(2). Measures designed to amend non-essential elements of this Regulation and adapting the Annex shall be adopted in accordance with the regulatory procedure with scrutiny referred to in Article 35(3).	Article 94 of this Regulation in the areas respectively of: (a) GMOs and genetically modified food and feed; and (b) feed additives.	(b) measures designed to amend non-essential elements of this Regulation and adapting the Annex.
Regulation (EC) No 1829/2003 *of the European Parliament and of the Council of 22 September 2003 on genetically modified food and feed*	**Article 5(5)(b) GM Food:** In the case of GMOs or food containing or consisting of GMOs, the application shall also be accompanied by: (b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent. **Article 17(5)(b) GM Feed:** In the case of GMOs or feed containing or consisting of GMOs, the application shall also be accompanied by: (b) a monitoring plan for environmental effects conforming with Annex VII to Directive 2001/18/EC, including a proposal for the duration of the monitoring plan; this duration may be different from the proposed period for the consent.	**Article 23(2)(a)(ii)** 2. The Commission is empowered to adopt delegated acts in accordance with Article 144 to supplement this Regulation… (ii) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in point (b) of Article 5(5) and point (b) of Article 17(5) of Regulation (EC) No 1829/2003; &	No change expected onto delivery/practice as its function is to confer the capability to apply additional or change the requirements of the monitoring plan for GMOs. There are no expected plans received from the Commission for this to happen.

		Article 23(3)(b) 3. The Commission may, by means of implementing acts, lay down rules on uniform practical arrangements for the performance of the official controls… is necessary to respond to recognised uniform hazards and risks of: (b) the cultivation of GMOs for food and feed production and the correct application of the plan for monitoring referred to in point (e) of Article 13(2) of Directive 2001/18/EC and in point (b) of Article 5(5) and point (b) of Article 17(5) of Regulation (EC) No 1829/2003.	
Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms	**ANNEX III** **Amendment to the Annex to Regulation (EC) No 1829/2003** **Point 3(b) & Point 4** "without prejudice to the responsibilities of the Community reference laboratories laid down in Article 32 of Regulation (EC) No 882/2004"	ANNEX V - CORRELATION TABLES REFERRED TO IN ARTICLE 146(2) **[Repeals]** 1. Regulation (EC) No 882/2004	No delivery required – was the text amending the ANNEX of 1829/2003, as had already been noted above UK Statutory Instruments > 2019 No. 705 > PART 4 Revocation of retained direct EU legislation Revocation of Commission Regulation (EC) No. 1981/2006

			390. Commission Regulation (EC) No. 1981/2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No. 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms is revoked.
2013/287/EU: Commission Implementing Decision of 13 June 2013 amending Implementing Decision 2011/884/EU on emergency measures regarding unauthorised genetically modified rice in rice products originating from China Text with EEA relevance	all instances of common entry document 'CED' & all instances of 'common veterinary entry document' 'CVED'	See above as commented in Commission Decision 2011/884/EU	No delivery required - as this is an amending implementing decision onto 2011/844, and is not required to be made again separate to amending 2011/844
Regulation (EC) No 1830/2003 of the European Parliament and of the Council of 22 September 2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC	**Article 9(2)** and the Community Reference Laboratory established under Regulation (EC) No 1829/2003.	Regulation (EC) No 1829/2003 – Article 32 References to 'Community' removed	
Commission Regulation (EC) No 641/2004 of 6 April 2004 on detailed rules for the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the application for the authorisation of new genetically modified food and feed, the	**ANNEX I Method Validation** Instances of "Community Reference Laboratory (CRL)"	Regulation (EC) No 1829/2003 – Article 32 References to 'Community' in 'Community Reference Laboratory' removed	No delivery required

notification of existing products and adventitious or technically unavoidable presence of genetically modified material which has benefited from a favourable risk evaluation			
Regulation 854/2004 Chapter 1 Article 1	Sets out the scope of the regulations	Commission delegated regulation EU 2019/624 Article 1 Subject, matter & scope	Details the subject, matter & scope of the regulations.
Regulation 854/2004 Chapter 1 Article 2 - Definitions	Article 2 provides definitions of wording that applies for the purpose of the regulation	Commission delegated regulation EU 2019/624 Article 2 Definitions	There are some additions to the 'Definitions' that apply for the purpose of the regulation. These are as follows: follows: (2) 'holding of provenance' means the holding where the animals were last reared. In the case of semi-domesticated cervids as defined in point 2(q) of Annex I to Regulation (EC) No 999/2001 of the European Parliament and of the Council (7), it includes round-ups intended to select animals for slaughter; (5) 'staff designated by the competent authorities' means a person other than the official auxiliary and the official veterinarian, who is qualified in accordance with this Regulation to act in such a capacity in cutting plants and to whom the competent authorities assign the performance of specific actions; (17) 'Low-capacity slaughterhouse' means a slaughterhouse designated by the competent authorities on the basis of a

			risk analysis and in which slaughtering takes place only during part of the working day or takes place during the whole working day but not on each working day of the week; (18) Low-capacity game-handling establishment' means a game-handling establishment designated by the competent authorities on the basis of a risk analysis and in which game-handling takes place only during part of the working day or takes place during the whole working day but not on each working day of the week; (19) 'livestock unit' means a livestock unit as defined in Article 17(6) of Regulation (EC) No 1099/2009;
Regulation 854/2004 Annex I Section III Chapter I point 2 and II Point 1 Annex I Section III Chapter II Point 2(a) Annex I Section III Chapter II Point 3	In relation to ante-mortem inspection and checks concerning the welfare of animals, official auxiliaries may only help with purely practical tasks at ante-mortem inspection which may include a preselection of animals with abnormalities.	Article 3(1) Article 3(2) Article 3(3)	There is more scope for the OA to undertake the AMI under the supervision of the OV on species other than poultry and lagomorphs provided the OV does the AMI where abnormalities are detected by the OA. There is no change to the tasks for an OA under the responsibility of an OV where AMI is undertaken at the holding of provenance by an OV (note OV includes approved veterinarian as defined in Regulation 2017/625 Article 3)

			There are no changes to the situations where the derogation allowing OAs to undertake AMI do not apply.
Regulation (EC) 854/2004, Annex I, Section II, Chapter V, Paragraph 1(a)	Meat from animals which do not undergo AMI before emergency slaughter must be declared as unfit for human consumption.	Article 4	With regards to domestic ungulates only, the OV may perform ante-mortem inspection outside of the slaughterhouse in the case of emergency slaughter. Official veterinarian includes approved veterinarian. Meat from emergency slaughter which passes AMI can enter the food chain.
Regulation 854/2004 Annex I Section IV Chapter IV, Chapter V, Chapter VI and VII	AMI is currently allowed at the holding of provenance for only for pigs, poultry, farmed lagomorphs and farmed game	Article 5 Article 6 Point 5	The CA may allow AMI at the holding of provenance for all species. There is species specific criteria and conditions laying down when ante-mortem inspections may be performed at the holding of provenance that now apply to all species. The completed health certificate must accompany the animals to slaughter but in the case of farmed game, the health certificate may be sent in advance and slaughter can be delayed for up to 28 days before a new AMI is required.
Regulation 1244/2007 Annex II Point 2a & 2b (amending Regulation 2074/2005)	Sets out the requirements for the official controls for the inspection of meat detailing that the competent authority may decide that the OV may need not be present at all times during post-mortem inspection, provided that certain	Article 7	Addition of thresholds for the maximum throughput at small slaughterhouses and game handling establishments which can take advantage of official auxiliaries carrying out PMI without an OV being present.

