STATUTORY INSTRUMENTS

2007 No. 1523

HUMAN TISSUE

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

Made - - - -	*24th May 2007*
Coming into force	
for the purposes of regulation 1(3)	*25th May 2007*
for all other purposes	*5th July 2007*

The Secretary of State is a Minister designated for the purposes of section 2(2) of the European Communities Act 1972 [M1] in relation to health protection measures regulating the use of material of human origin [M2];

A draft of this instrument was laid before Parliament in accordance with paragraph 2(2) of Schedule 2 to that Act and approved by a resolution of each House of Parliament;

Accordingly the Secretary of State, in exercise of the powers conferred by section 2(2) of that Act, makes the following Regulations:—

Marginal Citations

M1 1972 c.68.

M2 SI 2004/3037. In relation to measures in these Regulations relating to health protection measures regulating the use of material of human origin, the power of the Secretary of State under section 2(2) of the European Communities Act 1972 is exercisable in relation to Scotland by virtue of section 57(1) of the Scotland Act 1998 (c.46).

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 M3, or

(d) the Medicines for Human Use (Clinical Trials) Regulations 2004 M4.

(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)

Marginal Citations

M3 SI 2002/618, as amended by SI 2003/1697, SI 2005/2759 and 2909.

M4 SI 2004/1031, as amended by 2005/2754 and 2759 and SI 2006/1928 and 2984.

Designation of the competent authority

3. The Human Tissue Authority (in these Regulations referred to as "the Authority") is designated **[**F5, in relation to Northern Ireland,**]** the competent authority for the purposes of **[**F6the first, second, third and fourth Directives**]** so far as they relate to tissue and cells.

Textual Amendments

F5 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)**

F6 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 [M5],

"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 [M6], **[**[F7]as 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 **[**[F8]tissues 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;**]**

[[F9]"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

F7 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**

F8 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)**

F9 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

M5 OJ L102, 7.4.2004, p.48.

M6 OJ L38, 9.2.2006, p.40.

[F10Modifications 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

F10 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)**

[F10Modifications 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

F10 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)**

[F10Modifications 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

F10 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)**

[F10Modifications 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

F10 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)**

[F10Modifications 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

F10 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 [M7];

[[F11]"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;

[[F12]"a case of emergency" means any unforeseen situation in which there is no practical alternative other than to urgently import [F13]... 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;

[[F12]"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;**]**

[F14] . . . . . .

"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;

[F14] . . . . . .

[[F12]"importing licence holder" means a licence holder who is authorised by that licence to import tissues or cells intended for human application [F15]... 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;

[[F16]"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;**]**

[[F17]"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;**]**

[[F18]"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).

[[F19]"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**[**F20, 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 **[**F21and the Human Fertilisation and Embryology Act 2008**]**.

(4) For the purposes of these Regulations—

[F22(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**]**

[F23(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

F11 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)**

F12 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)**

F13 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)**

F14 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)**

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)(ib)** (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) 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)

F17 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)**

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

F19 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)**

F20 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)**

F21 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)

F22 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)**

F23 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

M7 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 **[**[F24](other than storage or import [F25]... 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, [F26]... or from which a third party exports **[**[F27]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

F24 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)**

F25 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)**

F26 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)**

F27 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)**

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.

[F28(1A) Subject to paragraphs (4) and (5), no person may import F29... 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 **[**F30(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, distributionF31... or export **[**F32from the United Kingdom to a third country**]** of tissue and cells intended for human application.

[F33(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.**]**

[F34(5) Where the Authority is satisfied that there is a case of emergency, it may authorise any person to distribute, import F35... from a third country or export from the United Kingdom to a third country tissues or cells.**]**

F36(6) . . . . . .

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

Textual Amendments

F28 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)**

F29 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)**

F30 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)**

F31 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)**

F32 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)**

F33 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)**

F34 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)**

F35 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)**

F36 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)**

[F37[F38Import into Northern Ireland from the EEA]

7A.—(1) No person may import tissues or cells intended for human application into **[**F39Northern Ireland**]** from an EEA state F40..., 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 stateF41... 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 F42... 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 stateF43... for the purpose of implementing the first, second or third Directives.**]**

Textual Amendments

F37 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)**

F38 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)**

F39 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)**

F40 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)**

F41 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)**

F42 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)**

F43 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 **[**F44 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

F44 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.

[F45 (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).

[F46(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 **[**F47paragraph (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

F45 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)**

F46 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)**

F47 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.

