STATUTORY INSTRUMENTS

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

Licensing requirement

7.—(1) No person shall store tissue or cells intended for human application otherwise than under the authority of a licence under Schedule 1.

[F1(1A) Subject to paragraphs (4) and (5), no person may import F2... from a third country tissues or cells that are intended for human application otherwise than under the authority of a licence under Schedule 1.**]**

(2) Subject to paragraphs (4) and **[**F3(5)**]**, no person shall do an activity to which this paragraph applies otherwise than—

(a) under the authority of a licence under Schedule 1, or

(b) in pursuance of a third party agreement.

(3) Paragraph (2) applies to the procurement, testing, processing, distributionF4... or export **[**F5from the United Kingdom to a third country**]** of tissue and cells intended for human application.

[F6(4) The Authority may authorise any person to distribute, import from a third country or export to a third country tissues or cells directly from where the procurement takes place to an organisation responsible for human application for immediate human application where that authorisation relates to tissues or cells specified by the Authority.**]**

[F7(5) Where the Authority is satisfied that there is a case of emergency, it may authorise any person to distribute, import F8... from a third country or export from the United Kingdom to a third country tissues or cells.**]**

F9(6) . . . . . .

(7) Schedule 1 shall apply in relation to licences for the purposes of this regulation.

Textual Amendments

F1 Reg. 7(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(1)(a)**

F2 Words in reg. 7(1A) 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(6)(a)** (as substituted by S.I. 2020/1306, regs. 1, **9**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Word in reg. 7(2) 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(1)(b)**

F4 Word in reg. 7(3) 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), **3(1)(c)(i)**

F5 Words in reg. 7(3) 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(1)(c)(ii)**

F6 Reg. 7(4) substituted (31.12.2020) by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(6)(b)** (as substituted by S.I. 2020/1306, regs. 1, **9**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Reg. 7(5) 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(1)(e)**

F8 Words in reg. 7(5) 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(6)(c)** (as substituted by S.I. 2020/1306, regs. 1, **9**); 2020 c. 1, **Sch. 5 para. 1(1)**

F9 Reg. 7(6) 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), **3(1)(f)**

[F10[F11Import into Northern Ireland from the EEA]

7A.—(1) No person may import tissues or cells intended for human application into **[**F12Northern Ireland**]** from an EEA state F13..., unless—

(a) the import is from a tissue establishment which is accredited, designated, authorised or licensed under the laws or other measures adopted in an EEA stateF14... for the purpose of implementing the first, second and third Directives; or

(b) the import—

(i) is from a person who is approved to procure tissues or cells intended for human application under the laws or other measures adopted in an EEA state F15... for the purpose of implementing the first, second or third Directives; and

(ii) follows the procurement of those tissues or cells in conditions accredited, designated, authorised or licensed under the laws or other measures adopted in an EEA stateF16... for the purpose of implementing the first, second or third Directives.**]**

Textual Amendments

F10 Reg. 7A 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(2)**

F11 Reg. 7A heading substituted (31.12.2020) by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(7)(a)** (as substituted by S.I. 2020/1306, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

F12 Words in reg. 7A(1) substituted (31.12.2020) by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(7)(b)(i)** (as substituted by S.I. 2020/1306, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

F13 Words in reg. 7A(1) 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(7)(b)(ii)** (as substituted by S.I. 2020/1306, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 7A(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(7)(c)** (as substituted by S.I. 2020/1306, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

F15 Words in reg. 7A(1)(b)(i) 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(7)(d)** (as substituted by S.I. 2020/1306, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Words in reg. 7A(1)(b)(ii) 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(7)(e)** (as substituted by S.I. 2020/1306, regs. 1, **10**); 2020 c. 1, **Sch. 5 para. 1(1)**

Application of the 2004 Act in relation to licences under Schedule 1

8.—(1) The provisions of the 2004 Act mentioned in paragraph (2) shall apply, subject to the modifications specified in paragraphs (4) to (7), in relation to a licence under Schedule 1 as they apply in relation to licences under paragraph 1 of Schedule 3 (licences for the purposes of section 16) to that Act.