	conditions are met.		
Regulation 854/2004 Annex I Section III Chapter II Point 3	Details the circumstances when PMI PMI must be carried out by the OV	Article 8	No change
Regulation 854/2004 Annex I Section III Chapter I Point 1	Permits the use of official auxiliaries to undertake audit activities in slaughterhouses and game handling establishments under the responsibility of the OV veterinarian, only as regards the collection of information on good hygiene practices and HACCP-based procedures	Article 9	There is no change to this practice
Regulation 854/2004 Annex I Section III Chapter III Point A & B	Provides provisions for the use of other staff as designated by the CA to carry out certain tasks of the OA under the supervision, direction & authority of the OV	Article 10	Makes provision for the use of staff as designated by the competent authority other than official veterinarians and official auxiliaries to undertake certain tasks at cutting plants. These staff now are required to meet minimum qualification requirements
		Article 11	Not applicable to official controls on meat
		Article 12	Specific derogations on certain species of deer as they apply in Finland and Sweden
Regulation 854/2004 Annex I Section III Chapter IV Point A & B	Sets out the professional qualifications/training requirements for OV's & OA's	Article 13	Details the requirements for minimum qualification requirements for 'other staff' that may be designated by the CA to carry out certain tasks.
Regulation 854/2004 Annex I Section III Chapter III Pont A & B	Details the professional qualifications/training requirements required for OV's & OA's	Article 14 & Chapter III Point 5	Details the training requirements of 'other staff' as designated by the CA
Regulation 854/2004 Article 1 Scope	No significant changes	Article 1	The Regulation details those official controls and actions to be performed by the competent authorities taking into account the requirements of Article 18(2), (3) and (5) of Regulation (EU) 2017/625

			and Delegated Regulation (EU) 2019/624.
Regulation 854/2004 Article 2 Definitions	Definitions – provides guidance for the purpose of this regulation	Article 2	No new definitions which are not included in the delegated regulation. Some definitions, e.g. Official veterinarian set out in Regulation 2017/625.
Regulation 854/2004 Chapter II Article 3 Approval of Establishments	Specific performance requirements for audits by the competent authorities in establishments handling products of animal origin	Article 3	Some changes to the detail of what audits should include, e.g. at A3 Point 3 They shall, in particular, determine whether the procedures guarantee, to the extent possible, that products of animal origin: (a) comply with Article 3 of Regulation (EC) No 2073/2005 as regards microbiological criteria; (b) comply with Union legislation on: — the monitoring of chemical residues, in accordance with Council Directive 96/23/EC and Commission Decision 97/747/EC; — maximum residue limits for pharmacologically active substances, in accordance with Commission Regulation (EU) No 37/2010 (33) and Commission Implementing Regulation (EU) 2018/470; — prohibited and unauthorised substances, in accordance with Commission Regulation (EU) No 37/2010, Council Directive 96/22/EC, Commission Decision 2005/34/EC; — contaminants, in accordance with Regulations (EC) No 1881/2006 and (EC) No 124/2009 setting maximum

			levels for certain contaminants in food; — pesticide residues, in accordance with Regulation (EC) No 396/2005 of the European Parliament and of the Council; (c) do not contain physical hazards, such as foreign bodies.
Regulation 854/2004 Article 4	9. The nature and intensity of auditing tasks in respect of individual establishments shall depend upon the assessed risk. To this end, the competent authority shall regularly assess: (a) public and, where appropriate, animal health risks; (b) in the case of slaughterhouses, animal welfare aspects; (c) the type and throughput of the processes carried out; and (d) the food business operator's past record as regards compliance with food law.	Article 4 (2)	Introduces the possibility of the competent authority (CA) examining 'private control systems or independent third-party certification' systems where these have been incorporated into food safety systems
Regulation 854/2004 Article 5 Fresh Meat	Specific requirement for identification marking (2) The health marking of carcasses of domestic ungulates, farmed game mammals other than lagomorphs, and large wild game, as well as half-carcasses, quarters and cuts produced by cutting half-carcasses into three wholesale cuts, shall be carried out in slaughterhouses and game-handling establishments in accordance with Section I, Chapter III, of Annex I. Health	Article 5	No change Compliance with the requirements of Regulation (EC) No 853/2004 concerning the application of identification marks shall be verified in all establishments approved in accordance with that Regulation, in addition to verification of compliance with other traceability requirements in accordance with Article 18 of Regulation (EC) No 178/2002.

	marks shall be applied by, or under the responsibility of, the official veterinarian when official controls have not identified any deficiencies that would make the meat unfit for human consumption.		
		Article 6 - technological developments	New and requires approval by the Commission/other MS before new technologies can be used as part of official controls.
Regulation 854/2004 Annex I Section I Chapter I		Article 7 - additional requirements for audits in establishments handling meat	Changes in detail plus Article 7 Point 3 includes reference to checking compliance with microbiological criteria in Article 3 of Regulation (EC) No 2073/2005.
		Article 8 - Official Control on Fresh Meat – Relevance of audit results	New statement of good practice in taking account of previous audits when deciding what areas to concentrate audits on.
		Article 9 Obligations of the competent authorities as regards checks of documents	A new requirement for the CA to ensure food chain information is in the appropriate form and that appropriate checks and communication of information takes place.
		Article 10 Obligations of the official veterinarian as regards checks of documents - Annex I Section I Chapter I A	Detail is broadly the same

Regulation 854/2004 Annex I Section I Chapter II B as supplemented by Section IV Specific Requirements	Sets out the requirements as regards ante-mortem inspection at the slaughterhouse	Article 11	There are no significant changes
Regulation 854/2004 Annex I Section I Chapter II D as supplemented by Section IV Specific Requirements	Sets out the requirements as regards ante-mortem inspection at the slaughterhouse	Article 12	There are no significant changes
		Article 13	New derogation on the timing of PMI which only applies to low-capacity slaughterhouses and low-capacity game handling establishments which allows an OV to undertake PMI up to 24 hours after slaughter/ arrival at a GHE where neither the official veterinarian nor the official auxiliary are present in the game-handling establishment or slaughterhouse during slaughter and dressing. This may have implications for the current policy on cold inspections.
Regulation 854/2004 Annex I Section I Chapter II, D 2	Sets out when additional examinations are to take place, such as palpation & incision of parts of the carcase & offal & laboratory tests, whenever considered necessary.	Article 14	There are no significant changes
Regulation 854/2004 Annex I Section I Chapter II D Point 3 & Point 4	Sets out the requirements for post-mortem inspection. Currently domestic solipeds, bovine animals over 6 months old & swine over 4 weeks old must be submitted for post-mortem inspection split lengthways into carcases down the spinal column**.**	Article 15	There are changes to the age at which the carcases have to be split. Now, the OV shall require that carcases of domestic solipeds, bovine animals over eight months old and domestic swine more than five weeks old are submitted for post-mortem inspection split lengthways into half carcases down the spinal column.

			There is also a new provision that low-capacity slaughterhouses or low-capacity game-handling establishments handling fewer than 1 000 livestock units per year, the OV may, for sanitary reasons, authorise the cutting into quarter carcases of adult domestic solipeds, adult bovine animals and adult large wild game before post-mortem inspection.
Regulation 854/2004 Annex I Section I Chapter II D Point 5	Requirements that in the event of emergency slaughter, the carcase shall be subjected to post-mortem examination as soon as possible.	Article 16	There are no significant changes
		Article 17	Confirms that PMI must be carried out in accordance with the requirements set out in the Regulation.
Regulation 854/2004 Annex I Section IV Chapter I A	Currently, bovine animals under six weeks old primarily undergo visible inspection. The trachea and the main branches of the bronchi must be opened lengthwise and the lungs must be incised in their posterior third, perpendicular to their main axes (these incisions are not necessary where the lung are excluded from human consumption)	Article 18	There is a significant change in that bovines animals under eight months old (or under 20 months old if reared without access to pasture land during their whole life in an officially tuberculosis-free Member State or region of a Member State in accordance with Article 1 of Decision 2003/467/EC) can undergo visual inspection of the following:- a) the head and throat; together with palpation and examination of the retropharyngeal lymph nodes, however, in order to ensure the surveillance of the officially tuberculosis free status, Member States may decide to carry out further investigations; inspection of the mouth and fauces