[F48(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);

[[F49](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 [F50]... 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

F48 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)**

F49 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)**

F50 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.

PART 3

REGULATION OF LICENSED ACTIVITIES

Import and export of tissue and cells

[F51 15. . . . . . .

Textual Amendments

F51 Reg. 15 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), **4(1)**

[F52 Directions: Great Britain]

F53 16.—(1) The Authority shall give directions to licence holders or designated individuals under section 23(1) of the 2004 Act, as applied by regulation 8, in accordance with Schedule 2 for the purpose of securing compliance with the requirements of **[F54** these Regulations, as they apply in relation to Great Britain**]**.

(2) The Authority shall give such other directions to licence holders or designated individuals under section 23(1) of that Act, as applied by regulation 8, as it considers necessary for securing

compliance by licence holders and third parties with any requirements of **[**[F55]these Regulations, as they apply in relation to Great Britain**]**.

[[F56](3) In this regulation, the references to securing compliance with these Regulations include a reference to securing compatibility with the principles set out in Article 12 of the first Directive as modified by section 32(3B) of the 2004 Act.**]**

Textual Amendments

F52 Reg. 16 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(10)(a)** (as substituted by S.I. 2020/1306, regs. 1, **13(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F53 Words in reg. 16 heading 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), **4(2)**

F54 Words in reg. 16(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(10)(b)** (as amended by S.I. 2020/1306, regs. 1, **13(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F55 Words in reg. 16(2) 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(10)(b)** (as amended by S.I. 2020/1306, regs. 1, **13(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F56 Reg. 16(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(10)(c)**; 2020 c. 1, **Sch. 5 para. 1(1)**

[[F57]Directions: compliance with first, second, third and fourth Directives as they apply in relation to Northern Ireland

16A.—(1) In relation to Northern Ireland, the Authority shall give directions to licence holders or designated individuals under section 23(1) of the 2004 Act, as applied by regulation 8, in accordance with Schedule 2 for the purpose of securing compliance with the requirements of the first, second, third and fourth Directives.

(2) In relation to Northern Ireland, the Authority shall give such other directions to licence holders or designated individuals under section 23(1) of that Act, as applied by regulation 8, as it considers necessary for securing compliance by licence holders and third parties with any requirements of the first, second, third and fourth Directives.**]**

Textual Amendments

F57 Reg. 16A 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(10A)** (as inserted by S.I. 2020/1306, regs. 1, **14**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 4

OBLIGATIONS OF THE AUTHORITY

Requirement for the Authority to provide information

17.—(1) The Secretary of State may serve a notice upon the Authority requiring it to provide any information which the notice specifies about the carrying out of its functions under these Regulations in relation to England and Wales or Northern Ireland.

(2) The Scottish Ministers may serve a notice upon the Authority requiring it to provide any information which the notice specifies about the carrying out of its functions under these Regulations in relation to Scotland.

(3) The Authority shall upon receipt of a notice under paragraph (1) or (2) provide the information requested within the period specified in the notice.

Register of licences

18.—(1) The Authority shall maintain a register recording the grant, suspension or revocation of every licence granted under Schedule 1.

(2) The register shall contain the following information—

(a) the name of the licence holder,

(b) the activities authorised, and

(c) any variation of the information referred to in sub-paragraph (a) or (b).

(3) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

Register of serious adverse events and serious adverse reactions

19.—(1) The Authority shall keep a register containing information provided to it under these Regulations about any serious adverse event or serious adverse reaction.

(2) The Authority shall make such of the information included in the register as it considers appropriate available to the public in such manner as it considers appropriate.

Duties of the Authority in relation to serious adverse events and serious adverse reactions

20.—(1) The Authority shall put in place procedures for communicating such information in relation to any serious adverse event or serious adverse reaction to—

[[F58](a) any person in the United Kingdom carrying-on procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application,**]**

(b) any person in the United Kingdom, of whom it is aware, using such tissue or cells for that purpose,

[[F59](c) in relation to Northern Ireland, the competent authorities in EEA states; and

(d) in relation to Northern Ireland, the European Commission,**]**

as is necessary for the purpose of enabling appropriate action to be taken, including where necessary the withdrawal from use of tissue and cells that are intended for human application but are known or suspected to be unsuitable for human application.

(2) The Authority shall investigate serious adverse events and serious adverse reactions and carry out appropriate control measures.

