STATUTORY INSTRUMENTS

2012 No. 1501

The Quality and Safety of Organs Intended for Transplantation Regulations 2012

PART 2

Interpretation and designation of the competent authority

Interpretation

3.—**[**F1(1)**]** In these Regulations—

"the 2004 Act" means the Human Tissue Act 2004 ;

"the 2006 Regulations" means the Human Tissue Act 2004 (Persons who Lack Capacity to Consent and Transplants) Regulations 2006 ;

"the 2006 Scotland Act" means the Human Tissue (Scotland) Act 2006 ;

"the 2006 Scotland Regulations" means the Human Organ and Tissue Live Transplants (Scotland) Regulations 2006 ;

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

"the Authority" means the Human Tissue Authority established under section 13 of the 2004 Act;

"consent", in respect of a donor, means **[**F2, where retrieval of an organ takes place**]** —

(a) in England **[**F3or**]** Northern Ireland, appropriate consent as defined in the 2004 Act ; F4...

(b) in Scotland, the authorisation referred to in Part 1 (transplantation etc.) of the 2006 Scotland Act or, as the case may be, the authorisation or lack of unwillingness of the donor referred to in the 2006 Scotland Regulations **[**F5; or

(c) in Wales, express consent where that is required under any of sections 4 to 7 of the Human Transplantation (Wales) Act 2013 or, where express consent is not required, deemed consent under section 4 or 9 of that Act;**]**

"the Directive " means Directive 2010/53/EU of the European Parliament and of the Council of 7th July 2010 on standards of quality and safety of human organs intended for transplantation **[**F6, as it applies in relation to Northern Ireland**]**;

"disposal" means the final placement of an organ where it is not used for transplantation;

"donation" means donating organs for the purposes of transplantation;

"donor" means a person who donates one or several organs, whether donation occurs during lifetime or after death;

"donor characterisation" means the collection of relevant information on the characteristics of the donor needed to evaluate the donor's suitability for donation, in order to undertake a risk assessment and to minimise the risks for the recipient, and optimise organ allocation;

[F7"the Implementing Directive" means Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation **[**F8, as it applies in relation to Northern Ireland;**]]**

"licensed activity", in relation to a licence, means an activity which the licence authorises under Schedule 1;

"licence holder" means a person who holds a licence under Schedule 1;

"organ" means a differentiated part of the human body, formed by different tissues, that maintains its structure, vascularisation, and capacity to develop physiological functions with a significant level of autonomy; and a part of an organ is also considered to be an organ if its function is to be used for the same purpose as the entire organ in the human body, maintaining the requirements of structure and vascularisation;

"organ characterisation" means the collection of the relevant information on the characteristics of the organ needed to evaluate its suitability for transplantation, in order to undertake a risk assessment and minimise the risks for the recipient, and optimise organ allocation;

"operating procedures" means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end outcome;

"preservation" means the use of chemical agents, alterations in environmental conditions or other means to prevent or retard biological or physical deterioration of organs from procurement to transplantation;

"procurement" means a process by which a donated organ becomes available for transplantation;

"procurement activity" means all or any of the following activities, undertaken for the purposes of procurement—

(a) donor characterisation;

(b) organ characterisation;

(c) preservation of an organ;

(d) making arrangements to transport an organ;

(e) retrieval of an organ;

[F9"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;**]**

"recipient" means a person who receives a transplant of an organ;

"serious adverse event" means any undesired and unexpected occurrence associated with any stage of the chain from donation to transplantation that might lead to the transmission of a communicable disease, to death or life-threatening, disabling or incapacitating conditions for a patient or which results in, or prolongs, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in the living donor or in the recipient that might be associated with any stage of the chain from donation to transplantation that is fatal, life-threatening, disabling, incapacitating, or which results in, or prolongs, hospitalisation or morbidity;

"traceability" means the ability to locate and identify the organ at each stage in the chain from donation to transplantation or disposal, including the ability to—

(a) identify the donor and the licence holder who retrieved the organ from the donor;

(b) identify the licence holder who implanted the organ in the recipient;

(c) identify the recipient at the premises at which the organ is implanted into the recipient; and

(d) locate and identify all relevant non-personal information relating to products and materials coming into contact with that organ;

"transplantation" means a process which is intended to restore certain functions of the human body by transferring an organ from a donor to a recipient; and

"transplantation activity" means all or any of the following activities, undertaken for the purposes of transplantation—

(a) organ characterisation;

(b) preservation of an organ;

(c) making arrangements to transport an organ;

(d) implantation of an organ.

[F10(2) In these Regulations, as they apply in relation to Great Britain, 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.**]**

F1 Reg. 3 renumbered as reg. 3(1) (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(a)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F2 Words in reg. 3 inserted (coming into force in accordance with art. 1(2) of the amending S.I.) by The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(a)**

F3 Word in reg. 3 substituted (coming into force in accordance with art. 1(2) of the amending S.I.) by The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(b)(i)**

F4 Word in reg. 3 omitted (coming into force in accordance with art. 1(2) of the amending S.I.) by virtue of The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(b)(ii)**

F5 Words in reg. 3 added (coming into force in accordance with art. 1(2) of the amending S.I.) by The Human Transplantation (Wales) Act 2013 (Consequential Provision) Order 2015 (S.I. 2015/865), arts. 1(2), **3(c)**

F6 Words in reg. 3(1) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(b)(i)** (as substituted by S.I. 2020/1305, regs. 1, **4(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Words in reg. 3 inserted (14.7.2014) by The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 (S.I. 2014/1459), regs. 1(1), **3**

F8 Words in reg. 3(1) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(b)(ii)** (as substituted by S.I. 2020/1305, regs. 1, **4(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Words in reg. 3(1) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(b)(iii)**; 2020 c. 1, Sch. 5 para. 1(1)

F10 Reg. 3(2) inserted (31.12.2020) by The Quality and Safety of Organs Intended for Transplantation (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/483), regs. 1, **3(2)(c)** (as amended by S.I. 2020/1305, regs. 1, **4(c)**); 2020 c. 1, Sch. 5 para. 1(1)

Changes to legislation:
There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Section 3.