(2) The provisions mentioned in paragraph (1) are—

(a) section 17 (persons to whom licence applies),

(b) section 19(1), (2), (5) and (7) (right to reconsideration of licensing decisions),

(c) sections 20 to 24 (which relate to appeals and powers to give directions),

(d) section 37(1) to (5) (directions), and

(e) paragraphs 2(4)(c) to (f) and (5), 5, 7 to 11, and 13 of Schedule 3 (licences for the purposes of section 16).

(3) In their application by virtue of this regulation, those provisions extend to Scotland (as well as to the rest of the United Kingdom).

(4) In its application by virtue of paragraph (2)(c), section 22 of the 2004 Act is to have effect in Scotland as if the reference to the High Court were a reference to the Court of Session.

(5) In its application by virtue of paragraph (2)(d), section 37(1) and (5) of the 2004 Act shall be read—

(a) as if the reference in subsection (1) to Part 2 of the 2004 Act were to these Regulations, and

(b) as if any reference in subsection (5) to a licence were to a licence under Schedule 1 to these Regulations.

(6) In their application by virtue of paragraph (2)(e), paragraphs 7(2)(b) and 9(3) of Schedule 3 to the 2004 Act shall be read as if the reference to section 18 of that Act were to regulation 12 of these Regulations.

(7) In its application by virtue of paragraph (2)(e), paragraph 7(2)(c) of Schedule 3 to the 2004 Act is to be read as including a reference to any relevant third party premises in relation to the licence and to the activity carried on on such premises in connection with the licensed activity.

Extension of other provisions of the 2004 Act to Scotland

9.—(1) Section **[**F17 14 (remit), section**]** 15(a), (b), (c)(ii), (d), (e) and (f) (general functions) and section 26(1) and (4) to (8) (preparation of codes) of the 2004 Act shall extend to Scotland (as well as to the rest of the United Kingdom), subject to the modifications specified in paragraph (2), so far as those provisions relate to activities within section 14(1)(h) of that Act.

(2) In its application by virtue of paragraph (1)—

(a) section 15(e) and (f) of the 2004 Act is to be read as including a reference to the Scottish Ministers;

(b) section 26(5) of the 2004 Act is to be read as including a duty to consult the Scottish Ministers if the code of practice relates to Scotland; and

(c) section 26(8) of the 2004 Act is to be read as including a reference to Scotland.

Textual Amendments

F17 Words in reg. 9(1) inserted (12.7.2012 for specified purposes, 27.8.2012 in so far as not already in force) by The Quality and Safety of Organs Intended for Transplantation Regulations 2012 (S.I. 2012/1501), regs. 1(2)(3), **28**

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.

[F18(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).

[F19(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 **[**F20paragraph (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

F18 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)**

F19 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)**

F20 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)**

Preconditions to grant of licence

11.—(1) The Authority may not grant a licence under Schedule 1 unless the following requirements are met.

(2) The proposed designated individual must—

(a) be the applicant for the licence, or

(b) consent to the application for the licence.

(3) The Authority must be satisfied that the proposed designated individual—

(a) is a suitable person to supervise the activity to be authorised by the licence,

(b) will perform the duty imposed by regulation 12,

(c) either—

(i) has a diploma, certificate or other evidence of formal qualification in the fields of medical or biological sciences awarded on completion of a university course of study, or other course of study recognised in the United Kingdom as equivalent, or

(ii) is otherwise considered by the Authority to be suitably qualified on the basis of academic qualifications and practical experience, and

(d) has at least two years' practical experience which is directly relevant to the activity to be authorised by the licence.

(4) Where the applicant for the licence is not the proposed designated individual, the Authority must be satisfied that the applicant is a suitable person to be the holder of the licence.

