



HOUSE OF LORDS

Secondary Legislation Scrutiny Committee

8th Report of Session 2019–21

Proposed Negative Statutory Instrument under the European Union (Withdrawal) Act 2018

Drawn to the special attention of the House:

Draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020 and two related Draft Codes of Practice

Includes an information paragraph on:

Health Protection (Notification)(Amendment)
Regulations 2020

Ordered to be printed 10 March 2020 and published 12 March 2020

Published by the Authority of the House of Lords

HL Paper 35

Secondary Legislation Scrutiny Committee

The Committee's terms of reference, as amended on 11 July 2018, are set out on the website but are, broadly:

To report on draft instruments and memoranda laid before Parliament under sections 8, 9 and 23(1) of the European Union (Withdrawal) Act 2018.

And, to scrutinise –

(a) every instrument (whether or not a statutory instrument), or draft of an instrument, which is laid before each House of Parliament and upon which proceedings may be, or might have been, taken in either House of Parliament under an Act of Parliament;

(b) every proposal which is in the form of a draft of such an instrument and is laid before each House of Parliament under an Act of Parliament,

with a view to determining whether or not the special attention of the House should be drawn to it on any of the grounds specified in the terms of reference.

The Committee may also consider such other general matters relating to the effective scrutiny of secondary legislation as the Committee considers appropriate, except matters within the orders of reference of the Joint Committee on Statutory Instruments.

Members

<u>Baroness Bakewell of Hardington Mandeville</u>	<u>Lord Hodgson of Astley Abbotts</u>	<u>The Earl of Lindsay</u>
<u>Rt Hon. Lord Chartres</u>	<u>(Chair)</u>	<u>Lord Lisvane</u>
<u>Rt Hon. Lord Cunningham of Felling</u>	<u>Lord Kirkwood of Kirkhope</u>	<u>Lord Sherbourne of Didsbury</u>
<u>Viscount Hanworth</u>	<u>Lord Liddle</u>	<u>Baroness Watkins of Tavistock</u>

Registered interests

Information about interests of Committee Members can be found in the last Appendix to this report.

Publications

The Committee's Reports are published on the internet at <http://www.parliament.uk/seclegpublications>

Committee Staff

The staff of the Committee are Christine Salmon Percival (Clerk), Helen Gahir (Adviser), Philipp Mende (Adviser), Jane White (Adviser), Louise Andrews (Committee Assistant) and Ben Dunleavy (Committee Assistant).

Further Information

Further information about the Committee is available at <https://committees.parliament.uk/committee/255/secondary-legislation-scrutiny-committee/>

The progress of statutory instruments can be followed at <https://statutoryinstruments.parliament.uk/>

The National Archives publish statutory instruments with a plain English explanatory memorandum on the internet at <http://www.legislation.gov.uk/ukxi>

Contacts

Any query about the Committee or its work, or opinions on any new item of secondary legislation, should be directed to the Clerk to the Secondary Legislation Scrutiny Committee, Legislation Office, House of Lords, London SW1A 0PW. The telephone number is 020 7219 8821 and the email address is hlseclegscrutiny@parliament.uk.

Eighth Report

PROPOSED NEGATIVE STATUTORY INSTRUMENTS UNDER THE EUROPEAN UNION (WITHDRAWAL) ACT 2018

Proposed Negative Statutory Instruments about which no recommendation to upgrade is made

- Railways (Interoperability) (Miscellaneous Amendments and Revocations) (EU Exit) Regulations 2020

INSTRUMENTS DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft Human Tissue (Permitted Material: Exceptions) (England) Regulations 2020

Date laid: 26 February 2020

Parliamentary procedure: affirmative

Human Tissue Authority Draft Code of Practice A: Guiding Principles and the Fundamental Principle of Consent

Human Tissue Authority Draft Code of Practice F: Donation of Solid Organs and Tissue for Transplantation

Date laid: 26 February 2020

Parliamentary procedure: negative

The Organ Donation (Deemed Consent) Act 2019 allows consent to organ donation from deceased donors in England to be assumed in certain circumstances. Under the Act, the Secretary of State is required to specify in regulations the types of organs, tissue and cells to which this deemed consent does not apply. These Regulations set out that list, which broadly includes the brain, spinal cord, reproductive organs, facial features (excluding the eyes) and limbs. The items listed can only be transplanted if specific consent is given.

*The Regulations were laid with two Codes of Practice, subject to the draft negative procedure, as guidance for healthcare professionals to help them ensure that valid consent is in place for organ and tissue donation for transplantation purposes. **The two draft Codes were not published on the internet on the date of laying. We regard this omission as unacceptable, especially given the sensitivity of the subject.***

The draft Regulations and Codes are drawn to the special attention of the House on the ground that they give rise to issues of public policy likely to be of interest to the House.

1. These draft affirmative Regulations have been laid by the Department for Health and Social Care and are accompanied by an Explanatory Memorandum (EM). The Regulations were laid with two Codes of Practice subject to the draft negative procedure, which are also accompanied by a separate EM. ***The two draft Codes were not published on the internet on the date of laying but were eventually published on the Human Tissue Authority website on 5 March 2020.¹ It was remiss of the Department to have delayed putting the Codes on the internet, thereby limiting the opportunity for interested parties to raise any issues in relation to them. We regard this omission as unacceptable, especially given the sensitivity of the subject.***

Where deemed consent will not apply

2. The Organ Donation (Deemed Consent) Act 2019 (“the 2019 Act”) amended the Human Tissue Act 2004 to allow consent for organ donation

¹ Human Tissue Authority. ‘Revised Code A and Code F 2020’: <https://www.hta.gov.uk/revised-code-and-code-f-2020> [accessed 6 March 2020].

from deceased donors in England to be deemed, that is, consent for organ and tissue donation can be assumed for most adults, unless they made a decision during their lifetime that they did not want to donate their organs or tissue (“opted out”). Deemed consent does not apply to living donors or to those under 18.

