

Agenda – Legislation, Justice and Constitution Committee

Meeting Venue:	For further information contact:
Video Conference via Zoom	P Gareth Williams
Meeting date: 10 January 2022	Committee Clerk
Meeting time: 13.30	0300 200 6565
	SeneddLJC@senedd.wales

Informal pre-meeting (13.00–13.30)

1 Introductions, apologies and substitutions

13.30

**2 Instruments that raise no reporting issues under Standing Order
21.2 or 21.3**

13.30–13.35

(Pages 1 – 2)

Attached Documents:

LJC(6)–01–22 – Paper 1 – Statutory instruments with clear reports

Made Negative Resolution Instruments

**2.1 SL(6)109 – The M48 Motorway (Eastbound and Westbound Exit Slip Roads at
Junction 2 (Newhouse Roundabout), Chepstow) (40 mph Speed Limit)
Regulations 2021**

**2.2 SL(6)111 – The Equality Act 2010 (Disabled School Pupils) (Wales)
Regulations 2021**

**2.3 SL(6)113 – The Federation of Maintained Schools (Wales) (Amendment)
Regulations 2021**



3 Instruments that raise issues to be reported to the Senedd under Standing Order 21.2 or 21.3

13.35–13.45

Made Negative Resolution Instruments

3.1 SL(6)102 – The Education (Student Fees, Awards and Support) (Amendment) (Wales) Regulations 2021

(Pages 3 – 4)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)–01–22 – Paper 2 – Draft report

3.2 SL(6)110 – The Eligible Community Councils (General Power of Competence) (Qualifications of Clerks) (Wales) Regulations 2021

(Pages 5 – 6)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)–01–22 – Paper 3 – Draft report

3.3 SL(6)104 – The Health Protection (Coronavirus, International Travel and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) (No. 4) Regulations 2021

(Pages 7 – 11)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)–01–22 – Paper 4 – Draft report

LJC(6)–01–22 – Paper 5 – Letter from the Minister for Health and Social Services to the Llywydd, 6 December 2021

3.4 SL(6)112 – The Health Protection (Coronavirus, International Travel and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) (No. 5) Regulations 2021

(Pages 12 – 16)

Attached Documents:

LJC(6)-01-22 – Paper 6 – Draft report

LJC(6)-01-22 – Paper 7 – Letter from the Minister for Health and Social Services to the Llywydd, 14 December 2021

3.5 SL(6)117 – The Coronavirus Act 2020 (Residential Tenancies: Extension of Period of Protection from Eviction) (No. 4) (Wales) Regulations 2021

(Pages 17 – 21)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 8 – Draft report

LJC(6)-01-22 – Paper 9 – Letter from the Minister for Climate Change to the Llywydd, 17 December 2021

3.6 SL(6)120 – The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 24) Regulations 2021

(Pages 22 – 26)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 10 – Draft report

LJC(6)-01-22 – Paper 11 – Letter from the First Minister to the Llywydd, 21 December 2021

3.7 SL(6)125 – The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 26) Regulations 2021

(Pages 27 – 31)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 12 – Draft report

LJC(6)-01-22 – Paper 13 – Letter from the First Minister to the Llywydd, 30 December 2021

Composite Negative Resolution Instrument

3.8 SL(6)106 – The Education (Student Loans) (Repayment) (Amendment) (No. 4) Regulations 2021

(Pages 32 – 33)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 14 – Draft report

Affirmative Resolution Instruments

3.9 SL(6)105 – The Council Tax Reduction Schemes (Prescribed Requirements and Default Scheme) (Wales) (Amendment) Regulations 2022

(Pages 34 – 36)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 15 – Draft report

Made Affirmative Resolution Instruments

3.10 SL(6)108 – The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 22) Regulations 2021

(Pages 37 – 40)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 16 – Draft report

LJC(6)-01-22 – Paper 17 – Letter from the First Minister to the Llywydd, 10 December 2021

**3.11 SL(6)118 – The Health Protection (Coronavirus Restrictions) (No. 5) (Wales)
(Amendment) (No. 23) Regulations 2021**

(Pages 41 – 45)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 18 – Draft report

LJC(6)-01-22 – Paper 19 – Letter from the First Minister to the Llywydd – 17
December 2021

**3.12 SL(6)124 – The Health Protection (Coronavirus Restrictions) (No. 5) (Wales)
(Amendment) (No.25) Regulations 2021**

(Pages 46 – 51)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 20 – Draft report

LJC(6)-01-22 – Paper 21 – Letter from the First Minister to the Llywydd, 22
December 2021

**3.13 SL(6)122 – The Landfill Disposals Tax (Tax Rates) (Wales) (Amendment)
Regulations 2021**

(Pages 52 – 54)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 22 – Draft report

LJC(6)-01-22 – Paper 23 – Letter from the Minister for Finance and Local
Government to the Llywydd, 20 December 2021

**4 Instruments previously considered for sifting and now subject to
scrutiny under Standing Orders 21.2 and 21.3**

13.45–13.50

4.1 SL(6)107 – The Food Information (Wales) (Amendment) Regulations 2021

(Pages 55 – 56)

[Regulations](#)

[Explanatory Memorandum](#)

Attached Documents:

LJC(6)-01-22 – Paper 24 – Draft report

5 Common Frameworks

13.50–13.55

5.1 Provisional organs, tissues and cells (apart from embryos and gametes) common framework

(Pages 57 – 97)

Attached Documents:

LJC(6)-01-22 – Paper 25 – Letter from the Minister for Health and Social Services, 3 December 2021

LJC(6)-01-22 – Paper 26 – The Organs, Tissues and Cells (apart from embryos and gametes) Provisional Common Framework

LJC(6)-01-22 – Paper 27 – Letter from the Health and Social Care Committee to the Minister for Health and Social Services, 17 December 2021

5.2 Provisional blood safety and quality common framework

(Pages 98 – 143)

Attached Documents:

LJC(6)-01-22 – Paper 28 – Letter from the Minister for Health and Social Services, 3 December 2021

LJC(6)-01-22 – Paper 29 – The Blood Safety and Quality Provisional Common Framework

LJC(6)-01-22 – Paper 30 – Letter from the Health and Social Care Committee to the Minister for Health and Social Services, 17 December 2021

5.3 Correspondence with the House of Lords Common Frameworks Scrutiny Committee: Scrutiny of the Common Frameworks Programme

(Pages 144 – 151)

Attached Documents:

LJC(6)–01–22 – Paper 31 – Letter from Baroness Andrews, Chair of the Common Frameworks Scrutiny Committee, 14 December 2021

LJC(6)–01–22 – Paper 32 – Letter to Baroness Andrews, Chair of the Common Frameworks Scrutiny Committee, 1 December 2021

6 Inter–Institutional Relations Agreement

13.55–14.00

6.1 Correspondence from the Minister for Climate Change: Inter–Ministerial Group on Environment, Food and Rural Affairs

(Pages 152 – 153)

Attached Documents:

LJC(6)–01–22 – Paper 33 – Letter from the Minister for Climate Change, 31 December 2021

7 Papers to note

14.00–14.10

7.1 Written statement by the Welsh Government: Public Service Pensions and Judicial Offices Bill

(Pages 154 – 155)

Attached Documents:

LJC(6)–01–22 – Paper 34 – Written statement by the Welsh Government, 6 December 2021

7.2 Correspondence from the Minister for Climate Change: Response to the Committee's reports on the Legislative Consent Memoranda on the Leasehold Reform (Ground Rent) Bill

(Pages 156 – 158)

Attached Documents:

LJC(6)-01-22 – Paper 35 – Letter from the Minister for Climate Change, 13 December 2021

7.3 Correspondence from the Minister for Finance and Local Government:

Legislative Consent Memorandum on the Rating (Coronavirus) and Directors Disqualification (Dissolved Companies) Bill

(Pages 159 – 160)

Attached Documents:

LJC(6)-01-22 – Paper 36 – Letter from the Minister for Finance and Local Government to the Llywydd, 16 December 2021

7.4 Correspondence from the Local Government and Housing Committee:

Legislative Consent Memorandum on the Building Safety Bill

(Pages 161 – 162)

Attached Documents:

LJC(6)-01-22 – Paper 37 – Letter from the Chair of the Local Government and Housing Committee, 17 December 2021

7.5 Correspondence from the Minister for Climate Change: Response to the Committee's report on the Legislative Consent Memorandum on the Building Safety Bill

(Pages 163 – 166)

Attached Documents:

LJC(6)-01-22 – Paper 38 – Letter from the Minister for Climate Change, 4 January 2022

7.6 Correspondence from the Minister for Finance and Local Government:

Response to the Committee's report on the Legislative Consent Memorandum on the Subsidy Control Bill

(Pages 167 – 168)

Attached Documents:

LJC(6)-01-22 – Paper 39 – Letter from the Minister for Finance and Local Government, 6 January 2022

7.7 Correspondence from the Minister for Rural Affairs and North Wales, and Trefnydd: Whelk Fishing Permit (Wales) Order 2021

(Pages 169 – 171)

Attached Documents:

LJC(6)-01-22 – Paper 41 – Letter from the Minister for Rural Affairs and North Wales, and Trefnydd, 9 December 2021

LJC(6)-01-22 – Paper 42 – Written statement by the Welsh Government, 9 December 2021

7.8 Correspondence from the Law Commission: The Law Commission's Report on Devolved Tribunals in Wales

(Page 172)

Attached Documents:

LJC(6)-01-22 – Paper 43 – Correspondence from the Law Commission, 13 December 2021

7.9 Correspondence from the Minister for Education and Welsh Language: Relationships and Sexuality Education (RSE) Draft Code

(Pages 173 – 176)

Attached Documents:

LJC(6)-01-22 – Paper 44 – Letter from the Minister for Education and Welsh Language to Members of the Senedd, 14 December 2021

7.10 Correspondence from the Minister for Rural Affairs and North Wales, and Trefnydd: The Approved Country Lists (Animals and Animal Products) (Amendment) (No. 2) Regulations 2021

(Pages 177 – 178)

Attached Documents:

LJC(6)-01-22 – Paper 45 – Letter from the Minister for Rural Affairs and North Wales, and Trefnydd, 17 December 2021

7.11 Correspondence from the Minister for Rural Affairs and North Wales, and Trefnydd: The Official Controls (Extension of Transitional Periods) (Amendment) (No. 2) Regulations 2021

(Pages 179 – 180)

Attached Documents:

LJC(6)-01-22 – Paper 46 – Letter from the Minister for Rural Affairs and North Wales, and Trefnydd, 20 December 2021

7.12 Correspondence from the Minister for Rural Affairs and North Wales, and Trefnydd: The Official Controls (Temporary Measures) (Coronavirus) (Amendment) (No.3) Regulations 2021

(Pages 181 – 184)

Attached Documents:

LJC(6)-01-22 – Paper 47 – Letter from the Minister for Rural Affairs and North Wales, and Trefnydd, 6 January 2022

LJC(6)-01-22 – Paper 48 – Written statement by the Welsh Government, 5 January 2022

7.13 Correspondence from the Chair of the Public Accounts and Public Administration Committee to the Chief Executive and Clerk, Senedd Commission: Use of the term BAME

(Pages 185 – 186)

Attached Documents:

LJC(6)-01-22 – Paper 49 – Letter from Correspondence from the Chair of the Public Accounts and Public Administration Committee, 10 December 2021

7.14 Correspondence from the First Minister: Protocol on scrutiny of regulations arising from the UK's exit from the European Union

(Pages 187 – 188)

Attached Documents:

LJC(6)-01-22 – Paper 50 – Letter from the First Minister, 29 December 2021

8 Motion under Standing Order 17.42 to resolve to exclude the public from the remainder of the meeting

14.10

9 Supplementary Legislative Consent Memorandum (Memorandum No. 3) on the Skills and Post-16 Education Bill

14.10-14.30

(Pages 189 – 217)

[Supplementary Legislative Consent Memorandum \(Memorandum No. 3\) – Skills and Post-16 Education Bill](#)

Attached Documents:

LJC(6)-01-22 – Paper 51 – Legal advice note

LJC(6)-01-22 – Paper 52 – Letter from the Minister for Education and Welsh Language to the Secretary of State for Education, 13 December 2021

LJC(6)-01-22 – Paper 53 – Draft report

10 Supplementary Legislative Consent Memorandum (Memorandum No. 3) on the Police, Crime, Sentencing and Courts Bill

14.30-14.50

(Pages 218 – 261)

[Supplementary Legislative Consent Memorandum \(Memorandum No. 3\) – Police, Crime, Sentencing and Courts Bill](#)

Attached Documents:

LJC(6)-01-22 – Paper 54 – Legal advice note

LJC(6)-01-22 – Paper 55 – Draft report

11 International agreements considered on 13 December 2021 – Consideration of draft report

14.50-14.55

(Pages 262 – 265)

Attached Documents:

LJC(6)-01-22 – Paper 56 – Draft report

Statutory Instruments with Clear Reports 10 January 2021

SL(6)109 – The M48 Motorway (Eastbound and Westbound Exit Slip Roads at Junction 2 (Newhouse Roundabout), Chepstow) (40 mph Speed Limit) Regulations 2021

Procedure: Made Negative

These [Regulations](#) introduce, on safety grounds, a reduction of the maximum speed limit to 40mph on lengths of the eastbound and westbound exit slip roads of the M48 Motorway at Junction 2 (Newhouse Roundabout) in the County of Monmouthshire.

Parent Act: Road Traffic Regulation Act 1984

Date Made: 10 December 2021

Date Laid: 13 December 2021

Coming into force date: 12 January 2022

SL(6)111 – The Equality Act 2010 (Disabled School Pupils) (Wales) Regulations 2021

Procedure: Made Negative

The purpose of this [statutory instrument](#) is to make regulations about the duties on local authorities under the Equality Act 2010 that relate to disability discrimination in schools. The regulations set out arrangements a local authority must make to provide advice and information about disability discrimination in schools to disabled pupils. They also make provision about the appointment of independent persons to facilitate the resolution of disputes about disability discrimination in schools. Finally, the regulations makes provision about the appointment of persons to provide independent advocacy services for disabled pupils.

Parent Act: Equality Act 2010

Date Made: 13 December 2021

Date Laid: 14 December 2021

Coming into force date: 5 January 2022



SL(6)113 – The Federation of Maintained Schools (Wales) (Amendment) Regulations 2021

Procedure: Made Negative

[The Federation of Maintained Schools \(Wales\) \(Amendment\) Regulations 2021](#) (“the Amendment Regulations”) amend the Federation of Maintained Schools (Wales) Regulations 2014 (“the 2014 Regulations”).

The 2014 Regulations set out the process local authorities and governing bodies are required to follow to federate, de-federate or dissolve a federation, set out the constitution and membership of a federated governing body, impose a cap on the number of schools which may federate, and set out the governance framework within which federated governing bodies operate and conduct their business.

Regulation 15(3) of the 2014 Regulations provides disqualification criteria for teacher governors if that person:

- (a) has previously been elected as a teacher governor to the same governing body within the last two years; or
- (b) is employed to work at the same federated school as any person elected as a teacher governor to that governing body within the last two years.

Regulation 16 provides the same criteria for staff governors.

These criteria provide an anomaly for federated governing bodies of two schools making it unnecessarily difficult to comply with the constitution requirements and have proper representation from each school on the governing body.

The Amendment Regulations provide that subparagraphs (a) and (b) above will not apply to federations made up of two schools, so that a person may be elected as a teacher or staff governor despite working at the same federated school as a previous teacher or staff governor who served within the past two years.

Parent Act: Education Act 2002

Date Made: 12 December 2021

Date Laid: 15 December 2021

Coming into force date: 4 February 2022



SL(6)102 - The Education (Student Fees, Awards and Support) (Amendment) (Wales) Regulations 2021

Background and Purpose

These [Regulations](#) amend seven sets of regulations concerning student finance. The student finance regulations amended by these Regulations contain criteria pursuant to which certain groups may be eligible for student support, home fee status and the tuition fee cap.

These Regulations amend student finance regulations as follows:

- Irish nationals resident in the EU before studying in Wales: the amendments make provision for Irish nationals studying in Wales who were resident in the EEA and Switzerland at the end of the transition period to be eligible for home fee status and fee support so that their position is comparable to that of a UK national;
- EU Withdrawal Agreement, EEA EFTA separation agreement and Swiss citizens' rights agreement: amendments relate to:
 - the rights of those making late applications to the EU Settlement Scheme and to future joining family members who have yet to apply and are still within the deadline for doing so; and
 - updates to the definition of a person with protected rights to ensure that the student finance regulations confer protections:
 - on a person, including a person who has submitted a late application, while their application is pending and during any appeal against a refusal of their application; and
 - on a person within the deadline for making an application, including a person joining a family member during the initial three months following their arrival in the UK; and
- Student support for those from Crown Dependencies: amendments to ensure that persons (other than certain Irish citizens) who come to Wales from the Isle of Man and the Channel Islands for the purpose of study are not eligible for support (the Explanatory Memorandum explains that this corrects an unintended consequence of previous amendments).

These Regulations came into force on 31 December 2021.

Procedure

Negative.



The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

The following point is identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements.

Regulation 56 of these Regulations inserts new paragraph 8BA in Schedule 2 to the Education (Student Support) (Postgraduate Master's Degrees) (Wales) Regulations 2019. Paragraph 8BA(2) refers to paragraph 1(5), but that reference appears to be erroneous – paragraph 1(5) defines the scope of citizens' rights provisions and does not relate to whether a person is treated as being ordinarily resident.

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument.

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd.

The preamble to these Regulations explains that they are made in exercise of the powers under sections 22(2)(a) and 42(6) of the Teaching and Higher Education Act 1998, amongst other powers.

The Explanatory Memorandum states that these Regulations are also made under section 22(2)(d) of the Teaching and Higher Education Act 1998. This appears to be an error. The power under section 22(2)(d) does not appear to be relevant to the scope of these Regulations.

Welsh Government is asked to confirm that the Explanatory Memorandum is incorrect and that it did not intend to rely on the enabling power under section 22(2)(d) of the Teaching and Higher Education Act 1998.

Welsh Government response

A Welsh Government response is required.

Legal Advisers

Legislation, Justice and Constitution Committee

5 January 2022



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

—
Welsh Parliament

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Legislation, Justice and Constitution Committee

SL(6)110 - The Eligible Community Councils (General Power of Competence) (Qualifications of Clerks) (Wales) Regulations 2021

Background and Purpose

These [Regulations](#) are made by the Welsh Ministers in exercise of the power conferred on them by section 30(3) of the Local Government and Elections (Wales) Act 2021 ("the 2021 Act").

These Regulations specify the qualifications that the clerk to a community council must hold in order for the community council to meet one of the three eligibility conditions to become an 'eligible community council' under section 30 of the 2021 Act, enabling the council to exercise the general power of competence. The clerk of a community council must hold at least one of the following qualifications:

- a Certificate in Local Council Administration (CiLCA)
- a Certificate of Higher Education in Community Governance
- a Certificate of Higher Education in Community Engagement and Governance; and
- a Certificate of Higher Education in Local Policy.

The Regulations come into force on 5 May 2022.

Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues or public policy likely to be of interest to the Senedd.



The Committee note that a new Regulatory Impact Assessment (RIA) has not been prepared as part of the Regulations. The likely costs and benefits of complying with the Regulations were assessed as part of the [RIA](#) for the 2021 Act (pp 125-126). The Welsh Government's Explanatory Memorandum provides that following a review of the RIA, it remained robust aside from one further cost being identified. On that basis, it was not considered necessary to carry out a new RIA. The Explanatory Memorandum further provides that:

"There is one addition to the RIA to the 2021 Act, specifically relating to paragraphs 10.56 to 10.61. It emerged during consultation that there was not full bilingual provision for the training and assessment of the Certificate in Local Council Administration (CiLCA). Bilingual provision enables clerks to undertake CiLCA in the language of their choice and supports the objectives of the Cymraeg 2050 Welsh language strategy to increase usage of the language. Securing the relevant translated materials and access to Welsh speaking assessors will cost £7,000 in the 2021-22 financial year. This cost will be met by Welsh Government."

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

21 December 2021



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament

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Legislation, Justice and Constitution Committee

SL(6)104 - The Health Protection (Coronavirus, International Travel and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) (No. 4) Regulations 2021

Background and Purpose

These Regulations amend the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020 (“the International Travel Regulations”) and the Health Protection (Coronavirus, Public Health Information for Persons Travelling to Wales etc.) Regulations 2020 (“the Passenger Information Regulations”).

These Regulations amend the International Travel Regulations, with effect from 4am 7 December 2021, so that:

- Fully vaccinated travellers above a certain age arriving in Wales from outside the Common Travel Area must now take a pre-departure test (those travelling from red-list countries remain prohibited from travelling to Wales) unless they meet specific exemptions;
- The age threshold for application of the above requirement has changed from 11 to 12 years old;
- The time before departure at which a pre-departure test must be taken has been reduced to no more than 48 hours prior to departure.

Before these amendments came into force, the position was that:

- Fully vaccinated travellers did not need to take a pre-departure test;
- The age threshold for application of the requirement for unvaccinated travellers to take a pre-departure test was 11 years old;
- The time before departure at which a pre-departure test must be taken was no more than 72 hours prior to departure.

The changes are being brought in to address the threat to public health posed by the Omicron variant, which may have a greater impact on vaccinated persons than current variants.

As a result of these changes to the International Travel Regulations, consequential changes are made to the Passenger Information Regulations to ensure the correct information is provided to travellers.



Procedure

Negative

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the breach of the 21-day rule (i.e. the rule that 21 days should pass between the date a “made negative” instrument is laid before the Senedd and the date the instrument comes into force), and the explanation for the breach provided by Eluned Morgan MS, Minister for Health and Social Services, in a letter to the Llywydd dated 6 December 2021.

“Not adhering to the 21 day convention allows these Regulations to come into force at the earliest opportunity and continue the four nation approach to international travel; in view of the changing evidence on risk in relation to this disease this is considered necessary and justifiable in this case.”

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the Welsh Government’s justification for any potential interference with human rights. In particular, we note the following paragraph in the Explanatory Memorandum:

“The amendments contained in these Regulations do not change the engagement under the International Travel Regulations of individual rights under the Human Rights Act 1998 and the European Convention on Human Rights; the Government considers that they are justified for the purpose of preventing the spreading of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate.”

3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:



“Given the serious and imminent threat arising from coronavirus and the need for an urgent public health response, there has been no public consultation in relation to these Regulations.”

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

10 December 2021



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament

Legislation, Justice and Constitution Committee

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Elin Jones, MS
Llywydd
Senedd Cymru
Cardiff Bay
CF99 1SN

6 December 2021

Dear Elin

The Health Protection (Coronavirus, International Travel and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) (No. 4) Regulations 2021

In accordance with sections 4(1) and 11A(4) of the Statutory Instruments Act 1946 I am notifying you that this Statutory Instrument has not adhered to the 21 day convention and will come into force at 04:00 hours on Tuesday 6 December, before it can be laid. I intend to lay this and an accompanying Explanatory Memorandum tomorrow.

This statutory instrument amends the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020, so that:

- Fully vaccinated travellers above a certain age arriving in Wales from outside the Common Travel Area must now take a pre-departure test (those travelling from red-list countries remain prohibited from travelling to Wales) unless they meet specific exemptions;
- The age threshold for application of the above requirement has changed from 11 to 12 years old;
- The time before departure at which a pre-departure test must be taken has been reduced to no more than 48 hours prior to departure.

In consequence of these changes, this statutory instrument also makes changes to the Health Protection (Coronavirus, Public Health Information for Persons Travelling to Wales etc.) Regulations 2020.

Bae Caerdydd • Cardiff Bay
Caerdydd • Cardiff
CF99 1SN

Canolfan Cyswllt Cyntaf / First Point of Contact Centre:
0300 0604400

Gohebiaeth.Eluned.Morgan@llyw.cymru
Correspondence.Eluned.Morgan@gov.wales

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Not adhering to the 21 day convention allows these Regulations to come into force at the earliest opportunity and continue the four nation approach to international travel; in view of the changing evidence on risk in relation to this disease this is considered necessary and justifiable in this case.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. E. Morgan'.

Eluned Morgan AS/MS

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

Agenda Item 3.4

SL(6)112 - The Health Protection (Coronavirus, International Travel and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) (No. 5) Regulations 2021

Background and Purpose

[The Health Protection \(Coronavirus, International Travel and Public Health Information to Travellers\) \(Wales\) \(Miscellaneous Amendments\) \(No. 5\) Regulations 2021](#) (“the Regulations”) amend the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020 (“the International Travel Regulations”) and the Health Protection (Coronavirus, Public Health Information for Persons Travelling to Wales etc.) Regulations 2020 (“Public Health Information Regulations”). The Public Health (Control of Disease) Act 1984, and regulations made under it, provide a legislative framework for health protection in England and Wales, and the Regulations are made in reliance on the powers in sections 45B, and 45P(2) of that Act.

The International Travel Regulations impose requirements on persons entering Wales after having been abroad. Non-exempt persons are prohibited from entering Wales where they have been in a country or territory listed in Schedule 3A (countries and territories subject to additional measures) (“red list countries”) to the International Travel Regulations within the last 10 days of arrival, pursuant to regulation 12E (additional measures applicable to persons travelling from a country or territory listed in Schedule 3A) of the International Travel Regulations.

Regulation 2 of the Regulations amends Schedule 3A to remove all countries from the list of countries or territories to which regulation 12E applies. The removal of all red list countries is made in response to community transmission of Omicron now being widespread in both the UK and non-red list countries. However, although now empty, the red list is maintained in the International Travel Regulations to facilitate a fast response to emerging variants.

The Public Health Information Regulations impose requirements on operators of international passenger services coming from outside the common travel area to an airport, heliport or seaport in Wales to provide passengers with specified public health information.

Regulation 3 of the Regulations amends the Public Health Information Regulations to ensure that the information that operators are required to provide to passengers travelling to the UK from outside the common travel area is consistent across the UK.

The changes made by the Regulations came into effect from 04:00 hours on Wednesday 15 December 2021.



Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following 3 points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the breach of the 21-day rule (i.e. the rule that 21 days should pass between the date a “made negative” instrument is laid before the Senedd and the date the instrument comes into force), and the explanation for the breach provided by Eluned Morgan MS, Minister for Health and Social Services, in a letter to the Llywydd dated 14 December 2021. In particular, we note the following in the letter:

“Not adhering to the 21 day convention allows these Regulations to come into force at the earliest opportunity and continue the four nation approach to international travel; in view of the changing evidence on risk in relation to this disease this is considered necessary and justifiable in this case.”

We note also that the letter refers to the breach of section 4(1) of the Statutory Instruments Act 1946, which requires that an instrument is laid before it comes into force, but where it is not:

“... notification shall forthwith be sent ... drawing attention to the fact that copies of the instrument have yet to be laid ... and explaining why such copies were not so laid before the instrument came into operation.”

Whereas the letter identifies that section 4(1) has not been complied with, it does not go on to explicitly set out the reason for the breach as required. However, on this occasion, we read the penultimate paragraph of the letter, which sets out the reason for breach of the 21-day rule, to also explain the reason for the breach of section 4(1). The reason for future breaches of section 4(1) should, however, be set out in the appropriate letter accompanying the instrument in question.



2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the Welsh Government's justification for any potential interference with human rights. In particular, we note the following paragraph in the Explanatory Memorandum:

"The amendments contained in these Regulations do not change the engagement under the International Travel Regulations of individual rights under the Human Rights Act 1998 and the European Convention on Human Rights; the Government considers that they are justified for the purpose of preventing the spreading of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate."

3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

"Given the serious and imminent threat arising from coronavirus and the need for an urgent public health response, there has been no public consultation in relation to these Regulations."

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

20 December 2021



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

—

Welsh Parliament **Pack Page 14**

Legislation, Justice and Constitution Committee



Elin Jones, MS
Llywydd
Senedd Cymru
Cardiff Bay
CF99 1SN

14 December 2021

Dear Elin

The Health Protection (Coronavirus, International Travel and Public Health Information to Travellers) (Wales) (Miscellaneous Amendments) (No. 5) Regulations 2021

In accordance with sections 4(1) and 11A(4) of the Statutory Instruments Act 1946 I am notifying you that this statutory instrument has not adhered to the 21 day convention and will come into force at 04:00 hours on Wednesday 15 December, before it can be laid. I attach a copy of the statutory instrument and I intend to lay this and an accompanying Explanatory Memorandum on 15 December.

This statutory instrument amends the Health Protection (Coronavirus, International Travel) (Wales) Regulations 2020, to:

- Remove 11 countries from the red list;
- Make minor amendments to the Passenger Information Regulations.

The removal of all red list countries is made in response to community transmission of Omicron now being widespread in both the UK and non-red list countries. However, although now empty, the red list is maintained in the International Travel Regulations to facilitate a fast response to emerging variants.

Minor changes are made to Part 1 to the Passenger Information Regulations to ensure that these Regulations are consistent in the terminology used.

Not adhering to the 21 day convention allows these Regulations to come into force at the earliest opportunity and continue the four nation approach to international travel; in view of the changing evidence on risk in relation to this disease this is considered necessary and justifiable in this case.

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Correspondence.Eluned.Morgan@gov.wales

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. E. Morgan'.

Eluned Morgan AS/MS

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services

SL(6)117 - The Coronavirus Act 2020 (Residential Tenancies: Extension of Period of Protection from Eviction) (No. 4) (Wales) Regulations 2021

Background and Purpose

Section 81 and Schedule 29 to the Coronavirus Act 2020 provide protection from eviction by increasing the notice period a landlord is required to give a tenant when seeking possession.

These Regulations extend until 24 March 2022 (from the previous end date of 31 December 2021) the period ('the relevant period') during which increased notice must be given to tenants granted tenancies under the Rent Act 1977 and the Housing Acts 1985, 1988 and 1996.

Procedure

Negative

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following points are identified for reporting under Standing Order 21.3 in respect of this instrument:

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the breach of the 21-day rule (i.e. the rule that 21 days should pass between the date a negative instrument is laid before the Senedd and the date the instrument comes into force), and the explanation for the breach provided by Julie James MS, Minister for Climate Change in a letter to the Llywydd dated 17 December 2021.

In particular, we note what the letter says regarding why these regulations breach the 21 day rule:

"In the light of the ongoing pandemic, and during a time when there remains a serious threat to public health, both as a result of Covid-19 case rates remaining high overall and



concern regarding the emergence of the new Omicron variant, the Welsh Ministers have concluded that there remains an urgent need to ensure that the number of tenants under threat of eviction from their homes is kept as low as possible. Doing so will assist with the containment of coronavirus, ease the burden on frontline staff, and ensure tenants are provided with appropriate support. The Regulations make an important contribution to meeting that urgent need. In order to ensure that the provisions of Schedule 29 continue to apply after 31 December 2021, the Regulations come into force on 31 December. Due to their urgency, the Regulations have not been subject to consultation and there has been insufficient time to carry out a Regulatory impact Assessment in relation to them.”

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

These Regulations engage a landlord’s rights under Article 1 Protocol 1 of the European Convention on Human Rights (“A1P1”). The Committee note that the Regulations will only extend the relevant period for a specified period (up to 24 March 2022).

We note the Welsh Government’s justification for any potential interference with human rights. In particular, we note the following paragraph in the Explanatory Memorandum:

“Since the time when the relevant period was last extended, there have been improvements in the public health situation as a consequence of the success of the vaccine programme. However, there has been a recent increase in case numbers which has led to an increase in hospitalisations, albeit at a lower rate than was the case before the roll out of the vaccination programme. The recent emergence of a new variant (Omicron) is of significant concern. As of 10 December 2021, Wales is remaining at Covid stable (Alert Level 0). However further guidance has been provided regarding additional testing and the use of face masks in hospitality settings. The most recent short to medium term projections show that the new variant is projected to cause a spike in infection and could very quickly overtake “Delta” as the dominant strain across the UK. Therefore, in light of increasing case rates overall and the threat from Omicron, delaying evictions will continue to help control the transmission of Covid-19.

