



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.