[F60(3) In relation to Northern Ireland, the duty under paragraph (2) includes a duty to investigate any serious adverse event or serious adverse reaction which has occurred in Northern Ireland, and to carry out appropriate control measures, at the request of a competent authority in an EEA state.**]**

Textual Amendments

F58 Reg. 20(1)(a) 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(11)(a)(i)** (as substituted by S.I. 2020/1306, regs. 1, **15(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F59 Reg. 20(1)(c)(d) 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(11)(a)(ii)** (as substituted by S.I. 2020/1306, regs. 1, **15(a)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F60 Reg. 20(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(11)(b)** (as substituted by S.I. 2020/1306, regs. 1, **15(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F61**Duties of the Authority in relation to application of the Single European Code [**F62**in relation to Northern Ireland]**

20A.—(1) **[**F63In relation to Northern Ireland, the Authority**]** must allocate to each licence holder one or more unique numbers to be the tissue establishment number or numbers in relation to that licence holder in accordance with Annex VII and paragraph 2(a) of Article 10b of the third Directive.

(2) Any number allocated under paragraph (1) must be in the format specified in Annex VII to the third Directive.

[F64(3) In relation to Northern Ireland, the Authority must take steps to enable the information specified in Annex VIII to be recorded in the EU Tissue Establishment Compendium in relation to each licence holder.**]**

F65(4) . . . . . .

[F66(5) The Authority must take the steps mentioned in paragraph (3) to enable the information mentioned in that paragraph to be recorded before the end of the period of 10 working days beginning with the day on which the person becomes a licence holder.**]**

(6) Paragraph (7) applies if the Authority becomes aware that any information recorded under paragraph (3) was incorrectly recorded or requires updating.

(7) **[**F67Where this paragraph applies, the Authority must take steps to enable the information to be corrected or updated—**]**

(a) in the case of a correction or update that the Authority considers to be a significant change to the information recorded under paragraph (3), before the end of the period of 10 working days beginning with the day on which the Authority became aware that the information was incorrectly recorded or required updating;

(b) in any other case, as soon as is reasonably practicable.

(8) Paragraph (9) applies if the Authority becomes aware that—

(a) any information recorded in the EU Tissue Establishment Compendium in respect of a tissue establishment in a relevant state was incorrectly recorded or requires updating; or

(b) a tissue establishment in a relevant state has not complied with the requirements of the laws or other measures adopted in that state for the purpose of implementing paragraph 1 of Article 10b of the third Directive and the non-compliance is significant.

(9) Where this paragraph applies, the Authority must inform the competent authority in the relevant state in question of the information to be corrected or updated or the non-compliance in question.

(10) If the Authority becomes aware that the information recorded in the EU Tissue and Cell Product Compendium requires updating, it must inform the European Commission and the competent authority in the relevant state.

(11) In this regulation—

[[F68]"relevant state" means an EEA state;**]**

"working day" means any day other than—

(a) a Saturday or Sunday;

(b) Christmas Day or Good Friday; or

(c) a day which is a bank holiday under the Banking and Financial Dealings Act 1971 in any part of the United Kingdom.**]**

Textual Amendments

F61 Regs. 20A-20C 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), **5(2)**

F62 Words in reg. 20A heading 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(12)(a)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F63 Words in reg. 20A(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(12)(b)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F64 Reg. 20A(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(12)(c)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F65 Reg. 20A(4) 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(12)(d)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F66 Reg. 20A(5) 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(12)(e)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F67 Words in reg. 20A(7) 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(12)(f)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F68 Words in reg. 20A(11) 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(12)(g)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F61]**Inspection of third country premises etc [**[F69]**, Northern Ireland]**

20B.—(1) Paragraph (2) applies where—

(a) qualifying tissues or cells are imported into **[**[F70]Northern Ireland**]** from a third country by an importing licence holder;

(b) the tissues or cells are distributed in an EEA state[F71]...; and

(c) the competent authority in that state [F72]... ("the requesting authority") requests the Authority to carry out any of the following activities—

(i) to arrange for an inspection of any third country premises to be carried out on behalf of the Authority;

(ii) to arrange for an inspection of any relevant documents held by a third country supplier to be carried out on behalf of the Authority;

(iii) to exercise the Authority's power under paragraph 7(2) of Schedule 3 to the 2004 Act to revoke a licence held by an importing licence holder;

(iv) to exercise the Authority's powers under paragraph 8(3) of Schedule 3 to the 2004 Act to vary a licence held by an importing licence holder; or

(v) other appropriate control measures.

(2) The Authority must carry out the activity in question specified in paragraph (1)(c), unless it considers that it would be inappropriate to do so in the particular circumstances of the case.