Generally, the virus remains a serious threat to public health, which would be significantly exacerbated if the current wave of cases were accompanied by a sudden wave of evictions and a resultant increase in homelessness. This will remain the case as we move through the winter months, where the impact of Covid-19, in conjunction with a possible resurgence in influenza infections and other normal winter pressures, may place the health service under significant strain. In these circumstances, taking continued action to limit the risk of a sudden spike in evictions so that public health continues to be protected, is considered appropriate.”



3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues or public policy likely to be of interest to the Senedd.

We note that there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

“Given the emergency, it has not been possible to conduct any consultation on these Regulations and there is no statutory requirement to do so. However, the Welsh Government has strong relationships with stakeholders from across the housing sector; bodies representing landlords have been informally engaged on the purpose and effect of these Regulations.”

4. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues or public policy likely to be of interest to the Senedd.

The Committee note that no regulatory impact assessment has been prepared for these Regulations and the Explanatory Memorandum states:

“The COVID-19 emergency and the urgency of making these Regulations means it has not been possible to prepare a quantified Regulatory Impact Assessment. ”

The Committee notes that section 6 of the Explanatory Memorandum attempts to set out a summary of the potential impact of these Regulations which does provide some qualitative assessment.

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

21 December 2021



Julie James AS/MS
Y Gweinidog Newid Hinsawdd
Minister for Climate Change



Llywodraeth Cymru
Welsh Government

Our ref MA/JJ/4427/21
Eich cyf/Your ref

Elin Jones MS
Llywydd
Senedd Cymru
Cardiff Bay
CARDIFF
CF99 1SN

17 December 2021

Dear Elin

The Coronavirus Act 2020 (Residential Tenancies: Extension of Period of Protection from Eviction) (No.4) (Wales) Regulations 2021

In accordance with section 11A(4) of the Statutory Instruments Act 1946, as inserted by Schedule 10 paragraph 3 of the Government of Wales Act 2006, I am notifying you that this statutory instrument will come into force on 31 December 2021, less than 21 days after it has been laid. A copy of the instrument and the Explanatory Memorandum that accompanies it are attached for your information.

The Regulations amend paragraph 1(1) of Schedule 29 to the Coronavirus Act 2020 (“the 2020 Act”) by extending until 24 March 2022, which is when the Coronavirus Act 2020 expires, the relevant period during which Schedule 29 applies.

The effect of these changes will be to extend the period during which landlords, in most circumstances, will need to provide tenants with increased notice before starting possession proceedings in the courts.

In the light of the ongoing pandemic, and during a time when there remains a serious threat to public health, both as a result of Covid-19 case rates remaining high overall and concern regarding the emergence of the new Omicron variant, the Welsh Ministers have concluded that there remains an urgent need to ensure that the number of tenants under threat of eviction from their homes is kept as low as possible. Doing so will assist with the

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

containment of coronavirus, ease the burden on frontline staff, and ensure tenants are provided with appropriate support. The Regulations make an important contribution to meeting that urgent need. In order to ensure that the provisions of Schedule 29 continue to apply after 31 December 2021, the Regulations come into force on 31 December. Due to their urgency, the Regulations have not been subject to consultation and there has been insufficient time to carry out a Regulatory impact Assessment in relation to them.

I am copying this letter to the Minister for Rural Affairs, North Wales and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee,, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely,



Julie James AS/MS

Y Gweinidog Newid Hinsawdd
Minister for Climate Change

Agenda Item 3.6

SL(6)120 - The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 24) Regulations 2021

Background and Purpose

Part 2A of the Public Health (Control of Disease) Act 1984 ("the 1984 Act") enables the Welsh Ministers, by regulations, to make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in Wales.

[The Health Protection \(Coronavirus Restrictions\) \(No. 5\) \(Wales\) \(Amendment\) \(No. 24\) Regulations 2021](#) ("the Regulations") are made in exercise of the powers conferred by sections 45C(1) and (3)(c) and 45P(2) of the 1984 Act in response to the threat to public health which is posed by the incidence and spread of COVID-19.

The Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (the "principal Regulations"), with effect from 12:00 on 22 December 2021 in relation to isolation requirements relating to close contacts of persons testing positive for coronavirus.

The amendments made will revert to existing provision within the legislation which exempts close contacts from self-isolation providing they meet one of the specified criteria.

The principal Regulations are now amended as follows:

- All close contacts, regardless of the variant of coronavirus concerned, will not be required to self-isolate if they:
 - are children,
 - have completed a course of doses of an authorised vaccine at least 14 days before the close contact takes place,
 - are participating in a clinical trial in the United Kingdom, or
 - are participating in a testing scheme.
- The Regulations also provide that where a person comes within these categories but was under a requirement to isolate immediately before the start of the day on 22 December 2021 as a result of having close contact with a known or suspected Omicron case, the isolation requirement ends at the start of the day on that date.



The Explanatory Memorandum states that the Welsh Government will issue guidance to advise exempt contacts to take 7 days of lateral flow tests. The requirement to take such lateral flow tests will be contained in guidance only and persons will not be under a legal obligation to take such tests.

Procedure

Made Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the Welsh Government's justification for any potential interference with human rights. In particular, we note the following in the Explanatory Memorandum:

"Whilst the principal Regulations, as amended by these Regulations, engage individual rights under the Human Rights Act 1998 and the European Convention on Human Rights, the Government considers that they are justified for the purpose of preventing the spread of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate.

Article 5 (right to liberty), Article 8 (right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 11 (freedom of assembly and association) and Article 1 of the First Protocol (protection of property) are engaged by the principal Regulations.

Each of these is a qualified right, which permits the Welsh Ministers to interfere with the exercise of the rights if necessary in a democratic society in the interests of public safety or for the protection of health. All such restrictions and requirements must be justified on the basis that they are in pursuit of a legitimate aim, namely of protecting public health, and are proportionate. Any interference with these rights also needs to be balanced with the state's positive obligations under Article 2 (right to life). The
adjustment of the



restrictions and requirements under the principal Regulations by these Regulations is a proportionate response to the spread of coronavirus. It balances the need to maintain an appropriate response to the threat posed by coronavirus against the rights of individuals and businesses, in a manner which remains proportionate to the need to reduce the rate of transmission of the coronavirus, taking into account the scientific evidence."

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note that there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

"Given the ongoing threat arising from coronavirus and the need for a prompt public health response, there has been no public consultation in relation to these Regulations. However, engagement has taken place with various stakeholders including the Equalities Division of the Welsh Government."

3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the breach of the 21-day rule (i.e. the rule that 21 days should pass between the date a "made negative" instrument is laid before the Senedd and the date the instrument comes into force), and the explanation for the breach provided by Mark Drakeford, the First Minister in a letter to the Llywydd dated 21 December 2021.

In particular, we note the following:

"These Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 ("the principal Regulations"). The Regulations come into force on 22 December 2021, within 21 days of their laying.

Not adhering with the 21-day convention and bringing the Regulations into force before they are laid before the Senedd also allows the Regulations to come into force at the earliest opportunity to a. mitigate the impact of protracted staff absences on essential public services in Wales b; align our position in Wales with that of the UK Government to mitigate any cross-border issues or confusion; c simplify our approach to self-isolation to aid public messaging and compliance."

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

5 January 2022





Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament

Legislation, Justice and Constitution Committee

Pack Page 25



Elin Jones MS
Llywydd
Senedd Cymru
Cardiff Bay
CARDIFF
CF99 1SN

21 December 2021

Dear Elin,

The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 24) Regulations 2021

I have today made these Regulations under sections 45C(1) and (3)(c) and 45P(2) of the Public Health (Control of Disease) Act 1984. I intend to lay these and an accompanying Explanatory Memorandum once the statutory instrument has been registered.

In accordance with section 11A(4) of the Statutory Instruments Act 1946 I am notifying you that this statutory instrument will come into force on 22 December 2021, less than 21 days after it has been laid. A copy of the statutory instrument and the Explanatory Memorandum that accompanies it are attached for your information.

In accordance with section 4(1) of the Statutory Instruments Act 1946, I am also notifying you that this instrument will come into force before it is laid before the Senedd.

These Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 ("the principal Regulations").

The Regulations come into force on 22 December 2021, within 21 days of their laying. Not adhering to the 21-day convention allows these Regulations to come into force at the earliest opportunity.

Before their amendment by these Regulations, regulations 8 and 9A of the principal Regulations require all close contacts of a person who has coronavirus which is or may be the Omicron variant to self-isolate for a 10-day period. The exemptions that ordinarily apply to close contacts that satisfy particular conditions (for example, close contacts that are vaccinated) do not have effect.

These Regulations amend the principal Regulations to remove the distinction between close contacts of known or suspected Omicron cases and close contacts of all other positive

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

cases. All close contacts, regardless of the variant of coronavirus concerned, will not be required to self-isolate if they are children, have completed a course of doses of an authorised vaccine at least 14 days before the close contact takes place, are participating in a clinical trial in the United Kingdom, or are participating in a testing scheme.

The Regulations also provide that where a person comes within these categories but was under a requirement to isolate immediately before the start of the day on 22 December 2021 as a result of having close contact with a known or suspected Omicron case, the isolation requirement ends at the start of the day on that date.

The amendments are required to remove this requirement in response to rising Omicron cases and the likelihood of the variant becoming dominant in the near future. The regulations are therefore no longer proportionate to the risk posed and clinical management of Omicron cases.

Not adhering with the 21-day convention and bringing the Regulations into force before they are laid before the Senedd also allows the Regulations to come into force at the earliest opportunity to a. mitigate the impact of protracted staff absences on essential public services in Wales b; align our position in Wales with that of the UK Government to mitigate any cross-border issues or confusion; c simplify our approach to self-isolation to aid public messaging and compliance.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

A handwritten signature in black ink that reads "Mark Drakeford". The signature is written in a cursive, slightly slanted style.

MARK DRAKEFORD

SL(6)125 - The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 26) Regulations 2021

Background and Purpose

These [Regulations](#) amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (“the principal Regulations”). These Regulations, with effect from the beginning of 31 December 2021:

- amend regulations 6 and 7 of the principal Regulations to provide that persons testing positive for coronavirus are now required to self-isolate for a 7-day period (rather than a 10-day period);
- provide that where a person was under a requirement to isolate immediately before these Regulations come into force, the end of the isolation period is to be determined in accordance with regulation 6 or 7 as amended by these Regulations;
- make a minor amendment in consequence of the changes made by the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 25) Regulations 2021.

Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following 4 points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the breach of the 21-day rule (i.e. the rule that 21 days should pass between the date a “made negative” instrument is laid before the Senedd and the date the instrument



comes into force), and the explanation for the breach provided by Mark Drakeford MS, the First Minister, in a letter to the Llywydd dated 30 December 2021. In particular, we note what the letter says regarding the breach of the rule:

“Not adhering with the 21-day convention allows the Regulations to come into force at the earliest opportunity to ensure that individuals are being asked to isolate in accordance with public health advice and not longer than needed which will help mitigate the impact of protracted staff absences on essential public services in Wales; and align our position in Wales with that of the UK Government to reduce any cross-border issues or confusion.”

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the Welsh Government’s justification for any potential interference with human rights. In particular, we note the following paragraphs at page 2 of the Explanatory Memorandum:

“Whilst the principal Regulations, as amended by these Regulations, engage individual rights under the Human Rights Act 1998 and the European Convention on Human Rights, the Government considers that they are justified for the purpose of preventing the spreading of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate.

Article 5 (right to liberty), Article 8 (right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 11 (freedom of assembly and association) and Article 1 of the First Protocol (protection of property) are engaged by the principal Regulations.

Each of these is a qualified right, which permits the Welsh Ministers to interfere with the exercise of the rights if necessary in a democratic society in the interests of public safety or for the protection of health. All such restrictions and requirements must be justified on the basis that they are in pursuit of a legitimate aim, namely of protecting public health, and are proportionate. Any interference with these rights also needs to be balanced with the State’s positive obligations under Article 2 (right to life). The adjustment of the restrictions and requirements under the principal Regulations by these Regulations is a proportionate response to the spread of coronavirus. It balances the need to maintain an appropriate response to the threat posed by coronavirus against the rights of individuals and businesses, in a manner which remains proportionate to the need to reduce the rate of transmission of the coronavirus, taking into account the scientific evidence.”



3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

“Given the need for an urgent public health response, there has been no public consultation in relation to these Regulations.”

4. Standing Order 21.3 (ii) - that it is of political or legal importance or gives rise to issues or public policy likely to be of interest to the Senedd

The Explanatory Memorandum provides that a summary impact assessment has been prepared in relation to these Regulations, however due to the need to put them in place urgently to deal with a serious and imminent threat to public health this is yet to be published - it will be published as soon as practicably possible.

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

5 January 2022



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament

Legislation, Justice and Constitution Committee

Pack Page 29



Elin Jones MS
Llywydd
Senedd Cymru
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CF99 1SN

30 December 2021

Dear Elin,

The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 26) Regulations 2021

I have today made these Regulations under sections 45C(1) and (3)(c) and 45P(2) of the Public Health (Control of Disease) Act 1984. I intend to lay these and an accompanying Explanatory Memorandum once the statutory instrument has been registered.

In accordance with section 11A(4) of the Statutory Instruments Act 1946 I am notifying you that this statutory instrument will come into force on 31 December 2021, less than 21 days after it has been laid. A copy of the statutory instrument and the Explanatory Memorandum that accompanies it are attached for your information.

These Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (“the principal Regulations”).

The Regulations come into force at the beginning of the day on 31 December, within 21 days of their laying. Not adhering to the 21-day convention allows these Regulations to come into force at the earliest opportunity.

Before their amendment by these Regulations, regulations 6 and 7 of the principal Regulations provided that persons testing positive for coronavirus were required to self-isolate for a 10-day period.

These Regulations amend the principal Regulations to now provide that persons testing positive for coronavirus are now required to self-isolate for a 7-day period (rather than a 10-day period). The Regulations also provide that where a person comes within this category but was under a requirement to isolate immediately before the start of the day on 31 December 2021 as a result of having a notification to self-isolate following a positive COVID-19 test result, the isolation period ends in accordance with regulation 6 or 7 of the principal Regulations as amended by these Regulations.

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

The amendments are required to respond to the evidence that has been presented by UK Health Security Agency's (UKHSA) Public Health Advice, Guidance and Expertise (PHAGE) group to the four Chief Medical Officers regarding the duration of self-isolation period for COVID-19 cases and the potential to reduce this period with support from repeat testing with Lateral Flow Devices (LFDs). It also recognises the rapidly rising number of cases and the staffing issues that are being felt across essential public services. Reducing the isolation period to 7 days alongside the advised use of Lateral Flow Tests, based on modelling, offers minimal increased risk of infectious individuals being released from isolation balanced against societal benefits from reducing the isolation period and the potential for the policy to increase compliance with isolation.

Not adhering with the 21-day convention allows the Regulations to come into force at the earliest opportunity to ensure that individuals are being asked to isolate in accordance with public health advice and not longer than needed which will help mitigate the impact of protracted staff absences on essential public services in Wales; and align our position in Wales with that of the UK Government to reduce any cross-border issues or confusion.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

A handwritten signature in black ink that reads "Mark Drakeford". The signature is written in a cursive, slightly slanted style.

MARK DRAKEFORD

Agenda Item 3.8

SL(6)106 - The Education (Student Loans) (Repayment) (Amendment) (No. 4) Regulations 2021

Background and Purpose

These [Regulations](#) amend the Education (Student Loans) (Repayment) Regulations 2009 (“the 2009 Regulations”). The 2009 Regulations provide the basis for the repayment of student loans made by the Welsh Ministers and include provision for interest to be charged on student loans.

These Regulations amend the 2009 Regulations to set a maximum interest rate on student loans of 4.4% in respect of borrowers with Plan 2 or Plan 3 loans. Plan 2 loans are post 2012 undergraduate loans and Plan 3 loans are postgraduate degree loans. The rates will apply for a fixed period of two months, expiring on 28 February 2022. After expiry of the Regulations on 28 February 2022, the interest rate on post 2012 undergraduate loans and postgraduate degree loans will return to the rate specified in the 2009 Regulations (unless further amending regulations are made).

Similar amending regulations were made to cover the three month period ending on 30 September 2021 (applying rates of 5.3% between 1 July 2021 and 31 August 2021 and 4.2% between 1 and 30 September 2021) and a further three month period ending on 31 December 2021 (applying a rate of 4.1%).

These Regulations came into force on 1 January 2022.

Procedure

Composite negative.

The Regulations were made by both the Welsh Ministers and the Secretary of State, before being laid before both the Senedd and the United Kingdom Parliament.

The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd. The United Kingdom Parliament can also annul the Regulations, in accordance with the rules for annulment that apply to the United Kingdom Parliament.

Technical Scrutiny

The following point is identified for reporting under Standing Order 21.2 in respect of this instrument.

1. Standing Order 21.2(ix) – that it is not made or to be made in both English and Welsh

These Regulations have been made as a composite instrument, meaning the Regulations



have been: (a) made by both the Welsh Ministers and the Secretary of State, and (b) laid before both the Senedd and the United Kingdom Parliament. As a result, the Regulations have been made in English only.

The Explanatory Memorandum explains that:

“As the Regulations will be subject to UK Parliamentary scrutiny, it is not considered reasonably practicable for this instrument to be made or laid bilingually. Therefore, the amending regulations are made in English only.”

Merits Scrutiny

No points are identified for reporting under Standing Order 21.3 in respect of this instrument.

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

5 January 2022



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament

Legislation, Justice and Constitution Committee

Pack Page 33

Agenda Item 3.9

SL(6)105 - The Council Tax Reduction Schemes (Prescribed Requirements and Default Scheme) (Wales) (Amendment) Regulations 2022

Background and Purpose

Council Tax Reduction Schemes (“CTRS”) are the mechanism by which local authorities provide support to low-income households in meeting their council tax liability.

These [Regulations](#) amend the Council Tax Reduction Schemes and Prescribed Requirements (Wales) Regulations 2013 and the Council Tax Reduction Schemes (Default Scheme) (Wales) Regulations 2013 by:

- updating certain figures used to calculate an applicant’s entitlement to a reduction under a CTRS, and the subsequent level of reduction to reflect increases in the cost of living;
- making changes which ensure that Afghan Nationals and UK Nationals from Afghanistan are eligible to be included in a local authority’s CTRS (and are eligible for a discount if they meet the other requirements of the CTRS);
- making changes which ensure that no one living in Wales that is an applicant of the redress scheme for survivors of historical child abuse in care in Scotland is negatively affected in terms of CTRS (any payments received by a person under that scheme, and/or any ex gratia payments made by the Scottish Ministers are disregarded for the purpose of calculating a person’s eligibility for CTRS); and
- making certain technical, presentational and consequential amendments.

Procedure

Draft Affirmative

The Welsh Ministers have laid a draft of the Regulations before the Senedd. The Welsh Ministers cannot make the Regulations unless the Senedd approves the draft Regulations.

Technical Scrutiny

The following points are identified for reporting under Standing Order 21.2 in respect of this instrument:

1. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements.



Regulation 12(1) provides that paragraph 19(5) of the Council Tax Reduction Schemes (Default Scheme) (Wales) Regulations 2013 (“the Default Scheme Regulations”) is amended in accordance with paragraphs (2) to (5) (of regulation 12). This is incorrect.

As currently drafted, regulation 12(2) attempts to amend sub-paragraphs in paragraph 19(5)(e) of the Default Scheme Regulations. However, paragraph 19(5)(e) does not contain any sub-paragraphs. It appears that paragraph 12(2) should amend paragraph 19(4)(e) (which does contain sub-paragraphs).

Paragraphs (3) to (5) of regulation 12 do amend paragraph 19(5) of the Default Scheme Regulations, and this should be expressly stated.

2. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements.

Regulation 12(2)(b) substitutes “;” with “,” in paragraph 19(4)(e) of the Default Scheme Regulations. This is incorrect - it should be a substitution of “.” with “;”.

3. Standing Order 21.2(vi) – that its drafting appears to be defective or it fails to fulfil statutory requirements.

There are two errors in regulation 12(5) that are linked to the error raised in the first technical reporting point (which highlighted that not all of the paragraphs in regulation 12 amend paragraph 19(5) of the Default Scheme Regulations).

Regulation 12(5) inserts a new paragraph (m) into regulation 19(5) of the Default Scheme Regulations. In the wording being inserted, there is a reference to “paragraph (e)”. This should be a reference to “sub-paragraph (4)(e)”, as it is not referring to paragraph (e) of the sub-paragraph into which it is being inserted (it is referring to sub-paragraph (4)(e) not sub-paragraph(5)(e)).

Similarly, regulation 12(5) inserts a new paragraph (n) into regulation 19(5). In the wording being inserted, there is a reference to “paragraph (e)(iv) or (m)”. This should be a reference to “sub-paragraph (e)(iv) or paragraph (m)”, for the same reason as outlined above (i.e. the former is located in a different sub-paragraph, whereas the latter is located in the same sub-paragraph).

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument:

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

No consultation has been undertaken in respect of these Regulations. The Explanatory Memorandum notes that:



"The 2013 CTRS Regulations were consulted upon and details are provided in the Regulatory Impact Assessments accompanying those Regulations."

Welsh Government response

Technical Scrutiny point: Defective Drafting

The drafting is correct and contains no defects.

Point 1:

Paragraph 19(5)(e) of the Council Tax Reduction Schemes (Default Scheme) (Wales) Regulations 2013 ("the Default Scheme") was substituted by regulation 16 of the Council Tax Reduction Schemes (Prescribed Requirements and Default Scheme) (Wales) (Amendment) Regulations 2014. Paragraph 19(5)(e) is intended to be amended and does consist of sub-paragraphs (i) to (iii). It mirrors regulation 28(5)(e) of the Council Tax Reduction Schemes and Prescribed Requirements (Wales) Regulations 2013.

Point 2:

Accordingly, the punctuation inserted by regulation 12(2)(b) to paragraph 19(5)(e) of the Default Scheme, is correct.

Point 3:

The references to paragraphs are correct, in accordance with Statutory Instrument Practice. Regulation 12(5) amends paragraph 19 of the Schedule to the Default Scheme, not regulation 19 of the Default Scheme.

Merit Scrutiny point: Consultation

There is no statutory requirement to consult in relation to these amendment regulations. However, the 2013 CTRS Regulations were consulted upon. A dialogue is maintained between Welsh Government officials and local authorities to continue to ensure that all changes made are to benefit applicants and that the content of the regulations is brought to their attention.

Legal Advisers

Legislation, Justice and Constitution Committee

17 December 2021



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament **Pack Page 36**

Legislation, Justice and Constitution Committee

SL(6)108 - The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 22) Regulations 2021

Background and Purpose

These [Regulations](#) are made in response to the threat to public health which is posed by the incidence and spread of COVID-19.

These Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (the "principal Regulations"), with effect from the beginning of 11 December 2021, to:

- Clarify that the auditorium of a theatre, cinema or concert hall and the viewing areas of an indoor arena or stadium is not to be treated as premises where food or drink is sold, or otherwise provided, for consumption on the premises. This change is designed to remove a potential ambiguity in the principal Regulations;
- Make face coverings a legal requirement during professional driving lessons and practical tests in Wales unless an individual is exempt.

The principal Regulations are further amended by these Regulations, from the beginning of 15 December 2021, to exclude prior recovery (or natural immunity) as a way of demonstrating COVID-19 status for the purposes of the COVID Pass.

Procedure

Made Affirmative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd must approve the Regulations within 28 days (excluding any days when the Senedd is dissolved or in recess for more than four days) of the date they were made for them to continue to have effect.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following four points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd



We note the Welsh Government's justification for any potential interference with human rights. In particular, we note the following in the Explanatory Memorandum:

"Whilst the principal Regulations, as amended by these Regulations, engage individual rights under the Human Rights Act 1998 and the European Convention on Human Rights, the Government considers that they are justified for the purpose of preventing the spread of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate.

Article 5 (right to liberty), Article 8 (right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 11 (freedom of assembly and association) and Article 1 of the First Protocol (protection of property) are engaged by the principal Regulations.

Each of these is a qualified right, which permits the Welsh Ministers to interfere with the exercise of the rights if necessary in a democratic society in the interests of public safety or for the protection of health. All such restrictions and requirements must be justified on the basis that they are in pursuit of a legitimate aim, namely of protecting public health, and are proportionate. Any interference with these rights also needs to be balanced with the state's positive obligations under Article 2 (right to life). The adjustment of the restrictions and requirements under the principal Regulations by these Regulations is a proportionate response to the spread of coronavirus. It balances the need to maintain an appropriate response to the threat posed by coronavirus against the rights of individuals and businesses, in a manner which remains proportionate to the need to reduce the rate of transmission of the coronavirus, taking into account the scientific evidence."

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note that there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

"Given the ongoing threat arising from coronavirus and the need for a prompt public health response, there has been no public consultation in relation to these Regulations. However, engagement has taken place with various stakeholders including the Equalities Division of the Welsh Government."

3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note there is no equality impact assessment for these Regulations and ask the Welsh Government to explain what arrangements it has made, in respect of these Regulations, to publish reports of equality impact assessments in accordance with regulation 8(1)(d) of the Equality Act 2010 (Statutory Duties) (Wales) Regulations 2011.



While it is noted that the Explanatory Memorandum states that “*summary impact assessments have been published previously which include impacts relating to face coverings*”, reference is not made to equality impacts relating to regulation changes that exclude prior recovery (i.e. natural immunity) as a way of demonstrating COVID-19 status for the purposes of the COVID Pass.

4. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

In relation to the exclusion of prior recovery (i.e. natural immunity) as a way of demonstrating COVID-19 status for the purposes of the COVID Pass, it is noted that the Explanatory Memorandum refers to the change being “*justified on public health grounds*”, as well as representing “*a strengthening of the requirements as previously proposed by the Technical Advisory Group*” that is “*supported by the Chief Medical Officer.*”

However, the Explanatory Memorandum does not contain any specific reference to the evidence on which Welsh Government relies when making provision under these Regulations.

We would be grateful if the Welsh Government could set out the evidence which shows that excluding prior recovery (i.e. natural immunity) as a way of demonstrating COVID-19 status for the purposes of the COVID Pass is “*justified on public health grounds*”.

Welsh Government response

A Welsh Government response is required in relation to points 3 and 4 above only.

Legal Advisers

Legislation, Justice and Constitution Committee

20 December 2021





Elin Jones MS
Llywydd
Senedd Cymru
Cardiff Bay
CARDIFF
CF99 1SN

10 December 2021

Dear Elin,

The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 22) Regulations 2021

I have today made these Regulations under sections 45C(1) and (3)(c), 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984, which come into force in part on 11 December and for all remaining purposes on 15 December 2021. I attach a copy of the statutory instrument and I intend to lay this and an accompanying Explanatory Memorandum once the statutory instrument has been registered.

In accordance with the procedure set out in section 45R of the Public Health (Control of Disease) Act 1984, this instrument must be approved by the Senedd by 27 January 2022 in order for it to remain in effect. In these circumstances I understand Standing Order 21.4A is relevant and the Business Committee may establish and publish a timetable for the responsible committee or committees to report. It may be helpful to know that I intend to hold the plenary debate for this item of subordinate legislation on 11 January 2022.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

MARK DRAKEFORD

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

SL(6)118 - The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 23) Regulations 2021

Background and Purpose

Part 2A of the Public Health (Control of Disease) Act 1984 (“the 1984 Act”) enables the Welsh Ministers, by regulations, to make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in Wales.

[The Health Protection \(Coronavirus Restrictions\) \(No. 5\) \(Wales\) \(Amendment\) \(No. 23\) Regulations 2021](#) (“the Regulations”) are made in exercise of the powers conferred by sections 45C(1) and (3)(c) and 45F(2) of the 1984 Act in response to the threat to public health which is posed by the incidence and spread of COVID-19.

The Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (the “principal Regulations”), with effect from 20 December 2021, to:

- list specifically allowing or requiring employees to work from home as a reasonable measure which employees may be required to take in accordance with the duty under Step 3 of regulation 16;
- place a new duty, under regulation 18B, on individuals to work, or provide voluntary or charitable services, from home where it is reasonably practicable for them to do so;
- create an offence under regulation 42A where a person, without reasonable excuse, contravenes the requirement in regulation 18B.

Procedure

Made Affirmative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd must approve the Regulations within 28 days (excluding any days when the Senedd is dissolved or in recess for more than four days) of the date they were made for them to continue to have effect.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.



Merits Scrutiny

The following four points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the Welsh Government's justification for any potential interference with human rights. In particular, we note the following in the Explanatory Memorandum:

"Whilst the principal Regulations, as amended by these Regulations, engage individual rights under the Human Rights Act 1998 and the European Convention on Human Rights, the Government considers that they are justified for the purpose of preventing the spread of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate.

Article 5 (right to liberty), Article 8 (right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 11 (freedom of assembly and association) and Article 1 of the First Protocol (protection of property) are engaged by the principal Regulations.

Each of these is a qualified right, which permits the Welsh Ministers to interfere with the exercise of the rights if necessary in a democratic society in the interests of public safety or for the protection of health. All such restrictions and requirements must be justified on the basis that they are in pursuit of a legitimate aim, namely of protecting public health, and are proportionate. Any interference with these rights also needs to be balanced with the state's positive obligations under Article 2 (right to life). The adjustment of the restrictions and requirements under the principal Regulations by these Regulations is a proportionate response to the spread of coronavirus. It balances the need to maintain an appropriate response to the threat posed by coronavirus against the rights of individuals and businesses, in a manner which remains proportionate to the need to reduce the rate of transmission of the coronavirus, taking into account the scientific evidence."

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note that there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

"Given the ongoing threat arising from coronavirus and the need for a prompt public health response, there has been no public consultation in relation to these Regulations. However, engagement has taken place with various stakeholders including the Equalities Division of the Welsh Government."



3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note there is no equality impact assessment for the Regulations and ask the Welsh Government to explain what arrangements it has made, in respect of the Regulations, to publish reports of equality impact assessments in accordance with regulation 8(1)(d) of the Equality Act 2010 (Statutory Duties) (Wales) Regulations 2011.

While it is noted that the Explanatory Memorandum states, “... *summary impact assessments are in preparation which will include impacts relating to working from home*”, it is unclear whether these will include an equality impact assessment and, in any event, they are not currently available to the citizen for the purpose of assessing the equalities impact of the new provisions being introduced by the Regulations.

4. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

Beyond the following statement, the Explanatory Memorandum does not set out or link to any specific evidence on which the Welsh Government relies when making provision under the Regulations:

“The Welsh Ministers are of the opinion that the restrictions and requirements set out in the principal Regulations, as amended by these Regulations, are necessary and proportionate as a public health response to the current threat posed by coronavirus, particularly the rapid rise in Omicron cases.”

We note, however, the following from the First Minister, Mark Drakeford MS’, written statement of 17 December 2021:

“At the last review of the coronavirus regulations on 9 December, I set out that we would move from a three-week to a one-week review to ensure we have the right measures in place to keep Wales safe in response to the emerging omicron variant.

This fast-moving, more transmissible variant is here in Wales and is spreading quickly.

.....

The number of confirmed cases of omicron infections is rising every day in Wales – and across the UK. By the end of the month omicron will likely become the dominant form of the virus. We are still learning about this new form of coronavirus. But all the information we have tells us we are facing a very serious situation.”

Bearing in mind the additional statutory duty the Regulations impose under new regulation 18B, particularly the creation of an offence in new regulation 42A, we would be grateful if the Welsh Government could set out the relevant evidence that supports the significant tightening of restriction around home working at this time.



Welsh Government response

A Welsh Government response is required in relation to points 3 and 4 above only.

Legal Advisers

Legislation, Justice and Constitution Committee

23 December 2021



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

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Welsh Parliament **Pack Page 44**

Legislation, Justice and Constitution Committee



Elin Jones MS
Llywydd
Senedd Cymru
Cardiff Bay
CARDIFF
CF99 1SN

17 December 2021

Dear Elin,

The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 23) Regulations 2021

I have today made these Regulations under sections 45C(1) and (3)(c) and 45F(2) of the Public Health (Control of Disease) Act 1984, which come into force on 20 December 2021. I attach a copy of the statutory instrument and I intend to lay this and an accompanying Explanatory Memorandum once the statutory instrument has been registered.

