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STATUTORY INSTRUMENTS

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**2007 No. 1523**

**The Human Tissue (Quality and Safety  
for Human Application) Regulations 2007**

**PART 2**

**LICENSING OF ACTIVITIES RELATING TO THE  
USE OF TISSUE FOR HUMAN APPLICATION**

**Breach of requirement to hold a licence or to act under a third party agreement**

**10.**—(1) A person who contravenes regulation 7(1) commits an offence unless he reasonably believes—

- (a) that what he does is not an activity to which regulation 7(1) applies; or
- (b) that he acts under the authority of a licence under Schedule 1.

[<sup>F1</sup>(1A) A person who contravenes regulation 7(1A) commits an offence unless he reasonably believes—

- (a) that what he does is not an activity to which regulation 7(1A) applies; or
- (b) that he acts—
  - (i) under the authority of a licence under Schedule 1; or
  - (ii) in pursuance of an authorisation under regulation 7(4).]

(2) A person who contravenes regulation 7(2) commits an offence unless he reasonably believes—

- (a) that what he does is not an activity to which regulation 7(2) applies; or
- (b) that he acts—
  - (i) under the authority of a licence under Schedule 1,
  - (ii) in pursuance of a third party agreement, or
  - (iii) in pursuance of an authorisation under regulation 7(4).

[<sup>F2</sup>(2A) A person who contravenes regulation 7A commits an offence unless he reasonably believes—

- (a) that what he does is not an activity to which regulation 7A applies; or
- (b) that an exception under regulation 7A(1)(a) or (b) applies.]

(3) A person guilty of an offence under [<sup>F3</sup>paragraph (1), (1A), (2) or (2A)] shall be liable—

- (a) on summary conviction to a fine not exceeding the statutory maximum;
- (b) on conviction on indictment—
  - (i) to imprisonment for a term not exceeding 2 years, or
  - (ii) to a fine, or

(iii) to both.

**Textual Amendments**

- F1** Reg. 10(1A) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), regs. 1(2)(3), **3(3)(a)**
- F2** Reg. 10(2A) inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), regs. 1(2)(3), **3(3)(b)**
- F3** Words in reg. 10(3) substituted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), regs. 1(2)(3), **3(3)(c)**

**Changes to legislation:**

There are currently no known outstanding effects for the The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Section 10.