

STATUTORY INSTRUMENTS

2007 No. 1523

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

PART 1

CITATION, COMMENCEMENT, EXTENT AND INTERPRETATION

References to third party agreements etc

6.—(1) For the purposes of these Regulations a third party agreement is an agreement in writing between a licence holder (or the designated individual on behalf of the licence holder) and another person, which is made in accordance with any directions given by the Authority under section 23(1) of the 2004 Act for the purpose of securing compliance with the requirements of Article 24 of the first Directive (relations between tissue establishments and third parties), and under which the other person—

- (a) carries on a licensed activity [^{F1}(other than storage or import ^{F2}... from a third country)], on behalf of the licence holder, or
- (b) supplies to the licence holder any goods or services which may affect the quality or safety of tissue or cells.

(2) In these Regulations—

“relevant third party premises”, in relation to a licence under Schedule 1, means any premises (other than premises to which the licence relates)—

- (a) on which a third party procures, tests, processes or distributes, ^{F3}... or from which a third party exports [^{F4}from the United Kingdom to a third country], tissue or cells on behalf of any person authorised by a licence to carry on that activity, or
- (b) from which a third party provides any goods or services which may affect the quality or safety of tissue or cells to any person in connection with licensed activities carried on by that person; and

“third party” means a person with whom a licence holder has a third party agreement.

Textual Amendments

- F1** Words in reg. 6(1)(a) 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), **2(5)(a)**
- F2** Words in reg. 6(1)(a) omitted (31.12.2020) by virtue of [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) \(EU Exit\) Regulations 2019 \(S.I. 2019/481\)](#), regs. 1, **3(5A)** (as inserted by [S.I. 2020/1306](#), regs. 1, **8**); 2020 c. 1, **Sch. 5 para. 1(1)**
- F3** Words in reg. 6(2) omitted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by virtue of [The Human Tissue \(Quality and Safety for Human Application\) \(Amendment\) Regulations 2018 \(S.I. 2018/335\)](#), regs. 1(2)(3), **2(5)(b)(i)**

Changes to legislation: *There are currently no known outstanding effects for the The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Section 6. (See end of Document for details)*

F4 Words in reg. 6(2) 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), **2(5)(b)(ii)**

Changes to legislation:

There are currently no known outstanding effects for the The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Section 6.