In accordance with the procedure set out in section 45R of the Public Health (Control of Disease) Act 1984, this instrument must be approved by the Senedd by 3 February 2022 in order for it to remain in effect. In these circumstances I understand Standing Order 21.4A is relevant and the Business Committee may establish and publish a timetable for the responsible committee or committees to report. It may be helpful to know that I intend to hold the plenary debate for this item of subordinate legislation on 11 January 2022.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

MARK DRAKEFORD

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Agenda Item 3.12

SL(6)124 - The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 25) Regulations 2021

Background and Purpose

Part 2A of the Public Health (Control of Disease) Act 1984 (“the 1984 Act”) enables the Welsh Ministers, by regulations, to make provision for the purpose of preventing, protecting against, controlling or providing a public health response to the incidence or spread of infection or contamination in Wales.

[The Health Protection \(Coronavirus Restrictions\) \(No. 5\) \(Wales\) \(Amendment\) \(No. 25\) Regulations 2021](#) (“the Regulations”) are made in exercise of the powers conferred by sections 45C(1) and (3)(c), 45F(2) and 45P(2) of the 1984 Act in response to the threat to public health which is posed by the incidence and spread of COVID-19.

The Regulations amend the Health Protection (Coronavirus Restrictions) (No. 5) (Wales) Regulations 2020 (the “principal Regulations”).

The Regulations amend the principal Regulations, with effect from 6:00 a.m. on 26 December 2021, so that:

- Wales moves from Alert Level 0 to Alert Level 2 meaning that the restrictions and requirements in [Schedule 2](#) to the principal Regulations take effect;
- persons responsible for “regulated premises” (i.e. workplaces, premises open to the public and public transport vehicles) are required to take all reasonable measures to ensure that a distance of 2 metres is maintained between persons on the premises, except between members of a permitted group comprising of no more than 6 persons or members of the same household at Alert Levels 1 and 2, or members of the same household at Alert Levels 3 and 4;
- in determining the extent it is reasonable to take a particular measure to ensure that a distance of 2 metres is maintained between persons on the premises, the person responsible for the premises may have regard to other measures taken to mitigate the risk of exposure to coronavirus on the premises;
- specific provision is made about the measures that must be taken to minimise the risk of exposure to coronavirus on licensed premises, including a requirement to control entry to the premises and for customers to be seated when ordering food or drink (subject to exceptions);



- specific provision is made about the measures that must be taken to minimise the risk of exposure to coronavirus on retail premises, including a requirement to control entry to the premises, to provide hand sanitisation products, to undertake additional sanitisation of baskets and trolleys etc., and to provide signs and make announcements to remind people of the 2 metre rule and to wear a face covering;
- face coverings must be worn in premises where food or drink is sold, or otherwise provided, for consumption on the premises, other than when seated;
- people playing in a team sport event or involved in coaching a team at an event are to be treated as working at the event and do not count towards any limit on numbers at the event (in the same way as referees and others involved in running the event);
- the restrictions on gathering in private dwellings and in holiday accommodation are removed, subject to it being an offence to participate in a gathering of more than 30 people indoors or more than 50 people outdoors in these places;
- the exemption to the restriction on events is changed to enable any number of people to attend a celebration of a marriage or civil partnership or a celebration of a recently deceased person held at regulated premises (subject to the maximum numbers permitted on the premises in accordance with the risk assessment and other reasonable measures taken under regulation 16 of the principal Regulations);
- adult entertainment venues and ice rinks are omitted from the list of businesses whose premises have to close. (The businesses that must close include nightclubs, discotheques, dance halls or other venues authorised for the sale or supply of alcohol where live or recorded music is provided for members of the public or members of the venue to dance.)

Procedure

Made Affirmative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd must approve the Regulations within 28 days (excluding any days when the Senedd is dissolved or in recess for more than four days) of the date they were made for them to continue to have effect.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.



Merits Scrutiny

The following four points are identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note the Welsh Government's justification for any potential interference with human rights. In particular, we note the following in the Explanatory Memorandum:

"Whilst the principal Regulations, as amended by these Regulations, engage individual rights under the Human Rights Act 1998 and the European Convention on Human Rights, the Government considers that they are justified for the purpose of preventing the spread of infectious diseases and/or the interference is permitted on the basis that it is in pursuit of a legitimate aim, namely of protecting public health, and are proportionate.

Article 5 (right to liberty), Article 8 (right to respect for private and family life), Article 9 (freedom of thought, conscience and religion), Article 11 (freedom of assembly and association) and Article 1 of the First Protocol (protection of property) are engaged by the principal Regulations.

Each of these is a qualified right, which permits the Welsh Ministers to interfere with the exercise of the rights if necessary in a democratic society in the interests of public safety or for the protection of health. All such restrictions and requirements must be justified on the basis that they are in pursuit of a legitimate aim, namely of protecting public health, and are proportionate. Any interference with these rights also needs to be balanced with the state's positive obligations under Article 2 (right to life). The adjustment of the restrictions and requirements under the principal Regulations by these Regulations is a proportionate response to the spread of coronavirus. It balances the need to maintain an appropriate response to the threat posed by coronavirus against the rights of individuals and businesses, in a manner which remains proportionate to the need to reduce the rate of transmission of the coronavirus, taking into account the scientific evidence."

2. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note that there has been no formal consultation on these Regulations. In particular, we note the following paragraph in the Explanatory Memorandum:

"Given the ongoing threat arising from coronavirus and the need for a prompt public health response, there has been no public consultation in relation to these Regulations. However, engagement has taken place with various stakeholders including the Equalities Division of the Welsh Government."



3. Standing Order 21.3(ii) – that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

We note that a regulatory impact assessment has not been prepared. In particular, we note the following paragraph in the Explanatory Memorandum:

“A regulatory impact assessment has not been yet in relation to these Regulations due to the need to put them in place to deal with a serious and imminent threat to public health. However, summary impact assessments are in preparation which will include the impacts of Wales moving to Alert Level 2.”

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

5 January 2022



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

—

Welsh Parliament

Legislation, Justice and Constitution Committee

Pack Page 49



Elin Jones MS
Llywydd
Senedd Cymru
Cardiff Bay
CARDIFF
CF99 1SN

22 December 2021

Dear Elin,

The Health Protection (Coronavirus Restrictions) (No. 5) (Wales) (Amendment) (No. 25) Regulations 2021

I have today made these Regulations under sections 45C(1) and (3)(c) and 45F(2) and 45P(2) of the Public Health (Control of Disease) Act 1984, which come into force at 6.00 a.m. on 26 December 2021. I attach a copy of the statutory instrument and I intend to lay this and an accompanying Explanatory Memorandum once the statutory instrument has been registered.

In accordance with the procedure set out in section 45R of the Public Health (Control of Disease) Act 1984, this instrument must be approved by the Senedd by 6 February 2022 in order for it to remain in effect. In these circumstances I understand Standing Order 21.4A is relevant and the Business Committee may establish and publish a timetable for the responsible committee or committees to report. It may be helpful to know that I intend to hold the plenary debate for this item of subordinate legislation on 11 January 2022.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, Siwan Davies, Director of Senedd Business, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely

MARK DRAKEFORD

Bae Caerdydd • Cardiff Bay
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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Agenda Item 3.13

SL(6)122 – The Landfill Disposals Tax (Tax Rates) (Wales) (Amendment) Regulations 2021

Background and Purpose

These [Regulations](#) prescribe the standard rate, lower rate and unauthorised disposals rate for landfill disposals tax which will apply to taxable disposals made on or after 1 April 2022.

The rates from 1 April 2022 are as follows:

- The standard rate is **£98.60** per tonne (increased from £96.70 per tonne),
- The lower rate is **£3.15** per tonne (increased from £3.10 per tonne)
- The unauthorised disposals rate is **£147.90** per tonne (increased from £145.05 per tonne).

Taxable disposals made on or after 1 April 2021 but before 1 April 2022 will remain subject to rates set by the Landfill Disposals Tax (Tax Rates) (Wales) (Amendment) (No. 2) Regulations 2020.

Procedure

Made Affirmative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd must approve the Regulations within 28 days (excluding any days when the Senedd is dissolved or in recess for more than four days) of the date they were made for them to continue to have effect.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument:

1. Standing Order 21.3(i) - that it imposes a charge on the Welsh Consolidated Fund or contains provisions requiring payments to be made to that Fund or any part of the government or to any local or public authority in consideration of any licence or consent or of any services to be rendered, or prescribes the amount of any such charge or payment.



Section 25 of the Tax Collection and Management (Wales) Act 2016 provides that the Welsh Revenue Authority must pay amounts collected in the exercise of its functions into the Welsh Consolidated Fund. These Regulations prescribe the three rates of landfill disposals tax in Wales.

Welsh Government response

A Welsh Government response is not required.

Legal Advisers

Legislation, Justice and Constitution Committee

22 December 2021



Senedd Cymru

Pwyllgor Deddfwriaeth, Cyfiawnder a'r Cyfansoddiad

—

Welsh Parliament

Legislation, Justice and Constitution Committee

Pack Page 53



Ein cyf/Our ref: MA/RE/4167/21

Elin Jones MS
Llywydd
Senedd Cymru
Cardiff Bay
CF99 1SN

20 December 2021

The Landfill Disposals Tax (Tax Rates) (Wales) (Amendment) Regulations 2021

I have today made The Landfill Disposals Tax (Tax Rates) (Wales) (Amendment) Regulations 2021 under sections 14(3) and (6), 46(4), 93 and 94(1) of the Landfill Disposals Tax (Wales) Act 2017 which comes into force on 1 April 2022. I attach a copy of the statutory instrument and the accompanying Explanatory Memorandum, which I intend to lay once the statutory instrument has been registered.

In accordance with the procedure set out in section 95 of the Landfill Disposals Tax (Wales) Act 2017, this instrument must be approved by the Senedd by 6 February 2022 in order for it to remain in effect. In these circumstances I understand Standing Order 21.4A is relevant and the Business Committee may establish and publish a timetable for the responsible committee or committees to report. It may be helpful to know that I intend to hold the Plenary debate for this item of subordinate legislation on 1 February 2022.

I am copying this letter to the Minister for Rural Affairs and North Wales, and Trefnydd, Huw Irranca-Davies (MS), Chair of the Legislation, Justice and Constitution Committee, Peredur Owen Griffiths MS, Chair of the Finance Committee, Sian Wilkins, Head of Chamber and Committee Services and Julian Luke, Head of Policy and Legislation Committee Service.

Yours sincerely,

Rebecca Evans MS
Y Gweinidog Cyllid a Llywodraeth Leol
Minister for Finance and Local Government

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

SL(6)107 - The Food Information (Wales) (Amendment) Regulations 2021

Background and Purpose

These [Regulations](#) are made using powers conferred by section 31(1)(a) of and paragraph 27 of Schedule 5 to the European Union (Future Relationship) Act 2020.

These Regulations implement Article 5 of Annex 15 to the Trade and Cooperation Agreement between the EU and the UK ("TCA"). Annex 15 to the TCA makes provision for trade in wine and Article 5 provides for transitional measures relating to the labelling and placing on the market of wine produced before the date of entry into force of the TCA. Regulation 2 makes consequential amendments to the Food Information (Wales) Regulations 2014 to ensure such wine can continue to be sold.

Procedure

Negative.

The Regulations were made by the Welsh Ministers before they were laid before the Senedd. The Senedd can annul the Regulations within 40 days (excluding any days when the Senedd is: (i) dissolved, or (ii) in recess for more than four days) of the date they were laid before the Senedd.

Technical Scrutiny

No points are identified for reporting under Standing Order 21.2 in respect of this instrument.

Merits Scrutiny

The following point is identified for reporting under Standing Order 21.3 in respect of this instrument.

1. Standing Order 21.3(ii) - that it is of political or legal importance or gives rise to issues of public policy likely to be of interest to the Senedd

A draft of these Regulations was laid before the Senedd for sifting in accordance with paragraph 9 of Schedule 5 to the European Union (Future Relationship) Act 2020. The Committee agreed that the negative procedure was the appropriate procedure for these Regulations.

Welsh Government response

A Welsh Government response is not required.



Legal Advisers
Legislation, Justice and Constitution Committee
13 December 2021



Eluned Morgan AS/MS
Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: MA/EM/3486/21

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Cc
Huw Irranca-Davies MS
Chair
Legislation, Justice and Constitutional Committee
SeneddLJC@senedd.wales

3 December 2021

Dear Russell and Huw,

I am pleased to share with the Committee a finalised provisional Framework for Organs, Tissues and Cells, as well as a Framework for Blood Safety and Quality (the Frameworks). Also included are related Concordat documents.

These Frameworks establish common expectations around key areas of cooperation in relation to quality and safety standards for organs, tissues, cells and blood in the context of the UK's departure from the EU. All four UK administrations agreed to work together to establish common approaches, known as Common Frameworks, in policy areas that were previously governed by EU law, and which intersect with areas of devolved competence.

Officials in the Welsh Government, together with their counterparts across the UK, and with relevant stakeholders in these fields, have been working jointly to develop these Frameworks to share with their respective scrutiny Committees for Parliamentary scrutiny.

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

The set of documents can be found at:

[The Organs, Tissues and Cells \(apart from embryos and gametes\) Provisional Common Framework - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

[The Blood Safety and Quality Provisional Common Framework - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. E. Morgan'.

Eluned Morgan AS/MS

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



HM Government

The Organs, Tissues and Cells (apart from embryos and gametes) Provisional Common Framework



The Organs, Tissues and Cells (apart from embryos and gametes) Provisional Common Framework

Presented to Parliament
by the Secretary of State for Health and Social Care
by Command of Her Majesty

December 2021

CP 516



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The Organs, Tissues and Cells (apart from embryos and gametes)

Provisional Common Framework

OUTLINE

SECTION 1: WHAT WE ARE TALKING ABOUT

1. Policy Area

Organs and Tissues and Cells (apart from embryos and gametes).

- 1.1 The Joint Ministerial Committee (EU Negotiations) agreed that officials should work together to develop arrangements for common frameworks (see Appendix I). This Framework relates to policy on the safety and quality of organs, tissues and cells, excluding reproductive tissues and cells. It encompasses elements of the EU Organs Directive (2010/53/EU) and the EU Tissues and Cells Directive (2004/23/EC) and the implementing acts which relate to the quality and safety of organs, tissues and cells for treating patients. This Framework sets out arrangements for co-operation between officials in the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Department of Health.
- 1.2 The Directives aim to establish minimum safety and quality standards for organs, tissues and cells to ensure a high level of health protection. For organs, it covers all steps in the organ transplantation process from donation, procurement, testing, characterisation, preservation, transport and finally transplantation. For tissues and cells, it covers issues such as donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells intended for human application. The Directives do not cover the use of organs, tissues and cells where they are not for human application (i.e. transplantation or transfusion) so do not regulate their use for e.g. research, education or training. The Directives that intersect with devolved competence in this policy area are listed in the section below.
- 1.3 In accordance with the retained EU law that implements the Organs and Tissues and Cells Directives, the UKG, SG, WG and NI Department of Health are obliged to ensure that quality and safety standards are maintained.

2. Scope

- 2.1 **Intersection with devolved competence:** This policy area (safety and quality of organs and tissues and cells) was previously governed by harmonised EU

Directives (set out below). The EU Directives are implemented in domestic legislation applicable across the whole of the UK. Enforcement of the implementing legislation is delegated to the UK-wide regulator, the Human Tissue Authority (HTA).

- 2.2 As the Transition Period has ended, the different governments have wider scope to use their powers to make changes to organs, tissues and cells safety and quality regulation.
- 2.3 This Framework will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. It will also adhere to the Belfast Agreement.
- 2.4 **EU Legislation:** Retained EU legislation is currently implemented on a UK-wide basis. The two main pieces of EU legislation that intersect with devolved competence in this policy area are Directive 2004/23/EC ('the European Tissues and Cells Directive') and Directive 2010/53/EU ('the European Organ Directive').
- 2.5 The implementing directives below, that implement the main EU directives, also intersect with devolved competence (for Northern Ireland, Scotland and Wales).
- 2.6 **Tissues and cells:**
- **Commission Directive 2006/17/EC:** regarding certain technical requirements for the donation, procurement and testing of human tissues and cells.
 - **Commission Directive 2006/86/EC:** concerning traceability requirements, notification of serious adverse reactions and events, additional technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells.
 - **Commission Directive 2012/39/EU:** amending Directive 2006/17/EC as regards certain technical requirements for the testing of human tissues and cells. **Commission Directive 2015/565:** amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells.
 - **Commission Directive 2015/566:** implementing Directive 2004/23/EC concerns the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.
 - **Commission Decision 2010/453/EC:** establishing guidelines concerning the conditions of inspections and control measures, and on the training and qualification of officials, in the field of human tissues and cells.

- **Commission Decision (2015) 4460:** establishing a model for agreements between the Commission and relevant organisations on the provision of product codes for use in the Single European Code (SEC).

2.7 Organs:

- **Commission Directive 2012/25/EU:** regarding the information procedures for exchange of human organs intended for transplantation, between EU countries.

2.8 Broadly, the retained EU law in this area sets the quality and safety standards for organs, tissues and cells which include:

- the procurement, testing, processing, and storage of tissues and cells (including reproductive cells);
- organ and donor characterisation, meaning the collection of the relevant information on the characteristics of the donor and the organ, including tissue typing tests, needed to evaluate suitability for organ donation and optimise organ allocation;
- transportation conditions of organs and distribution conditions of tissues and cells, including labelling and documentation;
- traceability requirements in respect of organs for transplantation and tissues such as corneas or bone and stem cells; and
- notification requirements in the event of serious adverse events or reactions which may impact the quality and safety of organs, tissue and cells.

2.9 Transfer of Commission Powers: The safety and quality of organs and non-reproductive tissues and cells is an area of devolved competence. Statutory instruments made in 2019 under powers in the European Union (Withdrawal) Act 2018 transferred to the UKG, SG, WG and the NI Department of Health power to make regulations on matters previously included in implementing Directives made by the European Commission. This includes powers to update technical requirements, for example, requirements to ensure traceability in line with scientific and technical developments. These powers are limited to authorities in Great Britain by statutory instruments made in order to implement the Ireland/Northern Ireland Protocol as the 2018 Act confers the necessary powers on the NI department.

2.10 Competence: Legislative competence for non-reproductive human tissues, cells and organs is devolved to Scotland, Wales and Northern Ireland. Therefore, the Framework has been made on a UK-wide basis with the agreement of the UKG, SG, WG and NI Department of Health. This will facilitate the continuity of good working relations, open communication and the maintenance of a compatible minimum set of high standards of safety and quality for organs, tissues and cells. The UKG, SG, WG and NI Department of

Health have agreed with the principles that will govern the development of the framework.

2.11 Extent: This Framework is UK-wide (covering England, Northern Ireland, Scotland and Wales), but does not cover the Crown Dependencies or Overseas Territories.

2.12 Scope within rules for different parts of the UK to do things differently: Maintaining a compatible minimum set of safety and quality standards between the UKG, SG, WG and NI Department of Health will make it easier for organs, tissues and cells to continue to be shared across the UK. This Framework Agreement sets out a process by which a government can suggest future changes to the standards and how such a proposal will be collectively considered before one or more governments introduce a change. It will allow for necessary divergence by one or more governments, as required, in order to respond to needs such as location-dependent public health concerns.

2.13 Interdependencies include:

- **The Common Framework for the safety and quality of blood and blood components** as there are joint UK-wide groups that advise Ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation.
- **Medical devices legislation:** as reagents (medical devices) are used in the collection and processing of organs, tissues and cells.

3. Definitions

3.1 Memorandum of Understanding (MoU) on Devolution: The overarching MoU which sets out the understanding of, on the one hand, the UKG, and on the other, the Scottish Ministers, the Welsh Ministers, and the Northern Ireland Executive Committee of the principles that will underlie relations between them. This is separate to the Joint Ministerial Committee (EU Negotiations) Communique of October 2017.

3.2 Joint Ministerial Committee (EU Negotiations) (JMC(EN)) Communique October 2017: The committee members included representatives from the UKG, SG, WG and NIE. The group was established to provide a means for the devolved governments to be fully engaged in determining the UK's approach to EU and trade related issues. On 16 October 2017 agreement was reached on the principles and definitions for the Common Frameworks for areas where EU law intersected with devolved competence. In June 2020, NIE Ministers agreed to the principles set out in the communique, following the restoration of the NIE in January 2020.

3.3 **Concordat:** Joint non-legislative agreement that gives effect to the Common Framework.

SECTION 2: PROPOSED BREAKDOWN OF POLICY AREA AND FRAMEWORK

4. Summary of proposed approach

- 4.1. **Purpose and general principles**¹: In 2018 it was agreed that a Common Framework in this area would be desirable across the UK. The JMC (EN) principles are described in the Joint Ministerial Committee's communique of 16 October 2017. The communique sets out that Common Frameworks will be established where they are necessary in order to:
- **enable the functioning of the UK internal market, while acknowledging policy divergence:** for organs, tissues and cells this will enable the transplant material to be shared around the UK;
 - ensure compliance with international obligations: this does not apply to the Organs, Tissues and Cells Framework;
 - ensure the UK can negotiate, enter into and implement new trade agreements and international treaties: this does not apply to the Organs, Tissues and Cells Framework;
 - enable the management of common resources;
 - administer and provide access to justice in cases with a cross-border element: this does not apply to the Organs, Tissues and Cells Framework;
 - **safeguard the security of the UK:** for organs, tissues and cells, the sharing of serious adverse events or reactions (SAERs) information to maintain patient safety.
- 4.2. The outcomes of the intergovernmental relations review are in the process of being implemented. Once confirmation has been provided from each government, the outcomes of the review and appropriate intergovernmental structures will be reflected in this Common Framework.
- 4.3. A level of commonality would be beneficial particularly for organisations that operate across UK borders and therefore, as is currently the case, close collaboration between the governments should continue.
- 4.4. There is currently good information sharing and collaboration across the UK. This Framework agreement should support the continuation of this.
- 4.5. **EU Exit SIs:** Although competence in respect of organs, tissues and non-reproductive tissues and cells is devolved, it was agreed that there would be

¹ The principles that are relevant for organs, tissue and cell safety and quality are in bold.

UK-wide legislation regarding the safety and quality standards for organs, tissues and non-reproductive tissues and cells in the event of a 'no-deal' EU exit (The 2019 Organs, Tissues and Cells Safety and Quality EU Exit SIs²). The legislation was made to ensure that the regulatory framework for organs, tissues and non-reproductive tissues and cells could operate as intended following the UK's departure from the EU, and to retain the safety and quality standards for organs, tissues and cells. The legislation also includes transfers of power to update certain aspects of the quality and safety regulations (such as updating safety and quality standards in response to technological advances) to either the Secretary of State for Health and Social Care on behalf of the UK (with the consent of Scottish and Welsh ministers and the Department of Health in Northern Ireland) or, to each of the Ministers in relation to their part of the UK.

- 4.6. The 2019 Organs, Tissues and Cells Safety and Quality EU Exit SIs were amended by the 2020 Organs, Tissues and Cells SIs³ to implement the Protocol on Ireland/Northern Ireland. These SIs limit the regulation-making powers in the 2019 SIs to Great Britain, as the EU (Withdrawal) Act 2018 now contains regulation making powers (section 8C and paragraph 11M of Schedule 2) enabling the Secretary of State and the NI Department to make regulations to implement the Protocol including in response to future changes in EU law.
- 4.7. **Non-legislative:** As the UKG, SG, WG and NI Department of Health will have the power to diverge from UK Regulations should they choose, a concordat (Annex I) between the four nations will be put into place to formally agree the ways of working set out in this Framework.
- 4.8. **Four governments collaborative working:** The governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and considering the UK-wide impact of such changes. They will follow the approach in this Framework to support collaborative decision making with a view to supporting continued sharing of organs, tissues and cells across the UK.
- 4.9. There is a need for continued robust policy development encompassing policy and technical expertise from all four governments, including the need to fully

² The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019/483 and The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019/481;

³ The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020/1305 and The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020/1306.

assess the potential impacts of legislative changes on all affected stakeholders. Governments may wish to do this work individually or in collaboration before initiating a UK-wide discussion of a potential change to the standards.

- 4.10. **Risk assessment and management:** As stated above, maintaining a compatible minimum set of safety and quality standards between the UKG, SG, WG and NI Department of Health will make it easier for organs, tissues and cells to continue to be shared across the UK.
- 4.11. One or more governments may initiate a risk assessment process that should include discussions with the national transplant services and the regulator, as appropriate. The assessment should include seeking advice from the relevant scientific advisory bodies. Final decisions at the end of the risk assessment process should require collective sign-off (e.g. legislative or operational changes) by all Ministers across the UK. While the ability to diverge is always available to any individual government, it will be important for any diverging government to consider the impact on patient safety and confidence and the JMC(EN) Common Frameworks principles.
- 4.12. Where appropriate, joint recommendations may be made to Ministers. Ministers will ultimately retain the right to take individual decisions for their government. For Ministers and officials, for areas within the scope of the Framework, a consensus/discussion to inform the other parties should first be sought.
- 4.13. The dispute resolution process is outlined in section 13 of this document.
- 4.14. **Divergence:** Maintaining a compatible minimum set of quality and standards between the UKG, SG, WG and NI Department of Health will make it easier for organs, tissues and cells to continue to be shared across the UK. The Framework sets out a process by which any government can suggest changes to the standards and how such a proposal will be collectively considered before one or more governments introduce a change. It will allow for necessary divergence by one or more governments as required, in order to respond to needs such as location-dependent health concerns.
- 4.15. **Dispute Resolution:** All four governments will retain the ability to diverge from generally harmonised rules within their part of the UK. Where divergence is not considered acceptable by one or more governments in the UK, every effort will be made to address disagreement at the lowest level possible. Only when all opportunities for avoiding a dispute at the policy level have been sought will the dispute resolution mechanism be engaged. Dispute resolution

is anticipated to only be required in a very small number of cases and is set out in section 13 of this agreement should it be needed.

The Protocol on Ireland/ Northern Ireland

4.16. The Agreement on the Withdrawal of the United Kingdom from the EU sets out the current arrangements where, although remaining within the UK's custom territory, Northern Ireland will remain aligned with the EU. The following paragraphs of Annex 2 of the Northern Ireland Protocol are relevant to this framework.

- Paragraph 22 - substances of human origin

4.17. This Framework reflects the specific circumstances in NI that arise as a result of the Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland.

4.18. Where one or more of UK Government, the Scottish Government or the Welsh Governments propose to change rules in a way that has policy or regulatory implications for the rest of the UK, or where rules in Northern Ireland change in alignment with the EU, the Framework is intended to provide governance structures and consensus-based processes for considering and managing the impact of these changes.

- As rules evolve to meet the emerging regulatory needs of the UK, Scottish and Welsh Governments, this Framework will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.
- Where rules in Northern Ireland change in alignment with the EU, the Framework will form the basis of a mechanism to ensure consideration by the four governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.

4.19. Where issues or concerns raised by the relevant Northern Ireland Executive Minister(s) in respect of GB-only proposals have not been satisfactorily addressed, they will have the right to trigger a review of the issue as set out in the dispute resolution process at section 13 of this document.

4.20. **The UK and EU Trade and Cooperation Agreement (TCA):** The area of policy covered by this Common Framework does not fall directly within the provisions of the Trade and Cooperation Agreement, although both the

Common Framework and that agreement will impact significantly on devolved and reserved responsibilities.

5. Detailed overview of proposed framework: legislation (primary or secondary)

5.1. N/A – no legislation to support the Framework is considered necessary.

6. Detailed overview of proposed framework: non-legislative arrangements

6.1. A concordat between UKG, SG, WG and NI Department of Health provides the basis for managing and maintaining the collaborative ways of working set out in this framework. Adopting a non-legislative approach maintains the existing good working relationships between the governments and allows for flexibility to adapt where change is needed.

6.2. The underlying principle is that the governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and allowing sufficient scope for UK-wide discussion and decision making.

6.3. If one or more government wishes to diverge from the UK-wide standards for safety and quality, it is agreed that this should be done after consultation with the other UK governments and after consideration of the impact on the existing standards of safety and quality for organs, tissues and cells.

7. Detailed overview of areas where no further action is thought to be needed

7.1. Not applicable.

OPERATIONAL DETAIL

SECTION 3: PROPOSED OPERATIONAL ELEMENTS OF FRAMEWORK

8. Decision making

8.1. Individual governments will be able to make decisions (at a Ministerial level where it relates to changes in legislation or significant policy changes) on the safety and quality standards for organs, tissues and cells where these are not routine decisions made by the licenced establishments themselves. This includes, but is not limited to, the following:

For non-reproductive tissues and cells

- updating technical requirements relating to tissues and cells;

- prescribing traceability requirements and notification requirements in relation to SAERs; and
- verifying equivalent standards of safety and quality where tissues and cells are imported from third countries.

For Organs

- updating requirements for organ and donor characterisation to mitigate risk to human health, usually in response to an emerging disease outbreak; and
- responding to SAERs which present a serious risk to human health.

8.2. If a government wants to make a change to the organs and/or tissues and cells safety and quality legislation, they will:

- notify all governments, setting out details of the proposal and invite comments;
- arrange a meeting with policy officials to discuss the detail of the proposals if a government requests this;
- seek to agree a way forward on the issue; and
- depending on the issue, seek input from the following:
 - advice from an advisory body, the regulator, the donation or blood services; and
 - consultation with stakeholders.

8.3. Officials will share information, advice and views so that each government can advise Ministers on the proposal and its impacts and seek Ministerial decisions.

8.4. If agreement is not reached on a way forward to assess a proposal or on the factual information within the advice to Ministers, any government can escalate the issue so that it can be discussed at senior official level. If an agreement is not reached at senior official level and all alternatives have been exhausted, the proposal can be escalated to be discussed at Ministerial level.

9. Roles and responsibilities of each party to the framework

9.1. The following sets out the role and responsibilities of officials and Ministers in this Framework.

Officials:

9.2. Regular meetings will continue to take place around Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) meetings to provide an opportunity to discuss organs, tissues and cells policy, share updates and consider the short-term and long-term impact of any developments. This will provide an opportunity to discuss this policy and share updates and consider the short-term and long-term impact of any developments. Advice will be shared with Ministers with the rationale for the approach taken (e.g. a UK/GB-wide approach), or why divergent policies may be necessary.

- 9.3. Specific ad-hoc meetings and day-to-day discussions on the policy covered by this Framework will continue. Advice will be put to Ministers outlining the rationale for the approach taken within this policy area (e.g. a UK/GB-wide approach), or why divergent policies may be arranged if/when a proposal arises. Officials across governments will convene to discuss policy issues as appropriate and keep colleagues regularly informed of any ramifications the policy may have on governments.
- 9.4. If officials do not agree when making decisions, issues discussed at a working level can be escalated to senior officials in line with the Framework's dispute avoidance and resolution mechanism (Appendix II).

Senior Officials:

- 9.5. Senior officials will provide strategic direction on the policy governed by this Framework. They may review an issue as per a framework's dispute avoidance and resolution mechanism if officials are not able to agree an approach, in another attempt to reach agreement. Senior officials should convene to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis.

Ministers:

- 9.6. Ministers may receive advice from their officials either concurrently across governments as issues arise or in the course of business as usual work for individual governments. If work is remitted to senior officials and an issue remains unresolved, the issue may be escalated to Ministers. Where Ministers are considering issues as part of the Framework's dispute avoidance and resolution mechanism this could be via several media, including inter-ministerial meetings or by correspondence.

Senior Ministers:

- 9.7. Terminology distinguishing Ministerial hierarchy is not universal across governments. Where there is a distinction, it is likely that advice presented to a Minister who is not a Senior Minister, will be copied to a Senior Minister who may provide an additional steer if needed. In some circumstances, the Senior Minister will also be the most appropriate Minister to make a decision and therefore the distinction between Senior Minister and Minister will not be relevant. In the case of UKG, a Senior Minister would be a Secretary of State (SofS).

Information sharing:

- 9.8. Each government will aim to provide each other with a full and open (as possible) access to scientific, technical and policy information including

statistics and research and, where appropriate, representations from third parties.