[F21(4A) In the case of an application for a licence to make qualifying imports (which are not one-off imports), the Authority must be satisfied that—

(a) the applicant has taken any measures as may be specified by the Authority for the purposes of ensuring that any qualifying tissues or cells imported from a third country will meet standards of quality and safety equivalent to those laid down in these Regulations;

(b) the applicant has provided to the Authority, whether in connection with this application or a previous application—

(i) the information set out in Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments);

(ii) the documents set out in Part F to Annex I to the fourth Directive (documentation to be provided by importing tissue establishments);

(c) the applicant has—

(i) made available for inspection by the Authority, whether in connection with this application or a previous application, any documents listed in Parts A and B of Annex

III to the fourth Directive (availability and provision of documentation by importing tissue establishments); and

(ii) if requested by the Authority, provided any documents falling within paragraph (i) to the Authority;

(d) the applicant has entered into a written agreement with any proposed third country supplier;

(e) any written agreement mentioned in sub-paragraph (d) complies with the requirements of Article 7(2) and (3) of the fourth Directive (written agreements); and

(f) the applicant has provided the Authority with a copy of any written agreement mentioned in sub-paragraph (d).

(4B) In the case of an application for a licence to make qualifying imports which are one-off imports, the Authority must be satisfied that—

(a) the applicant has taken any measures as may be specified by the Authority for the purposes of ensuring that any qualifying tissues or cells imported from a third country will meet standards of quality and safety equivalent to those laid down in these Regulations;

(b) the applicant has provided to the Authority, whether in connection with this application or a previous application, the information set out in Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments);

[[F22](c) in relation to Great Britain, the applicant has provided the Authority with any information or documents as may be specified by the Authority for the purposes of demonstrating—

(i) traceability; and

(ii) that the import is a one-off import within the meaning of paragraph (4C); and

(d) in relation to Northern Ireland, the applicant has provided the Authority with any information or documents as may be specified by the Authority for the purposes of securing compliance with the requirements of Articles 5(2) and 7(1) of the fourth Directive (requirements in relation to one off imports).**]**

(4C) In paragraphs (4A) and (4B)—

(a) a reference to a "one-off import" is a reference to an import of a specific type of tissues or cells, which will be for the personal use of an intended recipient who is known to the applicant and the third country supplier before the import occurs, and which, in relation to any given recipient, occurs only once, except where the proposed designated individual is satisfied that—

(i) the tissues or cells to be imported are of the same type as the tissues or cells previously imported and will be used for further treatment;

(ii) the quality and safety of any tissues or cells previously imported under paragraph (i) may not meet standards of quality and safety equivalent to those laid down in these Regulations and a further import is needed; or

(iii) it is desirable for those tissues or cells to be imported on separate occasions in order to protect against the risk of loss or damage in transit;

(b) "qualifying import" means the import [F23]... from a third country of tissues or cells intended for human application;

"qualifying tissues or cells" means tissues or cells intended for human application.**]**

(5) The Authority must be satisfied that—

(a) any premises in respect of which the licence is to be granted, and

(b) any premises which are proposed to be relevant third party premises in relation to the licence to be granted,

are suitable for the activity to be authorised by the licence.

(6) A copy of the conditions to be imposed by the licence must have been shown to, and acknowledged in writing by—

(a) the applicant for the licence, and

(b) where different, the proposed designated individual.

(7) In this regulation, references to the proposed designated individual are to the individual whom the application proposes that the licence should designate as the person under whose supervision the activity to be authorised by the licence is to be carried on.