			(b) the lungs, trachea and oesophagus; palpation of the lungs; palpation and examination of the bronchial and mediastinal lymph nodes; (c) the pericardium and heart; (d) the diaphragm; (e) the liver and the hepatic and pancreatic lymph nodes, (f) the gastro-intestinal tract, the mesentery and gastric and mesenteric lymph nodes (g) the spleen (h) the kidneys (i) the pleura and peritoneum (j) the umbilical region and the joints of young animals. When there are indications of possible risk to human health, animal health or animal welfare indicated in accordance with Article 24, then post-mortem inspection procedures using incision and palpation of the carcase and offal must be followed.
Regulation 854/2004 Annex I Section IV Chapter I Point B	Sets out the inspection procedures which relate to visible & incision PM requirements for bovine animals over 6 weeks old & includes that the lungs be incised in their posterior third, perpendicular to their main axes (these incisions are not necessary where the lungs are excluded from human).	Article 19	The new procedures relate to bovine animals over 8 months old (not 6 weeks as is current). The PMI procedures remain the same except that the lungs do not need to be incised, visual inspection and palpation is only required.
Regulation 854/2004 Annex I Section IV Chapter II	Sets out the inspection procedures for domestic sheep & goats of all ages.	Article 20	Distinguishes PMI requirements from sheep with erupted incisors and goats over 6 months old where the requirements are set out in Article 21. There are no significant changes.

Regulation 854/2004 Annex I Section IV Chapter II	Sets out the inspection procedures for domestic sheep & goats of all ages.	Article 21	Distinguishes PMI requirements from those sheep with no erupted incisors and goats under 6 months old. There are no significant changes.
Regulation 854/2004 Annex I Section IV Chapter III	Sets out the inspection procedures for domestic solipeds. Current procedures require that the includes that the lungs be incised in their posterior third, perpendicular to their main axes (these incisions are not necessary where the lungs are excluded from human). Current procedures also require that heart be incised so as to open the ventricles and cut through the interventricular septum.	Article 22	There is no need for incision of the lungs or heart unless there are indications of possible risk to human health, animal health or animal welfare indicated in accordance with Article 24. There are no other significant changes.
Regulation 854/2004 Annex I Section IV Chapter IV Point B	Sets out the inspection procedures for domestic swine	Article 23	There are no significant changes
		Article 24	Where there are indications of a possible risk to human health, animal health or animal welfare in domestic bovine animals, domestic sheep and goats, domestic solipeds and domestic swine, there is a new list detailing when PMI should revert to include incision and palpation.
Regulation 854/2004 Annex I Section IV Chapter V Point B	Sets out the inspection procedures for poultry & under current requirements, all birds are to undergo PMI. In addition, the OV is to personally carry out:- (a) daily inspection of the viscera and body cavities of a representative sample of birds; (b) a detailed inspection of a random sample, from each batch of birds having the same origin, of parts of birds or entire birds declared unfit for human	Article 25	All poultry shall undergo post-mortem inspection which may include the assistance of slaughterhouse staff provided the criteria in accordance with Article 18(3) of Regulation (EU) 2017/625 is met. In addition, the OA is permitted to carry out those checks which were previously carried out personally by the OV as detailed under the current arrangements.

	consumption following post-mortem inspection; and (c) any further investigations necessary when there is reason to suspect that the meat from the birds concerned could be unfit for human consumption.		However, there is a new derogation that may be applied (in paragraph 2) in that the CA may decide that only a representative sample of poultry from each flock undergoes post-mortem inspection provided certain conditions are met.
Regulation 854/2004 Annex I Section IV Chapter VI	Current procedures are that the inspection procedures for poultry are to apply to farmed lagomorphs	Article 26	There are no significant changes. The inspection procedures for poultry are to apply to farmed lagomorphs. The requirements for a single poultry flock applies to lagomorphs slaughtered the same day from single holding of provenance.
Regulation 854/2004 Annex I Section IV Chapter VII	Sets out the inspection procedures for farmed game. Current procedures are that PMI procedures described for bovine and ovine animals, domestic swine and poultry are to be applied to the corresponding species of farmed game.	Article 27	Various changes to PMI requirements for certain cervidae (deer) and suidae. In the case of small (< 100 kg) *Cervidae*, the post-mortem procedures for young domestic sheep and goats apply. However, in the case of reindeer the post-mortem procedures for older ovine animals apply and the tongue may be used for human consumption without inspection of the head. In the case of game of the family *Suidae*, the post-mortem procedures for domestic swine apply. in the case of large game of the family *Cervidae* and other large game, the post-mortem procedures for bovine animals apply. There are no other significant changes.
Regulation 854/2004 Annex I Section IV Chapter VIII	Sets out the inspection procedures for wild game.	Article 28	There are no significant changes
Regulation 854/2004	Annex I Section IV Chapter IX A	Article 29	Contains more detail on the checks

			required: 1.In addition to the requirements of Regulation (EC) No 999/2001 concerning the official controls to be carried out in relation to TSEs, the official veterinarian shall check the removal, separation and, where appropriate, marking of specified risk material also in accordance with the rules laid down in Article 8(1) of that Regulation and in Article 12 of Regulation (EC) No 1069/2009 on animal by-products. 2.The official veterinarian shall ensure that the food business operator takes all necessary measures to avoid contaminating meat with specified risk material during slaughter, including stunning. This includes the removal of specified risk material.
Regulation 854/2004 Annex I Section IV Chapter IX B		Article 30 - Practical arrangements for official controls for cysticercosis during post-mortem inspection in domestic bovine animals and Suidae	The requirements extend to Suidae and make provision for PMI in bovines not to include incision if certain criterion is met.
Regulation 854/2004 Annex I Section IV Chapter IX C		Article 31 - Practical arrangements for official controls for Trichinella during post-mortem inspection	No change
Regulation 854/2004 Annex I Section IV Chapter IX		Article 32 - Practical arrangements for	New requirements

D		official controls for glanders during post-mortem inspection of solipeds	1.Fresh meat of solipeds shall be placed on the market only if it was produced from solipeds kept for at least 90 days prior to the date of slaughter in a Member State or in a third country or region thereof from which it is authorised to bring solipeds into the Union. 17.5.2019 L 131/72 Official Journal of the European Union EN 2.In the case of solipeds originating from a Member State or third country or region thereof not meeting the World Organisation for Animal Health criteria for a glanders-free country, solipeds shall be inspected for glanders by a careful examination of the mucous membranes of the trachea, larynx, nasal cavities and sinuses and their ramifications, after splitting the head in the median plane and excising the nasal septum. 3.Meat produced from solipeds in which glanders has been diagnosed shall be declared unfit for human consumption.
Regulation 854/2004 Annex I Section IV Chapter IX E		Article 33 - Practical arrangements for official controls for tuberculosis during post-mortem inspection	No change is expected.
Regulation 854/2004 Annex I Section IV Chapter IX F		Article 34 - Practical arrangements for official controls for brucellosis during post-mortem inspection	No change is expected.
Regulation 854/2004 Annex I		Article 35 - Practical	No changes.