10. Roles and responsibilities of existing or new bodies

10.1. The current scientific advisory bodies are:

- **Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)**

The purpose of the JPAC is:

- To ensure that all relevant aspects dealing with the safety of blood and tissues in the UK are covered, and that the professional advice emanating from JPAC is communicated appropriately and in a timely fashion.
 - To prepare detailed service guidelines for the United Kingdom Blood Transfusion Services, taking account of the Blood Safety and Quality Regulations (2005), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and future UK legislation affecting the blood and tissue services. For example, the Tissue Donor Selection Guidelines - Deceased Donors.
 - To be an Advisory Committee to the United Kingdom Blood Transfusion Services, normally by reporting to the Medical Directors of the individual Services who are themselves individually accountable to the Chief Executives/ Directors of the Services. Decisions on policy and implementation would be vested in the individual Chief Executives/Directors and their Service boards and, where appropriate, their respective Health Departments.
- **[Advisory Committee on the Safety of Blood, Tissues and Organs \(SaBTO\)](#)**: Provides policy advice to Ministers in the four governments of the UK on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation.

10.2. Both of the groups above are independent from the UKG, SG, WG and NIE and provide advice to the whole of the UK.

10.3. **Official level meetings:** All parties will continue to regularly share information with one another in relation to the scope of this agreement and will continue to discuss:

- the impact of decisions on other governments, including any impacts on cross-cutting issues;
- prospective policy changes;
- emerging issues and intelligence, etc.

10.4. As mentioned in section 9, Senior Official meetings will be convened to provide strategic direction and to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis. Officials or Senior Officials will then report to the relevant Ministers if necessary, to provide an update or to escalate an issue.

11. Monitoring and enforcement

11.1. Ad-hoc official level meetings will continue to take place to monitor the Framework, where it is not monitored in the course of routine business. The purpose of monitoring is to assess:

- intergovernmental co-operation and collaboration as a result of the Framework;
- whether parties are implementing and complying with the Framework;
- whether divergence has taken place in contravention of the Common Framework principles;
- whether divergence has taken place in contravention of the appropriate intergovernmental structures; and
- whether harmful divergence has taken place that impacts on the policy area covered by the Framework.

11.2. The outcome of this monitoring will be used to inform joint decision-making going forward and the next review and amendment process. If there is an unresolved disagreement, the dispute avoidance and resolution mechanism should be used.

12. Review and amendment

12.1. Process:

- The Review and Amendment Mechanism (RAM) ensures the Framework can adapt to changing policy and governance environments in the future.
- There are two types of review which are outlined below. The process for agreeing amendments should be identical regardless of the type of review.
- The RAM relies on consensus at each stage of the process from the Ministers responsible for the policy areas covered by the non-legislative agreement.
- Third parties can be used by any party to the framework to provide advice at any stage in the process. These include other government departments or bodies as well as external stakeholders such as non-governmental organisations (NGOs) and interest groups.

- At the outset of the review stage, parties to the framework must agree timelines for the process, including the possible amendment stage.
- If agreement is not reached in either the review or amendment stage, parties to the Framework can raise it as a dispute through the Framework's dispute avoidance and resolution mechanism.

12.2. **Review Stage:**

- An initial review will take place one year after the Framework comes into effect; it will be used to determine if the arrangements are functional.
- Following the initial review, a periodic review of the Framework will take place every two years and will be, in line with official or, if required, ministerial-level meetings.
 - The period of two years starts from the conclusion of a periodic review and any amendment stages that follow.
 - During the periodic review, parties to the Framework will discuss whether the governance and operational aspects of the Framework are working effectively, and whether decisions made over the previous two years need to be reflected in an updated non-legislative agreement.
- An exceptional review of the Framework is triggered by a 'significant issue':
 - A significant issue must be time sensitive and fundamentally impact the operation and/or the scope of the framework.
 - The exceptional review may include a review of governance structures if all parties agree it is required. Otherwise, these issues are to be handled in the periodic review.
 - The same significant issue cannot be discussed within six months of the closing of that issue.
- The amendment stage can only be triggered through unanimous agreement by Ministers. If parties agree that no amendment is required, the relevant time period begins again for both review types (for example, it will be [2] years until the next periodic review and at least 6 months until the same significant issue can trigger an exceptional review).

12.2 **Amendment Stage:**

- Following agreement that all parties wish to enter the amendment stage, parties will enter into discussion around the exact nature of the amendment. This can either be led by one party to the framework or all.
- If an amendment is deemed necessary during either type of review, the existing framework will remain in place until a final amendment has been agreed.

- All amendments to the Framework must be agreed by all parties and a new non-legislative agreement signed by all parties.
- If parties cannot agree whether or how a framework should be amended this may become a disagreement and as such could be raised through the framework's dispute avoidance and resolution mechanism.

12.3 Changes to the Framework and concordat will be communicated to stakeholders via the current communication channels.

13. Dispute resolution

13.1. The goal of the dispute avoidance and resolution mechanism is to avoid escalation to the appropriate intergovernmental structures, by resolving any disagreements at the lowest possible level. A disagreement between parties of this framework becomes a 'dispute' when it enters the formal dispute avoidance and resolution process through the appropriate intergovernmental structures.

13.2. This mechanism will only be utilised when genuine agreement cannot be reached, and divergence would impact negatively on the ability to meet the Common Frameworks principles (as defined by the JMC (EN) principles). In those areas where a common approach is not needed in order to meet these principles, an "agreement to disagree" could be considered an acceptable resolution.

Process

13.3 The below diagram (Figure 1) states the levels of escalation of a disagreement to a dispute and the interaction between each level.

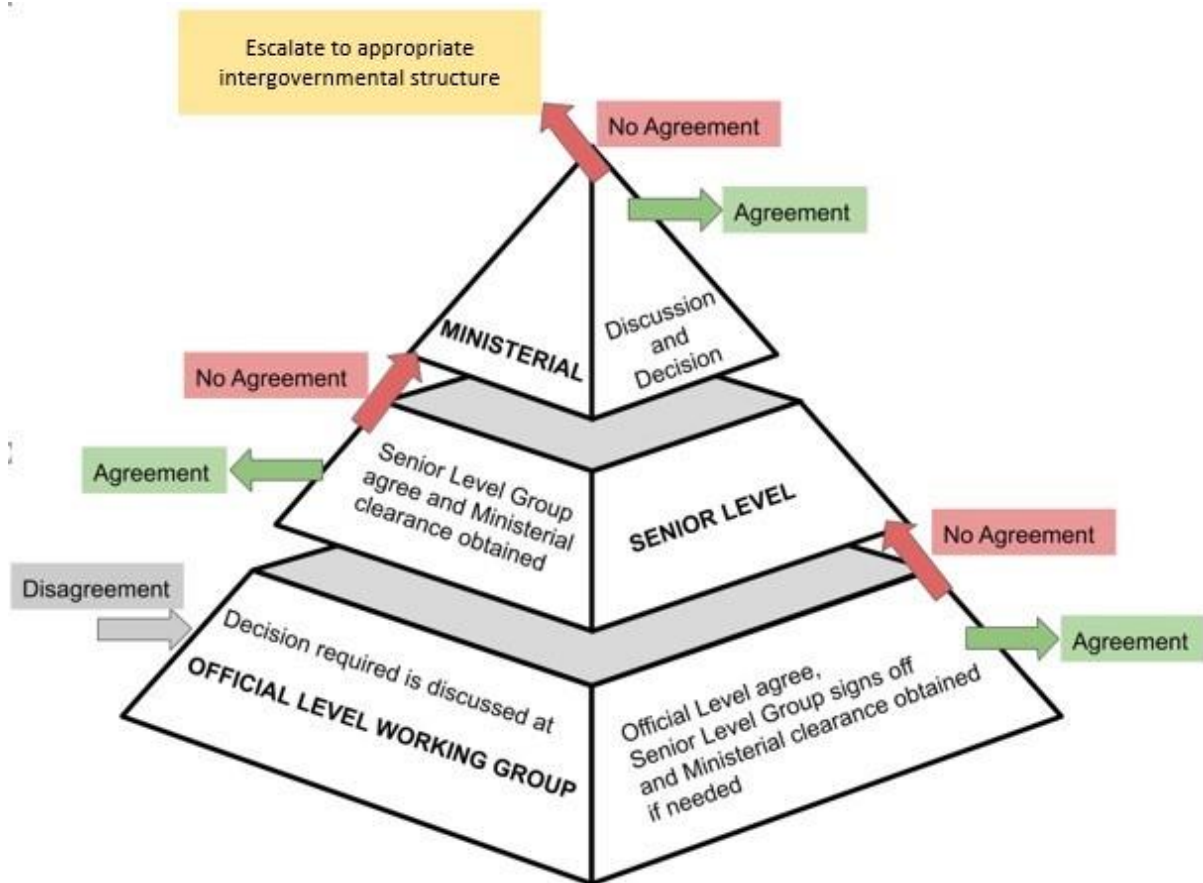


Figure 1: The levels of escalation for disagreements and disputes.

13.3.1 **Official level:** Following the approach set out in sections 8 and 9 and Appendix II of this Common Framework and within the spirit of the concordat, the four governments will seek every opportunity to resolve differences and reach agreement; either to recommend a UK-wide approach or to accept divergence, at official level through discussions. Regular official level meetings will continue to provide an opportunity to discuss organs and non-reproductive tissues and cells safety and quality policy, share updates and consider the short-term and long-term impact of any developments. Policy leads (e.g. Team Leaders) will provide strategic direction on the policy governed by this framework and take key operational decisions.

13.3.2 Where officials become aware of proposals, potential issues or areas of disagreement via any means, the first step will be to seek to resolve this amongst policy leads without escalation. This will usually be resolved via discussion with policy colleagues in each government, to determine the source of the disagreement, to examine evidence, to establish whether it is a significant concern and to work through possible solutions to the satisfaction of all parties. It is expected that most disagreements would be resolved at this point.

13.3.3 Senior Official level: Where it has not been possible to resolve any disagreement at official level, this will initially be referred to Senior Officials for resolution. At this stage Senior Officials can decide whether it would be appropriate to arrange a meeting with counterparts across governments. Alternatively, or after such a meeting, Senior Officials may determine that the issue cannot be resolved at this stage at which point the involvement of Ministers will be required.

13.3.4 Ministerial level: Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the Organs, Tissues and Cells Common Framework, the making of legislation may need to be postponed until all four governments are in agreement on how to proceed. The parties may conclude, having considered potential impacts on patient safety, the JMC (EN) principles and the appropriate intergovernmental structures, that divergence is appropriate.

13.3.5 Resolve through appropriate intergovernmental structure: As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated for resolution under the appropriate intergovernmental structures

Timescales for escalation

13.4 When a proposal is raised at official level, consideration will be given to the urgency of the proposal (i.e. how quickly a decision is required). This assessment will guide timescales for escalation of disagreement within the governance structure, with decisions requiring a more immediate resolution being escalated more quickly.

Evidence gathering

13.5 At each stage, further evidence may be requested from the preceding forum before the disagreement is discussed.

Third parties

13.6 JPAC and SaBTO may be used to provide scientific or technical advice to the UKG, SG, WG and the NI Department of Health.

SECTION 4: PRACTICAL NEXT STEPS AND RELATED ISSUES

14. Implementation

This Framework will take effect once agreed by all parties and approved by Ministers. The Common Framework will only be put in place once there is final ministerial sign off from all four governments.

APPENDIX I: Joint Ministerial Committee (EU Negotiations) Communique - October 2017

JOINT MINISTERIAL COMMITTEE (EU NEGOTIATIONS) COMMUNIQUE October 2017

The fifth Joint Ministerial Committee (EU Negotiations) met today in 70 Whitehall. The meeting was chaired by the Rt Hon Damian Green MP, First Secretary of State and Minister for the Cabinet Office.

The attending Ministers were:

From the UK Government: the First Secretary of State and Minister for the Cabinet Office, Rt Hon Damian Green MP; the Secretary of State for Exiting the EU, Rt Hon David Davis MP; the Secretary of State for Wales, Rt Hon Alun Cairns MP; the Secretary of State for Scotland, Rt Hon David Mundell MP; and, Parliamentary Under Secretary of State for Northern Ireland, Lord Bourne of Aberystwyth.

From the Welsh Government: Cabinet Secretary for Finance and Local Government, Mark Drakeford AM.

From the Scottish Government: the Minister for UK Negotiations on Scotland's Place in Europe, Michael Russell MSP.

In the absence of Ministers from the Northern Ireland Executive, a senior civil servant from the Northern Ireland Civil Service was in attendance.

The Chair opened the meeting by summarising the bilateral engagement and political developments that had taken place since JMC(EN) last met. The Secretary of State for Exiting the EU provided an update on the previous rounds of negotiations with the EU and the Committee discussed forthcoming priorities and the future relationship with the EU. The Committee discussed the establishment of common frameworks.

Ministers noted the positive progress being made on consideration of common frameworks and agreed the principles that will underpin that work (attached).

Common Frameworks: Definition and Principles

Definition

As the UK leaves the European Union, the Government of the United Kingdom and the devolved administrations agree to work together to establish common approaches in some areas that are currently governed by EU law, but that are otherwise within areas of competence of the devolved administrations or legislatures. A framework will set out a common UK, or GB, approach and how it will be operated and governed. This may consist of common goals, minimum or maximum standards, harmonisation, limits on action, or mutual recognition, depending on the policy area and the objectives being pursued. Frameworks may be implemented by legislation, by executive action, by memorandums of understanding, or by other means depending on the context in which the framework is intended to operate.

Context

The following principles apply to common frameworks in areas where EU law currently intersects with devolved competence. There will also be close working between the UK Government and the devolved administrations on reserved and excepted matters that impact significantly on devolved responsibilities.

Discussions will be either multilateral or bilateral between the UK Government and the devolved administrations. It will be the aim of all parties to agree where there is a need for common frameworks and the content of them.

The outcomes from these discussions on common frameworks will be without prejudice to the UK's negotiations and future relationship with the EU.

Principles

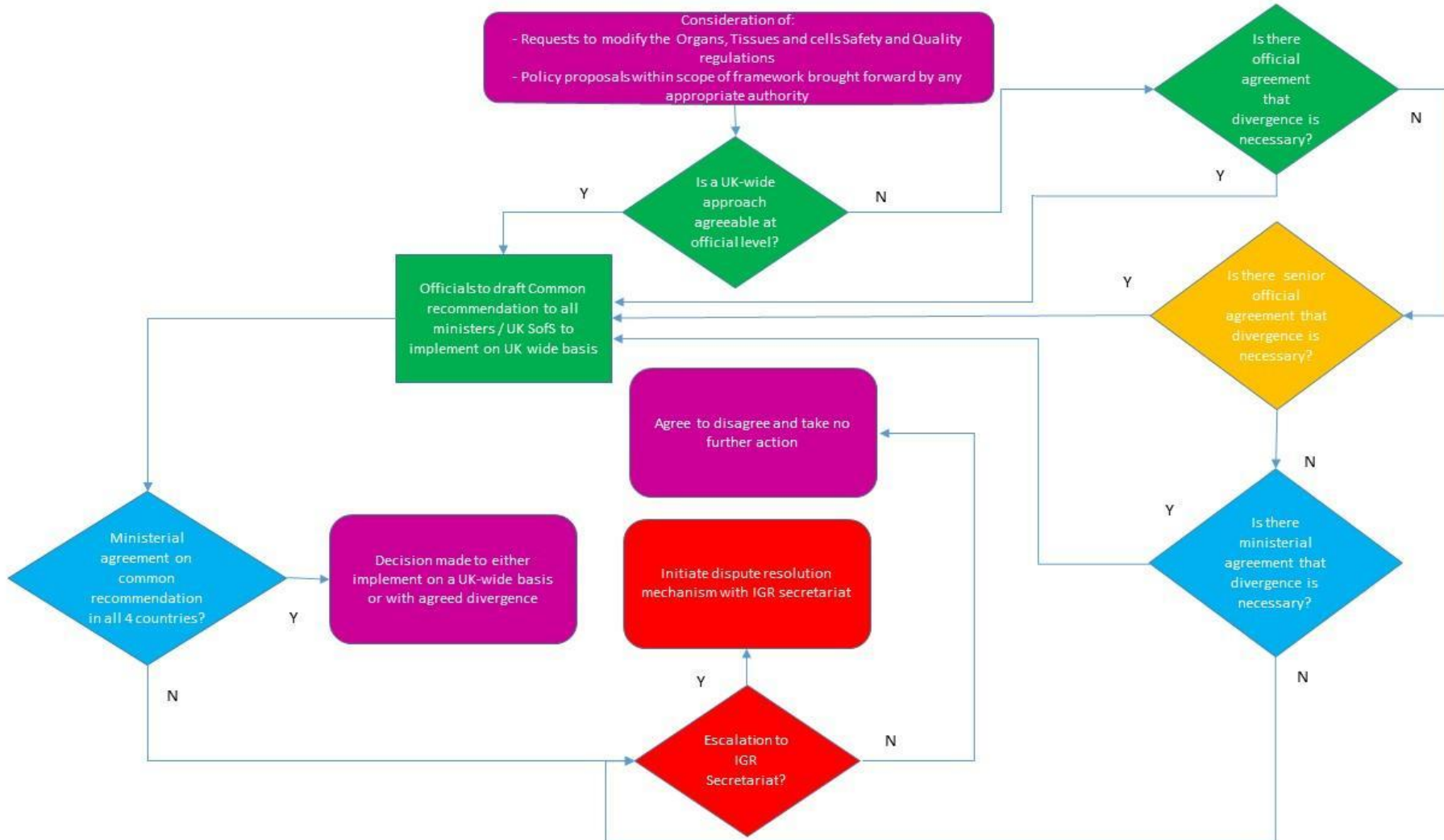
Common frameworks will be established where they are necessary in order to:

- enable the functioning of the UK internal market, while acknowledging policy divergence;
 - ensure compliance with international obligations;
 - ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
 - enable the management of common resources;
 - administer and provide access to justice in cases with a cross-border element;
 - safeguard the security of the UK.
1. Frameworks will respect the devolution settlements and the democratic accountability of the devolved legislatures, and will therefore:
 - be based on established conventions and practices, including that the competence of the devolved institutions will not normally be adjusted without their consent;

- maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by current EU rules;
 - lead to a significant increase in decision-making powers for the devolved administrations.
2. Frameworks will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK that shares a land frontier with the EU. They will also adhere to the Belfast Agreement.

APPENDIX II: Joint Decision-making Dispute Avoidance and Dispute Resolution Process

Key				
Inputs/Outputs	Senior Officials	Officials	Secretary of State (SofS)/ Portfolio Ministers	The ministerial committee outlined in the MoU on Devolution



Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
<p>Framework process</p> <p>In accordance with section 9 of the Framework Outline Agreement policy colleagues will meet regularly. Requests to modify legislation and policy proposals within scope of the framework may be brought forward by the appropriate authority.</p>	<p>1. Further discussions at official and senior official level.</p>	<p>1. Further discussion of issues.</p>
<p>Decisions on divergence</p> <p>• Scientific advice and wider risk management issues are considered to reach a consensus for a common recommendation to Ministers.</p> <p>All four governments submit the same common recommendations to Ministers for a decision (either for common approaches across the UK or divergent approaches).</p> <p>• Where agreement cannot be reached at official level issues are referred to senior officials for consideration.</p>	<p>2. Dispute avoidance initiated:</p> <ul style="list-style-type: none"> • Pause work progressing implementation of Ministerial decision until differences are resolved. • Senior officials from all four governments meet to consider ministerial views and determine whether there is any additional information available to support an agreed approach revert to consider any alternative approach. • Officials submit risk management common recommendations, informing Ministers of the revisions with rationale for the approaches now being recommended across all four governments. 	<p>2. Dispute avoidance initiated: Escalation to highest level, dispute resolution process initiated</p> <ul style="list-style-type: none"> • Pause work progressing implementation of SofS / Cab Sec / Perm Sec* level decision until differences are resolved. • Officials submit further/revised common recommendations, informing the appropriate intergovernmental structures of the approaches being recommended across all four governments. • The appropriate intergovernmental structures consider common recommendations and SofS / Cab Sec / Perm Sec views and consider any additional information available to support decision making. • If the approach being recommended is not the same across the UK, officials provide explanation of the different approaches being recommended and a summary rationale setting out why it is appropriate to diverge and why agreement has not been reached to date. If the approach being recommended is agreed across the UK, proceed to a ministerial decision. • The appropriate intergovernmental structures consider the common recommendation individually and provide a response to SofS / Min / Perm Sec private offices.

<p>3. Ministers review recommendation seeking decisions. Officials will be asking Ministers to agree to the recommended approach.</p>	<p>3. Recommendations made to Ministers in the four governments:</p> <ul style="list-style-type: none"> ● Officials submit further/ revised common recommendations, informing Ministers of the approaches being recommended across all four governments. ● If the recommended approach differs across the UK, officials provide explanation and a summary rationale setting out why it is appropriate to diverge. ● If the approach being recommended is NOT agreed by Ministers and officials from the four governments meet again. 	<p>3. SofS / Min/ Perm Sec reach agreed decision on common recommendation.</p> <ul style="list-style-type: none"> ● Private offices inform officials in their own respective government of the decision. ● Policy officials in all four governments share information on SofS / Min / Perm Sec decisions.
<p>4. Ministers reach agreed decision on common recommendations.</p> <p style="text-align: center;">Pack Page 85</p>	<p>4. Ministers receive risk management common recommendation seeking decision.</p> <ul style="list-style-type: none"> ● Each Minister considers the common recommendation individually and provides a response. ● If the approach being recommended is NOT agreed across the UK, senior officials meet to discuss the issues. 	
	<p>5. Ministers reach agreed decision on common recommendations.</p> <ul style="list-style-type: none"> ● If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK: <ul style="list-style-type: none"> ○ Private Offices inform officials in their own respective governments of the decision to implement agreed approach. 	

	<ul style="list-style-type: none">○ Policy officials in all four governments share information on the Ministers' decisions	
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SofS / Cab Sec / Perm Sec = Secretary of State/Cabinet Secretary/Permanent Secretary

SofS / Min/ Perm Sec = Secretary of State/Ministers/Permanent Secretary

ANNEX I:

Concordat on the safety and quality of organs and tissues and cells (apart from embryos and gametes)

Introduction

1. This Concordat is an agreement between the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Department of Health in the area of safety and quality of organs and non-reproductive tissues and cells. It gives effect to the Organs, Tissues and Cells (apart from embryos and gametes)⁴ Common Framework. It also sets out the continuation of good working relations, open communication; the maintenance of a compatible minimum set of high standards of safety and quality for organs and non-reproductive tissues cells; a dispute avoidance and resolution mechanism; and a review and amendment mechanism.
2. This agreement is a political commitment and is not intended to be legally binding or enforceable. It is in accordance with the overarching Memorandum of Understanding (MoU) on Devolution⁵ and the Common Frameworks principles agreed at the Joint Ministerial Committee (EU Negotiations) (JMC(EN)) on 16 October 2017⁶.

Scope

3. This agreement covers the subject matter of the EU Organs Directive (2010/53/EU) and EU Tissues and Cells Directive (2004/23/EC) and implementing acts. The 2019 Organs, Tissues and Cells safety and quality statutory instruments⁷ retain the UK's safety and quality standards for organs and non-reproductive tissues and cells and amends the regulations to ensure that they will operate as intended following the UK's departure from the EU. The 2019 Organs, Tissues and Cells Safety and Quality EU Exit SIs were amended by the 2020 Organs, Tissues and Cells SIs⁸.

Principles for working together

4. This agreement will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. It will also adhere to the Belfast Agreement.
5. The parties affirm their mutual commitment to work together on the application of retained EU law in relation to organs and non-reproductive tissues and cells safety and quality policy and their respective responsibilities. This co-operation is intended to give all parties the assurance, that working relationships will be conducted in a

⁴ References to non-reproductive tissues and cells means cells apart from embryos and gametes

⁵

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/316157/MoU_between_the_UK_and_the_Devolved_Administrations.pdf

⁶

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/652285/Joint_Ministerial_Committee_communique.pdf

⁷ The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019/483 and The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019/481.

⁸ The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2020 and The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020/1306.

manner that is both collaborative and helpful, aiming, where possible and appropriate, to achieve agreement on policy. In addition, all parties agree that regular contact will continue to discuss ongoing business of mutual interest.

6. This Concordat is intended to provide the basis for the management and maintenance of a compatible minimum set of safety and quality standards by setting out governance arrangements and a dispute resolution process. All parties to the Concordat agree that a Common Framework approach, that recognises the Common Frameworks principles agreed at JMC(EN) in 2017 and the finalised principles for intergovernmental relations, is highly desirable across the UK. The outcomes of the intergovernmental relations review are in the process of being implemented. Once confirmation has been provided from each government, the outcomes of the review and appropriate intergovernmental structures will be reflected in this Common Framework
7. Open communications will be maintained and information shared, to the extent permitted by law, at the earliest opportunity. This may include but is not confined to policy issues, stakeholder views, preparations for and outcome of consultations and research, media interest and lines to take, and emerging issues and intelligence (UK/EU/international).
8. The parties acknowledge that there may be a need for their separate responsibilities to be tackled with uniformity. For example, events could transpire that would require urgent action (such as, but not limited to, responding to emerging diseases). Each party shall consider promptly and thoroughly any concerns raised by the others. Where all agree that consistency is needed, consultation on a common approach shall be undertaken.
9. The parties shall inform each other at the earliest opportunity of any new policy proposals, before they are made public, to allow full consideration and a common approach to be reached wherever possible. Each party will also appraise the others of the ongoing development of such proposals. Where this will not be possible, each party will inform the others as soon as possible.
10. The parties to this agreement commit to resolving any issues at the lowest possible level and recognise that agreement to disagree can be an acceptable outcome, provided the JMC(EN) Common Frameworks principles remain upheld.
11. Where common recommendations may be made, Ministers will retain the right to take individual decisions for their government. For those areas within the scope of the Organs and Tissues and Cells (apart from embryos and gametes) Common Framework, the opportunity for consistency of approach across governments will be sought in the first instance. The ability for divergence must be retained, while taking account of its impact on patient safety and confidence, and the functioning of the UK internal market. Every effort will be made at working level to resolve any disagreements in difference of approach. Where a consensus cannot be reached by these arrangements (whether that is agreement to a UK wide approach or to accept divergence) the dispute avoidance and resolution mechanism would come into play.

Dispute avoidance and resolution

12. The goal of the dispute avoidance and resolution mechanism is to avoid escalation to formal processes through the appropriate intergovernmental structures, by resolving any disagreements at the lowest possible level. A disagreement between parties of

this Framework becomes a 'dispute' when it enters the formal dispute avoidance and resolution process through the appropriate intergovernmental structures.

- This mechanism will only be utilised when genuine agreement cannot be reached, and divergence would impact negatively on the ability to meet the JMC (EN) Common Frameworks principles. In those areas where a common approach is not needed in order to meet these principles, an "agreement to disagree" could be considered an acceptable resolution.

Process

- The below diagram (Figure 1) states the levels of escalation of a disagreement to a dispute and the interaction between each level.

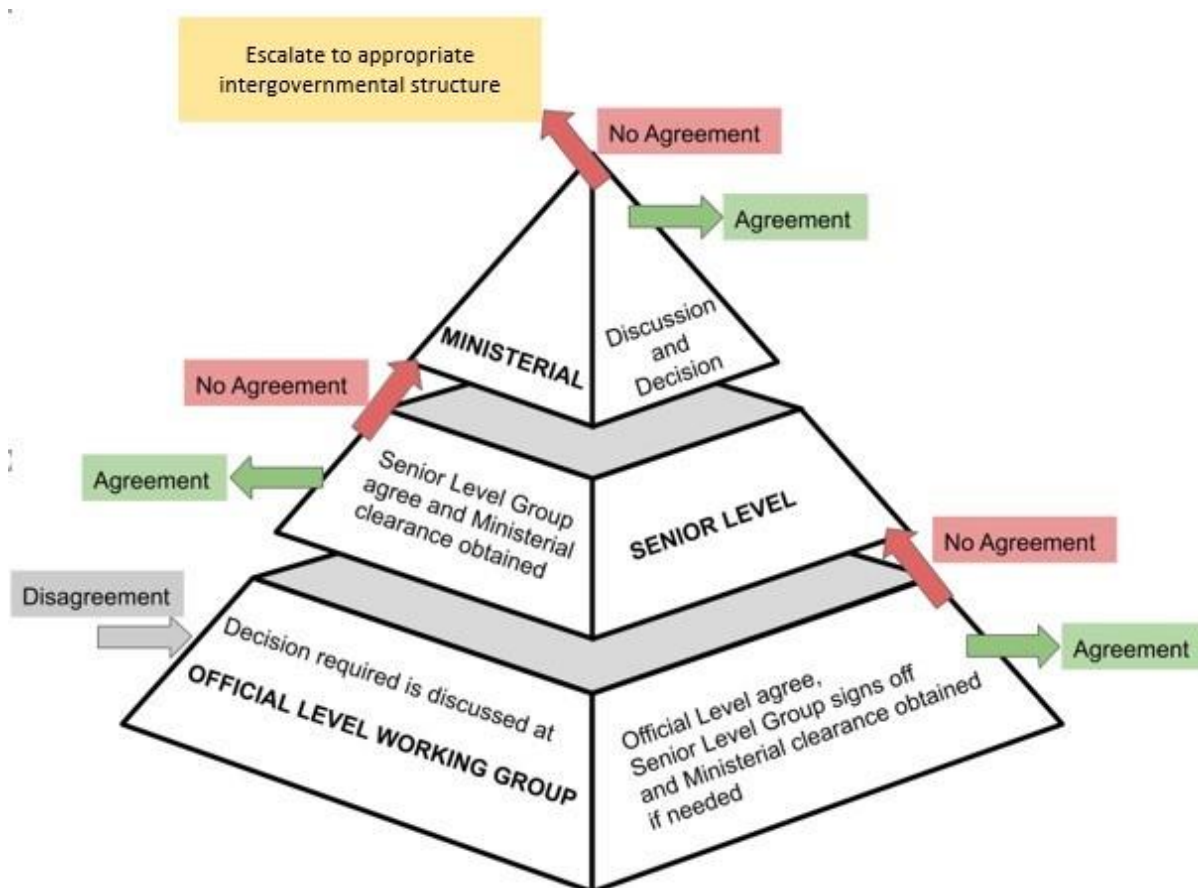


Figure 1: The levels of escalation for disagreements and disputes.

- Following the approach set out in section 8 and 9 and Appendix II of the Organs, Tissues and Cells Common Framework and within the spirit of this Concordat, all governments will seek every opportunity to resolve differences and reach agreement; either to recommend a UK-wide approach or to accept divergence, at official level through discussions.
- Where it has not been possible to resolve any disagreement in approach at official level, this will initially be referred to Senior Officials for resolution.
- Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the Organs, Tissues and Cells Common Framework. The parties may conclude, having

considered potential impacts on patient safety and the JMC principles and reflecting appropriate intergovernmental structures, that divergence is appropriate.

18. As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated to appropriate intergovernmental structures for resolution under the dispute resolution process set out in the appropriate intergovernmental structures.

Timescales for escalation

19. When a proposal is raised at official level, consideration will be given to the urgency of the proposal (i.e. how quickly a decision is required). This assessment will guide timescales for escalation of disagreement within the governance structure, with decisions requiring a more immediate resolution being escalated quicker.

Evidence gathering

20. At each stage further evidence may be requested from officials at the preceding level, or from stakeholders (listed below), before the disagreement is discussed.

Third parties

21. The Human Tissue Authority (HTA), the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) may be used to provide advice on the most appropriate ways to ensure the safety of cells, tissues and organs for transfusion/transplantation.

Official level meetings

1. **Official level organs and non-reproductive tissues and cells meetings:** All parties will continue to regularly share information with one another in relation to the scope of this agreement and will continue to discuss:
 - the impact of decisions on other governments, including any impacts on cross-cutting issues;
 - prospective policy changes;
 - emerging issues and intelligence, etc.
22. As previously mentioned, Senior Official meetings will be convened to provide strategic direction and to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis. Senior Officials will then report to the relevant Ministers as necessary, to provide an update or to escalate an issue.