Textual Amendments

F21 Reg. 11(4A)-(4C) 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(4)**

F22 Reg. 11(4B)(c)(d) substituted by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(9)(a)** (as substituted by S.I. 2020/1306, regs. 1, **12**); 2020 c. 1, **Sch. 5 para. 1(1)**

F23 Words in reg. 11(4C)(b) 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(9)(b)** (as substituted by S.I. 2020/1306, regs. 1, **12**); 2020 c. 1, **Sch. 5 para. 1(1)**

Modifications etc. (not altering text)

C1 Reg. 11(4A)-(4C) restricted (temp.) (31.12.2020) by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **4** (as amended by S.I. 2020/1306, regs. 1, **26**); 2020 c. 1, **Sch. 5 para. 1(1)**

Duty of designated individual

12. It shall be the duty of the designated individual to secure—

(a) that the other persons to whom the licence applies are suitable persons to participate in the carrying-on of the licensed activity,

(b) that suitable practices are used in the course of carrying on that activity, and

(c) that—

(i) the conditions of the licence,

(ii) the conditions of third party agreements, in relation to the licensed activities authorised to be carried on under his supervision, and

(iii) the requirements of regulation 13(1),

are complied with.

Information and confidentiality

13.—(1) It shall be a condition of every licence under Schedule 1 that all necessary arrangements are made to ensure that all information which is collected in pursuance of the licence or a third party agreement in relation to the licence—

(a) is available for the purpose of tracing donations;

(b) is kept up-to-date and corrected without delay where any discrepancy relating to such information is identified; and

(c) is held securely and subject to safeguards against unauthorised additions, deletions, modifications or transfer of information.

(2) Any information which is collected in pursuance of a licence under Schedule 1 or a third party agreement, and from which a donor (living or deceased) or recipient of tissue or cells may be identified, shall not be disclosed except where such disclosure—

(a) is of information which has been rendered anonymous so that neither the donor nor recipient is identifiable,

(b) is made in accordance with an order of a court,

(c) is otherwise required by law,

(d) is made to a person as a member or employee of the Authority,

(e) is made to a person who is otherwise acting on behalf of the Authority in the exercise of its functions under these Regulations, including in particular its functions under Part 5 of these Regulations,

(f) is made to a tissue establishment for the purpose of tracing a donation from donor to recipient or recipient to donor,

(g) is made to a licence holder or a person to whom a licence applies for the purposes of his functions under the licence,

(h) is made to a third party in relation to a licence for the purposes of his functions under a third party agreement,

(i) is made pursuant to any consent to disclosure given by the person, being the donor or recipient of the tissue or cells, whose identity would be disclosed,

(j) is necessary—

(i) for any purpose preliminary to proceedings,

(ii) for the purpose of, or in connection with, any proceedings,

(iii) for the purpose of reporting a suspected offence,

(iv) for the purpose of cooperating with a police investigation,

(v) for the purpose of investigating a serious adverse event or serious adverse reaction,

(k) is made by a licence holder or designated individual in accordance with directions given to that person by the Authority under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8, or

(l) is of information which has been lawfully made available to the public before the disclosure is made.

(3) References to proceedings in paragraph (2)(j) include any formal procedure for dealing with a complaint.

(4) Where a disclosure is made to a person pursuant to paragraph (2)(d) or (e), that person shall not further disclose the information received unless the disclosure—

(a) is made in accordance with paragraph (2), or

(b) is made by the Authority for the purpose of its obligations under regulations 17 and 20.

Breach of confidentiality requirement

14.—(1) Any person who discloses any information in breach of regulation 13(2) or (4) shall be guilty of an offence.

(2) A person guilty of an offence under paragraph (1) shall be liable—

(a) on summary conviction—

(i) to a fine not exceeding the statutory maximum, or

(ii) to imprisonment for a term not exceeding three months, or

(iii) to both;

(b) on conviction on indictment—

(i) to a fine, or

(ii) to imprisonment for a term not exceeding two years, or

(iii) to both.

(3) In any proceedings for an offence under paragraph (1), it shall be a defence for the person charged to prove that he took all reasonable precautions and exercised all due diligence to avoid commission of the offence.

Changes to legislation:
There are currently no known outstanding effects for the The Human Tissue (Quality and Safety for Human Application) Regulations 2007, PART 2.