Section IV Chapter IX G		arrangements for official controls for Salmonella	
Regulation 854/2004		Article 36 - Practical arrangements for official controls for Campylobacter	New requirement requiring the CA to undertake verification of FBOs implementation of the campylobacter PHC:
Regulation 854/2004		Article 37 - Specific requirements as regards laboratory tests	Cross references to other legislation where sampling/test methods are specified
Regulation 854/2004 Annex I Section I Chapter I Point 1		Article 38 - Official controls on animal welfare at transport and slaughter	Broadly the same
Regulation 854/2004 Annex I Section II Chapter I	Sets out the measures with regards to the communication of inspection results	Article 39	The measures are broadly the same but now includes a model document at Annex I which the OV may use for the purpose of communicating the relevant results of ante-mortem and post-mortem inspections to the holding of provenance where the animals were kept before slaughter. Also, where the animals were kept on a holding of provenance in another Member State, the competent authorities of the Member State in which they were slaughtered shall communicate the relevant results of ante-mortem and post-mortem inspections to the competent authorities in the Member State of provenance. They shall use the model document in Annex I in the official languages of both Member States involved or in a language agreed between

			both Member States.
Regulation 854/2004 Annex I Section II Chapter II		Article 40 - Measures in cases of non-compliance with requirements for food chain information	Requirements broadly the same
Regulation 854/2004 Annex I Section II Chapter II Point 4	Sets out the measures in cases of non-compliance recorded in food chain information	Article 41	There is no change to requirements
Regulation 854/2004 Annex I Section II Chapter II Point 5	Sets out the measures in cases of misleading food chain information	Article 42	There is no change to requirements
Regulation 854/2004 Annex I Section II Chapter III	Sets out the measures in cases of non-compliance with requirements for live animals & includes that when there are overriding animal welfare considerations, horses may undergo slaughter at the slaughterhouse even if the legally required information concerning their identity has not been supplied. However, this information must be supplied before the carcase may be declared fit for human consumption. These requirements also apply in the case of emergency slaughter of horses outside the slaughterhouse	Article 43	The requirements are broadly the same except that the reference relating to the measures in respect of the overriding animal welfare considerations for horses has been omitted.
Regulation 854/2004 Annex I Section II Chapter IV	Sets out the measures in cases of non-compliance with requirements for animal welfare	Article 44	There are no changes to these measures
Regulation 854/2004 Annex I Section II Chapter V	Sets out the measures in cases of non-compliance with requirements for fresh meat	Article 45	There are no changes to these measures
Regulation 854/2004 Article 4 3a) 4 & 5	Sets out the audit requirements in respect of good hygiene practices & d hazard analysis and critical control point	Article 46 This is a new measure in cases of non-	There is a new measure in cases of non-compliance with requirements on good hygiene practices, which allows the

	(HACCP)-based procedures	compliance with requirements on good hygiene practices	competent authority to require line-speeds to be reduced though in reality, this is currently being carried out where necessary. The competent authorities may instruct the food business operator to take immediate corrective action, including a reduction in the speed of slaughter, where this is considered necessary by the official present in the following cases: (a) where contamination is detected on external surfaces of a carcase or its cavities and the food business operator does not take appropriate action to rectify the situation; or (b) if the competent authorities consider that good hygiene practices are jeopardised. 2.In such cases, the competent authorities shall increase the intensity of inspection until such time as they are satisfied that the food business operator has regained control of the process.
Regulation 854/2004 Annex I Section II Chapter V Point 2	Sets out the restrictions for certain fresh meat	Article 47	There are no significant changes
Regulation 854/2004 Annex I Section I Chapter III	Sets out the requirements for health marking	Article 48 & Annex II	There are no significant changes
		Article 73	This is a new requirement for the ante-mortem and post-mortem inspection of reptiles. This is to be done in accordance with the ante-mortem & post-mortem

			requirements as for other species as detailed in Article 11 (AMI) & Articles 12, 13 & 14.
Article 47(2), Regulation 2017/625 BCP positive list A list/s will be drawn up of all animals and goods to be subject to veterinary controls at BCPs. Legislation is to be made under this provision which will set out these lists once published.	Not yet published - subject to a technical, indicative vote in the PAFF committee on Thursday 18 July.		Not yet published - subject to a technical, indicative vote in the PAFF committee
Published: Regulation 2019/478 (Article 47(3), Regulation 2017/625 Additional goods to be checked at BCPs) https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=uriserv:OJ.L_.2019.082.01.0004.01.ENG	The list of products that require veterinary checks is laid down in Commission Decision 2007/275 (as amended). The Decision also requires certain composite products and hay and straw to be checked. Hay and straw are subject to checks because the origin and subsequent destination may present a risk to spreading infectious and contagious animal diseases.		Amends Regulation 2019/625. Regulation (EU) 2017/625 establishes the framework for official controls and other official activities to verify the correct application of Union food and feed law. That framework includes official controls performed on animals and goods entering the Union from third countries. Regulation (EU) 2017/625 requires for certain categories of animals and goods that each consignment is made subject to official controls at designated border control posts of first arrival into the Union, because of the risk those categories of animals and goods may pose to public and animal health. In addition to the categories of

			consignments already listed in Regulation (EU) 2017/625, foodstuffs containing both products of plant origin and processed products of animal origin (composite products), as well as hay and straw should undergo official controls at border control posts as they too may pose a risk to public and animal health.
Published: Regulation 2019/1081 (Article 49 (5), Regulation 2017/625) Specific staff training requirements for BCP staff without OV status working with animals and POAO	UK ports employ Official Fish Inspectors (OFIs) to undertake controls of fish and fishery products at BIPs. A derogation allows this under Article 1 of Decision 93/352/EEC and Article 3 of Regulation 136/2004/EC. These Inspectors are suitably qualified Environmental Health Officers. Support staff often assist OVs and OFIs at the BIP with official controls. This is overseen by the OV and/or OFI. Note – the UK Food Law Code of Practice lays down the current qualifications and experience required by non-OV/OFI staff at the BIP.		
Published: Regulation 2019/1081 (Article 49 (5), Regulation 2017/625) Specific staff training requirements	UK ports employ Official Fish Inspectors (OFIs) to undertake controls of fish and fishery products at BIPs. A derogation allows this under Article 1 of Decision 93/352/EEC and Article 3 of Regulation 136/2004/EC. These Inspectors are		This Regulation introduces a new training requirement for non-OV staff at BCPs OV and plant health staff are exempt from this training.

for BCP staff without OV status working with animals and POAO	suitably qualified Environmental Health Officers. Support staff often assist OVs and OFIs at the BIP with official controls. This is overseen by the OV and/or OFI. Note – the UK Food Law Code of Practice lays down the current qualifications and experience required by non-OV/OFI staff at the BIP.		All other staff involved in POAO controls must undergo additional training which must cover the requirements of Article 3: 1. The content of the training programme shall be determined according to the animals and goods for which the border control posts are designated and the tasks and responsibilities to which the staff are assigned. 2. The training programme shall cover the following subject matters: (a) applicable Union legislation concerning the entry into the Union of animals and goods, including procedures and activities to be carried out during and after physical checks; (b) general principles of examination of animals; (c) examination of the fitness to travel of animals; (d) practical aspects of handling of animals in line with Union legislation, including arrangements to prevent or reduce delays at border control posts and, where necessary, to feed, water, unload and accommodate the animals; (e) sensorial examination of goods; (f) examination of the means of transport and the transport conditions, including the management of temperature-sensitive goods (cold chain) and the transport of animals; (g) identification of animal species, including, when appropriate,

			identification of invasive alien species as defined in point (2) of Article 3 of Regulation (EU) No 1143/2014 of the European Parliament and of the Council (4) introduced via animals and goods; (h) control procedures, concerning: (i) the use of equipment; (ii) the implementation of monitoring plans; (iii) sampling procedures and laboratory analysis with regard to animals and animal and public health aspects; (i) methods for the interpretation of laboratory test results and related decisions in accordance with the requirements of applicable Union legislation; (j) risk assessment, including data gathering in relation to animal and public health in order to carry out appropriately targeted physical checks; (k) prevention of cross-contamination and compliance with relevant biosecurity standards; (l) labelling requirements for goods referred to in Article 47(1)(b) of Regulation (EU) 2017/625; (m) investigations and control techniques aimed at detecting fraudulent or deceptive practices in trade.
Article 51, Regulation 2017/625 Rules on transhipment and onward movement	TBC – not yet published		TBC – not yet published
Article 52(1), Regulation 2017/625	TBC – not yet published		TBC – not yet published

