Agenda – Constitutional and Legislative Affairs Committee

Meeting Venue:
Committee Room 1 – Senedd
Meeting date: 3 December 2018
Meeting time: 14.30

For further information contact:
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Committee Clerk
0300 200 6362
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2 Instruments that raise no reporting issues under Standing Order 21.2 or 21.3

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Negative Resolution Instruments

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CLA(5)-31-18 – Paper 28 – Letter from the Chairs of the Procedure Committee, the European Statutory Instruments Committee and the Lords Secondary Legislation Scrutiny Committee to all Departments regarding the flow of instruments under the EU (Withdrawal) Act 2018

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6.3 **Letter from the Cabinet Secretary for Finance: Interparliamentary forum on Brexit**

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7 Motion under Standing Order 17.42 to resolve to exclude the public from the meeting for the following business:

8 Legislative Consent Memorandum: UK Agriculture Bill: Draft Report

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CLA(5)-31-18 – Paper 34 – Approach to scrutiny (Paper to follow)

CLA(5)-31-18 – Paper 35 – Research Service Briefing – Summary of responses to the Welsh Government's consultation on the draft Bill (Paper to follow)

12 Forward Work Programme

Statutory Instruments with Clear Reports

03 December 2018

SL(5)282 – The Non-Domestic Rating Contributions (Wales) (Amendment) Regulations 2018

Procedure: Negative

These Regulations, which apply in relation to Wales, amend the Non-Domestic Rating Contributions (Wales) Regulations 1992 ("the 1992 Regulations").

Under Part II of Schedule 8 to the Local Government Finance Act 1988, billing authorities (in Wales, county and county borough councils) are required to pay amounts (called non-domestic rating contributions) to the Welsh Ministers. The 1992 Regulations contain rules for the calculation of those contributions for Welsh billing authorities.

These Regulations amend the 1992 Regulations by substituting a new Schedule 4 (Adult Population Figures) containing updated adult population figures for each billing authority.

Parent Act: Local Government Finance Act 1988

Date Made: 15 November 2018

Date Laid: 20 November 2018

Coming into force date: 31 December 2018

SL(5)283 – The Non-Domestic Rating (Small Business Relief) (Wales) (Amendment) Order 2018

Procedure: Negative

The 2017 Order provides for a rate relief scheme which applies to certain categories of hereditament.

This Order increases the maximum rateable value of hereditaments meeting the childcare conditions set out in Article 8 of the 2017 Order to £100,000.

The effect of the amendments made by this Order is to exempt all hereditaments meeting the childcare conditions set out in Article 8 of the 2017 Order from the payment of non-domestic rates.

Parent Act: Local Government Finance Act 1988

Date Made: 15 November 2018

Date Laid: 20 November 2018

Coming into force date: 19 December 2018

SL(5)281 – The Beef and Veal Labelling (Wales) (Amendment) Regulations 2018

Background and Purpose

These Regulations are made in exercise of powers contained in section 2(2) of the European Communities Act 1972.

The Regulations make technical amendments to the Beef and Veal Labelling (Wales) Regulations 2011 (S.I. 2011/991) to reflect provisions in Regulation (EU) No 653/2014 of the European Parliament and of the Council amending Regulation (EC) No 1760/2000 as regards electronic identification of bovine animals and labelling of beef.

Procedure

Negative.

Technical Scrutiny

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

Merits Scrutiny

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

Implications arising from exiting the European Union

These Regulations implement EU obligations in relation to food labelling, and therefore these Regulations will form part of retained EU law after exit day.

The Intergovernmental Agreement on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks provides that food labelling is a policy area likely to be subject to regulations made under section 12 of the EU (Withdrawal) Act 2018. Therefore, the law covered by these Regulations is likely to be an area of EU law that is frozen while common frameworks are put in place.

Government Response

No government response is required.

Legal Advisers
Constitutional and Legislative Affairs Committee
28 November 2018

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

Llywodraeth Cymru
Welsh Government

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

Mick Antoniw AM
Chair
Constitutional and Legislative Affairs Committee
National Assembly for Wales

22 November 2018

Dear Mick,

This letter is to inform you that I have laid two Statutory Instrument Consent Memoranda in the National Assembly for Wales in respect of:

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

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

as required by Standing Order 30A (SO30A).

I am also writing to inform you that I am not minded to table a motion for a debate about this SI in this instance. I have reached this decision on the basis that this SI is restricted to making corrections to the deficiencies in law that will arise as a result of the UK leaving the EU. The provisions of the SI are technical in nature, and there is no divergence in policy between the Welsh Government and the UK Government in this case.

SO30A provides that any Member may table a motion for a debate on this SI. Given the volume of legislation that the Assembly is considering, I do not believe that a debate on this SI would be a productive use of valuable Plenary time and I will not myself be seeking to initiate such a debate.

Yours sincerely,

Vaughan Gething

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

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Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE	**The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019**
DATE	**22 November 2018**
BY	**Julie James AM, Leader of the House and Chief Whip**

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

The Law which is being amended
The Regulations will amend:

(a) the Human Tissue Act 2004
(b) the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006; and
(c) the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
This SI contains provisions which enable the Welsh Ministers to exercise functions in relation to Wales without encumbrance. It also contains provisions whereby the Welsh Ministers could provide consent to the Secretary of State to exercise functions in relation to Wales on their behalf.

Functions transferred to the Secretary of State with consent would constitute functions of a Minister of the Crown for the purposes Schedule 7B to Government of Wales Act 2006. This therefore may be a relevant consideration in the context of the Assembly's competence to legislate in the future in these areas.

The purpose of the amendments
The purpose of the amendments is to correct deficiencies in legislation relating to human tissues arising from the UK leaving the European Union.

Regulation 3 amends the Human Tissue (Quality and Safety for Human Application) Regulations 2007 to insert a new section relating to the traceability, quality and safety of imports, notification of serious adverse events and reactions, and various technical

requirements. The new regulation states that the ‘appropriate authority’ may prescribe the requirements in these areas. The appropriate authority is defined in relation to Wales as the Welsh Ministers or the Secretary of State acting with the consent of the Welsh Ministers. These regulations would set the procedures for ensuring that all tissues and cells procured, processed, stored or distributed in the UK, all relevant data relating to products and materials coming into contract with those tissues and cells, can be traced from the donor to the recipient and vice versa and technical requirements, including licensing or authorisation of tissue establishments; quality systems; training; and other areas.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here:
http://www.legislation.gov.uk/ukdsi/2019/9780111174821/contents

Why consent was given
There is no divergence between the Welsh Government and the UK Government on the policy for the correction. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting to a UK wide SI ensures that there is a single legislative framework across the UK which promotes clarity and accessibility during this period of change. In these exceptional circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

A Statutory Instrument Consent Memorandum has also been laid in the National Assembly in respect of the amendments to the Human Tissue Act 2004.

STATUTORY INSTRUMENT CONSENT MEMORANDUM

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

1. This Statutory Instrument Consent Memorandum is laid under Standing Order ("SO") 30A.2. SO 30A prescribes that a Statutory Instrument Consent Memorandum must be laid and a Statutory Instrument Consent Motion may be tabled before the National Assembly for Wales ("the Assembly") if a UK Statutory Instrument (SI) makes provision in relation to Wales amending primary legislation within the legislative competence of the Assembly.

2. The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 was laid before Parliament on 19 November 2018 and is now being laid before the Assembly. The order can be found at:

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

Summary of the Statutory Instrument and its objective

3. The objective of the SI is to correct deficiencies in legislation arising from the UK leaving the European Union relating to the quality and safety of human tissues and cells.

4. This SI makes technical corrections to the Human Tissue Act 2004. These corrections are required to ensure that the statute book will continue to operate after exit.

Relevant provision to be made by the SI

5. These Regulations amend the Human Tissue Act 2004 which applies to England, Wales and Northern Ireland, to make a minor technical amendment to remove section 46; power to give effect to EU obligations.

