
STATUTORY INSTRUMENTS

2012 No. 1501

**The Quality and Safety of Organs Intended
for Transplantation Regulations 2012**

PART 6

Amendments to other legislation

Amendment of the 2004 Act

25.—(1) The 2004 Act is amended as follows.

(2) In section 14 ^{M1} (remit)—

(a) in subsection (1) after paragraph (h) insert—

“(i) the donation, testing, characterisation, procurement, preservation, transport, transplantation and disposal of human organs, in so far as those activities are activities to which regulation 5(1) of the 2012 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (h).”; and

(b) after subsection (2A) insert—

“(2B) Expressions used in paragraph (i) of subsection (1) and in the 2012 Regulations have the same meaning in that paragraph as in those Regulations.”.

(3) In section 32 (prohibition of commercial dealings in human material for transplantation), after subsection (3) insert—

“(3A) The Authority may not designate a person under subsection (3) to engage in any activity relating to an organ (within the meaning given by Directive 2010/53/EU of the European Parliament and of the Council on standards of quality and safety of human organs intended for transplantation) for use for the purpose of transplantation.”.

(4) In section 41(1) ^{M2} (interpretation of Part 2), after the definition of “the 2007 Regulations” insert—

““the 2012 Regulations” means the Quality and Safety of Organs Intended for Transplantation Regulations 2012;”.

(5) In section 59(4) (provisions extending to Scotland)—

(a) before paragraph (a) insert—

“(za) section 13;” and

(b) in paragraph (f), after “and 61,” insert—

“(fa) Schedule 2;”.

(6) In Schedule 2 ^{M3} (the Human Tissue Authority), at the end of paragraph 1 (membership), insert—

“(3) The Scottish Ministers may nominate a person who is a member of the Authority to make representations about the carrying out of its functions in Scotland.”.

Changes to legislation: There are currently no known outstanding effects for the *The Quality and Safety of Organs Intended for Transplantation Regulations 2012*, Section 25. (See end of Document for details)

(7) In Schedule 3^{M4} (licences for the purposes of section 16), in paragraph 13 (applications under this Schedule), in sub-paragraph (1), for “and Schedule 1 to the 2007 Regulations” substitute “, Schedule 1 to the 2007 Regulations and Schedule 1 to the 2012 Regulations”.

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Marginal Citations

- M1** Amended by the [Human Fertilisation and Embryology Act 2008 \(c.22\)](#), [Schedule 7](#), paragraph 23 and by [S.I. 2007/1523](#).
- M2** Amended by [S.I. 2007/1523](#).
- M3** Amended by the [Health Act 2009 \(c.21\)](#), [Schedule 3](#), Part 1, paragraph 7.
- M4** Amended by [S.I. 2007/1523](#).

Changes to legislation:

There are currently no known outstanding effects for the The Quality and Safety of Organs Intended for Transplantation Regulations 2012, Section 25.