Rules for the performance of controls at BCPs			
Article 53, Regulation 2017/625 Official controls not performed at Border Control Posts	TBC – not yet published		TBC – not yet published
Article 54(3), Regulation 2017/625 Frequency rates for BCP controls	TBC – not yet published		TBC – not yet published
Article 54(4), Regulation 2017/625 Will merge Regulation 669/2009 and other temporary measures. Will look similar to existing system but contingent on Article 54(3) methodology.	TBC – not yet published		TBC – not yet published
Published: Regulation 2019/1013 (Article 58, Regulation 2017/625) Prior Notification https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1013&from=EN	FNAO – at least one day prior to the physical arrival of the consignment POAO – in advance of arrival currently.		Unifying rules on prior notification – major change is prior notification for animals and goods (POAO and FNAO) will now be one day. To note, there is a derogation when the consignment is transported from the place of dispatch to the border control post in less than 24 hours – notification at least four hours before the expected arrival.
Please note that the empowerment in Art.60(2) has been bundled with the one in Art.64(4) **Published:** Regulation 2019/1014 Article 60(2), Regulation 2017/625 Public listing of BCP information	More applicable to CCAs. BIP listings are currently contained in Decision 2009/821. The entry contains details such as the BIP name, the designation e.g. port or airport and		Given the change in designation, from BIP to BCP and broadened scope to include goods (FNAO) and plants, some additional administrative requirements

Article 64(4), Regulation 2017/625 BCP Facilities Requirements *See attached file also.	whether the facility is approved for human and/or animal consumption or live animals. Currently official controls on 'higher risk' FNAO are undertaken at either a Designated Point of Entry (DPE) or a Designated Point of Imports (DPI). Import legislation dictates which whether a DPE or DPI can be used. Minimum requirements for DPEs are laid down in Article 4 of Regulation 669/2009 and similar requirements for DPIs are laid down in Article 6 of Regulation 884/2014. POAO is required to be imported through a Border Inspection Post (BIP). These requirements are considered to be more stringent that the FNAO minimum requirements, and are laid down in Decision 2001/812 and Directive 97/78.		have been introduced such as the type of BCP (ports, airport, road or rail), full contact details inc. for inspection centres, categories of goods, animals and specifications plus any additional specifications regarding the scope of the designation. This Regulation lays down rules for the implementation of Regulation (EU) 2017/625 as regards: (a) common detailed rules on minimum requirements for the infrastructure, equipment and documentation of border control posts and control points other than border control posts; (b) specific detailed rules on minimum requirements for border control posts designated for the categories of animals and goods referred to in Article 47(1)(a) and (b) of Regulation (EU) 2017/625; (c) detailed rules on minimum requirements for inspection centres; (d) the format, categories, abbreviations and other information for the listing of border control posts and control points other than border control posts.

Please note the empowerment in Art.62(3) has been bundled with those in Art.64(2) and (5) **Published:** Regulation 2019/1012 Article 64(2), Regulation 2017/625 Situations in which BCPs may be located away from the immediate point of entry into the Union Article 62(3), Regulation 2017/625 Partial withdrawal of BCP status https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R1012&from=EN	These are derogations from the Regulation 2017/625 requirements. a.) Regulation (EU) 2017/625 provides that Member States are to notify the Commission before designating border control posts, so that the Commission can verify and, where necessary, carry out controls to check if they comply with the minimum requirements for the designation laid down therein. Regulation (EU) 2017/625 empowers the Commission to lay down certain detailed rules on these minimum requirements. Those detailed rules have been laid down in Commission Implementing Regulation (EU) 2019/1014 (2), (hereinafter collectively referred to as 'the minimum requirements'). Regulation (EU) 2017/625 also provides that Member States are to withdraw the designation of the border control post where it ceases to comply with the requirements for the designation for all or for certain categories of animals and goods for which the designation was made. (3) However, where the withdrawal of the designation was partial because it concerned a specific category of animals or a specific category of goods, or all categories of animals or all categories of goods where the border control post was designated for categories of animals and goods, Member States should be		This Regulation lays down derogation rules from the 2017/625 requirements concerning: (a) the designation of a border control post or of a control point other than a border control post where the designation has been partially withdrawn (Article 62(3) of Regulation 2017/625). The derogation from designation requirements are not relevant to control point as their designation need to be made in accordance with Art.59(1) only.; (b) border control posts situated at a distance other than in the immediate vicinity of the point of entry into the Union due to specific geographical constraints.

	allowed to re-designate the border control post for those categories of animals or goods for which the designation was withdrawn without being first required to give the Commission the opportunity to carry out controls to verify compliance with the minimum requirements. In such cases, addressing the non-compliance should not involve actions as extensive as those necessary to designate a border control post for the first time. It is therefore appropriate to establish rules whereby Member States are allowed to re-designate the border control post for those categories of animals or goods without being first required to give the Commission the opportunity to carry out controls to verify compliance with the minimum requirements. The derogation from the rules of Regulation (EU) 2017/625 concerning the designation of border control posts should only apply where the re-designation takes place within two years from the date of the partial withdrawal of the designation. If the re-designation takes place more than two years from the date of the partial withdrawal, in order to assess the changes that occurred at the border control posts, the Commission should retain the possibility to perform controls to verify that the border control post complies with the minimum requirements. (6)		

	Regulation (EU) 2017/625, in certain cases, allows official controls to be performed at control points other than border control posts and it requires that those control points comply with the minimum requirements and the requirements for the designation and withdrawal of the designation of border control posts. Therefore, it is appropriate that the rules of this Regulation, concerning the re-designation of border control posts also apply to control points. Point b.) Regulation (EU) 2017/625 requires border control posts to be located in the immediate vicinity of the point of entry into the Union. However, in order to enable the efficient organisation and performance of official controls and other official activities, rules should be laid down to specify the cases of specific geographical constraints and the conditions under which border control posts can be located at a distance other than in the immediate vicinity of the point of entry into the Union. Geographical constraints should be those that result from the natural characteristics and landscape of the point of entry, and the distance from the point of entry should not exceed what is strictly necessary to overcome the difficulties caused by the geographical constraints. Furthermore, that distance should not be such as to pose a risk to human, animal and plant health, animal welfare and the environment.		

	Specific geographical constraints should include those that may cause major transportation constraints like, for example, high passes with roads unsuitable for the movement of animals and goods or causing significant delays in their movement.		
Article 65(6), Regulation 2017/625 Rules for intensified controls at BCPs	TBC – not yet published		TBC – not yet published
Article 77(1), Regulation 2017/625 Rules for specific types of official controls at BCPs. Article 77 (3), Regulation 2017/625 Ship supply and re-import	TBC – not yet published		TBC – not yet published
Published: Regulation 2019/628 (Article 90, Regulation 2017/625) Official Certificates https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0628&from=EN	Where an original certificate has been lost or destroyed, the competent authority of exporting country may provide an authenticated copy of the original certificate. Codex rules allow for replacement certificates to be issued. Commission advice is that these should be used in limited circumstances such as lost or destroyed certificates and for minor mistakes in the original certificate. They should not be used for more fundamental problems such as misrepresentation of the consignment.		New model health certificate format to be used for electronic certification. Paper certificates are still acceptable. Some new certificates for rendered fats and greaves, insects and reptile meat. This comes from the new import conditions and the end of the transition period for those goods. Most model certificates have replaced what is currently in R.854/2004 Replacement certificates: Competent authorities may issue a replacement certificate only in the case of