6. It is the view of the Welsh Government that the provisions described in paragraph 5 above fall within the legislative competence of the National Assembly for Wales in so far as they relate to the quality and safety of human tissues and cells.

Why it is appropriate for the SI to make this provision

7. There is no divergence between the Welsh Government and the UK Government on the policy for the correction. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting to a UK wide SI ensures that there is a single legislative framework across the UK, which promotes

clarity and accessibility during this period of change. In these exceptional circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

Vaughan Gething AM
Cabinet Secretary for Health and Social Services

22 November 2018

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

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

2019 No. XXX

EXITING THE EUROPEAN UNION

HUMAN TISSUE

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

Made - - - - ***

Coming into force in accordance with regulation 1

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

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

PART 1

Introduction

Citation and commencement

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

PART 2

Amendment of primary legislation

Amendment of the Human Tissue Act 2004

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

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

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

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

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

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

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

PART 2

Amendment of subordinate legislation

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

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

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

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

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

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

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

Modifications to the first Directive

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

(2) Article 8 is to be read as if—

(a) in paragraph 1—

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

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

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

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

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

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

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

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

(4) Article 14 is to be read as if—

(a) in paragraph 1—

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

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

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

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

(c) in paragraph 3—

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

(ii) "in Member States" were omitted.

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

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

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

(8) Article 21 is to be read as if—

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

(b) in paragraph 5—

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

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

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

(9) Article 24 is to be read as if—

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

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

(10) The Annex is to be read as if—

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

(b) paragraph B.2 were omitted.

Modifications to the second Directive

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

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

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

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

(**a**) 2006 asp 4.

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

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

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

(7) Annex 4 is to be read as if—

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

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

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

(aa) the designated individual, or

(bb) the Authority;

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

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

Modifications to the third Directive

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

(2) Annex 1 is to be read as if—

(a) in paragraph A.1—

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

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

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

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

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

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

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

(3) Annex 2 is to be read as if—

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

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

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

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

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

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

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

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

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

Modifications to the fourth Directive

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

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

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

(4) Article 5(1) is to be read as if—

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

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

(5) Article 6 is to be read as if—

(a) in paragraph 2—

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

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

(b) in paragraph 3—

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

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

(6) Article 7 is to be read as if—

(a) in paragraph 1—

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

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

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

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

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

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

(8) Annex 1 is to be read as if—

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

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

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

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

(9) Annex 3 is to be read as if—

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

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

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

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

(10) Annex 4 is to be read as if—

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

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

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

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

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

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

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

(a) in paragraph (1)—

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

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

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

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

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

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

"traceability" means the ability to—

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

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

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

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

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

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

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

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

(a) omit paragraph (2A);

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

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

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

(i) traceability; and

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

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

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

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

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

(c) after paragraph (2), insert—

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

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

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

(b) omit paragraph (3).

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

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

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

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

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

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

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

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

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

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

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

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

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

(i) the licensing or authorisation of tissue establishments;

(ii) the procurement of tissues or cells;

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

(iv) laboratory tests required for donors;

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

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

(vi) the tissue and cell preparation process;

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

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

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

(6) In this regulation—

"appropriate authority" means—

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

(b) in relation to Wales—

(i) the Welsh Ministers; or

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

(c) in relation to Scotland—

(i) the Scottish Ministers; or

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

(d) in relation to Northern Ireland—

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

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

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

Scope and nature of powers

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

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

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

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

(a) different provision for different purposes;

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

Scrutiny of regulations

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

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

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

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

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

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

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

(a) for paragraph 1 substitute—

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

(b) omit paragraph 1A;

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

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

PART 4

Transitional Provision

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

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

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

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

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

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

(b) Schedule 2 to the Regulations.

(3) In this regulation—

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

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

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

Name
Parliamentary Under-Secretary of State,
Address

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

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

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

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EXPLANATORY MEMORANDUM TO

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

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

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

[2019] No. [XXXX]

1. Introduction

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

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

2. Purpose of the instruments

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

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

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

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

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

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

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

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

Explanations

What did any relevant EU law do before exit day?

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

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

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

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

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

Why is it being changed?

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

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

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

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

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

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

What will it now do?

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

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

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

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

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

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

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

3.2 The territorial application of these instruments is the UK.

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

4. Extent and Territorial Application

4.1 The territorial extent of these instruments is the UK.

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

5. European Convention on Human Rights

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

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

6. Legislative Context

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

6.2 The relevant UK legislation is:

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

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

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

7. Policy background

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

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

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

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

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

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

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

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

What is being done and why?

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

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

EU obligations that will no longer be relevant or appropriate

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

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

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

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

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

EU references which are redundant or inappropriate

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

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

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

Import from EEA/EU countries

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

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

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

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

References to EU Directives in UK law

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

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

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

Transfer of Commission Powers

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

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

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

Powers in the HFE SI and the Tissues and Cells SI

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Powers in the Organs SI

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

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

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

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

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

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

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

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

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

9. Consolidation

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

10. Consultation outcome

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

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

11. Guidance

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

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

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

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

12. Impact

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

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

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

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

13. Regulating small business

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

14. Monitoring & review

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

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

15. Contact

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

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

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

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

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

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

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

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

Part 2

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

1. Appropriateness statement

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

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

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

2. Good reasons

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

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

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

3. Equalities

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

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

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

3.3 This instrument will have no impact on equalities.

4. Explanations

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

UK MINISTERS ACTING IN DEVOLVED AREAS

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

Laid in UK Parliament: 19 November 2018

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

Commentary

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

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

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

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

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

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

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

Llywodraeth Cymru
Welsh Government

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

Mick Antoniw AM
Chair
Constitutional and Legislative Affairs Committee
National Assembly for Wales

22 November 2018

Dear Mick,

This letter is to inform you that I have laid two Statutory Instrument Consent Memoranda in the National Assembly for Wales in respect of:

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

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

as required by Standing Order 30A (SO30A).

I am also writing to inform you that I am not minded to table a motion for a debate about this SI in this instance. I have reached this decision on the basis that this SI is restricted to making corrections to the deficiencies in law that will arise as a result of the UK leaving the EU. The provisions of the SI are technical in nature, and there is no divergence in policy between the Welsh Government and the UK Government in this case.

SO30A provides that any Member may table a motion for a debate on this SI. Given the volume of legislation that the Assembly is considering, I do not believe that a debate on this SI would be a productive use of valuable Plenary time and I will not myself be seeking to initiate such a debate.

Yours sincerely,

Vaughan Gething

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

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Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

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

DATE **22 November 2018**

BY **Julie James AM, Leader of the House and Chief Whip**

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

The Law which is being amended
The Regulations will amend:

(a) the Human Tissue Act 2004
(b) the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006; and
(c) the Quality and Safety of Organs Intended for Transplantation Regulations 2012.

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
This SI contains provisions which enable the Welsh Ministers to exercise functions in relation to Wales without encumbrance. It also contains provisions whereby the Welsh Ministers could provide consent to the Secretary of State to exercise functions in relation to Wales on their behalf.

Functions transferred to the Secretary of State with consent would constitute functions of a Minister of the Crown for the purposes Schedule 7B to Government of Wales Act 2006. This therefore may be a relevant consideration in the context of the Assembly's competence to legislate in the future in these areas.

The purpose of the amendments
The purpose of the amendments is to correct deficiencies in legislation relating to organ donation arising from the UK leaving the European Union.

Regulation 3 amends the Quality and Safety of Organs Intended for Transplantation Regulations 2012 to insert a new section in relation to the procedures for the transmission and reporting of information relating to organs. The new regulation states that the

‘appropriate authority’ may by regulations amend the data sets in these areas. The appropriate authority is defined in relation to Wales as the Welsh Ministers or the Secretary of State acting with the consent of the Welsh Ministers.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here:
http://www.legislation.gov.uk/ukdsi/2019/9780111174807/contents

Why consent was given
There is no divergence between the Welsh Government and the UK Government on the policy for the correction. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting to a UK wide SI ensures that there is a single legislative framework across the UK which promotes clarity and accessibility during this period of change. In these exceptional circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

A Statutory Instrument Consent Memorandum has also been laid in the National Assembly in respect of the amendments to the Human Tissue Act 2004.

