STATUTORY INSTRUMENTS

2007 No. 1523

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

PART 1

CITATION, COMMENCEMENT, EXTENT AND INTERPRETATION

Citation and commencement

1.—(1) These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) Regulations 2007.

(2) Except as provided by paragraph (3), these Regulations shall come into force on 5 July 2007.

(3) These Regulations shall come into force on the day after the day on which they are made so far as necessary to enable anything (including the fixing of fees) to be done for the purposes of granting, varying, suspending or revoking licences in respect of activities required by virtue of these Regulations to be authorised by a licence on the commencement date.

Extent and application

2.—(1) These Regulations extend to England and Wales and Northern Ireland.

(2) Parts 1 to 5 and 7 of, and the Schedules to, these Regulations also extend to Scotland.

(3) These Regulations shall not apply in relation to the processing, preservation, storage, distribution, **[**F1**[**F2import from third countries**]** and export from the United Kingdom**]** of tissue or cells for use in manufactured products, including medical devices, to the extent that such activities are regulated by—

F3(a) . . . . . .

[F4(b) the Human Medicines Regulations 2012;**]**

(c) the Medical Devices Regulations 2002, F5...

(d) the Medicines for Human Use (Clinical Trials) Regulations 2004 **[**F6, or

(e) Regulation (EU) 2017/745 of the European Parliament and of the Council of 5 April 2017 on medical devices, amending Directive 2001/83/EC, Regulation (EC) No 178/2002 and Regulation (EC) No 1223/2009 and repealing Council Directives 90/385/EEC and 93/42/EEC.**]**

(4) Paragraph (3) does not limit the application of the amendments made by Part 6 of these Regulations.

Textual Amendments

F1 Words in reg. 2(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), **2(1)**

F2 Words in reg. 2(3) 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(1A)** (as inserted by S.I. 2020/1306, regs. 1, **3**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Reg. 2(3)(a) omitted (14.8.2012) by virtue of The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 92(a)** (with Sch. 32)

F4 Reg. 2(3)(b) substituted (14.8.2012) by The Human Medicines Regulations 2012 (S.I. 2012/1916), reg. 1(2), **Sch. 34 para. 92(b)** (with Sch. 32)

F5 Word in reg. 2(3)(c) omitted (27.7.2021) by virtue of The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **39(a)**

F6 Reg. 2(3)(e) and preceding word inserted (27.7.2021) by The Medical Devices (Northern Ireland Protocol) Regulations 2021 (S.I. 2021/905), regs. 1(2), **39(b)**

Designation of the competent authority

3. The Human Tissue Authority (in these Regulations referred to as "the Authority") is designated **[**F7, in relation to Northern Ireland,**]** the competent authority for the purposes of **[**F8the first, second, third and fourth Directives**]** so far as they relate to tissue and cells.

Textual Amendments

F7 Words in reg. 3 inserted (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(2)** (as substituted by S.I. 2020/1306, regs. 1, **4**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Words in reg. 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), **2(2)**

References to Directives

4. In these Regulations—

"the first Directive" means Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells **M1**,

"the second Directive" means Commission Directive 2006/17/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 8 February 2006 as regards certain technical requirements for the donation, procurement and testing of human tissues and cells **M2**, **[**F9as amended by Commission Directive 2012/39/EU,**]** and

"the third Directive" means Commission Directive 2006/86/EC implementing Directive 2004/23/EC of the European Parliament and of the Council of 24 October 2006 as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human **[**F10tissues and cells—

(a) in relation to Great Britain, as it had effect immediately before 29th April 2015 (the date on which the amendments made by Commission Directive 2015/565/EU came into force); and

(b) in relation to Northern Ireland, as amended by Commission Directive 2015/565/EU;**]**

[[F11]"the fourth Directive" means Commission Directive 2015/566 of 8th April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.**]**

Textual Amendments

F9 Words in reg. 4 inserted (15.12.2014) by The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2014 (S.I. 2014/2883), regs. 1, **2**

F10 Words in reg. 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(3)** (as substituted by S.I. 2020/1306, regs. 1, **5**); 2020 c. 1, **Sch. 5 para. 1(1)**

F11 Words in reg. 4 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(3)(b)**

Marginal Citations

M1 OJ L102, 7.4.2004, p.48.

M2 OJ L38, 9.2.2006, p.40.