	Replacement certificates should include the reference number of the cancelled certificate.		administrative errors in the initial certificate or where the initial certificate has been damaged or lost. The replacement certificate shall not modify information in the initial certificate concerning the identification, traceability and health guarantees of consignments. In addition, the replacement certificate shall: a.) make clear reference to the unique code referred to in Article 89(1)(a) and the date of issue of the initial certificate, and clearly state that it - replaces the initial certificate; b.) have a new certificate number different to that of the initial certificate; c.) carry the date when it was issued, as opposed to the date of issue of the initial certificate; and d.) be presented in its original to the competent authorities, except in the case of electronic replacement certificates submitted in IMSOC.
Published: Regulation 2019/625 (Article 126(1), Regulation 2017/625 Establishment of import conditions (third country listings, registered establishments and	Third country listings are laid down in multiple pieces of existing legislation. There are no third country listings for		Sets out framework for import conditions – third country listing, establishment requirements and certification.

certification requirements) https://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32019R0625&from=EN	some of the newly harmonised products such as reptile meat.		Linked to the repeal of Regulation 854/2004 – making good on requirements of Regulation 853/2004 Contains details of the third country listings – some products/categories are retained in existing legislation whilst others are now contained in the Annex to the Regulation e.g. snails, fish and fishery products, live bivalve molluscs, echinoderms etc and insects for human consumption. • In light of the introduction of the IMSOC, the format to model health certificates has been slightly altered to adapt to this usage where relevant. • Similarly, some certificates currently featured in regulation pursuant to Regulation 854/2004 has been transferred here and new certificates are introduced for sprouts and seeds, reptile meat, insects, other POAO, ante-mortem inspection at the holding of provenance and emergency slaughter outside of the slaughterhouse. Some significant changes: Composite products Sprouts

			Raw materials for gelatine and collagen
Published: Regulation 2019/626 (Article 127(2), Regulation 2017/625) Listing of third countries approved	Lists of third countries currently exist for harmonised products intended for import into the EU. Lists for non-harmonised products do not currently exist, for example reptile meat and insects for human consumption. These are currently subject to national rules, so variation may occur between Member States.		For the most part existing third country lists are retained and references are made to existing regulations (e.g. Regulation 206/2010 for fresh meat and meat preparations of ungulates). As a result of Regulation 854/2004 being repealed pursuant legislation which includes lists for frogs' legs, snails, fishery products and live bivalve molluscs is moved here. New third country lists are introduced for reptile meat and live insects for human consumption.
Article 134, Regulation 2017/625 The functioning of the IMSOC	TBC – not yet published		TBC – not yet published
Regulation 854/2004 Annex IV, Chapter 1	**Control of milk and colostrum production holdings.** Animals on milk and colostrum holdings must be subject to official controls to verify health requirements., in particular health status and use of veterinary medicinal products. IF there are grounds to suspect health requirements are not	49	Introduction of the requirement that the official veterinarian shall verify the health requirements for raw milk and colostrum products as laid down in Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004. In particular the OV shall verify; health status, absence of unauthorised

	being complied with, the general health status is to be checked, Milk and Colostrum holdings are also to undergo official controls to verify that the hygiene requirements are being complied with. If it is shown these are not being met the CA is to verify that appropriate steps are taken to correct the situation.		pharmacologically active substances, possible presence of residues of authorised pharmacologically active substances, pesticides or contaminants does not exceed the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005 or (EC) No 1881/2006. If there are grounds that the health requirements are not being met, the OV shall check the general health status of the animals. This will be managed through DHIs with OV oversight.
Regulation 854/2004 Annex IV, Chapter 1	**Control of raw milk and colostrum upon collection.** the competent authority is to monitor the checks carried out in accordance with Annex III, Section IX, Chapter I, Part III to Regulation (EC) No 853/2004. If the food business operator has not corrected the situation within three months of first notifying the competent authority of non-compliance with the criteria with regard to plate count and/or somatic cell count, delivery of raw milk and colostrum from the production holding is to be suspended or — in accordance with a specific authorisation of, or general instructions from, the competent authority — subjected to requirements concerning its treatment and use necessary to protect public health. This suspension or these	50	Minor change – When testing competent authorities shall use analytical methods set out in Annex III to check compliance with limits in Part III of Chapter I, Section IX of Annex III to Regulation (EC) No 853/2004 (**DETERMINATION OF PLATE COUNT AND SOMATIC CELL COUNT)** and verify application of pasteurisation process to dairy products in Part II of Chapter II, Section IX of Annex III to Regulation (EC) No 853/2004 (**DETERMINATION OF ALKALINE PHOSPHATASE ACTIVITY IN COW'S MILK)**.

	requirements are to remain in place until the food business operator has proved that the raw milk and colostrum again complies with the criteria.		
Regulation 854/2004 Annex IV, Chapter 1	**Control of milk and colostrum production holdings.** Animals on milk and colostrum holdings must be subject to official controls to verify health requirements., in particular health status and use of veterinary medicinal products. IF there are grounds to suspect health requirements are not being complied with, the general health status is to be checked, Milk and Colostrum holdings are also to undergo official controls to verify that the hygiene requirements are being complied with. If it is shown these are not being met the CA is to verify that appropriate steps are taken to correct the situation.	49	Introduction of the requirement that the official veterinarian shall verify the health requirements for raw milk and colostrum products as laid down in Part I of Chapter I of Section IX of Annex III to Regulation (EC) No 853/2004. In particular the OV shall verify; health status, absence of unauthorised pharmacologically active substances, possible presence of residues of authorised pharmacologically active substances, pesticides or contaminants does not exceed the levels laid down in Regulations (EU) No 37/2010, (EC) No 396/2005 or (EC) No 1881/2006. If there are grounds that the health requirements are not being met, the OV shall check the general health status of the animals. This will be managed through DHIs with OV oversight.
Regulation 854/2004 Annex II Chapter 1	This Annex applies to live bivalve molluscs and, by analogy, to live echinoderms, live tunicates and live marine gastropods.	51	Lists an exclusion that Title V does not apply to live marine gastropods and live *Holothuroidea* that are not filter feeders.
Regulation 854/2004 Annex II Chapter 2 Part A Paragraph 1 and 2	Classification of production and relaying areas for live bivalve molluscs	52	No change
Regulation 854/2004 Annex II Chapter 2 Part A paragraph 3	Classification requirements of Class A areas	53	No change
Regulation 854/2004 Annex II Chapter 2 Part A	Classification requirements of Class B areas	54	No change

paragraph 4			
Regulation 854/2004 Annex II Chapter 2 Part A paragraph 5	Classification requirements of Class C areas	55	No change
Regulation 854/2004 Annex II Chapter 2 Part A paragraph 6(a)(b)(c)	Requirements for deciding in principle to classify a production or relaying area it must	56	No significant change
Regulation 854/2004 Annex II Chapter 2 Part A paragraph 6(d)	establish a sampling programme of bivalve molluscs in the production area	57	No significant change
Regulation 854/2004 Annex II Chapter 2 Part A paragraph 6(d)	The competent authorities shall establish a procedure to ensure that the sanitary survey referred to in Article 56 and the monitoring programme referred to in Article 57 are representative of the area considered.	58	No significant change
Regulation 854/2004 Annex II Chapter II Part B Para 1	**Monitoring of classified production and relaying areas**	59	No significant change
Regulation 2074/2005 Annex III – Analytical methods in Chapter 1 to Chapter 3 are moved to Annex V of 2019/627	**RECOGNISED TESTING METHODS FOR DETECTING MARINE BIOTOXINS**	60	No significant change
Regulation 854/2004 Annex II Chapter II part B para 2 to 8	Sampling Plans	61	Minor Change (4) Change from 854/2004 which said that sampling frequency for toxin analysis in LBM is as a general rule to be weekly, which can be reduced in specific areas or specific types of molluscs if a risk assessment suggests a very low risk of toxic episodes. The wording “as a general rule” has been removed to read “shall be weekly” although the risk assessment still permits reduced