STATUTORY INSTRUMENT CONSENT MEMORANDUM

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

1. This Statutory Instrument Consent Memorandum is laid under Standing Order ("SO") 30A.2. SO 30A prescribes that a Statutory Instrument Consent Memorandum must be laid and a Statutory Instrument Consent Motion may be tabled before the National Assembly for Wales ("the Assembly") if a UK Statutory Instrument (SI) makes provision in relation to Wales amending primary legislation within the legislative competence of the Assembly.

2. The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 was laid before Parliament on 19 November 2018 and is now being laid before the Assembly. The order can be found at:

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

Summary of the Statutory Instrument and its objective

3. The objective of the SI is to correct deficiencies in legislation arising from the UK leaving the European Union relating to the quality and safety of organs intended for transplantation.

4. This SI makes technical corrections to the Human Tissue Act 2004. These corrections are required to ensure that the statute book will continue to operate after exit.

Relevant provision to be made by the SI

5. These Regulations amend the Human Tissue Act 2004 to make a minor technical amendment to remove references the Directives which are no longer appropriate.

6. It is the view of the Welsh Government that the provisions described in paragraph 5 above fall within the legislative competence of the National Assembly for Wales in so far as they relate to the quality and safety of organs intended for transplantation.

Why it is appropriate for the SI to make this provision

7. There is no divergence between the Welsh Government and the UK Government on the policy for the correction. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting to a UK wide SI ensures that there is a single legislative framework across the UK, which promotes clarity and accessibility during this period of change. In these exceptional

circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

Vaughan Gething AM
Cabinet Secretary for Health and Social Services

22 November 2018

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

DRAFT STATUTORY INSTRUMENTS

2019 No. 0000

EXITING THE EUROPEAN UNION

HUMAN TISSUE

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

Made - - - - 2019

Coming into force in accordance with regulation 1

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

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

PART 1

Introduction

Citation and commencement

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

PART 2

Amendment of primary legislation

Amendment of the Human Tissue Act 2004

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

(2) In subsection (3A)—

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

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

(b) at the end insert—

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

(3) After subsection (3A) insert—

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

(a) in paragraph 1—

(i) for the first subparagraph there were substituted—

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

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

(iii) the third subparagraph were omitted;

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

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

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

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

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

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

(a) in paragraph 1—

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

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

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

(c) in paragraph 3—

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

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

(d) in paragraph 4—

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

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

PART 3

Amendment of subordinate legislation

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

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

(2) In regulation 3 (interpretation)—

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

(b) in that paragraph (1)—

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

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

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

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

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

(c) after paragraph (1) insert—

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

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

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

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

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

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

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

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

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

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

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

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

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

(11) After regulation 24 insert—

"PART 5A

Power to amend data sets specified in Schedule 1A

Power for appropriate authority to amend Schedule 1A

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

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

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

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

(2) In this regulation—

"appropriate authority" means—

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

(b) in relation to Wales—

(i) the Welsh Ministers; or

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

(c) in relation to Scotland—

(i) the Scottish Ministers; or

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

(d) in relation to Northern Ireland—

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

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

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

Scope and nature of powers

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

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

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

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

(a) different provision for different purposes;

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

Scrutiny of regulations

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

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

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

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

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

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

(12) In Schedule 1 (licences)—

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

(b) in paragraph 5(b)—

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

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

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

(13) After Schedule 1 insert—

"SCHEDULE 1A

Regulation 5

Organ and Donor Characterisation

PART A

Minimum data set

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

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

(b) type of donor;

(c) blood group;

(d) gender;

(e) cause of death;

(f) date of death;

(g) date of birth or estimated age;

(h) weight;

(i) height;

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

(k) past or present history of malignant neoplasia;

(l) present history of other transmissible disease;

(m) HIV, HCV, HBV tests;

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

PART B

Complementary data set

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

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

General data

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

Donor data

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

Donor medical history

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

Physical and clinical data

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

Laboratory parameters

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

Image tests

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

Therapy

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

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

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

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

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

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

EXPLANATORY NOTE

(This note is not part of the Regulations)

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

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

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

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

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

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EXPLANATORY MEMORANDUM TO

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

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

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

[2019] No. [XXXX]

1. Introduction

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

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

2. Purpose of the instruments

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

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

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

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

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

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

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

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

Explanations

What did any relevant EU law do before exit day?

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

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

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

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

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

Why is it being changed?

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

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

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

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

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

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

What will it now do?

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

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

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

3. Matters of special interest to Parliament

Matters of special interest to the Joint Committee on Statutory Instruments

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

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

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

3.2 The territorial application of these instruments is the UK.

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

4. Extent and Territorial Application

4.1 The territorial extent of these instruments is the UK.

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

5. European Convention on Human Rights

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

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

6. Legislative Context

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

6.2 The relevant UK legislation is:

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

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

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

7. Policy background

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

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

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

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

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

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

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

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

What is being done and why?

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

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

EU obligations that will no longer be relevant or appropriate

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

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

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

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

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

EU references which are redundant or inappropriate

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

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

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

Import from EEA/EU countries

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

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

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

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

References to EU Directives in UK law

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

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

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

Transfer of Commission Powers

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

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

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

Powers in the HFE SI and the Tissues and Cells SI

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

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

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

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

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

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

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

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

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

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

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

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

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

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

Powers in the Organs SI

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

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

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

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

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

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

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

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

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

9. Consolidation

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

10. Consultation outcome

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

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

11. Guidance

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

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

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

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

12. Impact

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

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

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

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

13. Regulating small business

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

14. Monitoring & review

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

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

15. Contact

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

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

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

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

Annex

Statements under the European Union (Withdrawal) Act 2018

Part 1

Table of Statements under the 2018 Act

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

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

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

Part 2

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

1. Appropriateness statement

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

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

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

2. Good reasons

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

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

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

3. Equalities

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

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

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

3.3 This instrument will have no impact on equalities.

4. Explanations

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

UK MINISTERS ACTING IN DEVOLVED AREAS

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

Laid in UK Parliament: 19 November 2018

Sifting	
Subject to sifting in UK Parliament?	No
Procedure:	Draft Affirmative
Date of consideration by the House of Commons European Statutory Instruments Committee	N/A
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known
Date sifting period ends in UK Parliament	N/A
Written statement under SO 30C	Paper 10
SICM under SO 30A (because amends primary legislation)	Paper 11
Scrutiny procedure	
Outcome of sifting	N/A
Procedure	Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

These Regulations are proposed to be made by the UK Government pursuant to section 8(1) of, and paragraph 21(b) of Schedule 7 of the European Union (Withdrawal) Act 2018 to enable retained EU law to operate effectively following withdrawal of the United Kingdom from the European Union.

These Regulations are also made under section 23(1) of the EU Withdrawal Act in order to make a consequential amendment to regulation 24 of the Quality and Safety of Organs Intended for Transplantation Regulations 2012. This requires the Secretary of State to have regard to how the Organ Donation Directives have been implemented in EU member states when reviewing the regulations.

The purpose of these regulations is to make amendments to correct deficiencies in legislation relating to organ donation arising from the UK leaving the European Union.

The Regulations allow the Secretary of State and/or the Welsh Ministers (where within devolved competence) with powers previously held by the EU Commission which will allow them to update legislation on organs in response to emerging threats and changing safety and quality standards. These Regulations form part of a suite of statutory instruments covering the safety of organs, tissues and cells and reproductive cells for treating patients. They are all 'no deal' SIs which have been developed as part of contingency planning and will be needed in the event that the UK leaves the EU with no agreement in place.

