

## 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:	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.