Review and amendment mechanism

Process

23. The Review and Amendment Mechanism (RAM) ensures the Framework can adapt to changing policy and governance environments in the future.
24. There are two types of review which are outlined below. The process for agreeing amendments should be identical regardless of the type of review.
25. The RAM relies on consensus at each stage of the process from the Ministers responsible for the policy areas covered by this non-legislative agreement.

26. Third parties can be used by any party to the Framework to provide advice at any stage in the process. These include other government departments or bodies as well as external stakeholders such as non-governmental organisations (NGOs) and interest groups.
27. At the outset of the review stage, parties to the Framework must agree timelines for the process, including the possible amendment stage.
28. If agreement is not reached in either the review or amendment stage, parties to the Framework can raise it as a dispute through the Framework's dispute avoidance and resolution mechanism.

Review stage

29. An initial review will take place one year after the Framework comes into effect, it will be used to determine if the arrangements are functional.
30. Following the initial review, a periodic review of the Framework will take place every two years.
 - The period of two years starts from the conclusion of a periodic review and any amendment stages that follow.
 - During the periodic review, parties to the Framework will discuss whether the governance and operational aspects of the Framework are working effectively, and whether decisions made over the previous two years need to be reflected in an updated non-legislative agreement.
31. An exceptional review of the Framework is triggered by a 'significant issue':
 - A significant issue must be time sensitive and fundamentally impact the operation and/or the scope of the Framework.
 - The exceptional review may include a review of governance structures if all parties agree it is required. Otherwise, these issues are to be handled in the periodic review.
 - The same significant issue cannot be discussed within six months of the closing of that issue.
32. The amendment stage can only be triggered through unanimous agreement by Ministers. If parties agree that no amendment is required, the relevant time period begins again for both review types (for example, it will be two years until the next periodic review and at least six months until the same significant issue can trigger an exceptional review).

Amendment stage

33. Following agreement that all parties wish to enter the amendment stage, parties will enter into discussion around the exact nature of the amendment. This can either be led by one party to the Framework or all.
34. If an amendment is deemed necessary during either type of review, the existing Framework will remain in place until a final amendment has been agreed.
35. All amendments to the Framework must be agreed by all parties and a new non-legislative agreement signed by all parties.

36. If parties cannot agree whether or how a Framework should be amended this may become a disagreement and as such could be raised through the Framework's dispute avoidance and resolution mechanism.
37. Changes to the Framework and Concordat will be communicated to stakeholders via the current communication channels.

The Protocol on Ireland/ Northern Ireland

38. The Agreement on the Withdrawal of the United Kingdom from the EU sets out the current arrangements where, although remaining within the UK's custom territory, Northern Ireland will remain aligned with the EU. The following paragraphs of Annex 2 of the Northern Ireland Protocol are relevant to this framework.

Paragraph 22 - substances of human origin

39. This Framework reflects the specific circumstances in NI that arise as a result of the Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland.
40. Where one or more of UK Government, the Scottish Government or the Welsh Governments propose to change rules in a way that has policy or regulatory implications for the rest of the UK, or where rules in Northern Ireland change in alignment with the EU, the Framework is intended to provide governance structures and consensus-based processes for considering and managing the impact of these changes.
 - As rules evolve to meet the emerging regulatory needs of the UK, Scottish and Welsh Governments, this Framework will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.
 - Where rules in Northern Ireland change in alignment with the EU, the Framework will form the basis of a mechanism to ensure consideration by the four governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.
41. Where issues or concerns raised by the relevant Northern Ireland Executive Minister(s) in respect of GB-only proposals have not been satisfactorily addressed, they will have the right to trigger a review of the issue as set out in the dispute resolution process at section 13 of this document.

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Eluned Morgan MS
Minister for Health and Social Services
Welsh Government

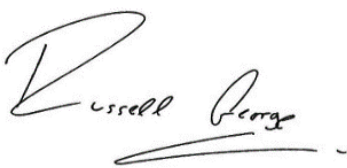
17 December 2021

Dear Eluned

Provisional common frameworks: Blood Safety and Quality, and Organs Tissues and Cells (apart from embryos and gametes)

To inform our consideration of the Blood Safety and Quality, and Organs Tissues and Cells (apart from embryos and gametes) common frameworks, we would welcome the views of the Welsh Government on the matters set out in the annex to this letter **by Thursday 13 January 2022**.

Yours sincerely



Russell George MS
Chair, Health and Social Care Committee

cc Huw Irranca-Davies, Chair, Legislation, Justice and Constitution Committee

Croesewir gohebiaeth yn Gymraeg neu Saesneg. We welcome correspondence in Welsh or English.

Annex: Common frameworks: request for further information

To assist our deliberations on the Blood Safety and Quality, and Organs Tissues and Cells (apart from embryos and gametes) common frameworks, we would welcome further information on the matters listed below. We would be grateful to receive your response **by Thursday 13 January**.

General

1. Why are common frameworks needed for these policy areas?
2. The Welsh Government has taken on new functions in these policy areas following the UK's exit from the EU. How has the Welsh Government ensured that it has the resources and expertise to exercise these functions effectively?
3. What role does the Welsh Government have in oversight of the work of the Independent Advisory Committee on the Safety of Blood, Tissues and Organs and the Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee?

Managing divergence

4. The frameworks state that they will allow for 'necessary divergence' within the UK. Could you set out what 'necessary' means in this context?
5. Do you consider that the frameworks give the Welsh Government and the Senedd appropriate scope to make law and policy for Wales?
6. Will the frameworks have any impact on any existing or planned Welsh legislation or policy?
7. How would the frameworks affect the Welsh Government's ability to respond to urgent situations, such as emerging new diseases?
8. The European Commission intends to adopt changes to legislation on blood, tissues and cells in early 2022. Does the framework allow sufficient scope for the Welsh Government to make equivalent changes for Wales, and do you plan to do this?
9. As part of its review of retained EU law, the UK Government is asking UK Government departments to consider whether such law should be amended or repealed by 'an accelerated process'. Would such changes be considered through the framework processes, and (if so) how?
10. Can the Welsh Government confirm that neither framework will interact with the UK Internal Market Act?

International obligations

11. What international obligations are there in these policy areas?
12. How does the framework take international obligations into account?
13. How will the framework be amended in future to reflect a new international obligations?

Governance and dispute resolution

14. Do you consider the dispute resolution mechanisms for the frameworks to be robust enough for their intended purpose?
15. Who will be the final arbiter in the event of a dispute, and will there be a right of appeal in the event that one of the parties is dissatisfied with the resolution of a dispute?
16. Will the Welsh Government notify the Senedd of disputes raised through the framework?

The development of the frameworks

17. How did the Welsh Government engage with stakeholders on the development of the frameworks? How does each framework reflect the responses of stakeholders in Wales?

Review and revision

18. How will the Senedd and stakeholders be updated on the continuing operation of the frameworks?
19. How will the Senedd and stakeholders be able to contribute to the review and amendment process for the frameworks?
20. If changes are made in future, how will the Senedd be notified? What scrutiny procedure will apply to the changes?

Agenda Item 5.2

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref: MA/EM/3486/21

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3 December 2021

Dear Russell and Huw,

I am pleased to share with the Committee a finalised provisional Framework for Organs, Tissues and Cells, as well as a Framework for Blood Safety and Quality (the Frameworks). Also included are related Concordat documents.

These Frameworks establish common expectations around key areas of cooperation in relation to quality and safety standards for organs, tissues, cells and blood in the context of the UK's departure from the EU. All four UK administrations agreed to work together to establish common approaches, known as Common Frameworks, in policy areas that were previously governed by EU law, and which intersect with areas of devolved competence.

Officials in the Welsh Government, together with their counterparts across the UK, and with relevant stakeholders in these fields, have been working jointly to develop these Frameworks to share with their respective scrutiny Committees for Parliamentary scrutiny.

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

The set of documents can be found at:

[The Organs, Tissues and Cells \(apart from embryos and gametes\) Provisional Common Framework - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

[The Blood Safety and Quality Provisional Common Framework - GOV.UK \(www.gov.uk\)](http://www.gov.uk)

Yours sincerely

A handwritten signature in blue ink, appearing to read 'M. E. Morgan'.

Eluned Morgan AS/MS

Y Gweinidog Iechyd a Gwasanaethau Cymdeithasol
Minister for Health and Social Services



HM Government

The Blood Safety and Quality Provisional Common Framework



The Blood Safety and Quality Provisional Common Framework

Presented to Parliament
by the Secretary of State for Health and Social Care
by Command of Her Majesty

December 2021

CP 517



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The Blood Safety and Quality Provisional Common Framework

OUTLINE

SECTION 1: WHAT WE ARE TALKING ABOUT

1. Policy Area

Blood Safety and Quality

- 1.1 The Joint Ministerial Committee (EU Negotiations) agreed that officials should work together to develop arrangements for Common Frameworks (see Appendix I). This Framework relates to blood safety policy. It encompasses elements of the Blood Directive (Directive 2002/98/EC) and the implementing acts which relate to the safety and quality of blood and blood components. This Framework sets out arrangements for co-operation between officials in the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Department of Health).
- 1.2 The Blood Directive aims to establish minimum safety and quality standards for human blood and its components to ensure a high level of health protection. It covers blood collection (including donation) and testing, as well as the processing, storage and distribution of blood when it is used in transfusions. The EU Directives that intersect with devolved competence in this policy area are listed in the section below.
- 1.3 In accordance with the retained EU law that implements the Blood Directive, the UKG, SG, WG and NI Department of Health are obliged to ensure that safety and quality standards are maintained.
- 1.4 **To note:** The safety and quality of blood products is regulated under separate legislation and is covered by Medicines policy. More information about this can be found in section 2.

2. Scope

- 2.1 **Intersection with devolved competence:** This policy area (blood safety and quality) was previously governed by harmonised EU Directives (set out below). The EU Directives are implemented in domestic legislation applicable across the whole of the UK. Enforcement of the implementing legislation is delegated to the UK-wide regulator, the Medicines and Healthcare products Regulatory Agency (MHRA).

2.2 As the Transition Period has ended, the different governments have wider scope to use their powers to make changes to blood safety and quality regulation.

2.3 This Framework will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. It will also adhere to the Belfast Agreement.

2.4 **EU Legislation:** EU legislation is currently implemented on a UK-wide basis. The main piece of EU legislation that intersects with devolved competence in this policy area is Directive 2002/98/EC (“the Blood Directive”). The Blood Directive sets the safety and quality standards in relation to blood and blood components.

2.5 The implementing directives that intersect with devolved competence (for Northern Ireland, Scotland and Wales) in this policy area are:

- **Commission Directive 2004/33/EC** as regards certain technical requirements for blood and blood components;
- **Commission Directive 2005/61/EC** as regards traceability requirements and notification responsibilities in case of serious adverse reactions and events;
- **Commission Directive 2005/62/EC** as regards European Union standards and specifications relating to the quality system for blood establishments;
- **Commission Directive 2009/135/EC** which allows for temporary exemptions from the requirements set out in Commission Directive 2004/33/EC in light of a risk of shortage of blood and blood components caused by the Influenza A (H1N1) pandemic; and
- **Commission Directives 2011/38/EU, 2014/110/EU and 2016/1214** which make amendments to the implementing directives referred to above.

2.6 **Broadly the retained EU law in this area:**

- sets the standard for the safety and quality of blood and blood components;
- sets the technical requirements for blood and blood donation and the traceability requirements and notification responsibilities in case of serious adverse events or reactions (SAERs);
- sets out Community standards and specifications relating to the quality system for hospital blood banks and facilities; and
- addresses quality system standards and specifications for blood establishments and sets some further specific technical requirements.

- 2.7 **Transfer of Commission Powers:** The safety and quality of blood is an area of devolved competence. Statutory instruments made in 2019 under powers in the European Union (Withdrawal) Act 2018 transferred to the UKG, SG, WG and the NI Department of Health power to make regulations on matters previously included in implementing Directives made by the European Commission. This includes powers to update technical requirements, for example, requirements to ensure traceability in line with scientific and technical developments. These powers are limited to authorities in Great Britain by statutory instrument made in order to implement the Ireland/Northern Ireland Protocol, as the 2018 Act confers the necessary powers on the NI Department.
- 2.8 **Competence:** Legislative competence for the safety and quality of blood and blood components is devolved to Northern Ireland, Scotland and Wales. Therefore, the Framework has been made on a UK-wide basis with the agreement of the UKG, SG, WG and NI Department of Health. This will facilitate the continuity of good working relations, open communication and the maintenance of a compatible minimum set of high standards of safety and quality for blood and blood components. The UKG, SG, WG and NIE have agreed with the principles that will govern the development of the Framework.
- 2.9 **Extent:** This Framework is UK-wide (covering England, Northern Ireland, Scotland and Wales), but does not cover the Crown Dependencies or Overseas Territories.
- 2.10 **Scope within rules for different parts of the UK to do things differently:** Maintaining a compatible minimum set of safety and quality standards between the UKG, SG, WG and NI Department of Health will make it easier for blood to continue to be shared across the UK. This Framework agreement sets out a process by which a government can suggest future changes to the standards and how such a proposal will be collectively considered before one or more governments introduces a change. It will allow for necessary divergence by one or more governments as required, in order to respond to needs such as location-dependent public health concerns.
- 2.11 **Out of Scope:** Blood products or plasma derivatives are covered by human medicines regulations. The manufacture of plasma-derived blood products is subject to pharmaceutical legislation as they are classified as medicines, while the donation, collection and testing of plasma is regulated by the same legislation as blood and blood components. Donated plasma, a component of blood, can be used to manufacture medicinal products like immunoglobulins, albumins and non-recombinant clotting factors (e.g. Factor VIII).

2.12 Interdependencies include:

- **The Common Framework for the safety and quality of organs, tissues and cells:** as there are joint UK-wide groups that advise Ministers and health departments on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion/transplantation.
- **Medicines Regulation:** UK plasma can be used for fractionation in order to produce some plasma-derived medicines, so there are also some interdependencies between the requirements of the Blood Safety and Quality Regulations 2005, which continue to govern the collection of plasma, and the Human Medicines Regulations 2012, which govern the manufacture of medicinal products from plasma.
- **Medical devices legislation:** as reagents (medical devices) are used in the collection and processing of blood and blood components.

3. Definitions

- 3.1 **Blood components:** A therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods.
- 3.2 **Blood products:** Any therapeutic product derived from human blood or plasma, this includes plasma derivatives manufactured from pooled plasma donations in plasma fractionation centres (such as albumin, coagulation factors and immunoglobulins). Plasma derivatives are covered by the Medicines Act and, like any other drug, must be prescribed by a licensed practitioner.
- 3.3 **Memorandum of Understanding (MoU) on Devolution:** The overarching MoU which sets out the understanding of, on the one hand, the UKG, and on the other, the Scottish Ministers, the Welsh Ministers, and the Northern Ireland Executive Committee of the principles that will underlie relations between them. This is separate to the Joint Ministerial Committee (EU Negotiations) Communique of October 2017.
- 3.4 **Joint Ministerial Committee (EU Negotiations) (JMC(EN)) Communique October 2017:** The committee members included representatives from the UKG, SG, WG and NIE. The group was established to provide a means for the devolved governments to be fully engaged in determining the UK's approach to EU and trade related issues. On 16 October 2017, agreement was reached on the principles and definitions for the Common Frameworks for areas where EU law intersects with

devolved competence. In June 2020, NIE Ministers agreed to the principles set out in the communique, following the restoration of the NIE in January 2020.

3.5 **Concordat:** Joint non-legislative agreement that gives effect to the Common Framework.

3.6 **2019 Blood Safety and Quality EU Exit SI:** The Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2019 (as amended by the Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2020).

SECTION 2: PROPOSED BREAKDOWN OF POLICY AREA AND FRAMEWORK

4. Summary of proposed approach

4.1 **Purpose and general principles**¹: In 2018 it was agreed that a Common Framework in this area would be desirable across the UK. The JMC (EN) principles are described in the Joint Ministerial Committee's communique of 16 October 2017. The communique sets out that Common Frameworks will be established where they are necessary in order to:

- **enable the functioning of the UK internal market, while acknowledging policy divergence:** for blood this will make it easier for blood and blood components to be shared around the UK.
- ensure compliance with international obligations;
- ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
- enable the management of common resources;
- administer and provide access to justice in cases with a cross-border element;
- **safeguard the security of the UK:** for blood the sharing of serious adverse events or reactions (SAERs) information to maintain patient safety.

4.2 The outcomes of the intergovernmental relations review are in the process of being implemented. Once confirmation has been provided from each government, the outcomes of the review and appropriate intergovernmental structures will be reflected in this Common Framework.

¹ The principles that are relevant for blood safety and quality are in bold.

- 4.3 A level of commonality would be beneficial particularly for organisations that operate across UK borders and therefore, as is currently the case, close collaboration between the governments should continue.
- 4.4 There is currently good information sharing and collaboration across the UK. This Framework agreement should support the continuation of this.

EU Exit SIs:

- 4.5 Although competence in respect of blood is devolved, it was agreed that there would be UK-wide legislation regarding the safety and quality standards for blood in the event of a 'no-deal' EU exit (The 2019 Blood Safety and Quality EU Exit SIs²). The legislation was made to ensure that the regulatory framework for blood could operate as intended following the UK's departure from the EU, and to retain the safety and quality standards for blood. The legislation also transfers power to update certain aspects of the quality and safety regulations (such as updating safety and quality standards in response to technological advances) to either the Secretary of State for Health and Social Care on behalf of the UK (with the consent of Scottish and Welsh Ministers and the Department of Health in Northern Ireland) or, to each of the Ministers in relation to their part of the UK.
- 4.6 The 2019 Blood Safety and Quality EU Exit SI was amended by the Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2020 (2020 Blood SI³) to implement the Protocol on Ireland/Northern Ireland. The 2020 Blood SI limits the regulation-making powers in the 2019 SI to Great Britain, as the EU (Withdrawal) Act 2018 now contains regulation-making powers (section 8C and paragraph 11M of Schedule 2), enabling the Secretary of State for Health and the NI Department of Health to make regulations to implement the Protocol including in response to future changes in EU law.

Non-legislative:

- 4.7 As the UKG, SG, WG and NI Department of Health will have the power to diverge from the UK Regulations should they choose, a concordat (Annex I) between the

² The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019/4

³ The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2020/1304

four nations will be put into place to formally agree the ways of working set out in this Framework.

Four governments collaborative working:

4.8 The governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and considering the UK-wide impact of such changes. They will follow the approach in this Framework to support collaborative decision making with a view to supporting continued sharing of blood and blood components across the UK.

4.9 There is a need for continued robust policy development encompassing policy and technical expertise from all four governments, including the need to fully assess the potential impacts of legislative changes on all affected stakeholders. Governments may wish to do this work individually or in collaboration before initiating a UK-wide discussion of a potential change to the standards.

Risk assessment and management:

4.10 As stated above, maintaining a compatible minimum set of safety and quality standards between the UKG, SG, WG and NI Department of Health will make it easier for blood and blood components to continue to be shared across the UK.

4.11 One or more governments may initiate the risk assessment process that should include discussions with the national blood services and the regulator, as appropriate. The assessment should include seeking advice from the relevant scientific advisory bodies. Final decisions at the end of the risk assessment process should require collective sign-off (e.g. legislative or operational changes) by all Ministers across the UK. While the ability to diverge is always available to any individual government, it will be important for any diverging government to consider the impact on patient safety and confidence, and compatibility with the JMC(EN) Common Frameworks principles.

4.12 Where appropriate, joint recommendations may be made to Ministers. Ministers will ultimately retain the right to take individual decisions for their government. For Ministers and officials, for areas within the scope of the Framework, a consensus/discussion to inform the other parties should first be sought.

4.13 The dispute resolution process is outlined in section 13 of this document.

Divergence:

4.14 Maintaining a compatible minimum set of quality and standards between the UKG, SG, WG and NI Department of Health will make it easier for blood and blood components to continue to be shared across the UK. The Framework sets out a process by which any government can suggest changes to the standards and how such a proposal will be collectively considered before one or more governments introduces a change. It will allow for necessary divergence by one or more governments as required, in order to respond to needs such as location-dependent health concerns.

Dispute Resolution:

4.15 All four governments will retain the ability to diverge from generally harmonised rules within their part of the UK. Where divergence is not considered acceptable by one or more governments in the UK, every effort will be made to address disagreement at the lowest level possible. Only when all opportunities for avoiding a dispute at the policy level have been sought, will the dispute resolution mechanism be engaged. Dispute resolution is anticipated to only be required in a very small number of cases and is set out in section 13 of this agreement should it be needed.

The Protocol on Ireland/ Northern Ireland:

4.16 The Agreement on the Withdrawal of the United Kingdom from the EU sets out the current arrangements where, although remaining within the UK's custom territory, Northern Ireland will remain aligned with the EU. The following paragraphs of Annex 2 of the Northern Ireland Protocol are relevant to this framework.

- Paragraph 22 - substances of human origin

4.17 This Framework reflects the specific circumstances in NI that arise as a result of the Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland.

4.18 Where one or more of UK Government, the Scottish Government or the Welsh Governments propose to change rules in a way that has policy or regulatory implications for the rest of the UK, or where rules in Northern Ireland change in

alignment with the EU, the Framework is intended to provide governance structures and consensus-based processes for considering and managing the impact of these changes.

- As rules evolve to meet the emerging regulatory needs of the UK, Scottish and Welsh Governments, this Framework will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.
- Where rules in Northern Ireland change in alignment with the EU, the Framework will form the basis of a mechanism to ensure consideration by the four governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.

4.19 Where issues or concerns raised by the relevant Northern Ireland Executive Minister(s) in respect of GB-only proposals have not been satisfactorily addressed, they will have the right to trigger a review of the issue as set out in the dispute resolution process at section 13 of this document.

The UK and EU Trade and Cooperation Agreement (TCA):

4.20 The area of policy covered by this Common Framework does not fall directly within the provisions of the Trade and Cooperation Agreement, although both the Common Framework and that agreement will impact significantly on devolved and reserved responsibilities.

5. Detailed overview of proposed framework: legislation (primary or secondary)

5.1 N/A – no legislation to support the framework is considered necessary.

6. Detailed overview of proposed framework: non-legislative arrangements

6.1 A concordat between UKG, SG, WG and NI Department of Health provides the basis for managing and maintaining the collaborative ways of working set out in this framework. Adopting a non-legislative approach maintains the existing good working relationships between the governments and allows for flexibility to adapt where change is needed.

- 6.2 The underlying principle is that the governments agree not to introduce changes to safety and quality standards legislation without first discussing proposals with each other and allowing sufficient scope for UK-wide discussion and decision making.
- 6.3 If one or more government wishes to diverge from the UK-wide standards for safety and quality, it is agreed that this should be done after consultation with the other governments and after consideration of the impact on the existing standards of safety and quality for blood and blood components.

7. Detailed overview of areas where no further action is thought to be needed

- 7.1 Not applicable.

OPERATIONAL DETAIL

SECTION 3: PROPOSED OPERATIONAL ELEMENTS OF FRAMEWORK

8. Decision making

8.1 Individual governments will be able to make decisions (at Ministerial level in relation to proposals for legislative change or other significant policy issues) on the safety and quality standards for blood and blood components. This includes, but is not limited to, the following:

- standards and requirements relating to a quality system for blood establishments;
- information to be provided to donors;
- information to be obtained from donors;
- blood quality and safety requirements;
- storage, transport and distribution requirements;
- quality and safety requirements;
- traceability requirements;
- deferral criteria for donors of blood and blood components. Deferral is defined in the Blood Safety and Quality Regulations 2005 and refers to the suspension (either permanent or temporary) of the eligibility of an individual to donate blood or blood components;
- requirements applicable to autologous transfusions; and
- the procedure for notifying serious adverse reactions and events.

8.2 If a government wants to make a change to the blood safety and quality legislation, they will:

- notify all governments setting out details of the proposal and invite comments;
- arrange a meeting with policy officials to discuss the detail of the proposals, if an government requests this;
- seek to agree a way forward on the issue; and
- depending on the issue, seek input from the following:
 - advice from an advisory body or the regulator; and
 - consultation with stakeholders.

8.3 Officials will share information, advice and views so that each government can advise Ministers on the proposal and its impacts and seek Ministerial decisions.

8.4 If agreement is not reached on a way forward, to assess a proposal or on the factual information within the advice to Ministers, any government can escalate the issue so that it can be discussed at senior official level. If an agreement is not reached at senior official level and all alternatives have been exhausted, the proposal can be escalated to be discussed at Ministerial level.

9. Roles and responsibilities of each party to the framework

9.1 The following sets out the role and responsibilities of officials and Ministers in this Framework.

Officials:

9.2 Regular meetings will be arranged by the Blood Safety team to take place around the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) meetings. This will provide an opportunity to discuss blood policy, share updates and consider the short-term and long-term impact of any developments. Advice will be shared with Ministers with the rationale for the approach taken (e.g. a UK/GB-wide approach), or why divergent policies may be necessary.

9.3 Specific ad-hoc meetings and day-to-day discussions on the policy covered by this Framework will continue. Advice will be put to Ministers outlining the rationale for the approach taken within this policy area (e.g. a UK/GB-wide approach), or why divergent policies may be arranged if/when a proposal arises. Officials across governments will convene to discuss policy issues as appropriate and keep colleagues regularly informed of any ramifications the policy may have on governments.

9.4 If officials do not agree when making decisions, issues discussed at a working level can be escalated to senior officials in line with the Framework's dispute avoidance and resolution mechanism (Appendix II).

Senior Officials:

9.5 Senior officials (e.g. Deputy Directors and Directors) will provide strategic direction on the policy governed by this Framework. They may review an issue as per a Framework's dispute avoidance and resolution mechanism if officials are not able to agree an approach, in another attempt to reach agreement. Senior officials should convene to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis.

Ministers:

9.6 Ministers may receive advice from their officials either concurrently across governments as issues arise or in the course of business as usual work for individual governments. If work is remitted to senior officials and an issue remains unresolved, the issue may be escalated to Ministers. Where Ministers are considering issues as part of the Framework's dispute avoidance and resolution mechanism this could be via several media, including inter-ministerial meetings or by correspondence.

Senior Ministers:

9.7 Terminology distinguishing Ministerial hierarchy is not universal across governments. Where there is a distinction, it is likely that advice presented to a Minister who is not a Senior Minister, will be copied to a Senior Minister who may provide an additional steer if needed. In some circumstances, the Senior Minister will also be the most appropriate Minister to make a decision and therefore the distinction between Senior Minister and Minister will not be relevant. In the case of UKG, a Senior Minister would be a Secretary of State (SofS).

Information sharing:

9.8 Each government will aim to provide each other with a full and open (as possible) access to scientific, technical and policy information including statistics and research and, where appropriate, representations from third parties.

10.Roles and responsibilities of existing or new bodies

10.1 The current scientific advisory bodies are:

- **Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC)**

The purpose of JPAC is:

- To ensure that all relevant aspects dealing with the safety of blood and tissues in the UK are covered, and that the professional advice emanating from JPAC is communicated appropriately and in a timely fashion.
- To prepare detailed service guidelines for the United Kingdom Blood Transfusion Services, taking account of the Blood Safety and Quality Regulations (2005), the Human Tissue (Quality and Safety for Human Application) Regulations 2007 and future UK legislation affecting the blood and tissue services. For example, the Tissue Donor Selection Guidelines - Deceased Donors.
- To be an Advisory Committee to the United Kingdom Blood Transfusion Services, normally by reporting to the Medical Directors of the individual Services who are themselves individually accountable to the Chief Executives/ Directors of the Services. Decisions on policy and implementation would be vested in the individual Chief Executives/Directors and their Service boards and, where appropriate, their respective Health Departments.

10.2 **Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO):**

Provides policy advice to Ministers in the four governments of the UK on the most appropriate ways to ensure the safety of blood, cells, tissues and organs for transfusion / transplantation.

10.3 Both of the groups above are independent from the UKG, SG, WG and NIE and provide advice for the whole of the UK.

10.4 **UK Blood Services Forum:** The UK Blood Transfusion Services have a body to coordinate co-operation-the UK Blood Forum. The Forum comprises the chief executives and medical directors of the four Services. JPAC are accountable to the medical directors who themselves are accountable to their chief executives. Both the UK Blood Forum and JPAC ensure consistency in professional matters.

10.5 Official level Blood Safety and Quality meetings: All parties will continue to regularly share information with one another in relation to the scope of this agreement. This is in order to: maintain public health and patient safety; allow for effective collaborative working and consideration of the Framework Principles, while acknowledging policy divergence.

10.6 Official level blood safety and quality meetings will continue to discuss:

- the impact of decisions on other governments, including any impacts on cross-cutting issues;
- prospective policy changes;
- emerging issues and intelligence etc.

10.7 As mentioned in section 9, Senior Official meetings will be convened to provide strategic direction and to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis. Officials or Senior Officials will then report to the relevant Ministers if necessary to provide an update or to escalate an issue.

10.8 The official level meetings will be arranged by the DHSC Blood Safety team and will include colleagues from the devolved governments.

11. Monitoring and enforcement

11.1 Official level Blood Safety and Quality meetings with policy teams across the four nations will take place around SaBTO meetings, to monitor the Framework, where not monitoring in the course of routine business. The purpose of monitoring is to assess:

- inter-governmental co-operation and collaboration as a result of the Framework;
- whether parties are implementing and complying with the Framework;
- whether divergence has taken place in contravention of the Common Framework principles;
- whether divergence has taken place in contravention of the principles of the intergovernmental relations review; and
- whether divergence has taken place that impacts on the policy area covered by the Framework.

11.2 The outcome of this monitoring will be used to inform joint decision-making going forward and the next review and amendment process. If there is an unresolved disagreement, the dispute avoidance and resolution mechanism should be used.

12. Review and amendment

12.1 Process:

- The Review and Amendment Mechanism (RAM) ensures the Framework can adapt to changing policy and governance environments in the future.
- There are two types of review which are outlined below. The process for agreeing amendments should be identical regardless of the type of review.
- The RAM relies on consensus at each stage of the process from the Ministers responsible for the policy areas covered by the non-legislative agreement.
- Third parties can be used by any party to the Framework to provide advice at any stage in the process. These include other government departments or bodies as well as external stakeholders such as non-governmental organisations (NGOs) and interest groups.
- At the outset of the review stage, parties to the Framework must agree timelines for the process, including the possible amendment stage.
- If agreement is not reached in either the review or amendment stage, parties to the Framework can raise it as a dispute through the Framework's dispute avoidance and resolution mechanism.

12.2 Review Stage:

- An initial review will take place one year after the Framework comes into effect; it will be used to determine if the arrangements are functional.
- Following the initial review, a periodic review of the Framework will take place every two years and will be in line with official or, if required, ministerial-level meetings.

- The period of two years starts from the conclusion of a periodic review and any amendment stages that follow.
- During the periodic review, parties to the Framework will discuss whether the governance and operational aspects of the Framework are working effectively, and whether decisions made over the previous two years need to be reflected in an updated non-legislative agreement.
- An exceptional review of the Framework is triggered by a 'significant issue':
 - A significant issue must be time sensitive and fundamentally impact the operation and/or the scope of the Framework.
 - The exceptional review may include a review of governance structures if all parties agree it is required. Otherwise, these issues are to be handled in the periodic review.
 - The same significant issue cannot be discussed within six months of the closing of that issue.
- The amendment stage can only be triggered through unanimous agreement by Ministers. If parties agree that no amendment is required, the relevant time period begins again for both review types (for example, it will be 2 years until the next periodic review and at least 6 months until the same significant issue can trigger an exceptional review).

12.3 **Amendment Stage:**

- Following agreement that all parties wish to enter the amendment stage, parties will enter into discussion around the exact nature of the amendment. This can either be led by one party to the Framework or all.
- If an amendment is deemed necessary during either type of review, the existing Framework will remain in place until a final amendment has been agreed.
- All amendments to the Framework must be agreed by all parties and a new non-legislative agreement signed by all parties.

- If parties cannot agree whether or how a Framework should be amended this may become a disagreement and as such could be raised through the Framework's dispute avoidance and resolution mechanism.