Legal Advisers agree with the statement laid by the Welsh Government dated 22 November 2018 regarding the effect of these Regulations.
The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

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

Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE	**The Leghold Trap and Pelt Imports (Amendment etc.) (EU Exit) Regulations 2018**
DATE	**22 November 2018**
BY	**Julie James AM, Leader of the House and Chief Whip**

The Leghold Trap and Pelt Imports (Amendment etc.) (EU Exit) Regulations 2018

The [retained EU] Law which is being amended

- Council Regulation (EEC) No 3254/91
- Council Decision 97/602
- Commission Regulation (EC) No 35/97

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
In terms of Leghold Trap and Pelt Imports the operability amendments will cover some devolved matters (prohibition on the use of leghold traps) and some reserved matters (import ban on pelts).

The purpose of the amendments
The purpose of this SI (negative procedure), to be introduced by the Department for Environment Food and Rural Affairs (DEFRA) will be to implement those UK wide modifications that are necessary to ensure EU legislation continues to operate effectively in terms of the prohibition of leghold traps and the introduction into the UK of pelts and manufactured goods of certain wild animal species originating in countries which catch them by means of leghold traps or trapping methods which do not meet international humane trapping standards.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here:https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-leghold-trap-and-pelt-imports-amendment-etc-eu-exit-regulations-2018

Why consent was given
Consent has been given for the UK Government to make these corrections in relation to,

and on behalf of, Wales for reasons of efficiency, expediency and due to the technical nature of the amendments. The amendments have been considered fully; and there is no divergence in policy. These amendments are to ensure that the statute book remains functional following the UK's exit from the EU. This is in line with the principles for correcting agreed by the Cabinet Sub-Committee on European Transition in May.

UK MINISTERS ACTING IN DEVOLVED AREAS	
The Leghold Trap and Pelt Imports (Amendment etc.) (EU Exit) Regulations 2018 *Laid in the UK Parliament: 21 November 2018*	
Sifting	
Subject to sifting in UK Parliament?	Yes
Procedure:	Proposed negative
Date of consideration by the House of Commons European Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	w/c 3 December 2019
Date sifting period ends in UK Parliament	6 December 2018
Written statement under SO 30C:	Paper 15
SICM under SO 30A (because amends primary legislation)	Not required
Scrutiny procedure	
Outcome of sifting	Not known
Procedure	Negative or Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

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

Council Regulation (EEC) 3254/91 prohibited the use of leghold traps in the European Union and the introduction into the EU of pelts and manufactured goods of certain wild animal species originating in countries which catch them by means of leghold traps or trapping methods which do not meet international humane trapping standards. These Regulations amend Council Regulation (EEC) 3254/91 and two pieces of associated legislation (Commission Regulation (EC) No 35/97 and Council Decision (EC) No 97/602) to ensure their operability following the UK's withdrawal from the EU. The Regulations also revoke the associated Commission Regulation 1771/94 and Commission Decisions 98/188/EC and 98/596.

Following the UK's withdrawal from the EU, Council Regulation (EEC) 3254/91 (as amended) will prohibit the use of leghold traps in the UK and the introduction into the UK (unless from Member States of the EU) of pelts, and manufactured goods incorporating pelts, of certain wild animal species unless the pelts originate from an approved country or are from animals which were captive-bred. Pelt import controls are not being imposed on EU Member States by these Regulations in order to avoid changing policy and expanding the remit of Council Regulation (EEC) 3254/91 to cover countries not currently covered.

Legal Advisers agree with the statement laid by the Welsh Government dated 22 November 2018 regarding the effect of these Regulations.
The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

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

Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE **The Equine (Records, Identification and Movement) (Amendment) (EU Exit) Regulations 2018**

DATE **22 November 2018**

BY **Julie James AM, Leader of the House and Chief Whip**

The Equine (Records, Identification and Movement) (Amendment) (EU Exit) Regulations 2018

- Commission Implementing Regulation (EU) 2015/262 of 17 February 2015 laying down rules pursuant to Council Directives 90/427/EEC and 2009/156/EC as regards the methods for the identification of equidae ("Equine Passport Regulation")
- Decision 92/353/EEC of 11 June 1992 laying down the criteria for the approval or recognition of organisations and associations which maintain or establish stud-books for registered equidae
- Commission Decision 92/216/EEC of 26 March 1992 on the collection of data concerning competitions for equidae as referred to in Article 4(2) of Council Directive 90/428/EEC
- Commission Decision 92/354/EEC of 11 June 1992 laying down certain rules to ensure coordination between organisations and associations which maintain or establish stud-books for registered equidae
- Agreement on the European Economic Area 2018/424, as amended by Decision of the EEA Joint Committee No 166/2016

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
Equine identification is a devolved function

The purpose of the amendments
The purpose of this SI (negative procedure), to be introduced by the Department for Environment Food and Rural Affairs (DEFRA) will be to implement those UK wide modifications that are necessary to preserve the application of EU Regulations in regards to equine identification. It will ensure that equivalent identification rules to those that are contained within Regulation (EU) 2015/262 can continue to work across the UK once the UK leaves the EU.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-equine-identification-england-amendment-eu-exit-regulations-2018

Why consent was given

Consent has been given for the UK Government to make these corrections in relation to, and on behalf of, Wales for reasons of efficiency, expediency and due to the technical nature of the amendments. The amendments have been considered fully; and there is no divergence in policy. These amendments are to ensure that the statute book remains functional following the UK's exit from the EU. This is in line with the principles for correcting agreed by the Cabinet Sub-Committee on European Transition in May.

UK MINISTERS ACTING IN DEVOLVED AREAS

The Equine (Records, Identification and Movement) (Amendment) (EU Exit) Regulations 2018

Laid in the UK Parliament: 20 November 2018

Sifting	
Subject to sifting in UK Parliament?	Yes
Procedure:	Proposed negative
Date of consideration by the House of Commons European Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	w/c 3 December 2018
Date sifting period ends in UK Parliament	5 December 2018
Written statement under SO 30C:	Paper 17
SICM under SO 30A (because amends primary legislation)	Not required
Scrutiny procedure	
Outcome of sifting	Not known
Procedure	Negative or Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

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

These Regulations are made in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.
These Regulations make amendments to the EU legislation in the field of equine identification, which, prior to withdrawal from the United Kingdom, had direct effect in the United Kingdom and is retained by virtue of the Withdrawal Act.

These Regulations will ensure that equines continue to be identified by way of a single lifetime document, maintaining high standards of biosecurity, equine movements, food safety and welfare. The Regulations

will help ensure that UK equines continue to be able to travel to and from the EU with the minimum of disruption.

Legal Advisers agree with the statement laid by the Welsh Government dated 22 November 2018 regarding the effect of these Regulations.
The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE	**The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019**
DATE	**22 November 2018**
BY	**Julie James AM, Leader of the House and Chief Whip**

The Blood Safety and Quality (Amendment) (EU Exit) Regulations 2019 ("the Regulations")

The [retained EU] Law which is being amended

The regulations will amend:

- The Blood Quality and Safety Regulations 2005

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
This SI confers powers on the Secretary of State and Welsh Ministers in relation to certain quality and safety standards and technical requirements relating to the collection, testing, processing, storage and distribution of blood and blood components. There is no effect on the Assembly's legislative competence or Welsh Ministers' executive competence.

Functions transferred to the Secretary of State with consent would constitute functions of a Minister of the Crown for the purposes Schedule 7B to Government of Wales Act 2006. This therefore may be a relevant consideration in the context of the Assembly's competence to legislate in the future in these areas.

The purpose of the amendments
The purpose of the amendments is to correct deficiencies in legislation arising from the UK leaving the European Union relating to Blood Quality and Safety:

Regulation 13 amends the Blood Quality and Safety Regulations 2005 to insert a new section regarding provisions in relation to setting standards and requirements in respect of blood and blood components collected and tested for the purpose of and use in autologous transfusion; including establishing standards and specifications for a quality system to be

carried out by a blood establishment;standards of quality and safety for the collection, testing, processing, storage and distribution of blood and blood components; traceability requirements; notification of serious adverse reactions and events; and various other technical requirements.

