STATUTORY INSTRUMENTS

2014 No. 1459

HUMAN TISSUE

The Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014

Made - - - -	*4th June 2014*
Laid before Parliament	*12th June 2014*
Coming into force - -	*14th July 2014*

The Secretary of State is a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to health protection measures regulating the use of material of human origin.

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972.

Citation, commencement and extent

1. (1) These Regulations may be cited as the Quality and Safety of Organs Intended for Transplantation (Amendment) Regulations 2014 and come into force on 14th July 2014.

(2) Subject to paragraph (3), these Regulations extend to England and Wales, Northern Ireland and Scotland.

(3) Regulation 12 extends to England and Wales and Northern Ireland only.

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

2. The Quality and Safety of Organs Intended for Transplantation Regulations 2012(**3**) are amended in accordance with regulations 3 to 10.

Amendment of regulation 3

3. In regulation 3 (interpretation), after the definition of "donor characterisation" insert—

(**1**) S.I. 2004/3037.
(**2**) 1972 c.68. Amended by section 27(1)(a) of the Legislative and Regulatory Reform Act 2006 and section 3(3) of, and Part 1 of the Schedule to, the European Union (Amendment) Act 2008.
(**3**) S.I. 2012/1501.

""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(**4**);".

Amendment of regulation 6

4. In regulation 6 (application of the 2004 Act in relation to licences under Schedule 1)—

(a) in paragraph (1), for "paragraphs (4) to (7)" substitute "paragraphs (4) and (5)";

(b) in paragraph (4)(a), omit "and section 19(4) shall apply as if sub-paragraph (c) were omitted"; and

(c) in paragraphs (4)(b), (4)(c) and (4)(e), after "the Directive" insert "and the Implementing Directive".

Amendment of regulation 12

5. In regulation 12 (guidance), in paragraph (1), after "the Directive" insert "and the Implementing Directive".

Amendment of regulation 13

6. In regulation 13 (framework and compliance with licensing conditions and directions), in paragraph (1), after "the Directive" insert "and the Implementing Directive".

Amendment of regulation 16

7. In regulation 16 (serious adverse events and serious adverse reactions), in paragraph (1)(a), for "such" substitute "the".

Amendment of regulation 18

8. In regulation 18 (organs sent to another country)—

(a) in the title, after "sent to" insert "or received from";

(b) in paragraph (1), for "any procedures established by the Commission under article 29 of the Directive" substitute "the requirements of Articles 4, 5 and 6(1) of the Implementing Directive";

(c) after paragraph (1), insert—

"(1A) Where an organ is received from another country in the European Union, the Authority shall ensure that—

(a) the requirements of Article 4 of the Implementing Directive in relation to information transmitted to the Authority in accordance with that Directive in respect of the organ have been complied with; and

(b) information to ensure the traceability of the organ is transmitted in accordance with Article 6(2) of that Directive."; and

(d) in paragraph (2)—

(i) for "a country" substitute "another country"; and

(ii) for "any procedures established by the Commission under article 29 of the Directive" substitute "the requirements of Articles 4 and 7 of the Implementing Directive".

(**4**) OJ No L 275, 10.10.2012, p27.

Amendment of regulation 27

9. In regulation 27 (amendment of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2004)—

(a) in the title, for "2004" substitute "2006"; and

(b) omit sub-paragraph (a).

Amendment of Schedule 2

10. In Schedule 2 (directions of the Authority), after paragraph (2), insert—

"**3.** For the purpose of ensuring compliance with the requirements of Articles 4(1), 4(2), 4(3), 5(2) and 5(3) of the Implementing Directive, the Authority shall specify in directions given under section 23(1) of the 2004 Act the requirements relating to the transmission of information that apply to a licence holder when an organ is sent to, or received from, another country in the European Union.".

Amendment of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006

11. In regulation 3 of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006(**5**) (exceptions from licensing requirement), in paragraph (5)(a), after "level of autonomy" insert—

", 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".

Amendment of the Human Tissue Act 2004

12. In section 32 of the Human Tissue Act 2004(**6**) (prohibition of commercial dealings in human material for transplantation), for subsection (3A) substitute—

"(3A) The Authority may not designate a person under subsection (3) if doing so could result in the United Kingdom being in breach of—

(a) Article 12 of Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells(**7**), or

(b) 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(**8**).".

(**5**) S.I. 2006/1260 amended by S.I. 2012/1501.
(**6**) 2004 c.30. Section 32(3A) was inserted by S.I 2012/1501, regulation 25(1), (3).
(**7**) OJ No L 102, 07.04.2004, p48.
(**8**) OJ No L 207, 06.08.2010, p14.

Signed by authority of the Secretary of State for Health.

Jane Ellison
Parliamentary Under-Secretary of State,
Department of Health

4th June 2014

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Quality and Safety of Organs Intended for Transplantation Regulations 2012 ("the Principal Regulations") in order to transpose Commission Implementing Directive 2012/25/EU laying down information procedures for the exchange, between Member States, of human organs intended for transplantation ("the Implementing Directive").

Regulation 3 inserts a definition of the Implementing Directive into regulation 3 of the Principal Regulations. Regulation 4 amends regulation 6 of the Principal Regulations to enable the Human Tissue Authority ("HTA") to issue directions made in relation to licences issued under the Principal Regulations to ensure compliance with the Implementing Directive. It also corrects minor drafting errors.

Regulation 5 amends regulation 12 of the Principal Regulations to enable the HTA to issue guidance in relation to the Implementing Directive.

Regulation 6 amends regulation 13 of the Principal Regulations so that the HTA's duty to establish a framework under that provision includes specifying how their requirements for the quality and safety of organs for transplantation shall be met in compliance with the Implementing Directive. Regulation 7 amends regulation 16 of the Principal Regulations to correct a minor drafting error.

Regulation 8 amends regulation 18 of the Principal Regulations so that where organs are sent to or received from another country, the HTA must ensure compliance with the information procedures in specified Articles of the Implementing Directive.

Regulation 10 amends Schedule 2 to the Principal Regulations so that the HTA is required to issue directions for the purpose of ensuring compliance with specified Articles of the Implementing Directive.

Regulation 11 amends regulation 3 of the Human Tissue Act 2004 (Ethical Approval, Exceptions from Licensing and Supply of Information about Transplants) Regulations 2006. This is to correct an error made by regulation 27(a) of the Principal Regulations to ensure that the definition of "organ" in that regulation is consistent with that specified in Directive 2010/53/EU of the European Parliament and of the Council of 7 July 2010 on standards of quality and safety of human organs intended for transplantation ("Directive 2010/53/EU"). Regulation 9 consequently omits regulation 27(a) of the Principal Regulations.

Regulation 12 amends the Human Tissue Act 2004. It substitutes section 32(3A) of that Act so that the HTA may not make a designation under section 32(3) if doing so could result in the United Kingdom's breach of Article 12 of Directive 2004/23/EC of the European Parliament and of the Council on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, or Article 13 of Directive 2010/53/EU.

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