3. This deemed consent only applies to “permitted material” such as cornea, heart, lungs, liver or kidneys that are routinely transplanted. Under the 2019 Act the Secretary of State is required to specify in regulations the types of organs, tissue and cells to which this deemed consent does not apply. These draft affirmative Regulations set out that list, which broadly includes the brain, spinal cord, reproductive organs, facial features (excluding the eyes) and limbs. The items listed can only be transplanted if specific consent is given.
4. The list of organs, tissue and cells that are set out in the draft Regulations are the result of extensive public consultation between April and July 2019 that attracted 3,279 responses. As a result of this consultation, the list of reproductive organs has been expanded to put beyond doubt that they will never be covered by deemed consent under any circumstances.

How consent is applied

5. The provisions of the Human Tissue Act 2004 (“the 2004 Act”) on the donation of solid organs and tissue for transplantation are supported by Code F. Part 1 of this Code deals with living donation and part 2 deals with donation after death; it is only this second half of the Code which is currently subject to parliamentary scrutiny.
6. Detailed guidance on the principles of consent are set out in Code A, which is included in the package but has only been subject to minor changes to cross-refer to the changes made in Code F.
7. The Codes of Practice are issued by the Human Tissue Authority (HTA) under section 26 of the 2004 Act as guidance for healthcare professionals to help them ensure that valid consent is in place for organ and tissue donation for transplantation purposes. The 2004 Act excludes certain groups from the deemed consent provisions, such as those under 18 and those who have not been living in England for 12 months. Code F also makes clear that permitted material cannot be removed for research purposes (paragraph 35), for ad hoc uses (paragraph 39), or as part of a commercial transaction (paragraph 40).
8. Paragraph 89 states that the family cannot revoke legally valid consent given by the donor. However, where the potential donor has died without making their wishes clear, the Code sets out the factors that can be presented by the family that would “lead a reasonable person to conclude that the potential donor would not have consented”(paragraphs 189–198) which would include any religious beliefs.
9. Code F confirms that the final decision about whether to proceed with the donation rests with the Specialist Nurse but requires that nurse to discuss the matter sensitively with the family (the “qualifying relationships” are listed in ranked order in paragraph 136). Code F also provides for the Specialist Nurse to seek guidance from the senior management team if the decision is particularly difficult (paragraph 154). The HTA also has a statutory role in superintending compliance with the Codes.

10. An advertising campaign has been in place since April 2019 to raise public awareness of the new system. **The House may wish to ask the Minister about the extent of the campaign and whether it has been effective in drawing the importance of these issues to the attention of the public.** Given the sensitivity of the subject, it is crucial that individuals are fully informed so they can decide whether they wish their organs to be used and make their families aware. If these instruments are approved, the Government intend to bring the deemed consent provisions into effect on 20 May 2020.

INSTRUMENTS OF INTEREST

Health Protection (Notification) (Amendment) Regulations 2020 (SI 2020/237)

11. This instrument makes COVID-19 a notifiable disease. It places a duty on medical practitioners to notify Public Health England (PHE) within three days when they identify a patient who has the disease, along with details that would enable the patient to be traced. Laboratories are also required to notify PHE within seven days if they identify SARS-CoV-2 (severe acute respiratory syndrome coronavirus 2) as a causative agent in a human sample. The instrument has immediate effect.

INSTRUMENTS NOT DRAWN TO THE SPECIAL ATTENTION OF THE HOUSE

Draft instruments subject to affirmative approval

Buckinghamshire (Structural Changes) (Supplementary Provision and Amendment) Order 2020
 Local Elections (Northern Ireland) (Amendment) Order 2020
 Parental Bereavement Leave and Pay (Consequential Amendments to Subordinate Legislation) Regulations 2020

Instruments subject to annulment

SI 2020/168	Combined Fire and Rescue Authorities (Membership and Allowances) (Amendment) Regulations 2020
SI 2020/170	Greater Manchester (Light Rapid Transit System) (Exemptions) (Amendment) Order 2020
SI 2020/179	Local Government Pension Scheme (Amendment) Regulations 2020
SI 2020/186	Hampshire and Isle of Wight Fire and Rescue Authority (Combination Scheme) Order 2020
SI 2020/188	Police Pensions (Contributions and Additional Voluntary Contributions Provider) (Amendment) (England and Wales) Regulations 2020
SI 2020/189	Controlled Drugs (Supervision of Management and Use) (Amendment) Regulations 2020
SI 2020/237	Health Protection (Notification) (Amendment) Regulations 2020

APPENDIX 1: INTERESTS AND ATTENDANCE

Committee Members' registered interests may be examined in the online Register of Lords' Interests at <http://www.parliament.uk/mps-lords-and-offices/standards-and-interests/register-of-lords-interests>. The Register may also be inspected in the Parliamentary Archives.

For the business taken at the meeting on 10 March 2020, Members declared no interests.

Attendance:

The meeting was attended by Baroness Bakewell of Hardington Mandeville, Lord Chartres, Lord Cunningham of Felling, Viscount Hanworth, Lord Hodgson of Astley Abbotts, Lord Liddle, the Earl of Lindsay, Lord Lisvane and Lord Sherbourne of Didsbury.