(3) Before an inspection of any premises is carried out pursuant to paragraph (2), the Authority must—

(a) make arrangements with the competent authority which made the request under paragraph (1) for that competent authority to participate in the inspection; or

(b) notify the competent authority which made the request under paragraph (1) that the Authority has decided that it is not appropriate for that competent authority to participate in the inspection and give reasons for that decision.

(4) For the purposes of ascertaining whether qualifying tissues or cells imported into **[**[F73]Northern Ireland**]** from a third country meet standards of quality and safety equivalent to those laid down in these Regulations, the Authority may arrange for either or both of the following to be carried out on its behalf—

(a) an inspection of any third country premises; or

(b) an inspection of any relevant document held by a third country supplier.

(5) The Authority may arrange for a report to be made on any inspection carried out in pursuance of paragraph (2) or (4).

(6) Any inspection carried out in pursuance of paragraphs (2) and (4) must be carried out by a person authorised by the Authority for the purposes of this regulation.

(7) An inspection of any premises made under this regulation must include, in particular—

(a) the inspection of any equipment found on the premises;

(b) the inspection and copying of any relevant documents or records found on the premises; and

(c) the observation of any activity relevant to ascertaining whether qualifying tissues or cells imported from a third country meet standards of quality and safety equivalent to those laid down in these Regulations.

(8) In this regulation—

"qualifying tissues or cells" means tissues or cells intended for human application;

"relevant documents" mean documents relevant for the purposes of ascertaining whether qualifying tissues or cells imported from a third country meet standards of quality and safety equivalent to those laid down in these Regulations;

"requesting authority" has the meaning given in paragraph (1)(c).**]**

Textual Amendments

F61 Regs. 20A-20C 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), **5(2)**

F69 Words in reg. 20B heading 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(13)(a)** (as substituted by S.I. 2020/1306, regs. 1, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F70 Words in reg. 20B(1)(a) 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(13)(b)** (as substituted by S.I. 2020/1306, regs. 1, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F71 Words in reg. 20B(1)(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(13)(c)** (as substituted by S.I. 2020/1306, regs. 1, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F72 Words in reg. 20B(1)(c) 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(13)(d)** (as substituted by S.I. 2020/1306, regs. 1, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

F73 Words in reg. 20B(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(13)(e)** (as substituted by S.I. 2020/1306, regs. 1, **17**); 2020 c. 1, **Sch. 5 para. 1(1)**

[F61Third country premises and third country suppliers: report of inspections etc [F74, Northern Ireland]

20C.—(1) This regulation applies [F75in relation to Northern Ireland] where the European Commission or a competent authority in an EEA state[F76]... requests the Authority to provide it with—

(a) a copy of a report or information on any inspection of third country premises or relevant documents carried out in pursuance of regulation 20B(2) or (4);

(b) information on any exercise of the Authority's powers under paragraph 7(2), 8(3) or 9(1) of Schedule 3 to the 2004 Act (licences for the purposes of section 16) in relation to a licence held by an importing licence holder (whether in pursuance of regulation 20B(2) or otherwise); or

(c) information on any appropriate control measures (whether in pursuance of regulation 20B(2) or otherwise).

(2) The Authority must provide the report or information in question to the person requesting it, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.]

Textual Amendments

F61 Regs. 20A-20C 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), **5(2)**

F74 Words in reg. 20C heading 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(14)(a)** (as substituted by S.I. 2020/1306, regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

F75 Words in reg. 20C(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(14)(b)(i)** (as substituted by S.I. 2020/1306, regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

F76 Words in reg. 20C(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(14)(b)(ii)** (as substituted by S.I. 2020/1306, regs. 1, **18**); 2020 c. 1, **Sch. 5 para. 1(1)**

PART 5

INSPECTION, ENTRY, SEARCH AND SEIZURE

Inspection of documents

21.—(1) A duly authorised person may require a person to produce for inspection any documents relevant to compliance with these Regulations.

(2) Where records or documents to which paragraph (1) applies are stored in any electronic form, the power under this regulation includes power to require the records or documents to be made available for inspection in a visible and legible form or in a form from which they can readily be produced in a visible and legible form.

(3) A duly authorised person may inspect and take copies of any documents produced for inspection in pursuance of a requirement under paragraph (1).