[[F12]**Modifications to the first, second, third and fourth Directives: general**

4A. For the purposes of these Regulations, as they apply in relation to Great Britain, the first, second, third and fourth Directives are to be read subject to the modifications set out in regulations 4B to 4E.**]**

Textual Amendments

F12 Regs. 4A-4E inserted (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(4)** (as amended by S.I. 2020/1306, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F12]**Modifications to the first Directive**

4B.—(1) The modifications to the first Directive are as follows.

(2) Article 8 is to be read as if—

(a) in paragraph 1, the reference to Member States were a reference to the Authority;

(b) in paragraph 1, for "on their territory" there were substituted "in Great Britain";

(c) paragraphs 2, 3, 5 and 6 were omitted.

(3) Article 10(1) is to be read as if—

(a) for the reference to "the requirements referred to in Article 28(f)" there were substituted " the requirements referred to in paragraph 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) the reference to the competent authority or authorities were a reference to the Authority;

(c) for "an annual report on these activities" there were substituted " a report on these activities upon request ";

(d) the words "This report shall be publicly accessible" were omitted.

(4) Article 14 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(ii) for "within the scope of this Directive" there were substituted " in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) in paragraph 2, for "they" there were substituted "the Authority";

(c) in paragraph 3—

(i) the first reference to Member States were a reference to the Authority;

(ii) "in Member States" were omitted.

(5) Article 15 is to be read as if paragraphs 1, 2 and 4 were omitted.

(6) Article 19(5) is to be read as if the words ", in accordance with Article 8" were omitted.

(7) Article 20 is to be read as if, in paragraph 1, the reference to Article 28(h) were a reference to the requirements of Annex 2 of the third Directive listed in paragraph 14 of Schedule 2 to these Regulations.

(8) Article 21 is to be read as if—

(a) in paragraph 4, for "laid down in this Directive" there were substituted " of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) in paragraph 5—

(i) the first reference to Member States were a reference to the Authority;

(ii) the reference to a tissue establishment accredited, designated, authorised or licensed in accordance with Article 6 were a reference to a tissue establishment authorised or licensed in accordance with the provisions of the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or these Regulations;

(iii) for the words "Member States' legislation" there were substituted " legislation ".

(9) Article 24 is to be read as if—

(a) in paragraph 2, for "laid down in this Directive" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority.

(10) The Annex is to be read as if—

(a) in paragraph B.1, for "the legislation in force in Member States" there were substituted " the requirements of the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) paragraph B.2 were omitted.**]**

Textual Amendments

F12 Regs. 4A-4E inserted (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(4)** (as amended by S.I. 2020/1306, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F12Modifications to the second Directive

4C.—(1) The modifications to the second Directive are as follows.

(2) Article 2 is to be read as if, in paragraph 1, the reference to Member States were a reference to the Authority.

(3) Articles 3, 4 and 5 are to be read as if any reference to the competent authority or authorities were a reference to the Authority.

(4) Annex 1 is to be read as if, in the first paragraph, for "responsible person as defined in Article 17 of Directive 2004/23/EC" there were substituted " designated individual in accordance with regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(5) Annex 2 is to be read as if, in paragraph 2.1 the reference to the competent authority in the Member State were a reference to the Authority.

(6) Annex 3 is to be read as if, in paragraph 3.6, for "in force in Member States" there were substituted " of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ".

(7) Annex 4 is to be read as if—

(a) in paragraphs 1.1.1 and 1.2.1, the reference to an authorised person were to—

(i) the designated individual in accordance with regulations 11 and 12 of these Regulations, or

(ii) a person authorised to carry out the specified tasks by—

(aa) the designated individual, or

(bb) the Authority;

(b) in paragraph 1.1.1(a), for "Article 13 of Directive 2004/23/EC" there were substituted " the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(c) in paragraph 1.4.4 the reference to the competent authority were a reference to the Authority.**]**

Textual Amendments

F12 Regs. 4A-4E inserted (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(4)** (as amended by S.I. 2020/1306, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F12Modifications to the third Directive

4D.—(1) The modifications to the third Directive are as follows.

(2) Annex 1 is to be read as if—

(a) in paragraph A.1—

(i) for "responsible person" there were substituted " designated individual ";

(ii) for "as provided in Article 17 of Directive 2004/23/EC there were substituted " in accordance with the requirements of regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) in paragraph A.4, for "laid down in this Directive" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(c) in paragraph C.6, for the words from "the requirements of Council" to the end there were substituted " the requirements of the Medical Devices Regulations 2002 ";

(d) in paragraph D.1, for "laid down in this Directive" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(e) in paragraph E.1, for "laid down in this Directive" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(f) in paragraph E.8, the reference to the competent authority were a reference to the Authority.