12.4 Changes to the Framework and concordat will be communicated to stakeholders via the current communication channels.

13. Dispute resolution

13.1 The goal of the dispute avoidance and resolution mechanism is to avoid escalation to formal processes through the appropriate intergovernmental structures, by resolving any disagreements at the lowest possible level. A disagreement between parties of this Framework becomes a 'dispute' when it enters the formal dispute avoidance and resolution process through the appropriate intergovernmental structures.

13.2 This mechanism will only be utilised when genuine agreement cannot be reached, and divergence would impact negatively on the ability to meet the Common Frameworks principles (as defined by the appropriate intergovernmental structures). In those areas where a common approach is not needed in order to meet these principles, an "agreement to disagree" could be considered an acceptable resolution.

Process

13.3 The below diagram (Figure 1) states the levels of escalation of a disagreement to a dispute and the interaction between each level.

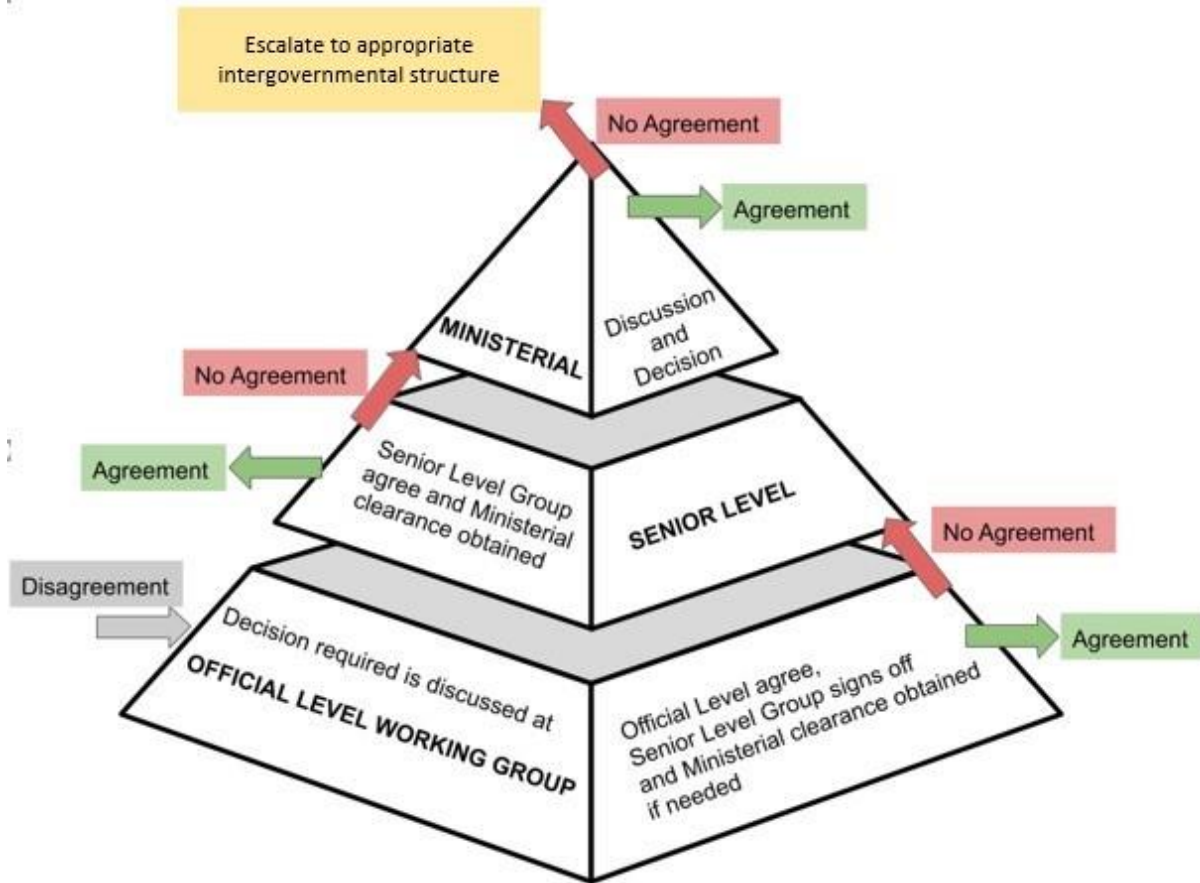


Figure 1: The levels of escalation for disagreements and disputes.

13.3.1 **Official level:** Following the approach set out in sections 8 and 9 and Appendix II of this Common Framework and within the spirit of the Concordat, the four governments will seek every opportunity to resolve differences and reach agreement; either to recommend a UK-wide approach or to accept divergence, at official level through discussions. Regular official level meetings will continue to provide an opportunity to discuss blood safety and quality policy, share updates and consider the short-term and long-term impact of any developments. Policy leads (e.g. Team Leaders) will provide strategic direction on the policy governed by this Framework and take key operational decisions.

13.3.2 Where officials become aware of proposals, potential issues or areas of disagreement via any means, the first step will be to seek to resolve this amongst policy leads without escalation. This will usually be resolved via discussion with policy colleagues in each government, to determine the source of the disagreement, to examine evidence, to establish whether it is a significant concern and to work through possible solutions to the satisfaction of all parties. It is expected that most disagreements would be resolved at this point.

13.3.3 **Senior Official level:** Where it has not been possible to resolve any disagreement at official level, this will initially be referred to Senior Officials for resolution. At this stage Senior Officials can decide whether it would be appropriate to arrange a meeting with counterparts across governments. Alternatively, or after such a meeting, Senior Officials may determine that the issue cannot be resolved at this stage, at which point the involvement of Ministers will be required.

13.3.4 **Ministerial level:** Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the Blood Safety and Quality Common Framework, the making of legislation may need to be postponed until all four governments are in agreement on how to proceed. The parties may conclude, having considered potential impacts on patient safety, the JMC (EN) principles and the finalised principles for Intergovernmental Relations, that divergence is appropriate.

13.3.5 **Resolve through appropriate intergovernmental structure:** As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated under the appropriate intergovernmental structures

Timescales for escalation

13.4 When a proposal is raised at official level, consideration will be given to the urgency of the proposal (i.e. how quickly a decision is required). This assessment will guide timescales for escalation of disagreement within the governance structure, with decisions requiring a more immediate resolution being escalated more quickly.

Evidence gathering

13.5 At each stage, further evidence may be requested from the preceding forum before the disagreement is discussed.

Third parties

13.6 JPAC and SaBTO may be used to provide scientific or technical advice to the UKG, SG, WG and NI Department of Health.

SECTION 4: PRACTICAL NEXT STEPS AND RELATED ISSUES

14. Implementation

14.1 This Framework will take effect once agreed by all parties and approved by Ministers. The Common Framework will only be put in place once there is final ministerial sign off from all four governments

APPENDIX I: Joint Ministerial Committee (EU Negotiations) Communique - October 2017

JOINT MINISTERIAL COMMITTEE (EU NEGOTIATIONS) COMMUNIQUE October 2017

The fifth Joint Ministerial Committee (EU Negotiations) met today in 70 Whitehall. The meeting was chaired by the Rt Hon Damian Green MP, First Secretary of State and Minister for the Cabinet Office.

The attending Ministers were:

From the UK Government: the First Secretary of State and Minister for the Cabinet Office, Rt Hon Damian Green MP; the Secretary of State for Exiting the EU, Rt Hon David Davis MP; the Secretary of State for Wales, Rt Hon Alun Cairns MP; the Secretary of State for Scotland, Rt Hon David Mundell MP; and, Parliamentary Under Secretary of State for Northern Ireland, Lord Bourne of Aberystwyth.

From the Welsh Government: Cabinet Secretary for Finance and Local Government, Mark Drakeford AM.

From the Scottish Government: the Minister for UK Negotiations on Scotland's Place in Europe, Michael Russell MSP.

In the absence of Ministers from the Northern Ireland Executive, a senior civil servant from the Northern Ireland Civil Service was in attendance.

The Chair opened the meeting by summarising the bilateral engagement and political developments that had taken place since JMC(EN) last met. The Secretary of State for Exiting the EU provided an update on the previous rounds of negotiations with the EU and the Committee discussed forthcoming priorities and the future relationship with the EU. The Committee discussed the establishment of common frameworks.

Ministers noted the positive progress being made on consideration of common frameworks and agreed the principles that will underpin that work (attached).

Common Frameworks: Definition and Principles

Definition

As the UK leaves the European Union, the Government of the United Kingdom and the devolved administrations agree to work together to establish common approaches in some areas that are currently governed by EU law, but that are otherwise within areas of competence of the devolved administrations or legislatures. A framework will set out a common UK, or GB, approach and how it will be operated and governed. This may consist of common goals, minimum or maximum standards, harmonisation, limits on action, or mutual recognition, depending on the policy area and the objectives being pursued. Frameworks may be implemented by legislation, by executive action, by memorandums of understanding, or by other means depending on the context in which the framework is intended to operate.

Context

The following principles apply to common frameworks in areas where EU law currently intersects with devolved competence. There will also be close working between the UK Government and the devolved administrations on reserved and excepted matters that impact significantly on devolved responsibilities.

Discussions will be either multilateral or bilateral between the UK Government and the devolved administrations. It will be the aim of all parties to agree where there is a need for common frameworks and the content of them.

The outcomes from these discussions on common frameworks will be without prejudice to the UK's negotiations and future relationship with the EU.

Principles

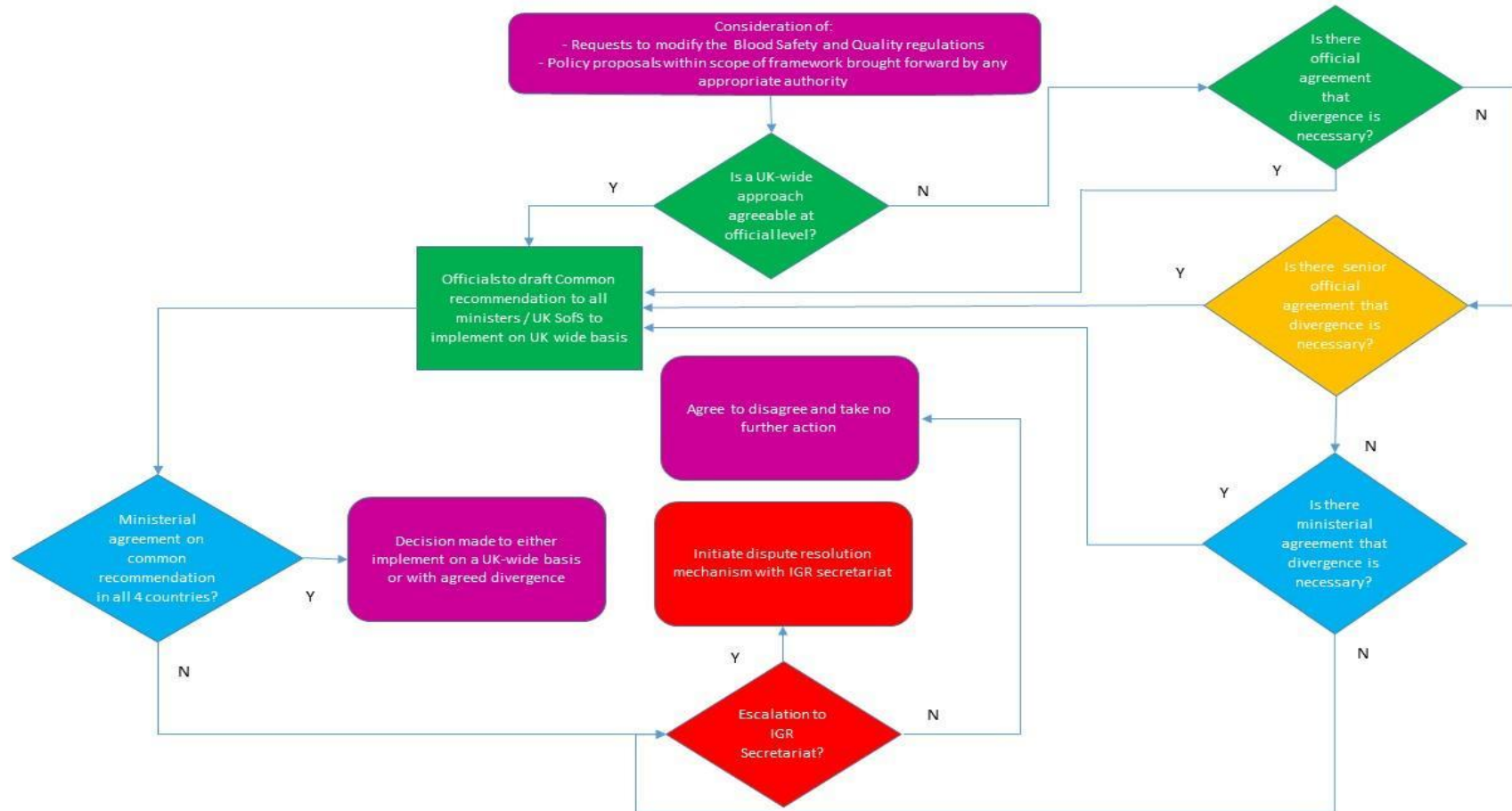
1. Common frameworks will be established where they are necessary in order to:
 - enable the functioning of the UK internal market, while acknowledging policy divergence;
 - ensure compliance with international obligations;
 - ensure the UK can negotiate, enter into and implement new trade agreements and international treaties;
 - enable the management of common resources;
 - administer and provide access to justice in cases with a cross-border element;
 - safeguard the security of the UK.

2. Frameworks will respect the devolution settlements and the democratic accountability of the devolved legislatures, and will therefore:
 - be based on established conventions and practices, including that the competence of the devolved institutions will not normally be adjusted without their consent;
 - maintain, as a minimum, equivalent flexibility for tailoring policies to the specific needs of each territory as is afforded by current EU rules;
 - lead to a significant increase in decision-making powers for the devolved administrations.

3. Frameworks will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK that shares a land frontier with the EU. They will also adhere to the Belfast Agreement.

APPENDIX II: Joint Decision-making Dispute Avoidance and Dispute Resolution Process

Key				
Inputs/Outputs	Senior Officials	Officials	Secretary of State (SofS)/ Portfolio Ministers	The ministerial committee outlined in the MoU on Devolution



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Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
<p>1. In accordance with section 9 of the Framework Outline Agreement policy colleagues will meet regularly. Requests to modify legislation and policy proposals within scope of the framework may be brought forward by the appropriate authority.</p> <p>2. Scientific advice and wider risk management issues are considered to reach a consensus for a common recommendation to Ministers.</p> <p>3. All four governments submit the same common recommendations to Ministers for a decision (either for common approaches across the UK or divergent approaches). Where agreement cannot be reached at official level issues are referred to senior officials for consideration.</p> <p>4. Ministers review recommendation seeking decisions. Officials will be asking Ministers to agree to the recommended approach.</p> <p>5. Ministers reach agreed decision on common recommendations.</p>	<p>1. Further discussions at official and senior official level.</p> <p>2. Dispute avoidance initiated:</p> <ul style="list-style-type: none"> ● Pause work progressing implementation of Ministerial decision until differences are resolved. ● Senior officials from all four governments meet to consider ministerial views and determine whether there is any additional information available to support an agreed approach revert to consider any alternative approach. ● Officials submit risk management common recommendations, informing Ministers of the revisions with rationale for the approaches now being recommended across all four governments. <p>3. Recommendations made to Ministers in the four governments:</p> <ul style="list-style-type: none"> ● Officials submit further/ revised common recommendations, informing Ministers of the approaches being recommended across all four governments. 	<p>1. Further discussion of issues.</p> <p>2. Dispute avoidance initiated: Escalation to highest level, dispute resolution process initiated</p> <ul style="list-style-type: none"> ● Pause work progressing implementation of SofS / Cab Sec / Perm Sec* level decision until differences are resolved. ● Officials submit further/ revised common recommendations, informing the appropriate intergovernmental structures of the approaches being recommended across all four governments. ● The appropriate intergovernmental structures consider common recommendations and SofS / Cab Sec / Perm Sec views and consider any additional information available to support decision making. ● If the approach being recommended is not the same across the UK, officials provide explanation of the different approaches being recommended and a summary rationale setting out why it is appropriate to diverge and why agreement has not been reached to date. If the approach being recommended is agreed across the UK, proceed to a ministerial decision. ● The appropriate intergovernmental structures consider the common recommendation individually and provide a response to SofS / Min / Perm Sec private offices. <p>3. SofS / Min / Perm Sec reach agreed decision on common recommendation.</p>

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 12/09/2019
 Page 12

Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
<p style="writing-mode: vertical-rl; transform: rotate(180deg);">Pack Page 130</p>	<ul style="list-style-type: none"> ● If recommended approach differs across the UK, officials provide explanation and a summary rationale setting out why it is appropriate to diverge. ● If the approach being recommended is NOT agreed by Ministers and officials from the four governments meet again. <p>4. Ministers receive risk management common recommendation seeking decision.</p> <ul style="list-style-type: none"> ● Each Minister considers the common recommendation individually and provides a response. ● If the approach being recommended is NOT agreed across the UK, officials meet to discuss the issues. <p>5. Ministers reach agreed decision on common recommendations.</p> <ul style="list-style-type: none"> ● If the approach being recommended (either for common approaches across the UK or divergent approaches) is agreed across the UK: <ul style="list-style-type: none"> ○ Private Offices inform officials in their own 	<ul style="list-style-type: none"> ● Private offices inform officials in their own respective government of the decision. ● Policy officials in all four governments share information on SofS / Min / Perm Sec decisions.

Joint Decision-making	Dispute Avoidance	Dispute Resolution (THE MINISTERIAL COMMITTEE OUTLINED IN THE MOU level)
	<p>respective governments of the decision to implement agreed approach.</p> <ul style="list-style-type: none"> ○ Policy officials in all four governments share information on the Ministers' decisions. 	

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ofS / Cab Sec / Perm Sec= Secretary of State/ Cabinet Secretary /Permanent Secretary

ofS / Min / Perm Sec= Secretary of State/ Ministers /Permanent Secretary

ANNEX I

Concordat on blood (and blood components) safety and quality

Introduction

1. This Concordat is an agreement between the UK Government (UKG), Scottish Government (SG), Welsh Government (WG), and Northern Ireland Department of Health in the area of blood safety and quality. It gives effect to the Blood Safety and Quality Common Framework. It also sets out the continuation of good working relations, open communication; the maintenance of a compatible minimum set of high standards of safety and quality for blood and blood components; a dispute avoidance and resolution mechanism; and a review and amendment mechanism.
2. This agreement is a political commitment and is not intended to be legally binding or enforceable. It is in accordance with the overarching Memorandum of Understanding (MoU) on Devolution⁴ and the Common Frameworks principles agreed at the Joint Ministerial Committee (EU Negotiations) (JMC(EN)) on 16 October 2017⁵.

Scope

3. This agreement covers the subject matter of the EU Blood Directive (2002/98/EC) and implementing acts. The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 retain the UK's safety and quality standards for blood and blood components and amends the regulations to ensure that they will operate as intended following the UK's departure from the EU. The 2019 Blood Safety and Quality EU Exit SI was amended by the Blood (Safety and Quality) (Amendment) (EU Exit) Regulations 2020.

Principles for working together

4. This agreement will ensure recognition of the economic and social linkages between Northern Ireland and Ireland and that Northern Ireland will be the only part of the UK which shares a land frontier with the EU. It will also adhere to the Belfast Agreement.
5. The parties affirm their mutual commitment to work together on the application of retained EU law in relation to blood safety and quality policy and their respective responsibilities. This cooperation is intended to give all parties the assurance that working relationships will be conducted in a manner that is both collaborative and helpful, aiming, where possible and appropriate, to achieve agreement on policy. In addition, all parties agree that regular contact will continue to discuss ongoing business of mutual interest.

4

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/316157/MoU_between_the_UK_and_the_Devolved_Administrations.pdf

5

https://assets.publishing.service.gov.uk/government/uploads/system/uploads/attachment_data/file/652285/Joint_Ministerial_Committee_communique.pdf

6. This Concordat is intended to provide the basis for the management and maintenance of a compatible minimum set of safety and quality standards by setting out governance arrangements and a dispute resolution process. All parties to the Concordat agree that a Common Framework approach, that recognises the Common Frameworks principles agreed at JMC(EN) in 2017 and the finalised principles for intergovernmental relations, is highly desirable across the UK. The outcomes of the intergovernmental relations review are in the process of being implemented. Once confirmation has been provided from each government, the outcomes of the review and appropriate intergovernmental structures will be reflected in this Common Framework.
7. Open communications will be maintained and information shared, to the extent permitted by law, at the earliest opportunity. This may include but is not confined to policy issues, stakeholder views, preparations for and outcome of consultations and research, media interest and lines to take, and emerging issues and intelligence (UK/EU/international).
8. The parties acknowledge that there may be a need for their separate responsibilities to be tackled with uniformity. For example, events could transpire that would require urgent action (such as, but not limited to, responding to emerging diseases). Each party shall consider promptly and thoroughly any concerns raised by the others. Where all agree that consistency is needed, consultation on a common approach shall be undertaken.
9. The parties shall inform each other at the earliest opportunity of any new policy proposals, before they are made public, to allow full consideration and a common approach to be reached wherever possible. Each party will also appraise the others of the ongoing development of such proposals. Where this will not be possible, each party will inform the others as soon as possible.
10. The parties to this agreement commit to resolving any issues at the lowest possible level and recognise that agreement to disagree can be an acceptable outcome, provided the JMC(EN) Common Frameworks principles remain upheld.
11. Where common recommendations may be made, Ministers will retain the right to take individual decisions for their government. For those areas within the scope of the Blood Safety and Quality Common Framework, the opportunity for consistency of approach across governments will be sought in the first instance. The ability for divergence must be retained, while taking account of its impact on patient safety and confidence, and the functioning of the UK internal market. Every effort will be made at working level to resolve any disagreements in difference of approach. Where a consensus cannot be reached by these arrangements (whether that is agreement to a UK-wide approach or to accept divergence) the dispute avoidance and resolution mechanism would come into play.

Dispute avoidance and resolution

12. The goal of the dispute avoidance and resolution mechanism is to avoid escalation to formal processes through the appropriate intergovernmental structures, by resolving any disagreements at the lowest possible level. A disagreement between parties to this Framework becomes a 'dispute' when it enters the formal dispute avoidance and resolution process through the appropriate intergovernmental structures.
13. This mechanism will only be utilised when genuine agreement cannot be reached, and divergence would impact negatively on the ability to meet the JMC (EN) Common Frameworks principles. In those areas where a common approach is not needed in order to meet these principles, an "agreement to disagree" could be considered an acceptable resolution.

Process

14. The below diagram (Figure 1) states the levels of escalation of a disagreement to a dispute and the interaction between each level.

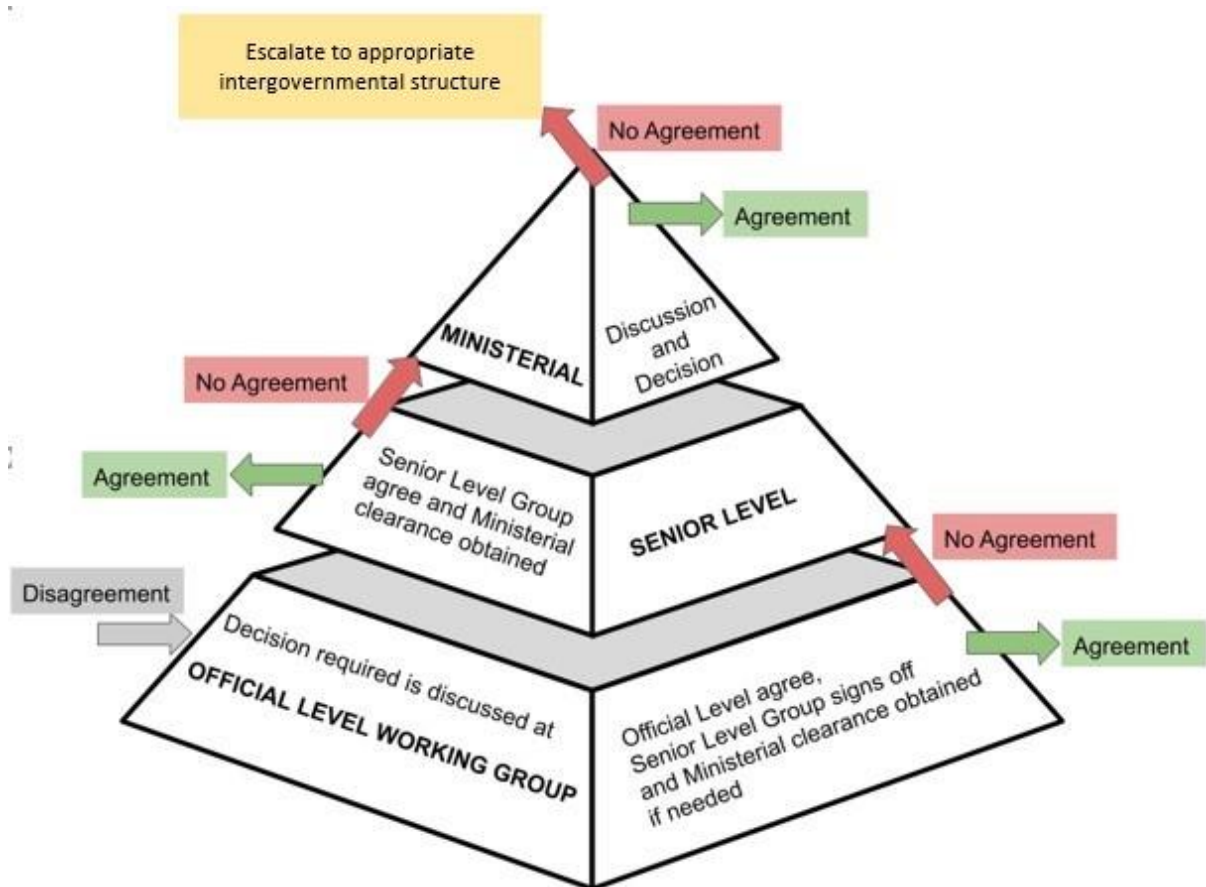


Figure 1: The levels of escalation for disagreements and disputes.

15. Following the approach set out in section 8 and 9 and Appendix II of the Blood Safety and Quality Common Framework and within the spirit of this Concordat, the all governments will seek every opportunity to resolve

differences and reach agreement; either to recommend a UK-wide approach or to accept divergence, at official level through discussions.

16. Where it has not been possible to resolve any disagreement in approach at official level, this will initially be referred to Senior Officials for resolution.
17. Any continuing disagreement, which cannot be resolved at official level in the ways set out above, will be referred to Portfolio Ministers for resolution and as set out in the Blood Safety and Quality Common Framework. The parties may conclude, having considered potential impacts on patient safety and the JMC principles and reflecting the appropriate intergovernmental structures, that divergence is appropriate.
18. As a last resort, where the above steps for resolving a disagreement have been unsuccessful, the issue will be escalated to the appropriate intergovernmental structures for resolution under the dispute resolution process set out in the appropriate intergovernmental structures.

Timescales for escalation

19. When a proposal is raised at official level, consideration will be given to the urgency of the proposal (i.e. how quickly a decision is required). This assessment will guide timescales for escalation of disagreement within the governance structure, with decisions requiring a more immediate resolution being escalated quicker.

Evidence gathering

20. At each stage further evidence may be requested from officials at the preceding level, or from stakeholders (listed below), before the disagreement is discussed.

Third parties

21. During policy development and dispute resolution, Medicines and Healthcare products Regulatory Agency (MHRA), the Advisory Committee on the Safety of Blood, Tissues and Organs (SaBTO) and the Joint United Kingdom (UK) Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee (JPAC) may be used to provide scientific or technical advice on the most appropriate ways to ensure the safety of blood for transfusion.

Official level meetings

22. **Official level blood safety and quality meetings:** All parties will continue to regularly share information with one another in relation to the scope of this agreement and will continue to discuss:
 - the impact of decisions on other governments, including any impacts on cross-cutting issues;
 - prospective policy changes;

- emerging issues and intelligence etc.

23. As previously mentioned, Senior Official meetings will be convened to provide strategic direction and to discuss issues as appropriate where there is a dispute, either by meeting regularly or on an ad hoc basis. Senior Officials will then report to the relevant Ministers as necessary, to provide an update or to escalate an issue.

Review and amendment mechanism

Process

24. The Review and Amendment Mechanism (RAM) ensures the Framework can adapt to changing policy and governance environments in the future.
25. There are two types of review which are outlined below. The process for agreeing amendments should be identical regardless of the type of review.
26. The RAM relies on consensus at each stage of the process from the Ministers responsible for the policy areas covered by this non-legislative agreement.
27. Third parties can be used by any party to the Framework to provide advice at any stage in the process. These include other government departments or bodies, as well as external stakeholders such as non-governmental organisations (NGOs) and interest groups.
28. At the outset of the review stage, parties to the Framework must agree timelines for the process, including the possible amendment stage.
29. If agreement is not reached in either the review or amendment stage, parties to the Framework can raise it as a dispute through the Framework's dispute avoidance and resolution mechanism.

Review stage

30. An initial review will take place one year after the Framework comes into effect, it will be used to determine if the arrangements are functional.
31. Following the initial review, a periodic review of the Framework will take place every two years.
- The period of two years starts from the conclusion of a periodic review and any amendment stages that follow.
 - During the periodic review, parties to the Framework will discuss whether the governance and operational aspects of the Framework are working effectively, and whether decisions made over the previous two years need to be reflected in an updated non-legislative agreement.
32. An exceptional review of the Framework is triggered by a 'significant issue':

- A significant issue must be time sensitive and fundamentally impact the operation and/or the scope of the Framework.
- The exceptional review may include a review of governance structures if all parties agree it is required. Otherwise, these issues are to be handled in the periodic review.
- The same significant issue cannot be discussed within six months of the closing of that issue.

33. The amendment stage can only be triggered through unanimous agreement by Ministers. If parties agree that no amendment is required, the relevant time period begins again for both review types (for example, it will be two years until the next periodic review and at least six months until the same significant issue can trigger an exceptional review).

Amendment stage

34. Following agreement that all parties wish to enter the amendment stage, parties will enter into discussion around the exact nature of the amendment. This can either be led by one party to the Framework or all.
35. If an amendment is deemed necessary during either type of review, the existing Framework will remain in place until a final amendment has been agreed.
36. All amendments to the Framework must be agreed by all parties and a new non-legislative agreement signed by all parties.
37. If parties cannot agree whether or how a Framework should be amended this may become a disagreement and as such could be raised through the Framework's dispute avoidance and resolution mechanism.
38. Changes to the Framework and Concordat will be communicated to stakeholders via the current communication channels.

The Protocol on Ireland/ Northern Ireland

39. The Agreement on the Withdrawal of the United Kingdom from the EU sets out the current arrangements where, although remaining within the UK's custom territory, Northern Ireland will remain aligned with the EU. The following paragraphs of Annex 2 of the Northern Ireland Protocol are relevant to this framework.

- *Paragraph 22 - substances of human origin.*

40. This Framework reflects the specific circumstances in NI that arise as a result of the Protocol and remains UK wide in its scope. As such decision making and information sharing will always respect the competence of all parties to the Framework and in particular the provisions in Article 18 of the Protocol on democratic consent in Northern Ireland.

41. Where one or more of UK Government, the Scottish Government or the Welsh Governments propose to change rules in a way that has policy or regulatory implications for the rest of the UK, or where rules in Northern Ireland change in alignment with the EU, the Framework is intended to provide governance structures and consensus-based processes for considering and managing the impact of these changes.

- As rules evolve to meet the emerging regulatory needs of the UK, Scottish and Welsh Governments, this Framework will ensure the full participation of Northern Ireland in discussions such that the views of the relevant Northern Ireland Executive Minister(s) are taken into account in reaching any policy or regulatory decisions by the UK, Scottish or Welsh Governments.
- Where rules in Northern Ireland change in alignment with the EU, the Framework will form the basis of a mechanism to ensure consideration by the four governments of any changes, and will enable them to determine any impacts and subsequent actions arising from these changes.