The new regulation states that the ‘appropriate authority’ may by regulations make provisions in these areas. The appropriate authority is defined in relation to Wales as the Welsh Ministers or the Secretary of State acting with the consent of the Welsh Ministers.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here:
http://www.legislation.gov.uk/ukdsi/2019/9780111174814/contents

Why consent was given
There is no divergence between the Welsh Government and the UK Government on the policy for the correction. Therefore, making separate SIs in Wales and England would lead to duplication, and unnecessary complication of the statute book. Consenting to a UK wide SI ensures that there is a single legislative framework across the UK which promotes clarity and accessibility during this period of change. In these exceptional circumstances, the Welsh Government considers it appropriate that the UK Government legislates on our behalf in this instance.

UK MINISTERS ACTING IN DEVOLVED AREAS

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

Laid in the UK Parliament: 19 November 2018

Sifting	
Subject to sifting in UK Parliament?	No
Procedure:	Draft Affirmative
Date of consideration by the House of Commons European Statutory Instruments Committee	N/A
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	3 December 2018
Date sifting period ends in UK Parliament	N/A
Written statement under SO 30C:	Paper 19
SICM under SO 30A (because amends primary legislation)	Not required
Scrutiny procedure	
Outcome of sifting	N/A
Procedure	Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

These Regulations are proposed to be made by the UK Government pursuant to section 8 of the European Union (Withdrawal) Act 2018. These Regulations are being made in order to address failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

These Regulations amend the Blood Safety and Quality Regulations 2005 (S.I. 2005/50) to ensure that blood safety and quality legislation will continue to function after exit day.

Legal Advisers agree with the statement laid by the Welsh Government dated 22 November 2018 regarding the effect of these Regulations. The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

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

Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE **The Organic Products (Amendment) (EU Exit) Regulations 2018**

DATE **23 November 2018**

BY **Julie James AM, Leader of the House and Chief Whip**

The Organic Products (Amendment) (EU Exit) Regulations 2018

The law which is being amended
The legislation amended by these regulations is the Organic Products Regulations 2009.

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
This statutory instrument contains provisions which are within devolved competence.

The purpose of the amendments
The Organic Products (Amendment) (EU Exit) Regulations 2018 makes amendments to legislation, which provides powers to administer and enforce retained EU legislation relating to organic production and labelling rules, in order to ensure that it remains operable after the UK's exit from the EU.

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-organic-products-amendment-eu-exit-regulations-2018

Why consent was given
Consent has been given for the UK Government to make these corrections in relation to, and on behalf of, Wales for reasons of efficiency, expediency and due to the technical nature of the amendments. The amendments have been considered fully; and there is no divergence in policy. These amendments are to ensure that the statute book remains functional following the UK's exit from the EU. This is in line with the principles for correcting agreed by the Cabinet Sub-Committee on European Transition in May.

UK MINISTERS ACTING IN DEVOLVED AREAS

The Organic Products (Amendment) (EU Exit) Regulations 2018

Laid in the UK Parliament: 20 November 2018

Sifting	
Subject to sifting in UK Parliament?	Yes
Procedure:	Proposed negative
Date of consideration by the House of Commons European Statutory Instruments Committee	No known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	w/c 3 December 2018
Date sifting period ends in UK Parliament	5 December 2018
Written statement under SO 30C:	Paper 21
SICM under SO 30A (because amends primary legislation)	Not required
Scrutiny procedure	
Outcome of sifting	Not known
Procedure	Negative or Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

These Regulations are proposed to be made by the UK Government pursuant to section 8 (1) of the European Union (Withdrawal) Act 2018.

These Regulations amend subordinate legislation relating to organic products (the Organic Products Regulations 2009), addressing failures of domestic legislation and other deficiencies arising from the withdrawal of the United Kingdom from the European Union.

Legal Advisers agree with the statement laid by the Welsh Government dated 23 November 2018 regarding the effect of these Regulations.
The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal)

Bill and the Establishment of Common Frameworks in relation to these Regulations.

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

Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE **The Zoonotic Disease Eradication and Control (Amendment) (EU Exit) Regulations 2018**

DATE **23 November 2018**

BY **Julie James AM, Leader of the House and Chief Whip**

The Zoonotic Disease Eradication and Control (Amendment) (EU Exit) Regulations 2018

The law which is being amended

The retained EU law which is being amended or revoked by these Regulations is:

- Commission Decision 2003/644/EC established additional guarantees regarding salmonella for consignments to Finland and Sweden of breeding poultry and day-old chicks for introduction into flocks of breeding poultry or flocks of productive poultry;
- Regulation (EC) No 2160/2003 on the control of salmonella and other specified food-borne zoonotic agents;
- Commission Decision 2004/235/EC establishing additional guarantees regarding salmonella for consignments to Finland and Sweden of laying hens;
- Commission Decision 2004/665/EC concerning a baseline study on the prevalence of salmonella in laying flocks of *Gallus gallus*;
- Commission Regulation (EC) No 1177/2006 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards requirements for the use of specific control methods in the framework of the national control programmes for the control of salmonella in poultry;
- Commission Regulation (EU) No 200/2010 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of *Salmonella* serotypes in adult breeding flocks of *Gallus gallus* ;
- Commission Regulation (EU) No 517/2011 implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as regards a Union target for the reduction of the prevalence of certain *Salmonella* serotypes in laying hens of *Gallus gallus*;
- Commission Regulation (EU) No 200/2012 concerning a Union target for the

reduction of the prevalence of *Salmonella enteritidis* and *Salmonella typhimurium* flocks of broilers;

- Commission Regulation (EU) No 1190/2012 concerning a Union target for the reduction *Salmonella* Enteritidis and *Salmonella* Typhimurium in flocks of turkeys; and
- Commission Implementing Decision 2013/652/EU on the monitoring and reporting of antimicrobial resistance in zoonotic and commensal bacteria.

They also amend the EEA Agreement.

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence
This statutory instrument contains provisions which are within devolved competence.

In relation to the Zoonotic Disease Eradication and Control (EU Exit) (Amendments) Regulations 2018, three functions have been transferred so that they are exercisable by the SoS alone (in one instance only with the consent of the Devolved Authorities in relation to devolved territories.)

Functions transferred to the SoS constitute functions of a Minister of the Crown for the purposes of Schedule 7B to GoWA 2006. A future Assembly Bill seeking to remove or modify these functions could trigger a requirement to consult the UKG.

The purpose of the amendments
The purpose of the amendments is to make some of the amendments which are necessary to ensure that legislation which protects public health from zoonotic disease and in particular from salmonella remains operable after the UK's exit from the EU

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-zoonotic-disease-eradication-and-control-amendment-eu-exit-regulations-2018

Why consent was given
Consent has been given for the UK Government to make these corrections in relation to, and on behalf of, Wales for reasons of efficiency, expediency and due to the technical nature of the amendments. The amendments have been considered fully; and there is no divergence in policy. These amendments are to ensure that the statute book remains functional following the UK's exit from the EU. This is in line with the principles for correcting agreed by the Cabinet Sub-Committee on European Transition in May.

UK MINISTERS ACTING IN DEVOLVED AREAS

The Zoonotic Disease Eradication and Control (Amendment) (EU Exit) Regulations 2018

Laid in the UK Parliament: 20 November 2018

Sifting	
Subject to sifting in UK Parliament?	Yes
Procedure:	Proposed negative
Date of consideration by the House of Commons European Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	w/c 3 December
Date sifting period ends in UK Parliament	5 December 2018
Written statement under SO 30C:	Paper 23
SICM under SO 30A (because amends primary legislation)	Not required
Scrutiny procedure	
Outcome of sifting	Not known
Procedure	Negative or Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

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

The Zoonotic Disease Eradication and Control (Amendment) (EU Exit) Regulations 2018 amend, and to a smaller degree revoke, retained EU law which protects human health against zoonotic disease (in particular, salmonella) so that it will continue to be operable after the UK leaves the EU. Zoonotic diseases are those that may transfer from animals to humans.