(3) Annex 2 is to be read as if—

(a) in the first paragraph the reference to the competent authority were a reference to the Authority;

(b) in paragraph A, for the words from "the tissues and cells must" to the end there were substituted " tissue establishment procedures must ensure that the licence conditions in paragraph 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 are met ";

(c) in paragraph B.3, for the words from "the standards" to the end there were substituted " the requirements of paragraph 13 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(d) in paragraph B.8, the second sentence were omitted;

(e) in paragraph C.2, for "laid down in this Directive" there were substituted " of paragraph 14 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(f) in paragraphs C.4 and C.5, any reference to the responsible person as defined or specified in Article 17 of Directive 2004/23/EC were a reference to the designated individual in accordance with regulations 11 and 12 of these Regulations;

(g) in paragraph D.5, the reference to the competent authority were a reference to the Authority;

(h) in paragraph E.2(h), for "as set out in Articles 5 to 6" there were substituted " in accordance with paragraph 4 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ".**]**

Textual Amendments

F12 Regs. 4A-4E inserted (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(4)** (as amended by S.I. 2020/1306, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F12Modifications to the fourth Directive

4E.—(1) The modifications to the fourth Directive are as follows.

(2) The Directive is to be read as if references to a third country were references to any country other than the United Kingdom.

(3) Article 2 is to be read as if for "the Union", in each place where it occurs, there were substituted "Great Britain".

(4) Article 5(1) is to be read as if—

(a) for "laid down in Directive 2004/23/EC" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) the references to the competent authority or authorities were references to the Authority.

(5) Article 6 is to be read as if—

(za) in paragraph 1, the reference to the competent authority or authorities were a reference to the Authority;

(a) in paragraph 2—

(i) the reference to the competent authority or authorities were a reference to the Authority;

(ii) the words from "The information laid out" to the end were omitted;

(b) in paragraph 3—

(i) the first reference to the competent authority or authorities were a reference to the Authority;

(ii) the reference to the competent authority or authorities in subparagraph (b) were a reference to the authority in the third country concerned responsible for regulating tissue establishments in that country.

(6) Article 7 is to be read as if—

(a) in paragraph 1—

(i) in the first subparagraph, for "the Union", in each place where it occurs, there were substituted "Great Britain";

(ii) for the second subparagraph, there were substituted " This requirement does not apply to one-off imports as defined in regulation 11(4C)(a) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 provided that the requirements in regulation 11(4B) of those regulations are met. ";

(b) in paragraph 2, for "laid down in Directive 2004/23/EC" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(c) in paragraph 3, the reference to the competent authority or authorities were a reference to the Authority;

(d) in paragraph 4, the reference to the competent authority or authorities were a reference to the Authority.

(7) Article 8(1) is to be read as if the word "annual" were omitted.

(8) Annex 1 is to be read as if—

(a) in paragraph A.4, for "TE compendium code" there were substituted " reference number previously allocated to the tissue establishment by the Authority ";

(b) in paragraph B.4, the reference to the Responsible Person were a reference to the designated individual in accordance with regulations 11 and 12 of these Regulations;

(c) in paragraph C.2, the words "(where applicable, in accordance with the EU generic list)" were omitted;

(d) in paragraph F.3, the references to a third country competent authority or authorities were references to the authority in the third country responsible for regulating tissue establishments in that country.

(9) Annex 3 is to be read as if—

(a) in the first paragraph, the reference to the competent authority or authorities were a reference to the Authority;

(b) in paragraph A.1, for "as laid down in Directive 2004/23/EC" there were substituted " in accordance with regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(c) in paragraph A.3, the words "applying the Single European Code," were omitted;

(d) in paragraph B.7, the reference to a third country competent authority or authorities were a reference to the authority in the third country responsible for regulating tissue establishments in that country.