42. Where issues or concerns raised by the relevant Northern Ireland Executive Minister(s) in respect of GB-only proposals have not been satisfactorily addressed, they will have the right to trigger a review of the issue as set out in the dispute resolution process at section 13 of this document.

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Eluned Morgan MS
Minister for Health and Social Services
Welsh Government

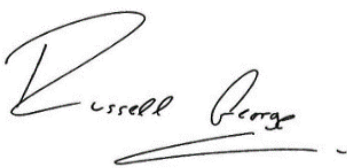
17 December 2021

Dear Eluned

Provisional common frameworks: Blood Safety and Quality, and Organs Tissues and Cells (apart from embryos and gametes)

To inform our consideration of the Blood Safety and Quality, and Organs Tissues and Cells (apart from embryos and gametes) common frameworks, we would welcome the views of the Welsh Government on the matters set out in the annex to this letter **by Thursday 13 January 2022**.

Yours sincerely



Russell George MS
Chair, Health and Social Care Committee

cc Huw Irranca-Davies, Chair, Legislation, Justice and Constitution Committee

Croesewir gohebiaeth yn Gymraeg neu Saesneg. We welcome correspondence in Welsh or English.

Annex: Common frameworks: request for further information

To assist our deliberations on the Blood Safety and Quality, and Organs Tissues and Cells (apart from embryos and gametes) common frameworks, we would welcome further information on the matters listed below. We would be grateful to receive your response **by Thursday 13 January**.

General

1. Why are common frameworks needed for these policy areas?
2. The Welsh Government has taken on new functions in these policy areas following the UK's exit from the EU. How has the Welsh Government ensured that it has the resources and expertise to exercise these functions effectively?
3. What role does the Welsh Government have in oversight of the work of the Independent Advisory Committee on the Safety of Blood, Tissues and Organs and the Joint UK Blood Transfusion and Tissue Transplantation Services Professional Advisory Committee?

Managing divergence

4. The frameworks state that they will allow for 'necessary divergence' within the UK. Could you set out what 'necessary' means in this context?
5. Do you consider that the frameworks give the Welsh Government and the Senedd appropriate scope to make law and policy for Wales?
6. Will the frameworks have any impact on any existing or planned Welsh legislation or policy?
7. How would the frameworks affect the Welsh Government's ability to respond to urgent situations, such as emerging new diseases?
8. The European Commission intends to adopt changes to legislation on blood, tissues and cells in early 2022. Does the framework allow sufficient scope for the Welsh Government to make equivalent changes for Wales, and do you plan to do this?
9. As part of its review of retained EU law, the UK Government is asking UK Government departments to consider whether such law should be amended or repealed by 'an accelerated process'. Would such changes be considered through the framework processes, and (if so) how?
10. Can the Welsh Government confirm that neither framework will interact with the UK Internal Market Act?



International obligations

11. What international obligations are there in these policy areas?
12. How does the framework take international obligations into account?
13. How will the framework be amended in future to reflect a new international obligations?

Governance and dispute resolution

14. Do you consider the dispute resolution mechanisms for the frameworks to be robust enough for their intended purpose?
15. Who will be the final arbiter in the event of a dispute, and will there be a right of appeal in the event that one of the parties is dissatisfied with the resolution of a dispute?
16. Will the Welsh Government notify the Senedd of disputes raised through the framework?

The development of the frameworks

17. How did the Welsh Government engage with stakeholders on the development of the frameworks? How does each framework reflect the responses of stakeholders in Wales?

Review and revision

18. How will the Senedd and stakeholders be updated on the continuing operation of the frameworks?
19. How will the Senedd and stakeholders be able to contribute to the review and amendment process for the frameworks?
20. If changes are made in future, how will the Senedd be notified? What scrutiny procedure will apply to the changes?

Agenda Item 5.3



HOUSE OF LORDS

Common Frameworks Scrutiny Committee

House of Lords

London

SW1A 0PW

Tel: 020 7219 8664

hlcommonframeworks@parliament.uk

14 December 2021

Huw Irranca-Davies MS
Welsh Parliament
Cardiff Bay
Cardiff
CF99 1SN

Dear Huw,

Thank you for your letter of 1 December, and the enclosed correspondence with Mick Antoniw MS.

I am glad that our correspondence with Michael Gove MP was of interest to your Committee and that you also consider the points we raise of utmost importance. Our Committee are fully aware that scrutiny and engagement from all the legislatures on the Common Frameworks Programme are vital for its success. We therefore welcome your approach to scrutinising the Programme and that of the relevant subject committees in the Senedd.

We are also concerned about the tight deadline for scrutiny of frameworks and welcome your offer to continue interparliamentary cooperation. Our Committee, and indeed the Programme itself, have already benefitted from close interparliamentary cooperation with the relevant committees in the devolved legislatures. I know this has particularly been the case at official level, where committees have shared intelligence, conclusions and recommendations on frameworks, and also relevant correspondence such as this. I know this is continuing for new frameworks being shared and am assured that this will continue throughout the rest of our life as a Committee. I also look forward to engaging with you in any relevant discussions that may occur via a reconvened Interparliamentary Forum.

As requested, I am enclosing further correspondence we have had with Michael Gove MP. This includes his response to our original letter of the 27 October and a follow up letter we sent on the 30 November, to which we have not yet had a response, setting out the wider concerns we have on the Union more generally.

I am copying this letter to the Northern Ireland Assembly's Committee for the Executive Office, the Scottish Parliament's Constitution, Europe, External Affairs and Culture Committee, and the House of Commons' Public Administration and Constitutional Affairs Committee.

Yours sincerely,

Baroness Andrews
Chair of the Common Frameworks Scrutiny Committee



HOUSE OF LORDS

Common Frameworks Scrutiny Committee

House of Lords

London

SW1A 0PW

Tel: 020 7219 8664

hlcommonframeworks@parliament.uk

30 November 2021

Michael Gove MP
Secretary of State for Levelling Up, Housing and Communities
Department for Levelling Up, Housing and Communities
4th Floor, Fry Building
2 Marsham Street
London SW1P 4DF

Dear Michael,

Thank you for your letter of 11 November.

We appreciate your reassurances regarding the importance of the Common Frameworks Programme. The update made to Neil's portfolio is certainly a positive step in the right direction. I would, however, like to reiterate that the Committee continue to be concerned that no thought appears to be being given to the future coordination of the programme. We note that you say it will be for individual departments to take forward the implementation of frameworks once the development phase is complete. As we made clear in our exchanges with the Minister on 13 October, central coordination from the Cabinet Office needs to be continued given the great uncertainty, and the fragmentation of the Programme in terms of standards, communications, engagement, effectiveness, and future parliamentary scrutiny. To be frank, steering from the centre will be imperative for determining the likelihood that the frameworks will be as effective as they need to be.

We also have wider concerns related to the relationships between the four countries generally. It has been evident in our scrutiny of the Programme that certain policy delivery bodies representing England have their role conflated with representing the UK. We noticed this most recently in our consideration of the Public Health framework, with regards to the UK Health Security Agency, the successor to Public Health England. We remain concerned that this elision between England and the UK may lead to further confusion and make it harder to distinguish which delivery bodies are accountable to which nation. We seek to raise this issue with you specifically, not only to ensure that when this does occur it be reconsidered within the frameworks programme, but in terms of the signal it sends to the Union more generally.

These are issues we look forward to pursuing with Neil on 11 January, and we will look forward to inviting you to join us later in the spring as we accelerate our ongoing inquiry.

Yours sincerely,

Baroness Andrews
Chair of the Common Frameworks Scrutiny Committee



Department for Levelling Up,
Housing & Communities

Rt Hon Michael Gove MP
*Secretary of State for Levelling Up,
Housing and Communities
Minister for Intergovernmental Relations*

**Department for Levelling Up, Housing
and Communities**
4th Floor, Fry Building
2 Marsham Street
London SW1P 4DF

Baroness Andrews
Chair, Common Frameworks Scrutiny Committee
House of Lords
London SW1A 0PW

Email: michael.gove@communities.gov.uk

11 November 2021

Dear Baroness Andrews,

Thank you for your letters of 27 October and for your interest and engagement with the UK Common Frameworks programme. We would like to thank the committee for your continued work to scrutinise individual Frameworks and the wider programme, and we welcome the debate that took place on 13 October in the House of Lords.

Thank you for your kind words regarding our recent Ministerial appointments at the Department for Levelling Up, Housing and Communities (DLUHC). We would like to reassure the committee that DLUHC remains committed to delivering robust UK Common Frameworks. Neil, who has taken on responsibility for the Common Frameworks programme, looks forward to meeting with the committee in the near future and building on your existing positive working relationship with the UK Government. Officials are working with your clerks to find a suitable date. Furthermore, in line with your helpful feedback, we are updating the new department's gov.uk page to clarify the details of Neil's Common Frameworks portfolio.

The UK government intends to operate under the new ways of working set out in the Review of Intergovernmental Relations. These arrangements will strengthen the working of the Union through regular and formalised intergovernmental engagement, not least facilitating the smooth operation and continued momentum of the Common Frameworks programme. Since the debate, the second Intergovernmental Relations Quarterly Report, which Lord Dunlop referred to in the recent Common Frameworks 'take note' debate, has been published. The third report is anticipated for publication this Autumn.

UKG officials working on the UK Common Frameworks programme will continue to support UK departments throughout the development phases, working closely with the devolved administrations. Once the development phases of Frameworks are complete it will be for departments to take forward implementation.

We look forward to working with the committee on the UK Common Frameworks programme in the coming months.

With every good wish,

Handwritten signature of Michael Gove in black ink.

**Rt Hon Michael Gove MP
Secretary of State for Levelling Up,
Housing and Communities
and Minister for Intergovernmental
Relations**

Handwritten signature of Neil O'Brien in black ink.

**Neil O'Brien MP
Minister for Levelling Up,
the Union and Constitution**

Baroness Andrews
Chair, Common Frameworks Scrutiny Committee,
House of Lords

1 December 2021

Dear Lady Andrews,

Common Frameworks

Thank you for sending my Committee a copy of the letter you sent to the Rt Hon Michael Gove MP about common frameworks, which we considered at our meeting on 15 November. We would also welcome sight of any response you receive given the important points you raised.

It may be helpful if I set out the role I envisage for my Committee in relation to the scrutiny of common frameworks. We will be undertaking a general oversight role focusing on the overall impact of frameworks on the operation of the devolution settlement, including their relationships with the *United Kingdom Internal Market Act 2020* and international obligations. While we may look to scrutinise some individual frameworks, we expect that role to fall largely on subject committees in the Senedd.

We are concerned at the delays to publishing provisional common frameworks and the limited time that may be available as a consequence for committees to scrutinise them. Nevertheless, we would welcome the opportunity to discuss with you and counterpart committees in the Scottish Parliament and Northern Ireland Assembly how we might work together on scrutiny of provisional frameworks.

On this point you may wish to be aware of the following comment by the Welsh Government's Counsel General in correspondence with the Committee:

"The length of the framework scrutiny process is of course a matter for committees. It would be hugely desirable if the frameworks could be scrutinised and signed off before the beginning of Northern Ireland's pre-election period. This date has not

yet been confirmed but it is likely to be in late March if the elections take place as scheduled on 5 May."

We share your recognition that the common frameworks programme is an iterative process, and we consider it likely that ongoing scrutiny will be needed as the frameworks develop over time and the effects of their operation become more apparent.

We believe there is considerable scope for interparliamentary co-operation on the scrutiny of frameworks, in addition to any discussion that may take place within the ambit of a reconvened Interparliamentary Forum. In that spirit of co-operative working I enclose an exchange of correspondence we have had with the Welsh Government (that I have referred to above), which highlights some of our concerns but also provides useful information on how, from the Welsh Government's perspective, matters are progressing between governments.

I am copying this letter to the Northern Ireland Assembly's Committee for the Executive Office, the Scottish Parliament's Constitution, Europe, External Affairs and Culture Committee, and the House of Commons' Public Administration and Constitutional Affairs Committee.

Yours sincerely,

Huw Irranca-Davies

Huw Irranca-Davies
Chair

Agenda Item 6.1

Julie James AS/MS
Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd

Julie James AS/MS
Y Gweinidog Newid Hinsawdd
Minister for Climate Change



Llywodraeth Cymru
Welsh Government

Huw Irranca-Davies MS
Chair
Legislation, Justice and Constitution Committee

31 December 2021

Dear Huw,

We are writing in accordance with the inter-institutional relations agreement to let you know that the Inter-Ministerial Group for Environment Food and Rural Affairs are expected to be held on the following dates throughout 2022:

- 31 January
- 21 March
- 16 May
- 27 June
- 12 September
- 24 October
- 5 December

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0300 0604400

Gohebiaeth.Lesley.Griffiths@llyw.cymru
Correspondence.Lesley.Griffiths@gov.wales

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Caerdydd • Cardiff
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Gohebiaeth.Julie.James@llyw.cymru
Correspondence.Julie.James@gov.wales

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Lesley Griffiths AS/MS
Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd



Julie James AS/MS
Y Gweinidog Newid Hinsawdd
Minister for Climate Change

Llywodraeth Cymru
Welsh Government

We will be representing the Welsh Government. Agendas are generally issues only a week before these meetings, however they will usually focus on areas where it is beneficial for the four nations to work together (particularly in areas of climate change and resilience of our sectors), and on areas of dispute (particularly in relation to the Common Frameworks), as well as on sectoral funding. We expect that issues relating to our borders and the Northern Ireland Protocol will continue to be discussed throughout the year.

A communique will be issued on the UK Government website after each meeting.

This letter will also be sent to the Climate Change, Environment, and Infrastructure Committee, and to the Economy, Trade and Rural Affairs Committee.

Regards,

Lesley Griffiths AS/MS
Y Gweinidog Materion Gwledig a Gogledd
Cymru, a'r Trefnydd
Minister for Rural Affairs and North
Wales, and Trefnydd

Julie James AS/MS
Y Gweinidog Newid Hinsawdd
Minister for Climate Change

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Gohebiaeth.Julie.James@llyw.cymru
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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.



WRITTEN STATEMENT BY THE WELSH GOVERNMENT

TITLE **Public Service Pensions and Judicial Offices Bill**

DATE **06 December 2021**

BY **Hannah Blythyn, Deputy Minister for Social Partnership**

This written statement is laid under Standing Order 30 – Notification in relation to UK Parliament Bills. It relates to the specific provisions in the Public Service Pensions and Judicial Offices Bill (the Bill), which will modify the Welsh Ministers’ functions, but do not require a Legislative Consent Motion under Standing Order 29 as the Senedd does not have legislative competence in respect of those provisions. Occupational pensions are a reserved matter. However, the Welsh Ministers are the responsible authority for firefighters’ pensions in Wales and have executive functions in that context.

The Bill was introduced in the House of Lords on 19 July 2021 and, on 12 August, I laid a written statement setting out provisions in the Bill which impact on the executive functions of Welsh Ministers in respect of the firefighter pension schemes in Wales. That statement also set out the background to the Bill and its broad aims, and this further written statement should be read in that context.

<https://gov.wales/written-statement-laid-under-standing-order-30c-34>).

This written statement updates members on several amendments to the Bill tabled at Report Stage in the House of Lords. All of these amendments expand the Welsh Ministers’ functions in this area; they do not restrict or withdraw them. Other amendments tabled at this stage have no effect at all on the Welsh Ministers’ functions.

Relevant amendments to the provisions in the Bill

Clause 4 of the Bill defines the meaning of a “Chapter 1” scheme referred to throughout the relevant provisions in the Bill. For clarity a Chapter 1 legacy scheme includes :

- The Firefighters’ Pension (Wales) Scheme (also known as the 1992 Scheme);
- The New Firefighters’ Pension Scheme (Wales) (also known as the 2007 Scheme).

The Firefighters' Pension Scheme (Wales) 2015 (the 2015 Scheme) is a Chapter 1 new scheme.

Clause 20 (Further powers to make provision about special cases)

Clause 20 as introduced, would provide the Welsh Ministers with powers to make regulations in respect of a Chapter 1 scheme which make further provision about a number of areas where steps may need to be taken by schemes to ensure that schemes operate as intended. This is in order to ensure that members receive the correct legacy or new scheme benefits to that which they would have been entitled in relation to their remediable service.

New sub-clauses have been added to Clause 20 to provide Welsh Ministers with the power to ensure appropriate provision can be made in respect of injury and compensation benefits payable under a relevant injury and compensation scheme to, or in respect of, a member who has remediable service. In particular, it will enable appropriate changes to be made to the 2007 Firefighters' Compensation Scheme for Wales. This is not a pension scheme – it provides compensation to firefighters who are injured or killed on duty – but entitlement to compensation under it is partly driven by pension entitlements.

New Clause inserted after Clause 22 (remedial arrangements to pay voluntary contributions to legacy schemes).

This new clause would allow the Welsh Ministers to make regulations in respect of a Chapter 1 legacy scheme to make provision allowing members with remediable service to enter into new arrangements to pay voluntary contributions into their legacy schemes after they transfer into the 2015 Scheme. This is because if those members had properly remained in their legacy schemes in 2015, they may have chosen to make such contributions.

Reasons for making these provisions

The Bill seeks to remedy discrimination across public sector schemes by placing all eligible members back into the position that they would have been in if the discrimination had never occurred. The new clauses provide further clarity and detail to ensure the pension schemes operate as intended and members receive the pension rights that they would have been entitled to, had the discrimination not taken place.

I consider that it is appropriate for these amended provisions to apply in relation to Wales and for them to be included in this Bill.



Huw Irranca-Davies MS
Chair – Legislation, Justice and Constitution Committee
Senedd Cymru
Cardiff Bay
Cardiff
CF99 1SN
SeneddLJC@senedd.wales

13 December 2021

Dear Huw,

Thank you for the Committee's report of 7 December on the legislative consent memorandum on the Leasehold Reform (Ground Rent) Bill and for the Committee's report of 9 December on supplementary legislative consent memorandum (Memorandum No.2). I write in response to the recommendations made by the Committee in its reports. The recommendations and my response are set out below.

Recommendation 1. *In advance of the debate on the relevant legislative consent motion, the Minister should explain:*

- *why the Memorandum lacks a Wales focus in explaining the relevant clauses, all of which fall within the Senedd's legislative competence;*
- *why the Memorandum did not refer to wider aspects of the leasehold reform programme potentially being outside of the legislative competence of the Senedd;*
- *which specific aspects of the leasehold reform programme are potentially outside of the legislative competence of the Senedd and the timing of any future UK Government Bill that they will be included in.*

In response to the first bullet point, I think it is vital to bear in mind that the provisions of the Bill apply equally to both Wales and England. They are intended to address an unfairness in relation to a system that currently operates in exactly the same way across both countries. Research has also shown that leaseholders in Wales face the same issues regarding unfairness as those in England¹. Therefore, save for a few minor exceptions (relating, for example, to the existence of the Leasehold Valuation Tribunal in Wales) the Bill addresses that unfairness in exactly the same way across the two countries. It therefore does not have a specific Wales focus.

¹ [Research into the sale and use of leaseholds in Wales | GOV.WALES](https://gov.wales/research-sale-and-use-leaseholds-wales) See: <https://gov.wales/research-sale-and-use-leaseholds-wales>

In relation to the second bullet point, the Memorandum stated that *'given the complexity of the existing leasehold legislation, a coherent and consistent approach would be beneficial to both England and Wales.'* Although not explicitly mentioned, the potential issue of competence in relation to aspects of wider leasehold reform is an important element of the 'complexity' to which the Memorandum refers and which underpins desirability of a consistent legislative approach across the two countries. I accept that the point could have been made more clearly and I understand the Committee's view that would have been helpful. However, the focus of the Memorandum is on competence in relation to the current Bill rather than on potential legislation to be made in the future.

In answer to the final bullet point, the Committee is aware that future leasehold reform will be based around the recommendations made by the Law Commission in its three reports dealing with different aspect of leasehold reform; namely leasehold enfranchisement, commonhold and the right to manage. I am unable to comment at this time on which specific aspects of the further legislation may or may not deal with matters that are not within the legislative competence of the Senedd as the legislation has not yet been drafted. I feel it is appropriate at the current time that the focus should be on working with the UK Government to secure a coherent set of legislative reforms that work for all leaseholders, irrespective of where they live. Regarding the timescale for the introduction of those further legislative reforms, the stated aim of the UK Government is for a Bill to be brought forward in the next session of Parliament.

Recommendation 2 (and the recommendation set out in the report of 9 December).
Before seeking the Senedd's consent for the Bill, the Minister should ensure that it is amended to provide that all delegated powers to make subordinate legislation in Wales in devolved areas are to be exercised by the Welsh Ministers.

For the reasons set out my letter to the Committee, and which the Committee has quoted in paragraph 8 of its report², I do not consider it necessary for the powers that have not been delegated to the Welsh Ministers, to be delegated. I therefore do not intend to pursue further amendments to Bill that would result in the delegation of these powers. The debate schedule for 14 December will be the last time that, in light of the Bill's timetable, the Senedd will have to debate and have a meaningful vote on the motion.

Recommendation 3. *The Minister should, in advance of the debate on the relevant consent motion explain how the approach adopted by the Welsh Government as advocated in her letter of 16 November 2021 (in particular as referred to in paragraphs 21 to 22 and 49 to 57 of this report) is consistent with the Welsh Government's principles for UK Bills.*

The Welsh Government's principles for UK Bills document sets out that primary legislation in devolved areas should be enacted by the Senedd but it also states clearly *'that there are, and will continue to be, circumstances in which it is sensible and advantageous if provision which would be within the Senedd's legislative competence is sought for Wales in UK Parliament Bills, with the consent of the Senedd'*.

The document says that *'taking provision in a UK Bill can enable pragmatic solutions to be reached in a timely fashion, while simultaneously respecting the legislative competence of the Senedd through the legislative consent process. It can be a matter of practical good government for such provisions to be included in a UK Bill.'*

² My letter of the 16 November referenced a power to make regulations amending the definition of home finance plan leases. It suggested that this power was at Clause 2(6) of the Bill. This should have been Clause 2(8).

I am confident that the approach I outlined in my letter to the Committee properly accords with the spirit of these principles. Three of the five examples of situations where taking provision in a UK Bill is said by the document to be appropriate, relate directly to the circumstances of this Bill or to the further leasehold reform legislation that is to follow. These situations are:

- *when the UK Government's legislative proposal would also be appropriate for Welsh circumstances but there is no time available for similar provisions to be brought forward in the Senedd;*
- *where the interconnected nature of the relevant Welsh and English administrative systems mean that it is most effective and appropriate for provision for both to be taken forward at the same time in the same legislative instrument;*
- *where the UK Bill covers both devolved and reserved matters and the UK Parliament route must be taken in order to achieve the policy objective.*

The ways in which these examples are pertinent are, I believe, reflected in the information that I have previously provided to the Committee.

I trust that the responses I have provided above will prove useful.

I am copying this letter to John Griffiths MS, Chair of the Local Government and Housing Committee.

Yours sincerely



Julie James AS/MS
Y Gweinidog Newid Hinsawdd
Minister for Climate Change

Ein cyf/Our ref: MA-RE-2314-21

Llywodraeth Cymru
Welsh Government

Elin Jones, MS
Llywydd
Senedd Cymru
Cardiff Bay
CF99 1SN
Llywydd@senedd.wales

16 December 2021

Dear Elin,

Correction of the Record – Debate on the Legislative Consent Motion on the Rating (Coronavirus) and Directors Disqualifications (Dissolved Companies) Bill, 23 November 2021

I am writing to correct the record concerning remarks made during the above [debate](#) on 23 November.

During the debate, the Chair of the Legislation, Justice and Constitution Committee remarked¹ that I had not formally responded to the Committee's report on the Legislative Consent Memorandum on the Bill, whilst confirming receipt of a letter to all Members which addressed two specific recommendations in the Committee's report, issued on 22 November.

In my reply², I said that I had responded to the Committee. However, I was in fact referring to a letter issued on 20 November which responded to remarks on related secondary legislation, the Valuation for Rating (Wales) (Coronavirus) Regulations 2021.

I would like to confirm that at the time of the debate on 23 November, I had yet to issue a formal response to the Committee's report. I have since done so, providing the Committee with a formal response to its report on 9 December. I apologise for any confusion my remarks might have caused.

¹ RoP, paragraph 385

² RoP, paragraph 404

I am copying this letter to Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee, and Paul Davies MS, Chair of the Economy, Trade and Rural Affairs Committee as both Committees reported on the Legislative Consent Memorandum on the Bill.

Yours sincerely,

A handwritten signature in black ink that reads "Rebecca Evans". The signature is written in a cursive style with a large initial 'R' and a distinct 'E'.

Rebecca Evans AS/MS

Y Gweinidog Cyllid a Llywodraeth Leol
Minister for Finance and Local Government

Huw Irranca-Davies MS

Chair

Legislation, Justice and Constitution Committee

17 December 2021

Dear Huw

Legislative Consent Memorandum (LCM) on the Building Safety Bill

As you'll be aware the LCM on the Building Safety Bill was remitted to the Local Government and Housing Committee. We wrote to you on 13 October outlining the concerns of some Members of the Committee at the Welsh Government's increased use of LCMs on UK Bills, including the Building Safety LCM, to legislate in devolved areas rather than using Senedd legislation. We received evidence from the Minister for Climate Change on this LCM at our meeting on 17 November.

Following the evidence session, and following the publication of our report on the Building Safety LCM, we agreed to write to you to highlight the concerns of some Members and ask that you consider these concerns in relation to your work on LCMs.

The majority of the Members of the Committee are concerned about the limited scrutiny available when considering LCMs compared with primary legislation, including the lack of opportunity for engagement with stakeholders. Some Members are also concerned that a precedent for using the LCM process to legislate in devolved areas is being set for the Sixth Senedd.

Some Members are also concerned by the Minister's comments that resource and capacity issues have restricted the Welsh Government's ability to progress a Senedd building safety Bill as a matter of urgency. If there are resource issues that restrict the introduction of Senedd Bills, then we would like to ask what is being done to address the matter and whether there has been any communication between the Senedd and Welsh Government on the matter.

I would be grateful if your Committee could take these concerns into consideration in any communications with the Llywydd and the Welsh Government in relation to your own work on the use of LCMs.

Yours sincerely

A handwritten signature in black ink that reads "John". The letters are cursive and connected.

John Griffiths MS

Chair

Croesewir gohebiaeth yn Gymraeg neu Saesneg.

We welcome correspondence in Welsh or English.



Huw Irranca-Davies MS
Chair – Legislation, Justice and Constitutional Committee
Senedd Cymru
Cardiff Bay
Cardiff
CF99 1SN
SeneddLJC@senedd.wales

4 January 2022

Dear Huw

Thank you for the Committee's report of 10 December on the legislative consent memorandum on the Building Safety Bill (the Bill). I write in response to the recommendations made by the Committee. The recommendations and my response are set out below.

Recommendation 1. *Before seeking the Senedd's consent for the Bill, the Minister should ensure that it is amended to provide that the Welsh Ministers are given equivalent commencement powers relating to the provisions in the Bill for Wales to those already given to the Secretary of State, so that the Welsh Ministers are fully in control of when the provisions for Wales come into force*

Response

I do not consider it necessary for the commencement powers that have not been delegated to the Welsh Ministers, to be delegated. Officials have worked very closely with the UK Government to ensure that the Welsh Ministers have the power to commence provisions in Wales where it is necessary and appropriate for us to have such powers. I therefore do not intend to pursue further amendments to Bill that would result in the delegation of additional commencement powers.

Recommendation 2. *The Minister should, in advance of the debate on the relevant legislative consent motion, provide a full and detailed assessment of her view that:*

- *the cumulative constitutional implications of asking and allowing the UK Parliament to legislate in wholly devolved areas within her remit are limited, and*
- *her approach does not in any way undermine the fact that the Senedd has legislative competence in this area.*

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Correspondence.Julie.James@gov.Wales

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Response

We have stated we will take a pragmatic approach to using UK legislation to achieve the Welsh Government's objectives where necessary in devolved areas. Nothing in the Bill limits the Senedd's competence in this area. I therefore see no cumulative constitutional implications as a consequence of the Bill's provisions which I view as discrete and self-contained.

Recommendation 3. *The Minister should, in advance of the debate on the relevant legislative consent motion, provide a full explanation as to why she made the decision to allocate resources in her department to support the drafting and passage of the UK Bill rather than allocate resources to facilitate the drafting and scrutiny of a Welsh Bill. In doing so, the Minister should provide details on how many Welsh Government officials have been allocated to, and how much time has been spent on, the tasks of:*

- *preparing the legal instructions that would have been used by the UK Government legal counsel to prepare the bespoke provisions for Wales in the Bill;*
- *scrutinising and amending the draft clauses prepared by the UK Government legal counsel drafters before they were included in the Bill for introduction to the UK Parliament;*
- *continued and ongoing intergovernmental working on the Bill, including the negotiation and drafting of any amendments to the Bill;*
- *monitoring the passage of the Bill through the UK Parliament and providing the necessary advice and updates*

Response

My response to the committee chair letter of 16 November 2021 set out the rationale for taking the opportunity the UK Government Bill presented to make improvements to the building control system in response to the Independent report findings and recommendations. The proposed approach was set out in the Safer Buildings in Wales white paper and clearly supported by responses to the consultation. [Safer buildings in Wales | GOV.WALES](#)

The Building Safety Expert Group roadmap had been published in March 2019 supporting many of the major changes that the independent report proposed but at the time we were considering the use of the Building Safety Bill we had yet to publish the white paper and timing of any Senedd Bill had yet to be decided. It would have been likely that two Bills would have been needed i.e. separate Bills dealing with construction and occupation phases as the latter required fundamental rethinking of regulation whereas the independent report recommendations for construction entailed the improvement of an existing (building control) system.

Our assessment concluded that the opportunity to utilise the UK Govt Bill presented real benefits over a Senedd Bill covering essentially the same ground sometime in the future. The level of policy and legal resources required for the modification of the Building Safety Bill meant that the work could be contained within existing provision. This remains the case for the ongoing passage of the Bill through Parliament.

There is no comparison between the use of the UK Government Bill and the significant resources needed to establish a Bill team for a Senedd Bill in competition with other legislation and policy priorities.

Recommendation 4. *The Minister should, in advance of the debate on the relevant legislative consent motion, provide a detailed explanation as to how her plans to use both*

this Bill and a future Welsh Bill in this Senedd term relating to building safety complies with the Welsh Government's commitment to improve the accessibility of Welsh law. In doing so, the Minister should address the fact that the Welsh Government has already identified housing and building regulations as areas of law which it may seek to consolidate in the Sixth Senedd term

Response

As I have set out, taking all the proposals through the Senedd would have likely been taken forward in two separate Bills, due to the different stages of development of policy on construction and the occupation phase.

Whilst it is regrettable that the primary legislation will be in English only, as I said in my response, the crucial detail that operationalises the Bill provisions and which the outside world will tend to interface with, namely the secondary legislation, will be bilingual.

These, and supporting procedural guidance, will ensure all parties understand their roles and responsibilities going forward under the new system.

The inclusion of Building Regulations as an area to explore for consolidation in The Future of Welsh Law: Accessibility Programme 2021 to 2026 is testament to this role regulations play in design and construction. To ensure maximum value out of the process any consolidation of Buildings Regulations would need to be completed after the amendments regulations to insert the new system have been made.

Recommendation 5. *The Minister should confirm that she will publish and consult on draft regulations that will give effect to the provisions in the Bill.*

Response

My letter of 16 November set out that we will in due course be considering our approach to the development and consultation arrangements for the secondary legislation including the possibility to consult on draft regulations.

The regulations we subsequently bring forward will be subject to consultation and engagement according to our principles and procedures as set out in the Legislation handbook on subordinate legislation. I fully agree with this guidance that the development of subordinate legislation should be founded on appropriate engagement and consultation with stakeholders, based on the best available evidence. Our consultation will include the draft legislation setting out our proposed definition of a higher risk building, and where draft legislation is not included, sufficient policy detail will be included to enable comprehensive responses to be provided.

Yours sincerely



Julie James AS/MS

Y Gweinidog Newid Hinsawdd
Minister for Climate Change

Eich cyf/Your ref
Ein cyf/Our ref

Llywodraeth Cymru
Welsh Government

6th January 2022

Dear Huw

Thank you for your letter regarding the clarification sought by the Committee on the Legislative Consent Memorandum on the Subsidy Control Bill.