The minor and technical changes made by the instrument are designed to ensure that retained EU law continues to operate effectively. The changes include removing or amending references to EU institutions such as “Community reference laboratories” and “the Commission” which will

no longer be appropriate after exit. Imports of live poultry and hatching eggs from the EU will continue on the same basis after exit day.
The existing EU legislation sets out controls that protect public health from zoonotic disease and in particular from salmonella. The UK Government has expressed its wish to retain those standards of health protection on EU exit and is making amendments to retained EU legislation to allow this.

Legal Advisers agree with the statement laid by the Welsh Government dated 23 November 2018 regarding the effect of these Regulations.
The above summary and the content of the Explanatory Memorandum to these Regulations confirm their effect and the extent to which these Regulations would enact new policy in devolved areas.

Legal Advisers do not consider that any significant issues arise under paragraph 8 of the Memorandum on the European Union (Withdrawal) Bill and the Establishment of Common Frameworks in relation to these Regulations.

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

Llywodraeth Cymru
Welsh Government

WRITTEN STATEMENT
BY
THE WELSH GOVERNMENT

TITLE **The European Structural and Investment Funds Common Provisions Rules etc (Amendment etc) (EU Exit) Regulations 2018**

DATE **26 November 2018**

BY **Julie James AM, Leader of the House and Chief Whip**

The European Structural and Investment Funds Common Provisions Rules etc (Amendment etc) (EU Exit) Regulations 2018

The law which is being amended

The following instruments are being amended:

- Commission Delegated Regulation(EU) No 480/2014;
- Commission Implementing Regulation (EU) No 215/2014;
- Commission Delegated Regulation (EU) No 240/2014;
- Commission Implementing Regulation (EU) No 821/2014;
- Commission Implementing Regulation (EU) No 964/2014;
- Commission Delegated Regulation (EU) No 2015/1076; and
- Commission Delegated Regulation (EU) No 2015/1516).

The following instruments are being revoked:

- Commission Implementing Regulation (EU) No 184/2014;
- Commission Implementing Regulation (EU) No 1011/2014; and
- Commission Implementing Decision (EU) No 2014/660

Any impact the SI may have on the Assembly's legislative competence and/or the Welsh Ministers' executive competence

Functions in relation to the administration of the common agricultural policy (CAP) have been transferred by this instrument so that they are exercisable by the Welsh Ministers alone

The purpose of the amendments

This instrument addresses failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the UK from the EU. It deals with corrections that

are technical in nature and do not make any significant policy changes, instead corrections adjust the retained EU Regulations to incorporate new (agreed) terms to ensure the existing EU EAFRD and EMFF programmes will continue to be funded for the remainder of the 2014 to 2020 programme, if there is no deal. This SI is the second UK correcting Statutory Instrument included as part of the wider package to correcting the CAP

The SI and accompanying Explanatory Memorandum, setting out the effect of each amendment is available here: https://www.gov.uk/eu-withdrawal-act-2018-statutory-instruments/the-european-structural-and-investment-funds-common-provisions-rules-etc-amendment-etc-eu-exit-regulations-2018

Why consent was given

Consent has been given for the UK Government to make these corrections in relation to, and on behalf of, Wales for reasons of efficiency, expediency and due to the technical nature of the amendments. The amendments have been considered fully; and there is no divergence in policy. These amendments are to ensure that the statute book remains functional following the UK's exit from the EU. This is in line with the principles for correcting agreed by the Cabinet Sub-Committee on European Transition in May.

UK MINISTERS ACTING IN DEVOLVED AREAS

The European Structural and Investment Funds Common Provisions Rules etc (Amendment etc) (EU Exit) Regulations 201

Laid in the UK Parliament: 21 November 2018

Sifting	
Subject to sifting in UK Parliament?	Yes
Procedure:	Proposed negative
Date of consideration by the House of Commons European Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	w/c 3 December 2018
Date sifting period ends in UK Parliament	6 December 2018
Written statement under SO 30C:	Paper 25
SICM under SO 30A (because amends primary legislation)	Not required
Scrutiny procedure	
Outcome of sifting	Not known
Procedure	Negative or Affirmative
Date of consideration by the Joint Committee on Statutory Instruments	Not known
Date of consideration by the House of Commons Statutory Instruments Committee	Not known
Date of consideration by the House of Lords Secondary Legislation Scrutiny Committee	Not known

Commentary

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

This instrument addresses failures of retained EU law to operate effectively and other deficiencies arising from the withdrawal of the UK from the EU. It deals with corrections that are technical in nature and do not make any significant policy changes, instead corrections adjust the retained EU Regulations to incorporate new (agreed) terms to ensure the existing EU European Agricultural Fund for Rural Development (EAFRD) and European Maritime and Fisheries Fund (EMFF) programmes will continue to be funded for the remainder of the 2014 to 2020 programme, if there is no deal. This SI is the second UK correcting Statutory Instrument included as part of the wider package to correcting the CAP.

Legal Advisers agree with the statement laid by the Welsh Government dated 26 November 2018 regarding the effect of these Regulations.

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

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

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

Mick Antoniw AM
Chair
Constitutional and Legislative Affairs Committee
National Assembly for Wales
Cardiff Bay
CF99 1NA

Your ref:
Our ref: EJ/HF

27 November 2018

Dear Mick

Assembly reform: legislative competence

As you know, the Assembly Commission is leading work on behalf of the institution to explore how powers devolved in the Wales Act 2017 over the Assembly's electoral arrangements might be used to make our legislature more effective, accessible and diverse, should the required degree of political consensus for electoral reform emerge. This includes consideration of the Assembly's legislative competence. I am writing to update you on my correspondence with the Secretary of State for Wales in respect of these matters.

As I announced in a Written Statement to the Assembly in July 2018, I am confident from conversations to date, and from the response to the Assembly Commission's Creating a Parliament for Wales public consultation, that there is sufficient support for the Expert Panel's recommendation that there should be an increase in the number of Assembly Members. However, there is not yet consensus among political parties on the voting system that should be used to elect that larger institution. It is clear that more time is needed for discussions to

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take place on how Members should be elected and the approach to be taken to improve diversity of representation in Wales.

While these discussions take place, the Assembly Commission is exploring how the recommendations made by the Expert Panel for the reform of the Assembly's electoral arrangements might be taken forward, should political consensus emerge. This includes the Panel's recommendations for measures to improve diversity of representation.

As you will be aware, the Wales Office intends to bring forward a Section 109 Order this autumn, primarily to address issues arising in relation to Brexit. Assembly Commission officials have had initial conversations with Wales Office officials as to whether this Order, or a subsequent Section 109 Order, could offer a suitable legislative vehicle to clarify the Assembly's legislative competence as it relates to matters within the scope of the Assembly reform work.

One such issue is whether the reservation of equal opportunities inadvertently constrains the Assembly legislative competence in relation to electoral matters. I enclose a copy of a letter to the Secretary of State for Wales in respect of this matter. Clarification of the Assembly's competence in this regard by means of a Section 109 Order would give full expression to the devolution of legislative competence over the Assembly's electoral arrangements. Such clarification would ensure that the Assembly itself is able to determine if and how it wishes to respond to the Expert Panel's recommendations.

If you would like to discuss this matter, I would be happy to do so.

Yours sincerely

Elin Jones

Llywydd

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

The Rt Hon Alun Cairns MP
Secretary of State for Wales

27 November 2018

Dear Alun

Equal opportunities and the Assembly's electoral arrangements

With effect from 1 April 2018, the Wales Act 2017 devolved power to the Assembly over its own elections. You will be aware that I am leading proposals to reform the Assembly and its electoral arrangements, which includes consideration of diversity of representation.

I have received advice that the reservation of 'Equal opportunities' may inadvertently constrain the Assembly's capacity to legislate in relation to electoral matters. I would therefore welcome your views on the mechanism by which the Assembly's legislative competence in this respect might be clarified, and the timescales for such clarification.