(10) Annex 4 is to be read as if—

(a) in paragraph 1, for "laid down in Directive 2004/23/EC" there were substituted " required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ";

(b) in paragraph 4, the reference to a third country competent authority or authorities were a reference to the authority in the third country responsible for regulating tissue establishments in that country;

(c) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority;

(d) in paragraph 7, for "EU data protection rules" there were substituted " data protection legislation within the meaning of section 3(9) of the Data Protection Act 2018 ";

(e) in paragraph 8, for the words from "requirements" to the end there were substituted " quality and safety standards required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ".**]**

Textual Amendments

F12 Regs. 4A-4E inserted (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(4)** (as amended by S.I. 2020/1306, regs. 1, **6**); 2020 c. 1, **Sch. 5 para. 1(1)**

Interpretation of other terms

5.—(1) In these Regulations—

"the 2004 Act" means the Human Tissue Act 2004 [M3];

[[F13]"the Authority" means the Human Tissue Authority;**]**

"autologous graft" means tissue or cells removed from and applied in the same person within the same surgical procedure;

"blood" means whole human blood collected from a donor and processed either for transfusion or for further manufacturing;

"blood component" means a therapeutic constituent of human blood (red cells, white cells, platelets and plasma) that can be prepared by various methods, but does not include lymphocytes intended for use for the purpose of haematopoietic stem cell transplantation;

[[F14]"a case of emergency" means any unforeseen situation in which there is no practical alternative other than to urgently import [F15]... from a third country or to export from the United Kingdom to a third country tissues or cells for immediate application to a known recipient whose health would otherwise be seriously endangered;**]**

"the commencement date" means 5 July 2007;

"cells" means individual human cells or a collection of human cells when not bound by any form of connective tissue, including cell lines grown outside the human body but not including—

(a) gametes,

(b) embryos outside the human body, or

(c) blood and blood components;

"designated individual", in relation to a licence under Schedule 1, means the individual designated in the licence as the person under whose supervision the licensed activity is authorised to be carried on;

[F14"distribution" in relation to tissues or cells intended for human application means transportation or delivery to any person in or outside the United Kingdom for human application, and related terms are to be interpreted accordingly;**]**

F16 . . . . . .

"human application", in relation to tissue or cells, means use on or in a human recipient, including use in extracorporeal applications but not including use for autologous graft;

F16 . . . . . .

[F14"importing licence holder" means a licence holder who is authorised by that licence to import tissues or cells intended for human application F17... from a third country;**]**

"licence holder" means a person who holds a licence under Schedule 1;

"licensed activity", in relation to a licence, means an activity which the licence authorises under Schedule 1;

"relevant third party premises" has the meaning given by regulation 6(2);

"serious adverse event" means any untoward occurrence which may be associated with the procurement, testing, processing, storage or distribution of tissue or cells intended for human application and which, in relation to a donor of tissue or cells intended for human application or a recipient of tissue or cells—

(a) might lead to the transmission of a communicable disease, to death, or life-threatening, disabling or incapacitating conditions, or

(b) might result in, or prolong, hospitalisation or morbidity;

"serious adverse reaction" means an unintended response, including a communicable disease, in a donor of tissue or cells intended for human application or a recipient of tissue or cells, which may be associated with the procurement or human application of tissue or cells and which is fatal, life-threatening, disabling, incapacitating or which results in, or prolongs, hospitalisation or morbidity;

"storage" means maintaining tissue or cells, whether by preservation or in any other way, for more than 48 hours, and "store" is to be interpreted accordingly;

"tissue" means all constituent parts of the human body formed by cells, but does not include—

(a) gametes,

(b) embryos outside the human body, or

(c) organs or parts of organs if it is their function to be used for the same purpose as the entire organ in the human body;

[F18"third country" means—

(a) in relation to the import of tissues or cells into, or the export of tissues and cells from, Great Britain, a country other than the United Kingdom;

(b) in relation to the import of tissues or cells into Northern Ireland, a country other than Northern Ireland or an EEA state; and

(c) in relation to the export of tissues or cells from Northern Ireland, a country other than the United Kingdom or an EEA state;**]**

[F19"third country premises", in relation to Northern Ireland, means premises in a country other than Northern Ireland or an EEA state on or from which a third country supplier procures, tests, processes, stores, distributes or exports tissues or cells that are intended for import into Northern Ireland for human application;**]**

[F20"third country supplier" means—

(a) in relation to tissues or cells intended for import into Great Britain for human application, a person in a country other than the United Kingdom who has an agreement with an importing licence holder for exporting such tissues or cells to Great Britain; and

(b) in relation to tissues or cells intended for import into Northern Ireland for human application, a person in a country other than Northern Ireland or an EEA state who has an agreement with an importing licence holder for exporting such tissues or cells to Northern Ireland;**]**

"third party" has the meaning given by regulation 6(2); and

"third party agreement" has the meaning given by regulation 6(1).