I would also take this opportunity to thank you and the Committee for your consideration of these important matters, your agreement with our position on the legislative consent of the Senedd being required for clauses 63 to 69, 70 to 75 and 80 to 92 of the Bill, and the support provided in your conclusions for amendments to the Bill to address our concerns.

In response to your specific questions:-

Recommendation 1. For the avoidance of doubt, the Ministers should clarify whether the Welsh Government believes that clauses 41 and 42 require the Senedd's consent and, accordingly, whether it is seeking the Senedd's consent for them.

Clause 41 seeks to define the financial threshold for the exemption of certain Services of Public Economic Interest (SPEI) from the subsidy regime's transparency requirements. Clause 42 seeks to empower the Secretary of State for Business, Enterprise and Industrial Strategy to amend or lower the maximum thresholds for SPEI transparency reporting and Minimal or SPEI Financial Assistance.

Whilst clauses 41 and 42 do not directly impose functions on Devolved Governments in relation to subsidies, their content will impact upon the exercising of devolved functions. For this reason, we consider that these clauses make provision with regard to devolved areas. Consequently, to provide absolute clarity the Welsh Government has today laid a Supplementary Legislative Consent Memorandum.

Additionally, it is vital that any decisions on future changes to the thresholds for SPEI and Minimal or SPEI Financial Assistance are done on the basis of mutual consent. Accordingly, we will be seeking amendments to the Bill requiring that any such decisions can only be taken on the basis of mutual consent between the four Governments in the UK.

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We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Recommendation 2. The UK Government should publish draft regulations and guidance for both UK Parliamentarians and Members of the Senedd to consider the details of the subsidy control regime and to better understand the potential impacts of the Bill.

We are pressing, and will continue to press, for the UK Government to provide greater clarity on the future regime. Given the impact this Bill will have across a broad range of both reserved and devolved policy areas it is vital that UK Parliamentarians and Members of the Senedd are given sufficient detail on how this regime will operate in practice to better understand the potential economic and societal impact of the Bill upon Wales and the wider UK.

Yours sincerely,

A handwritten signature in black ink that reads "Rebecca Evans." The signature is written in a cursive, flowing style.

Rebecca Evans AS/MS

Y Gweinidog Cyllid a Llywodraeth Leol
Minister for Finance and Local Government

Our ref: MA-LG-3970-21

Huw Irranca-Davies MS
Chair – Legislation, Justice and Constitutional Committee

Huw.irranca-davies@senedd.wales

9 December 2021

Dear Huw,

On 7 December I signed the Whelk Fishing Permit (Wales) Order 2021. The purpose of the Order is to conserve whelk in the Welsh zone and ensure the sustainability of the fishery through adaptive management.

The Order applies to all UK and foreign licensed fishing vessels who wish to fish for whelk in the Welsh zone and bring the following into statute:

Permits - anyone fishing for whelk using pots in the Welsh zone now require an annual permit with conditions. From 2023 onwards there will be a fee for this permit.

Permit Period - the annual permitted fishing season will run from 00:00 on 1 March each year to 23:59 on the last day of February the following year.

Annual Catch Limit (ACL) - An Annual Catch Limit (ACL) of 5298 tonnes for the permitted fleet for the first permit period will be in place. Annual whelk surveys will begin to build up data to set the annual catch limit based on actual stock levels.

Flexible Monthly Catch Limit (MCL) – All permit holders will be issued the same MCL in any given month.

Monthly Catch Returns – All permit holders will be required to submit an accurate catch return.

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We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Further details about the Order will be available on gov.wales from 14 December 2021.

Regards,

A handwritten signature in black ink that reads "Lesley Griffiths". The signature is written in a cursive style with a large, sweeping flourish at the end of the name.

Lesley Griffiths AS/MS
Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd



Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT BY THE WELSH GOVERNMENT

TITLE **Whelk Order**

DATE **09 December 2021**

BY **Lesley Griffiths MS, Minister for Rural Affairs and North Wales,
and Trefnydd**

In 2019 I published the 'Brexit and our Seas' consultation as the first step in developing a fisheries policy which works for Wales. One of the key issues identified was the need for more modern and flexible management systems to ensure the sustainability of non-quota stocks.

In light of this, in March 2020 I published a consultation on proposals for new whelk management measures including:

- An authorisation scheme for all vessels taking whelks with pots in the Welsh zone,
- An annual limit on the total amount of whelk that can be taken from the Welsh zone,
- A flexible monthly catch limit for each authorised vessel.

The consultation ended on 7 June 2020 and was later extended to 1 November 2020 because of disruption caused by the Covid-19 pandemic during the original consultation period. In total, 60 responses were received from a range of stakeholders and I am grateful to all those who took the time to respond. There was strong support in favour of the proposed measures in the consultation.

Today I am announcing the coming into force of the Whelk Fishing Permit (Wales) Order 2021. This Order will, for the first time, introduce an adaptive management system for a non-quota stock in Wales to enable more timely interventions in response to changes in stock levels and the environment.

The Order will protect the whelk stock and the wider marine environment in the Welsh zone. As a result, it will ensure the sustainability of the fishery so it continues to provide social and economic benefits to coastal communities in the future. I remain fully committed to introducing similar evidence based flexible management regimes for a range of other stocks to safeguard the marine environment and the fishing industry in Wales.

Agenda Item 7.8



Law Commission
Reforming the law
Comisiwn y Gyfraith
Diwygio'r gyfraith

Sent on behalf of Nicholas Paines QC
The Law Commission's Report on Devolved Tribunals in Wales

Dear Sir or Madam,

I am pleased to inform you that the Law Commission's Report on Devolved Tribunals in Wales has been published, having been presented to the Senedd on 8 December 2021. It outlines our recommendations for the creation of a new, unified tribunal system in Wales, replacing the current system with one which is more coherent, and better placed to evolve with the changing demands placed upon it. Ultimately, our hope is that it will enable the system to continue to meet the needs of its users, both now and in the future. Versions of the report in both English and Welsh can be downloaded from our website at <https://www.lawcom.gov.uk/project/devolved-tribunals-in-wales/>. It is published alongside a summary, which is also available in both English and Welsh.

Rydw i'n falch o gael eich hysbysu bod Adroddiad Comisiwn y Gyfraith ar y Tribiwnlysoedd Datganoledig yng Nghymru wedi cael ei gyhoeddi, a'i gyflwyno i'r Senedd ar 8 Rhagfyr 2021. Mae'r Adroddiad yn amlinellu ein argymhellion i greu system unedig newydd o dribiwnlysoedd yng Nghymru, a fydd yn disodli'r system gyfredol gyda system drefnus, fydd yn fwy parod i esblygu gyda'r gofynnion cynyddol amrywiol fydd arni. Yn y pen draw, rydym yn gobeithio bydd hyn yn galluogi'r system i barhau i gyflawni gofynnion ei defnyddwyr, heddiw ac i'r dyfodol.

Gellir canfod a lawrlwytho yr Adroddiad yn y Gymraeg a'r Saesneg o'n gwefan <https://www.lawcom.gov.uk/project/devolved-tribunals-in-wales/>. Yn ogystal â'r Adroddiad llawn, gellir canfod y crynodeb ar y wefan, sydd ar gael yn ddwyieithog hefyd.

Devolved Tribunals in Wales | Law Commission | Comisiwn y Gyfraith
1st Floor, Tower, Post Point 1.52, 52 Queen Anne's Gate, London, SW1H 9AG
(Mynediad trwy / access via 102 Petty France)
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Gwefan / Web: www.lawcom.gov.uk
E-bost / Email: DevolvedTribunalsWales@lawcommission.gov.uk



14 December 2021

Dear Members,

Further to my letter on 29th November 2021, I am writing to you with an update about the Relationships and Sexuality Education (RSE) draft Code and supporting statutory guidance.

Relationships and Sexuality Education (RSE) Draft Code

Relationships and Sexuality Education (RSE) is a statutory requirement in the Curriculum for Wales framework and is mandatory for all learners from age 3-16.

RSE has a positive and protective role in learners' education. Schools and settings have an important role to play in creating safe and empowering environments in supporting learners' rights to enjoy fulfilling, healthy and safe relationships throughout their lives.

RSE will be implemented in primary schools, maintained nursery schools, and non-maintained nursery settings from September 2022.

The world around us is evolving rapidly and significantly. As a society we are becoming ever more aware of:

- changing family structures and relationships
- shifting social, cultural and religious norms in relation to sex, gender and sexuality
- advances in technology including the rising influence of social media and increased use of digital communications and devices,
- changing laws and rights around relationships, sex, gender and sexuality.

In this context, RSE is an important support in enabling learners to navigate these changes.

Violence Against Women Domestic Abuse and Sexual Violence (VAWDASV) and Relationships and Sexuality Education (RSE)

Promoting and supporting healthy relationships is already a key part of our approach to end Violence Against Women Domestic Abuse and Sexual Violence (VAWDASV) and, recognising the long term nature of our ambition, has already informed the new Curriculum for Wales.

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We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

The Welsh Government's new draft VAWDASV strategy will run alongside the new Relationships and Sexuality Education (RSE) Code and statutory guidance and underpins learners' rights to enjoy fulfilling, healthy and safe relationships throughout their lives. The RSE statutory guidance should be read alongside the Code and includes explicit reference to VAWDASV and direct references to violence against women and girls. A reference to the VAWDASV Act was removed from the Code because it was technically not correct as it referred to legal sanctions which the Act does not provide.

Within the new RSE statutory guidance, it is clear that the approach to RSE should be positive, protective and preventative, considering how learners might need to be supported to *'have the knowledge to recognise all forms of discrimination, violence, abuse and neglect, including violence against women, domestic abuse and sexual violence* and a link is included to a toolkit of resources to support schools and settings on this important issue. The guidance aligns and links with the Welsh Government's Whole Education Approach to Violence against Woman, Domestic Abuse and Sexual Violence in Wales: Good Practice Guide and toolkit developed with Welsh Women's Aid. The statutory guidance also expands on and clarifies approaches to teaching and learning which supports this and Estyn's review of peer on peer harassment in schools will further inform the development and delivery in schools.

The statutory guidance has expanded and clarified approaches to teaching and learning which will support this. More broadly we continue to promote healthy relationships in the way we support families and vulnerable individuals. By promoting a consistent concept of what healthy relationships look like we will support our whole society approach to end the abuse of women and girls in Wales. Our new strategy will be delivered through a genuine partnership approach including education, health, police, specialist services and survivors *to create a Blueprint for action*.

A number of organisations supported the development of the RSE statutory guidance and code which will support learners' safety, by enabling them to recognise unsafe or harmful relationships and situations.

Equality and inclusivity

Equality and inclusivity are at the heart of the underlying principles for RSE:

In line with the mandatory requirements of the RSE Code, RSE will be realised in a way that is inclusive in accordance with the principles of equality. This helps ensure that all learners can see themselves, their families, their communities and each other reflected across the curriculum and can learn to value difference and diversity as a source of strength. This contributes to a cohesive, fair and equitable society that equips learners with skills for life. This of course includes gender equity and LGBTQ+ inclusivity.

Learners are growing up in a world where gender and sexual identity, cultures, rights and legislation are changing or evolving around the world. In order to be effective, inclusive RSE must start early. From a young age learners can learn about their own uniqueness, how to appreciate diversity and respect the rights of others. This is the foundation for later going on to explore diversity in relationships, gender and sexual identity and for developing the skills and values needed to think critically about sex, gender and sexuality norms, rights and inequities. This should include consideration of a range of influences that shape our values and identity. It should help learners to develop understanding of different values, religious beliefs and non-religious convictions that can inform our values and identity around relationships and sexuality.

Developmentally-appropriate phases

Schools should have regard to the mandatory strands of developmentally appropriate content within the RSE Code to develop their approach, and should recognise learners' social, physical, emotional and cognitive development and needs during their planning.

The phases are designed to help schools and settings make judgements about whether learning is developmentally-appropriate for specific learners. The ages set out in the code indicate broadly when practitioners should start to consider whether learning in a phase is developmentally appropriate for their learners.

This may mean some learners will be ready for specific learning before the broad indications given in the Code, but likewise it may mean that some learners need opportunity for further development before they engage with specific learning.

Pornography

The Code has been designed to recognise learners' needs and experiences. Online safety, consent and sexual health are all included in the Code at developmentally appropriate stages and are handled in a sensitive way. We have reflected upon feedback from a wide range of sources, including teachers, parents and carers, experts and wider stakeholders. It is clear that the effect of pornography is a big issue, and one that children and young people across Wales will have huge difficulty navigating.

Within the RSE Code, practitioners will consider learners' developmental appropriateness for learning on this issue, and when appropriate, learners will develop:

“Understanding the impacts associated with sexual material and intimacy online, including the ethical and legal implications.” And, “An awareness of how sexual material and media often represents gender, sexual activity, bodily appearance and relationships in unrealistic and harmful ways.”

Gender Stereotypes

The draft RSE Code outlines learning around *‘positive and harmful behaviours and norms and having the confidence to speak up (for themselves) and to speak out and advocate for the rights and respect of others’*.

In early development this behaviour should be modelled by practitioners in schools and settings. However, as learners develop, they progress to learning about knowing *‘how to safely respond to and challenge gender and sexual stereotypes and unfair behaviour’*. *This culminates in the later development phase to the ‘ability to critically explore and understand how a range of social, cultural and religious norms and influences about relationships, sex, gender and sexuality can shape perceptions and our well-being and can be both positive and harmful’*.

Development of the Statutory Guidance and Code

Stakeholders who developed the draft RSE Guidance and Code, alongside practitioners, included among others: the NSPCC, Office of the Children's Commissioner, Estyn, Stonewall Cymru and Welsh Women's Aid.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'Jeremy Miles', written in a cursive style.

Jeremy Miles AS/MS
Gweinidog y Gymraeg ac Addysg
Minister for Education and Welsh Language

Huw Irranca-Davies MS
Chair
Legislation, Justice and Constitution Committee

huw.Irranca-Davies@senedd.wales

17 December 2021

Dear Huw,

The Approved Country Lists (Animals and Animal Products) (Amendment) (No. 2) Regulations 2021 - DEFRA/AH/062

The above titled Statutory Instrument is required to allow the import into Great Britain of poultry and poultry products to resume from certain regions of Ukraine and the whole of Australia following the successful control of avian influenza outbreaks in those countries.

These Regulations are made by the Secretary of State in exercise of powers conferred by the Trade in Animals and Animal Products (Legislative Functions) and Veterinary Surgeons (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/1225), in particular, regulation 7.

They amend Annex 1 to retained Commission Regulation (EC) No 798/2008 laying down a list of third countries, territories, zones or compartments from which poultry and poultry products may be imported into and transit through Great Britain and the veterinary certification requirements applicable to export of those goods. The Regulations also amend certain 'closing' and 'opening' dates which specify the periods when exports from affected regions are either prohibited or permitted, reflecting the dynamic nature of diseases.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private, voluntary or public sector is foreseen. This instrument essentially allows trade to resume from areas temporarily affected by avian influenza, in line with current policy agreed between all governments of Great Britain.

I am writing to let you know that I give my consent to the Secretary of State to make this statutory instrument in relation to Wales. I have laid a Written Statement, which can be found at: [Written Statement: The Approved Country Lists \(Animals and Animal Products\) \(Amendment\) \(No. 2\) Regulations 2021](#). It has not been possible in this instance to provide advance notice of my intention to consent, as per the recent commitment given by the First Minister, owing to the timescales involved in bringing this urgent SI forward.

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We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

As there is a functioning Common UK Animal Health and Welfare Framework through which the policy has been agreed and because goods of this nature move freely within Great Britain, there is no reason for policy divergence between GB nations. Furthermore, these Regulations do not amend any Welsh Instrument made by Welsh Ministers.

I am copying this letter to the Counsel General and Minister for the Constitution, and Minister for Health and Social Services.

Yours sincerely,

A handwritten signature in black ink that reads "Lesley Griffiths". The signature is written in a cursive style with a large, sweeping flourish at the end of the name.

Lesley Griffiths AS/MS
Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd

Ein cyf/Our ref: MA-LG-3951-21

Huw Irranca-Davies MS
Chair
Legislation, Justice and Constitution Committee

20 December 2021

Dear Huw

The Official Controls (Extension of Transitional Periods) (Amendment) (No. 2) Regulations 2021

The Secretary of State proposes to make the above named Statutory Instrument (SI) (“the Instrument”) under powers conferred by:

- article 144(6) of, and paragraph 2 of Annex 6 to, Regulation (EU) 2017/625 of the European Parliament and of the Council on 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; and
- paragraph 11A(1) of Schedule 2 to the Trade in Animals and Related Products Regulations 2011.

Operability legislation made in late 2020 under the European Union (Withdrawal) Act 2018 set out a ‘transitional staging period’, to allow controls on EU SPS imports to be introduced over several months. The staging is intended to help trade sectors and related controls’ infrastructure to be ready for the additional volume of biosecurity checks, which are one consequence of the decision to leave the European Union.

The Instrument amends, in relation to Wales, England and Scotland, the appointed end date of the transitional staging period insofar as it relates to documentary, identity and physical checks on products of animal origin and certain animal by-products. This instrument also waives the pre-notification requirement in relation to goods imported from the island of Ireland.

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We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

The following legislation will be amended:

- Regulation (EU) 2017/625 of the European Parliament and of the Council on 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 Trade in Animals and Related Products Regulations 2011 (applies to England only);
- the Plant Health etc. (Fees) (England) Regulations 2018 (applies to England only);
- the Plant Health (Amendment etc.) (EU Exit) Regulations 2020;
- the Meat Preparations (Amendment and Transitory Modification) (England) (EU Exit) Regulations 2020 (applies to England only); and
- the Official Controls (Extension of Transitional Periods) Regulations 2021.

Amendments will be made in Welsh legislation to mirror amendments to the England only legislation listed above.

The UK Government's last minute decision to waive pre-notification for goods from Northern Ireland *and* Ireland is not ideal as officials will not receive anticipated trade flow data flows between January and July to assist further planning and preparedness activity. It may also raise questions in relation to the WTO and the Trade and Cooperation Agreement. However, I'm satisfied that these risks do not fall to Welsh Ministers.

Furthermore, without these amendments, from 1 January 2022, import and exports businesses in GB and EU respectively will be obliged to comply with the SPS control requirements as currently set out in legislation – including the need to enter Great Britain through a Border Control Post.

The extension will allow businesses in Wales affected by the pandemic to familiarise themselves with the new SPS compliance requirements and IT systems and ensure that necessary infrastructure and processes are in place at Border Control Points, further minimising the risk of any disruption.

I am therefore writing to let you know I give my consent to the Secretary of State to make the Instrument in relation to Wales. I understand the SI will be laid before the Houses of Parliament on 15 December and will be subject to the negative procedure. However, in order to ensure the requirements do not take effect from 1 January 2022, the Instrument will breach the 21 day convention.

I am copying this letter to the Minister for the Economy, Counsel General and Minister for the Constitution, Minister for Climate Change, Deputy Minister for Mental Health and Wellbeing and the Chair of the Climate Change, Environment and Infrastructure Committee.

Yours sincerely



Lesley Griffiths AS/MS
Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd

Huw Irranca-Davies MS
Chair
Legislation, Justice and Constitution Committee

06 January 2022

Dear Huw,

The Official Controls (Temporary Measures) (Coronavirus) (Amendment) (No. 3) Regulations 2021

The above titled SI amended Retained Regulation (EU) 2020/466, which expired on 31 December 2021, and is required to allow the continuation of certain temporary measures to the system of official controls implemented as a result of the Coronavirus pandemic to be in place until 1 July 2022.

In relation to Wales, the amendment provides competent authorities with the continued ability to introduce temporary measures to help prevent disruptions to the food supply chain, ensuring that official controls can still be conducted in compliance with wider social distancing guidelines and procedures put in place to deal with staff shortages as a result of the Coronavirus pandemic.

The SI is subject to the negative procedure, and was laid before Parliament on 04 January 2022 with a commencement date of 30 December 2021. UK Government explained the reasons for backdating it coming into force to be due to procedural issues with obtaining consent over recess, and due to the need to ensure continuity in the legality of temporary measures.

I am writing to let you know as these amendments are temporary emergency easements, I have given my consent, pursuant to Article 3(2B)(b)(i) of the retained Regulation (EU) 2017/625, to the Secretary of State to make this SI in relation to Wales. I have laid a Written Statement, which can be found at <https://senedd.wales/media/psrdpd3t/ws-1d14807-e.pdf>

It is normally the policy of the Welsh Government to legislate in matters of devolved competence; however, in this instance I am giving consent owing to the urgent need to make these changes before 31 December 2021. I have previously consented to equivalent extensions to these regulations in January and May this year.

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We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

These measures are temporary and do not amend existing Welsh legislation. There are functioning Common UK Frameworks in the policy areas of Animal Health and Welfare, Food and Feed Safety, and Plant Health that provide robust governance arrangements. There is consensus between policy officials of each government in Great Britain that these measures are beneficial, in the context of growing concerns in relation to Covid-19 and wider pressures on authorities conducting official controls. These measures will help protect these authorities and their staff from further disruption.

Not proceeding with or delaying this legislation could mean that competent authorities in Wales would not benefit from temporary official control measures when required. This could potentially, compromise their ability to deliver official controls those while minimising risks to staff from Covid-19 at a time where there are wider pressures on access to labour as a result of EU Exit, particularly in the veterinary workforce within the meat industry.

I am copying this letter to the Deputy Minister for Mental Health and Wellbeing and the Counsel General and Minister for the Constitution.

Regards,

A handwritten signature in cursive script that reads "Lesley Griffiths". The signature is written in a light grey or blue ink.

Lesley Griffiths AS/MS

Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd



Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT BY THE WELSH GOVERNMENT

TITLE **The Official Controls (Temporary Measures) (Coronavirus)
(Amendment) (No.3) Regulations 2021**

DATE **5 January 2022**

Lesley Griffiths AS/MS

**Y Gweinidog Materion Gwledig a Gogledd Cymru, a'r Trefnydd
Minister for Rural Affairs and North Wales, and Trefnydd**

BY

Lynne Neagle AS/MS

**Y Dirprwy Weinidog Iechyd Meddwl a Llesiant
Deputy Minister for Mental Health and Wellbeing**

Members of the Senedd will wish to be aware that we are giving consent to the Secretary of State exercising a subordinate legislation-making power in a devolved area in relation to Wales.

Agreement was sought by Victoria Prentis MP, Minister of State (Minister for Farming, Fisheries and Food), to make a Statutory Instrument (SI) titled The Official Controls (Temporary Measures) (Coronavirus) (Amendment) (No.3) Regulations 2021 to apply in relation to Great Britain.

The above titled SI will be made by the Secretary of State in exercise of powers conferred by Article 141 of the Retained Regulation (EU) 2017/625 on official controls and other official activities.

The SI amends Retained Regulation (EU) 2020/466, which expired on 31 December 2021, to allow the continuation of certain temporary measures to the system of official controls implemented as a result of the Coronavirus pandemic to be in place until 1 July 2022.

The amendment provides competent authorities with the continued ability to introduce temporary measures to help prevent disruptions to the food supply chain, ensuring that

official controls can still be conducted in compliance with wider guidelines and procedures put in place to deal with staff shortages as a result of the Coronavirus pandemic.

The regulations were laid before Parliament on 4 January 2022 to come into force on 31 December 2021.

Manon Antoniazzi
Chief Executive and Clerk
Senedd Commission

10 December 2021

Dear Manon

Use of the term BAME

During the Committee's consideration of its draft report, Scrutiny of Accounts: Senedd Commission 2020-21, there were a number of references to the acronym BAME. One Member asked that this not be used as citizens who represent this community, feel it is offensive. The Committee Members were in full agreement and where the term had been used in the narrative rather than a direct quote from a publication or the Record of Proceedings, it was amended to read 'ethnic minority communities'. I am sure you will have seen this phrase in our recently published report.

The Committee asked that I write to you requesting that the Senedd Commission stops using the term BAME. The Commission on Race and Ethnic Disparities produced an independent Report in April 2021 for the UK Government to investigate race and ethnic disparities in the UK. One of the areas considered, was the use of the terms BAME and BME, and in March 2021, the Commission on Race and Ethnic Disparities recommended that the UK government stop using the term BAME. The UK government is currently considering its response to the Commission's Report.

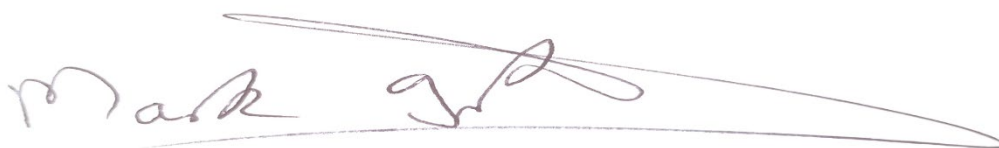
The Committee would welcome the Senedd Commission's views on this request once it has been fully considered.

Croesewir gohebiaeth yn Gymraeg neu Saesneg.
We welcome correspondence in Welsh or English.

I am copying this letter to all Committee chairs requesting that consideration be given to not using the term BAME in any committee correspondence and publications.

Thank you

Regards

A handwritten signature in black ink, appearing to read 'Mark Isherwood', with a long horizontal line extending to the right from the end of the signature.

Mark Isherwood MS
Committee Chair



Huw Irranca-Davies
Chair
Legislation, Justice and Constitution Committee
Senedd Cymru
Cardiff Bay
Cardiff
CF99 1SN

SeneddLJC@senedd.wales

29 December 2021

Dear Huw,

I am writing with reference to the protocol on scrutiny of regulations arising from the UK's exit from the European Union. The protocol played a vital role in ensuring that the Welsh Government and the Senedd worked effectively together in the extraordinary circumstances of Brexit and the significant legislative workload created, to ensure the continued operability of the law and respect for the devolution settlement.

I understand that our officials have been jointly considering the future of the protocol. The primary purposes of the protocol were to ensure, as far as practicably possible, early warning and a smooth flow of regulations for scrutiny; and to commit the Welsh Government to following the principles of Standing Order 30C in relation to a broader set of EU Exit related regulations. The first of these is no longer necessary as the volume of EU Exit regulations is likely to be very small indeed. And the second has been superseded, in my view, by the much wider commitment I have given in the context of our joint work to update the inter-institutional relations agreement:

"I can confirm that the Welsh Government will write to your committee and other relevant committees to inform them of an intention to consent to the UK Government exercising a delegated legislative power in a devolved area in relation to Wales, explaining the rationale for the intention to consent. Where time allows we will provide an opportunity for the Senedd to express a view before consent is formally given. Further, the Welsh Government will lay a Written Statement in relation to every exercise of a delegated legislative power by a UK Minister in a devolved area to which the Welsh Ministers have given consent, explaining the rationale for that consent, normally within three working days of the laying before or notification to the UK Parliament."

Bae Caerdydd • Cardiff Bay
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Canolfan Cyswllt Cyntaf / First Point of Contact Centre:
0300 0604400

Gohebiaeth.Mark.Drakeford@llyw.cymru
Correspondence.Mark.Drakeford@gov.wales

Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

As this relates to all UK Government legislative functions exercised in relation to Wales in devolved areas to which the Welsh Ministers consent, including those relating to EU Exit to which Standing Order 30C applies and to which the protocol would have applied, and commits the Welsh Government to pre-notification, which is a requirement of neither Standing Order 30C nor the protocol, I consider that retaining the protocol would have no practical value and would risk confusion about the processes which are agreed.

If you agree, I suggest that we allow the protocol to lapse and focus instead on the new arrangements set out above. I am aware that we are not yet managing to pre-notify in all cases as the arrangements become established throughout the Welsh Government. I have impressed upon my officials the importance of ensuring that we move to full compliance as soon as possible.

Yours sincerely,

A handwritten signature in black ink that reads "Mark Drakeford". The signature is written in a cursive, slightly slanted style.

MARK DRAKEFORD

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Jeremy Miles AS/MS
Gweinidog y Gymraeg ac Addysg
Minister for Education and Welsh Language



Llywodraeth Cymru
Welsh Government

Ein cyf/Our ref JMEWL/4120/21

Rt Hon Nadhim Zahawi MP
Secretary of State for Education
Sanctuary Buildings Great Smith Street
Westminster
London SW1P 3B

13 December 2021

Dear Nadhim

Thank you for your letter of 2 December in connection with the UK Government's amendments tabled to the Skills and Post-16 Education Bill at House of Commons Committee stage and your updated devolution analysis of the Bill.

Local Skills Improvement Plans

The UK Government's amendments tabled on 23 November and subsequently agreed at Commons Committee stage on 2 December remove Welsh further and higher education institutions from the scope of the local skills improvement plans duties under clause 1 of the Bill. I am pleased to confirm that the amendments address my concerns about the imposition of statutory duties on Welsh institutions.

I welcome the constructive engagement that has taken place between our officials and your recognition of the devolved matters affected by the local skills improvement plans proposals. In light of the amendments made to the Bill I consider that **clauses 1 and 4** no longer require the consent of the Senedd.

Devolution analysis of the Bill

Thank you for providing your updated devolution analysis of the Bill.

I consider **clause 15** (clause 14 in the Bill as introduced) engages section 107(6) of the Government of Wales Act 2006. The Legislative Consent Memorandum which I laid before the Senedd in July indicates that I am content to recommend that the Senedd gives its consent in respect of this clause.

I agree with your conclusions regarding **clauses 27, 28 and 35** concerning insolvency and designation arrangements. It is my view that these clauses do not require the legislative consent of the Senedd.

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Rydym yn croesawu derbyn gohebiaeth yn Gymraeg. Byddwn yn ateb gohebiaeth a dderbynnir yn Gymraeg yn Gymraeg ac ni fydd gohebu yn Gymraeg yn arwain at oedi.

We welcome receiving correspondence in Welsh. Any correspondence received in Welsh will be answered in Welsh and corresponding in Welsh will not lead to a delay in responding.

Clause 17 concerning Universal Credit conditionality does not, in my view, require the legislative consent of the Senedd.

Finally, in respect of **clauses 18 and 25** my view is that these clauses would require the consent of the Senedd if they remained in the Bill. It is important that any legislation affecting further and higher education in Wales takes into consideration the specific Welsh context. It appears that these clauses have not taken either the devolution settlement or the Welsh context into account. I am therefore pleased to note that the UK Government has tabled amendments which seek to remove them from the Bill.

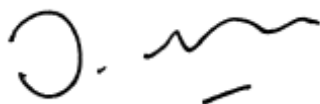
I have laid a further supplementary [Legislative Consent Memorandum \(Memorandum No. 3\)](#) in respect of amendments to the Bill.

Prohibition of essay mills

I would also like to note the amendments accepted at House of Lords Report stage on essay mills. I consider a UK-wide approach is needed to tackle this issue. I am encouraged to note Baroness Barran, in her letter to peers on 6 October, stated that the UK Government does want to continue discussions on a UK-wide approach to this issue with the devolved governments. I discussed this matter with your colleague Michelle Donelan MP, Minister of State for Higher and Further Education, on 8 December and I am pleased that she is supportive of joint working. I am grateful for the continued engagement of your officials with my officials during the passage of the Bill. This is something I support and encourage. I hope that discussions at official level to consider how a UK-wide approach to tackling essay mills might be achieved can commence as soon as possible.

I am copying this letter to the Secretary of State for Wales, to my colleague Vaughan Gething MS, Minister for Economy and to Jayne Bryant MS, Chair of the Children, Young People, and Education Committee, Huw Irranca-Davies MS, Chair of the Legislation, Justice and Constitution Committee and Paul Davies MS, Chair of the Economy, Trade, and Rural Affairs Committee.

Yours sincerely,

A handwritten signature in black ink, appearing to be 'J. Miles', with a wavy line underneath.

Jeremy Miles AS/MS
Gweinidog y Gymraeg ac Addysg
Minister for Education and Welsh Language

By virtue of paragraph(s) vii of Standing Order 17.42

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Agenda Item 10

By virtue of paragraph(s) vii of Standing Order 17.42

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Agenda Item 11

By virtue of paragraph(s) vii of Standing Order 17.42

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