The Expert Panel on Assembly Electoral Reform recommended in December 2017 that the Assembly should have between 80 and 90 Members. Increasing the size of the legislature requires reform of the way in which Members are elected. The Panel recommended that this reform should include measures to support and encourage the election of a legislature which more closely reflects the diversity of the people and communities it serves. Such measures might include, for example, the integration of candidate gender quotas into the electoral system or the introduction of legislative requirements for political parties to publish anonymised data on the diversity of their candidates.

Should the Assembly Commission decide to legislate in relation to the above, it will need to explore how the relevant recommendations might be taken forward.

Paragraph 187 of Schedule 7A of the Government of Wales Act 2006 reserves "Equal opportunities", although the reservation does include a number of

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exceptions. The definition of 'equal opportunities' in paragraph 187 is: "the prevention, elimination or regulation of discrimination". The purpose of any legislation introduced by the Assembly Commission to implement the Expert Panel's recommendations would be to achieve greater diversity of representation by improving the gender balance among electoral candidates. This would not engage the functions specified in the definition of 'equal opportunities' in paragraph 187.

It is clear, therefore, that having regard to the 'purpose and effect' test, a respectable argument can be advanced that seeking to achieve a gender-balanced Assembly is not reserved. However, there is currently no explicit exception for Assembly elections. Clarifying the equal opportunities reservation by means of a Section 109 order would place this matter beyond doubt, and would give full expression to the devolution of legislative competence over the Assembly's electoral arrangements. Such clarification would ensure that the Assembly itself is able to determine if and how it wishes to respond to the Expert Panel's recommendations.

I welcome the way in which your officials have been willing to engage with Assembly Commission officials in initial discussion of these matters. I look forward to hearing your views, including the timescales within which any Section 109 Order might be brought forward in order to inform cross-party discussions on electoral reform.

Yours sincerely

Elin Jones

Llywydd

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

cc The Rt Hon Carwyn Jones AM, First Minister

HOUSE OF LORDS
Secondary Legislation Scrutiny Committee

House of Lords
London
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1 November 2018

To all Ministers with departmental responsibility for secondary legislation

Flow and volume of secondary legislation

We are writing this joint letter in our capacity as Chairmen of the House of Lords Secondary Legislation Scrutiny Committee (SLSC) and its sub-committees, the House of Commons European Statutory Instruments Committee (ESIC) and the House of Commons Procedure Committee. As you know, the SLSC and ESIC are charged with considering all proposed negative instruments laid under the European Union (Withdrawal) Act 2018. In addition, the SLSC considers all negative and affirmative instruments whether laid under the Withdrawal Act or other Acts of Parliament, as well as treaties laid under the Constitutional Reform and Governance Act 2010.

The Government have said on a number of occasions that they anticipate that the decision to withdraw from Europe would give rise to 800 to 1,000 instruments. Of those Brexit-related instruments, a significant proportion would be "proposed negative instruments" laid under provisions of the European Union (Withdrawal) Act 2018 ("the Withdrawal Act") which provide for a choice between the affirmative and negative resolution procedure.

From an early stage, when it became clear that the decision to leave the European Union would result in a large number of additional statutory instruments, committees in the Lords and the Commons have pressed the Government to ensure that the flow of instruments should be as even as possible and to keep Parliament informed about anticipated numbers. The SLSC, in evidence to the House of Commons Procedure Committee, for example, urged the Government to ensure "proper management of the flow of instruments …, offering advance information about the planned flow". The House of Commons Procedure Committee, in its report on the scrutiny of delegated legislation under the Withdrawal Act, said: "We expect the [PBL Committee] to take an active role in managing the flow of secondary legislation under the Act. The Government must ensure a steady even flow of instruments for scrutiny for the Parliamentary process to work effectively."

Whilst both Houses have made every effort to ensure that they are well-placed to undertake the scrutiny work resulting from the decision to withdraw from the EU, we are disappointed to observe that, so far, the flow of both Brexit-related statutory instruments and of proposed negative instruments has been very slow to start. We note that the Hansard Society has recently suggested that only 9% of Brexit-related instruments have been laid before Parliament. Bearing in mind the deadline to which we are working, it is vital that our Committees and the Houses more generally are given more information about what we can expect in the coming months. To this end, we would be grateful if you would provide answers to the following questions. We are writing to all departments and would like responses from each department so that we can, ourselves, piece together the Whitehall-wide picture.

Questions

1. How many Brexit-related statutory instruments in total remain to be laid by your department, and under which Acts of Parliament?

2. With regard to your department, for each of the months from November 2018 to March 2019:

   (a) how many statutory instruments subject to the negative procedure (excluding *proposed* negative instruments) and how many statutory instruments subject to the affirmative procedure will be laid before Parliament?

   (b) what proportion of those instruments are Brexit-related instruments and are therefore included in the Government's estimate of 800 to 1,000 Brexit-related instruments?

   (c) how many proposed negative instruments will be laid before Parliament?

   (d) how many treaties under CRAG will be laid before Parliament?

3. Is the underlying assumption of those figures deal (with an implementation period) or "no deal"? How would they change if the assumption were reversed?

4. When does the department think it can lay the last proposed negative instruments before Parliament, allowing enough time to schedule a debate should the committees recommend upgrades to the affirmative procedure?

5. Does the department expect to use the "urgent cases" procedure under the Withdrawal Act?

In addition, please can you provide your departmental planning document setting out which statutory instruments – whether Brexit-related only or all statutory instruments – are to be laid and when.

The Committees are anxious to receive this information as soon as possible. We would be grateful if you could reply by **Friday 16 November**, to the email addresses provided below. We may decide to publish your response.

Yours sincerely

The Rt Hon. The Lord Trefgarne
Chairman
SLSC and of Sub-Committee A of the SLSC
House of Lords
hlseclegscrutiny@parliament.uk

The Rt Hon. The Lord Cunningham of Felling DL
Chairman
Sub-Committee B of the SLSC
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Rt Hon. Sir Patrick McLoughlin MP
Chair
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Mr Charles Walker OBE MP
Chair
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Office of the Leader of the House of Commons

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Department for Exiting the European Union

Chris Heaton-Harris MP
Parliamentary Under Secretary of State for Exiting the European Union
9 Downing Street
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Mr Charles Walker OBE MP
Chair, Procedure Committee
House of Commons
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Rt Hon Sir Patrick McLoughlin MP
Chair, ESIC
House of Commons,
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The Rt Hon. the Lord Trefgarne
Chairman, Secondary Legislation Scrutiny Committee
House of Lords
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The Rt Hon. the Lord Cunningham of Felling DL
Chairman, Secondary Legislation Scrutiny Committee
Sub-Committee B
House of Lords
London
SW1A 0PW

19 November 2018

Dear Charles, Sir Patrick, Lord Trefgarne and Lord Cunningham,

FLOW AND VOLUME OF SECONDARY LEGISLATION

Thank you for your letter to Departmental SI Ministers of 1 November asking for further information on the remaining EU exit SIs we are expecting to lay between now and the end of March next year. We are responding on their behalf.

We agree that the laying of EU exit SIs has accelerated rapidly from a low base. However, as there are many parts to the process in Government and Parliament, it has been useful to allow the system to be tested without huge pressure. We welcome the constructive discussions we have had with you and your Committees, and have been happy to go beyond what is usually expected by providing a forecast of the likely number of SIs, broken down by month, and indicating the departments that will be laying the most SIs.

We hope this has helped your Committees to plan your work better whilst ensuring Parliament has more clarity on when it can expect to scrutinise exit SIs. We want to provide further assurances and assist in your Committees' planning. We have therefore set out at Annex A an indication of the likely percentage of EU exit SIs each department expects to lay. We hope that this information, taken alongside that previously provided (including on the number of SIs expected to be laid each month, which we re-attach in Annex B) provides you with a sufficient forward look to enable you to plan your resources.

We want to be as helpful as possible to the Committees and we have gone further than any previous Government in being open and transparent about our plans regarding secondary legislation.