[F21"tissue establishment" means a tissue bank or a unit of a hospital or another body which procures, tests, processes, preserves, stores or distributes human tissues and cells;

"traceability" means the ability to—

(a) identify and locate tissues and cells during any step from procurement to use for human application and disposal;

(b) identify the donor and recipient of particular tissues and cells;

(c) identify any person who has carried out any activity in relation to particular tissues and cells; and

(d) identify and locate all relevant data relating to products and materials coming into contact with particular tissues and cells and which can affect their quality and safety.**]**

(2) Subject to paragraph (1) and except as otherwise provided in these Regulations, words and expressions used in these Regulations have the same meaning as in Article 3 of the first Directive, Article 1 of the second Directive**[**F22, Article 2 of the third Directive and Article 2 of the fourth Directive (definitions)**]**.

(3) Subject to paragraphs (1) and (2) and except as otherwise provided in these Regulations, words and expressions used in these Regulations have the same meaning as in the 2004 Act as amended by these Regulations **[**F23and the Human Fertilisation and Embryology Act 2008**]**.

(4) For the purposes of these Regulations—

[F24(a) a person who, from any premises, controls the provision of services for transporting or delivering tissues or cells to any person in or outside the United Kingdom for human application is to be taken to distribute tissues or cells on those premises; and**]**

[F25(b) any reference in these Regulations to a requirement of any provision of the first, second, third or fourth Directive—

(i) in the application of these Regulations in relation to Great Britain, is to be read as a reference to a requirement which that provision would require to be imposed if the provision formed part of the law of England and Wales or Scotland;

(ii) in the application of these Regulations in relation to Northern Ireland, is to be read as a reference to a requirement which that provision requires to be imposed in relation to the procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application.**]**

Textual Amendments

F13 Words in reg. 5(1) inserted (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(5)(a)(i)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F14 Words in reg. 5(1) 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(4)(a)(i)**

F15 Words in reg. 5(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(5)(a)(ia)** (as inserted by S.I. 2020/1306, regs. 1, **7(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F16 Words in reg. 5(1) 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(4)(a)(ii)**

F17 Words in reg. 5(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(5)(a)(ib)** (as inserted by S.I. 2020/1306, regs. 1, **7(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F18 Words in reg. 5(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(5)(a)(ii)** (as amended by S.I. 2020/1306, regs. 1, **7(b)**); 2020 c. 1, Sch. 5 para. 1(1)

F19 Words in reg. 5(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(5)(a)(iia)** (as inserted by S.I. 2020/1306, regs. 1, **7(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F20 Words in reg. 5(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(5)(a)(iib)** (as inserted by S.I. 2020/1306, regs. 1, **7(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F21 Words in reg. 5(1) inserted (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(5)(a)(iii)**; 2020 c. 1, **Sch. 5 para. 1(1)**

F22 Words in reg. 5(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), **2(4)(b)**

F23 Words in reg. 5(3) inserted (1.10.2009) by The Human Fertilisation and Embryology (Consequential Amendments and Transitional and Saving Provisions) Order 2009 (S.I. 2009/1892), art. 1(1)(b), **Sch. 3 para. 7** (with Sch. 4)

F24 Reg. 5(4)(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(4)(c)(i)**

F25 Reg. 5(4)(b) 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(5)(b)** (as substituted by S.I. 2020/1306, regs. 1, **7(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Marginal Citations

M3 2004 c.30.

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 **[**F26(other than storage or import F27... 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, F28... or from which a third party exports **[**F29from 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

F26 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)**

F27 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)**

F28 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)**

F29 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 outstanding changes not yet made by the legislation.gov.uk editorial team to The Human Tissue (Quality and Safety for Human Application) Regulations 2007. Any changes that have already been made by the team appear in the content and are referenced with annotations.
View outstanding changes

Changes and effects yet to be applied to :

– Regulations applied by S.I. 2002/618, reg. 68(15) (as inserted) by S.I. 2019/791 reg. 10 (This amendment not applied to legislation.gov.uk. Reg. 10 omitted immediately before IP completion day by virtue of S.I. 2020/1478, regs. 1(3), Sch. 2 para. 54)

Changes and effects yet to be applied to the whole Instrument associated Parts and Chapters:
Whole provisions yet to be inserted into this Instrument (including any effects on those provisions):

– reg. 2(3)(f) and word inserted by S.I. 2024/221 reg. 21(b)