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STATUTORY INSTRUMENTS

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**2014 No. 1459**

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

**Amendment of the Human Tissue Act 2004**

**12.** In section 32 of the Human Tissue Act 2004<sup>(1)</sup> (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<sup>(2)</sup>, 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<sup>(3)</sup>.”

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<sup>(1)</sup> [2004 c.30](#). Section 32(3A) was inserted by [S.I 2012/1501](#), regulation 25(1), (3).

<sup>(2)</sup> OJ No L 102, 07.04.2004, p48.

<sup>(3)</sup> OJ No L 207, 06.08.2010, p14.