Flow of Brexit SIs

As Chris Heaton-Harris outlined in his letter of 25 October, the number of EU exit SIs being laid started to increase significantly from 1 November onward, and progress has already been made. As of 16 November 138 SIs have been laid since Royal Assent of the EU (Withdrawal) Act - 56 were laid in October alone. 87 proposed negatives have so far been

laid for consideration by the Sifting Committees and we expect around 146 more negatives under the EU (Withdrawal) Act to be laid ahead of exit day. 42 affirmative SIs have been laid of which 37 are under the EU (Withdrawal) Act or a combination of that Act and other powers. The final number of affirmatives will of course depend on the sifting recommendations.

Ever since we published the white paper for what became the EU (Withdrawal) Act in January 2017, we have indicated we expect that the total number of Brexit SIs needed before exit day to be between 800-1,000. As Chris Heaton-Harris noted in his letter of 25 October, we have been clear that this total would likely fluctuate and could only be an indicative figure as departmental plans were finalised and negotiations progressed. This figure has continued to become clearer as policy decisions have crystalised, other exit-related primary legislation has received Royal Assent, and legal drafting finalised, which is why we now expect the total number of EU exit SIs we need will be fewer than 800. We now expect the total number to be up to 700, although again this may fluctuate.

The Government has always said that the objective is to ensure a functioning statute book. To do this, SIs necessary for exit day have been prioritised, and other SIs with less time pressure will be laid later in the process to enable a manageable flow and allow the necessary scrutiny by Parliament.

Departments quite rightly continue to refine the drafting and policy content of each SI and, in some cases, have combined measures to form coherent packages and/or to aid public understanding. Furthermore, around a quarter of statutory instruments will legislate on behalf of the devolved administrations adding another layer of complexity. This all impacts the number of SIs and the departmental breakdown. For these reasons, providing a reliable department-by-department month-by-month snapshot would be misleading. But we hope that you will find the detail provided at Annex A useful to understand the likely percentage breakdown of the total number of SIs we expect each department to lay.

Your letter also asked about ‘business as usual’ SIs. In the months between now and exit day We are very confident that the volume of non-EU exit SIs will be much lower than in comparable months in previous sessions. As the SLSC noted in its interim report on the work of that Committee in this session so far, the number of routine SIs laid before Parliament has remained at a relatively low level.

The number of treaties to be laid under the Constitutional Reform and Governance Act 2010 will be determined by the wider EU exit scenario. In the unlikely event of no deal, we will seek to put a number of successor international agreements with third countries in place by the end of March 2019 to replace EU international treaties and ensure continuity. In a deal scenario, our existing EU international agreements would continue to apply and so we would seek to bring successor treaties into force for the end of the Implementation Period.

Parliamentary scrutiny

You asked in your letter about the secondary legislation required for a deal scenario and a no deal scenario. The majority of EU exit SIs will be needed for a no deal scenario as well as for a deal at the end of the implementation period. Once the withdrawal agreement is legislated for, the SIs that are currently being laid under the EU (Withdrawal) Act will be deferred, amended or revoked by the Withdrawal Agreement Bill, ready for the end of an implementation period rather than for exit day.

Proper parliamentary scrutiny is a vital part of our democracy and the Government is keen to ensure Parliament has sufficient time to scrutinise these important pieces of legislation. We

do not plan to use the urgent procedure under the EU (Withdrawal) Act. This power is there as a very last resort.

We will continue to work closely with you and your Committees at both Ministerial and official levels and we will write to you again with a further update before the end of the year.

I am copying this letter to the other Business Managers and all SI Ministers.

RT HON ANDREA LEADSOM MP
LEADER OF THE HOUSE OF COMMONS

CHRIS HEATON-HARRIS MP
PARLIAMENTARY UNDER SECRETARY OF STATE FOR EXITING THE EUROPEAN UNION

Annex A

Department	Percentage of Brexit SIs
BEIS	10-15%
CO	up to 5%
DCMS	0-5%
DEFRA	15-20%
DExEU	up to 5%
DfE	up to 5%
DfT	10-15%
DHSC	up to 5%
DIT	up to 5%
DWP	up to 5%
FCO	up to 5%
FSA	up to 5%
HMRC	10-15%
HMT	10-15%
HO	up to 5%
MHCLG	up to 5%
MOJ	up to 5%
Other	up to 5%

ANNEX B

Projected flow of SIs provided in letter from Chris Heaton-Harris of 25 October 2018:

- 50-100 SIs, of which 55% are likely to be negative under the EUWA in October;
- 150-200 SIs, of which 55% are likely to be negative under the EUWA in November;
- 100-150 SIs, of which 35% are likely to be negative under the EUWA in December;
- 100-150 SIs, of which 25% are likely to be negative under the EUWA in January;
- 10-50 SIs, of which 20% are likely to be negative under the EUWA in February;
- 10-50 SIs, of which 30% are likely to be negative under the EUWA in March.

Mark Drakeford AC/AM
Ysgrifennydd y Cabinet dros Gyllid
Cabinet Secretary for Finance

Llywodraeth Cymru
Welsh Government

Eich cyf/Your ref
Ein cyf/Our ref

Mick Antoniw AM, Chair of the Constitutional and Legislative Affairs Committee
David Rees AM, Chair of the External Affairs and Additional Legislation Committee
National Assembly for Wales

29 November 2018

Dear both,

Thank you for copying to me your letter of 29 October, sent on behalf of the Interparliamentary Forum on Brexit to the Chancellor of the Duchy of Lancaster.

I welcome the Forum's interest in the relations between governments across the UK. The Welsh Government has been in the vanguard of calls for reform of intergovernmental relations; we set these out in 'Brexit and Devolution', which we published almost 18 months ago, and which itself built on positions outlined initially in 'Securing Wales' Future'. I believe our ideas are gaining traction: there is a growing recognition that we need a different way of working, because the current structures are not capable of bearing the weight EU withdrawal is placing upon them.

Our position in these matters is very much aligned with those expressed by a number of committees in recent years, as summarised in the annex to your letter, and I am able to assure you that we are taking careful note of the findings of these committees. Indeed, one of the first products undertaken as part of the IGR review was a review of the evidence from external commentators, including parliamentarians and academics, about the current state of intergovernmental relations, and recommendations for reform.

The need for reform is further demonstrated by our recent experiences in respect of the Ministerial Forum for EU negotiations. We welcomed the creation of the Forum, which is a sub-group of the JMC (EN) and a useful addition to the intergovernmental machinery, with the aim of allowing the views of the Devolved Administrations to feed into the negotiations process.

However, the quality of engagement in that Forum has been below expectations. Whilst some fruitful discussions have now been held on specific topics like cooperative accords, engagement on major elements of the negotiations has been unsatisfactory.

We remain disappointed and frustrated by the lack of meaningful engagement more widely. We were not shown or provided the detail of the draft Withdrawal Agreement or the political declaration before it was published, despite the fact that the UK Government cannot speak for the whole UK on many of the issues covered – many are in areas within the devolved competence of Welsh Ministers and the National Assembly for Wales.

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It nevertheless remains essential that we present the Welsh Government's position at every opportunity. We fully expect to be involved in the detailed negotiations with the EU on the future economic partnership on matters within our devolved competence, and have made clear that we believe the model used to prepare for Council negotiations on fisheries in particular is one we should build upon to make sure the views of the devolved administrations are incorporated into the UK negotiating position.

The Welsh Government is keen to see the development of inter-parliamentary relationships through initiatives such as the Forum, and whilst these relationships are a matter for the Assembly and the other legislatures, we would be willing to participate in work to facilitate their development.

I am copying this letter to the Chancellor of the Duchy of Lancaster, and the Cabinet Secretary for Government Business and Constitutional Relations at the Scottish Government.

Best wishes,

Mark Drakeford AC/AM
Ysgrifennydd y Cabinet dros Gyllid
Cabinet Secretary for Finance

Agenda Item 8

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