			sampling. (8) Change of regulation from Regulation EC No 466/2001 to Regulation (EC) No 1881/2006.
Regulation 854/2004 Annex II Chapter II Part C Para 1	Closing production area where results of sampling show the health standards are exceed or that there may be risk to health. The CA can reclassify an area as Class B or C if it meets the requirements in Part A	62	Significant Change – Flexibility When the results of microbiological monitoring show that the health standards (In Article 53, Requirement for Class A areas) are not met, the CA may, only on a temporary and non-recurring basis, on the basis of a risk assessment, permit the continued harvesting without closure or reclassification subject to a) The classified production area and all approved establishments receiving LBM are under official control of the same CA. b) The LBM are subjected to appropriate restrictive measures i.e. purification, relaying or processing. 3The accompanying registration document, as referred to in Chapter I of Section VII of Annex III to Regulation (EC) No 853/2004, shall include all the information concerning the application of paragraph 2. 4. The competent authorities shall establish the conditions under which paragraph 2 can be availed of in order to

			ensure, for the production area concerned, maintenance of the compliance with the criteria established in Article 53.
Regulation 854/2004 Annex II Chapter II Part C Para 2	Re-opening of production areas after closure due to presence of plankton or excessive levels of toxins in molluscs.	63	Minor amendment – where there was a previous generic requirement to comply with Community legislation, the specific EU Regulations have been stated in paragraph 1. Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004 and present no other risk to human health. 2. point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004, point 2 of Chapter V of Section VII of Annex III to Regulation (EC) No 853/2004
Regulation 854/2004 Annex II, Chapter 2 part D Para 1 and 2	Setting up a control system of laboratory tests to verify FBOs compliance with requirements for the end product.	64	No significant change
854/2004 Annex II, Chapter 2 part E Para (c) and Part F	act promptly where the controls prescribed in this Annex indicate that a production area must be closed or reclassified or can be re-opened. Taking into account FBO's own checks	65	Minor change – Article 65 (1) adds flexibility where live bivalve molluscs are subject to the application of measures as referred to in Article 62(2).
Regulation 854/2004 Annex II, Chapter 2, Part E, Para (a), (b)	Establish an up to date list of approved production areas and relaying areas and their classification	66	Minor change – change of wording from 'approved production area' to 'classified production area'
Regulation 854/2004 Annex III Chapter 1, para 1	List of official controls on the production and placing on the market of fishery products	67	Minor change – change of wording to include verification of compliance with the requirements set out in Section VIII of Annex III to Regulation (EC) No 853/2004,
Regulation (EC) 854/2004 Annex	Site of official controls	68	Minor Change –

III Chapter 1 Para 2			(1) change from 'may carry out' to 'shall carry out'. This does not alter the frequency of official controls on vessels and can continue on a risk basis (2) Wording has been simplified but content is the same.
Regulation (EC) 854/2004 Annex III, Chapter I, paragraph 3	Inspection of a factory or freezer vessel flying the flag of a Member State carried out with a view to the approval of the vessel, inspection of the vessel while it is at sea or when it is in a port in another Member State or in a third country. Approval of another member state to carry out inspection.	69	Minor change – Inclusion of reefer vessels. Reefer vessels have been defined in 2019/625 as 'reefer vessel' means a vessel equipped to store and transport palletized or loose cargo (bulk) goods in temperature controlled holds or chambers; They have been listed as a vessel requiring approval in the "Technical specifications in relation to the master list and the lists of EU approved food establishments and certain other specified food establishments" since at least the 2014 revision under Section 0: General activity establishments. Therefore there has been an existing requirement for them to be approved. To note, the longer approval time limits in R2017/625 - Article 148(4) apply only to factory and freezer vessels.
Regulation (EC) 854/2004 Annex III, Chapter II	Official Control of Fishery Products – official controls are to include at least the following elements organoleptic examinations, freshness indicators, histamine, residues and contaminants, microbiological checks, parasites and poisonous fishery products checks	70	Minor changes – where there was a previous generic requirement to comply with Community legislation, the specific EU Regulations have been stated in Annex VI, Chapter of 2019/627 A - Council Regulation (EC) No 2406/96 B – In accordance with Annex VI, Chapter 2 C - Regulation (EC) No 2073/2005. D

			Monitoring arrangements shall be established in accordance with Directive 96/23/EC and Decision 97/747/EC to control compliance with the EU legislation on: — maximum residue limits for pharmacologically active substances, in accordance with Regulations (EU) No 37/2010 and (EU) No 2018/470; — prohibited and non-authorised substances, in accordance with Regulation (EU) No 37/2010, Directive 96/22/EC and Decision 2005/34/EC; — contaminants, in accordance with Regulation (EC) No 1881/2006 setting maximum levels for certain contaminants in food; and — pesticide residues, in accordance with Regulation (EC) No 396/2005. E - Regulation (EC) No 2073/2005. F – Part D of Chapter III of Section VIII of Annex III to Regulation (EC) No 853/2004 and Section I of Annex II to Regulation (EC) No 2074/2005.
Regulation (EC) 854/2004 Annex III, Chapter III	**Decisions after controls** Declaring fishery products unfit for human consumption if organoleptic, chemical, physical or microbiological checks or checks for parasites have shown that they are not in compliance with the relevant Community legislation;	71	Minor changes - where there was a previous generic requirement to comply with Community legislation, the specific EU Regulations have been stated (a) Section VII of Annex III of Regulation (EC) No 853/2004 and/or Regulation (EC) No 2073/2005; (EU) No 37/2010, (EC) No 396/2005, (EC) No 1881/2006, or residues of substances that are prohibited or unauthorised in accordance with

			Regulation (EU) No 37/2010 or Directive 96/22/EC, or are not in compliance with any other relevant Union legislation on pharmacologically active substances;
Regulation (EC) 2074/2004 Article 6c	**Requirements concerning the official controls on fishery products caught by vessels flying the flag of Member States entering the Union after being transferred in third countries with or without storage**	72	Minor Changes – 2074/2005 has been amended and 854/2004 has been repealed by 2017/625 therefore references to model health certificates and provisions for lists of third countries and establishments in third countries are no longer listed in 854 (1) third countries listed as provided for in Article 126(2)(a) of Regulation (EU) 2017/625 & in accordance with the model health certificate set out in Chapter B of Part II to Annex III to Implementing Regulation (EU) 2019/628. (2) shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625 (3) third country shall be listed as provided for in Article 3 of Delegated Regulation (EU) 2019/625 and the vessel shall appear in a list as provided for in Article 5 of Delegated Regulation (EU) 2019/625.
882/2004 - Article 12(1)	CA required to designate OLs to carry out the analysis of official control samples.	2017/625 Article 37(1) - designation of official laboratories	Possibilities for designation extended to include a laboratory in a different member state
882/2004 – Article 12	CAs may designate OLs that are accredited to specific European standards to carry out the analysis of official control samples.	2017/625 Article 37(2) on the designation of OLs located in another MS or third country	More restrictive - rules specified for nominating a laboratory in a different MS, sub-contracting of analyses to other MS labs must be only to an official laboratory that is officially recognised in the receiving MS.

		2017/625 Article 37(3)	Designation of an official laboratory shall be in writing and include specified detailed descriptions
882/2004 - Article 12(2)	CA may only designate laboratories that are accredited in accordance with listed specific European Standards	2017/625 Article 37(4)	Designation conditions move beyond European standards to include principles in a list of expected criteria to be met. All OLs must be accredited in accordance with ISO Standard 17025.
882/2004 - Article 12(3)	The accreditation and assessment of testing laboratories may relate to individual tests or groups of tests.	2017/625 Article 37(5)	Inclusions for the scope of the accreditation of an official laboratory are specifically listed and more prescriptive.
		2017/625 Article 37(6)	In cases where there is a new or particularly uncommon test (and no designated OLs have capacity to perform it), CA can request laboratories which don't meet required criteria to perform the tests.
		2017/625 Article 38(1) - Obligations of official laboratories	New requirements for laboratories to immediately notify the competent authorities in case of identification of a risk, unless there a specific arrangement in place for this not to be done immediately.
		2017/625 Article 38(2)	Official laboratories to take part in inter-laboratory comparative tests and proficiency tests when requested by EU-RL or NRLs.
		2017/625 Article 38(3)	At the request of CAs, OLs shall make publicly available the names of the methods used for analyses, tests or diagnoses performed in the context of official activities.
		2017/625 Article 38(4)	At the request of CAs, OLs shall indicate, together with the results, the method used for each analysis performed in the context

			of official activities.
882/2004 - Article 12(4)	CA may cancel an OL designation when the required conditions are no longer fulfilled.	2017/625 Article 39- Audits of official laboratories	CAs will be expected to take a more proactive role in audits of OLs and organise audits of the OLs on a regular basis and as necessary. Audits can be carried out by other bodies, such as in agreement with UKAS.
		2017/625 Article 40 (1)	Introduces new derogations from the mandatory accreditation for certain official laboratories whose sole activity is the detection of Trichinella in meat; or laboratories which carry out analyses in the context of other official activities, with specific listed provisions.
		2017/625 Article 40(2)	Clarifies that results performed by laboratories subject to a derogation from mandatory accreditation must be confirmed by a lab that has full mandatory accreditation.
		2017/625 Article 40(3)	Clarifies that no designation in other MS is possible for laboratories subject to a derogation from mandatory accreditation.
		2017/625 Article 41	Delegated act concerning when derogations from mandatory accreditation will be permitted providing labs have met specified conditions.
		2017/625 Article 42	CA has flexibility to temporarily designate existing OLs located in same MS for use of a method they are not accredited for, subject to certain conditions in instances where a new method is required or in an emergency situation. The designation may only last one year and only be renewed once.
Regulation (EC) No 882/2004	Art 30(1)(c) - Without prejudice to	Art 88(2)	Schedule 4 of OFFC 2009 Regulations to

	requirements concerning official certification adopted for animal health or animal welfare purposes, requirements may be adopted, in accordance with the procedure referred to in Article 62(3), concerning: (c) qualifications of the certifying staff;		be updated.
Regulation (EC) No 882/2004	Art 30(2)(a),(b)	Art 89(1)	Need to check position re: dual language
Regulation (EC) No 882/2004	Art 54(1)	Art 138(1)	Update Schedule 4 of OFFC 2009 Regulations.
The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016	Part 1 introductory – Interpretation and scope – 2(4)(c) provides a definition of feed		We are reviewing with the VMD the definition to check the accuracy. A definition is also in the VMD 2013 Regulations, the Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016and the Official Feed and Food Controls (Wales) Regulations 2009. Discussions with the VMD is on-going.
The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016	Procedure relating to samples for analysis – 15	36	For **on-line (Internet) selling** and in order to provide national enforcers with the necessary tools, the OCR provides that: • a sample ordered on-line by the CAs without identifying themselves can be validly used for the purposes of an official control • once the CA gets the sample, they would need to inform the operator that such a sample has been taken and, where appropriate, is being analysed in

			the context of an official control. Amend Regulation 15 of The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016 – also update feed code of practice. also need to check Sections 75 and 78 of the Agriculture Act 1970 – in case amendments required there.
The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016	Secondary analysis by the Government Chemist - 16	Art 35	Provisions relating to the second expert opinion are better specified (i.e. operators, at their own expenses, have the right to request a documentary review of the sampling, analysis or diagnosis by another recognised and appropriately qualified expert, and, where relevant and technically possible, another analysis or diagnosis of the sample). Amend after Regulation 16 of the Animal Feed (Hygiene, Sampling etc and Enforcement) (England) Regulations 2015 – also need to check Sections 75 and 78 of the Agriculture Act 1970 – in case amendments required there.
The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016	Powers of entry and inspection - Article 15 of Regulation (EU) No. 2017/625 sets out requirements for the obligations of operators – in that in the performance of official controls operators shall, where required by the competent authorities give staff of the competent authorities' access to: • Equipment, means of transport, premises and other places under their control and their	Art 15	The OCR better specifies that operators, during official controls, are required to **assist and cooperate** with the staff of the CA. More specifically, to the extent necessary to perform official controls, **operators would need to give CAs access** to their: • equipment, • means of transport,

	surroundings; • Their computerised information management systems; • Animals and goods under their control; • Their documents and other relevant information.		• premises, • computers, • documents and any other relevant information • animals and goods under their controls Amend Regulation 30 of The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016
The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016	Liability for expenditure -33(1) - makes a Reference to Article 54(5) of Regulation 882/2004.	Art 138(4)	
The Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016	Liability for expenditure -33(2) - states that 'this Regulation does not apply in relation to Art 54(2)(g), (measures referred to in Art 19 on consignments from third countries), of Regulation 882/2004. The corresponding reference in Regulation (EU) No. 2017/625 appears to be Art 138(2). Additionally, Art 67 says that goods entering the Union from third countries presenting a risk – the measures referred to in the Article shall be applied at the expense of the operator responsible for the consignment.	Art 138 (2) Art 67	Amend Reg 33 of the Animal Feed (Hygiene, Sampling etc and Enforcement) (Wales) Regulations 2016
The Animal Feed (Composition, Marketing and Use) (Wales) Regulation 2016	Part 9 Amendment and Revocation – 20 (2)	-	Need to update the legislation to make reference to the following: • Animal Feed (Composition, Marketing and Use) (England)(Amendment) Regulations 2019; and

			• Animal Feed (Basic Safety Standards) (Wales) Regulations 2018
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 3.—(1) provides that Schedule 4 outlines the delegated authority and operational criteria between the FSA and local authorities ***Art 4 (1) – Regulation 882/2004*** *1. Member States shall designate the competent authorities responsible for the purposes and* *official controls set out in this Regulation.* ***Art 4 (3) – Regulation 882/2004*** *3. When a Member State confers the competence to carry out official controls on an authority or* *authorities other than a central competent authority, in particular those at regional or local level, efficient and effective coordination shall be ensured between all the competent authorities involved, including where appropriate in the field of environmental and health protection.*	Art 4	Schedule 4 of OFFC 2009 Regulations to be updated.
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 12 – provides details of right of appeal. This covered by Article 19(4) of Regulation (EC) No 882/2004 on official controls performed to ensure the verification of compliance with feed and food law, animal health and animal welfare rules 2004	Article 7	References to Regulation 882/2004 need to be amended to state Regulation 2017/625
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 22 provides a definition of 'feed'.		Reviewing with the VMD the definition to check the accuracy. A definition is also in the VMD 2013 Regulations, and 2015 Animal Feed (Hygiene, Sampling etc, Enforcement) Regulations and OFFC

			2009 Regulations. Discussions with the VMD is on-going.
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 22 provides explanation of 'product' making reference to Article 15 of Regulation 882/2004.	Article 44	This reference should be amended to read 'Article 44 of Regulation (EU) No. 2017/625'
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 25 makes reference to Art 24 of Regulation and Art 10 of Regulation 669/2009 in terms of the functions of the Commissioners.	Art 75(1), Art 57, Art 46 and Art 76	In terms of Art 75(1) and 46 it is proposed that Schedule 4 of the OFFC Regulations 2009 are amended and that guidance on local authority controls and the feed code of practice are updated.
Official Feed and Food Controls (Wales) Regulations 2009	Regulation 29(1) (2) and (3) outlines the checks on feed and food of non – animal origin that need to be undertaken under Art 16 of Regulation 882/2004.	Art 45(1), 44(2), 45(2) and Art 34(5)	No action is required.
-	No equivalent in Regulation 882/2004	Art 38 – obligations of official laboratories	Need to be designated as competent authority. Updated Schedule 4 and Regulation 3 of OFFC 2009 Regulations. Need to liaise with SERD and Imports.
-	No equivalent in Regulation 882/2004	Art 75	Amend Schedule 4 of OFFC 2009 Regulations.