[F77Inspection of documents to be held by an importing licence holder [F78, Northern Ireland]

21A.—(1) This regulation applies where—

(a) qualifying tissues or cells are imported into **[**F79Northern Ireland**]** from a third country by an importing licence holder;

(b) the tissues or cells are then distributed or will be distributed in an EEA state F80...; and

(c) the competent authority in that state F81... requests the Authority to arrange for an inspection to be carried out of any relevant documents held by an importing licence holder.

(2) The Authority must arrange for an inspection to be carried out by a duly authorised person, unless the Authority considers that it would be inappropriate in the particular circumstances of the case.

(3) A duly authorised person may require a person to produce for inspection any relevant documents.

(4) Where relevant documents are stored in electronic form, a duly authorised person may require an importing licence holder to make the documents available for inspection—

(a) in a visible and legible form; or

(b) in a form from which they can readily be produced in a visible and legible form.

(5) A duly authorised person may take copies of any relevant documents inspected in pursuance of a requirement under this regulation.

(6) In this regulation—

"duly authorised person" in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision;

"qualifying tissues or cells" means tissues or cells intended for human application; and

"relevant documents" means a document relevant for the purposes of ascertaining whether tissues or cells imported from a third country meet standards of quality and safety equivalent to those laid down in these Regulations.**]**

Textual Amendments

F77 Reg. 21A 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), **6(1)**

F78 Words in reg. 21A heading 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(15)(a)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F79 Words in reg. 21A(1)(a) 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(15)(b)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F80 Words in reg. 21A(1)(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(15)(c)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F81 Words in reg. 21A(1)(c) 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(15)(d)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

Entry and inspection of premises

22.—(1) The Authority may arrange for any premises in respect of which a licence is in force, or any relevant third party premises, to be inspected on its behalf, and for a report on the inspection to be made to it, for any of the purposes referred to in paragraph (6).

(2) The Authority shall arrange for an inspection under paragraph (1) of any premises in respect of which a licence is in force not less than once in every interval of two years.

(3) The Authority may arrange for any premises to be inspected on its behalf, and for a report on the inspection to be made to it, for the purpose of satisfying itself under regulation 11(5) that—

(a) the premises are suitable for use for the carrying-on of a licensed activity, or

(b) the premises are suitable to be relevant third party premises in relation to a licence.

(4) If associated with any licensed activity there occurs any serious adverse event or serious adverse reaction, the Authority shall, where it is appropriate to do so, arrange for any premises to which the licence relates and any relevant third party premises to be inspected on its behalf and for a report on the inspection to be made.

(5) For the purpose of carrying out an inspection under paragraph (1), (3) or (4), a duly authorised person may at any reasonable time enter and inspect—

(a) any premises specified, or proposed to be specified, in the licence as premises where the licensed activities are authorised to be carried on; or

(b) any relevant third party premises or any premises proposed to be such premises.

(6) The purposes for which an inspection may be carried out under paragraph (1) are for—

(a) ensuring compliance by the licence holder with—

(i) these Regulations,

(ii) the conditions of the licence, or

(iii) directions given under section 23(1) or 24(1) of, or paragraph 2(4) of Schedule 3 to, the 2004 Act, as applied by regulation 8;

(b) ensuring compliance by the designated individual with the duty under regulation 12; or

(c) ensuring compliance by a third party with a third party agreement.

[F82Importing licence holders: requests for inspections [F83, Northern Ireland]

22A.—(1) This regulation applies where—

(a) any licensed activity in relation to qualifying tissues or cells imported into **[**F84Northern Ireland**]** from a third country is carried out on any premises—

(i) to which a licence held by an importing licence holder relates; or

(ii) which are relevant third party premises in relation to an importing licence holder;

(b) the tissues or cells are distributed in an EEA state F85...; and

(c) the competent authority in that state F86... requests the Authority to arrange for an inspection of the premises to be carried out.

(2) The Authority must arrange for an inspection of the premises in question to be carried out under regulation 22(1) by a duly authorised person, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.

(3) Before an inspection is carried out under paragraph (2), the Authority must make arrangements with the requesting authority for it to participate in the inspection, unless the Authority considers that the participation of the requesting authority is not appropriate in the circumstances.

(4) Where the Authority considers that the participation of the requesting authority in the inspection would not be appropriate in the circumstances, the Authority must notify the requesting authority of its decision and give reasons for that decision.

(5) In this regulation—

"duly authorised person" in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision;

"qualifying tissues or cells" means tissues or cells intended for human application;

"requesting authority" means the competent authority which made the request under paragraph (1) for the Authority to arrange for the inspection to be carried out.**]**

Textual Amendments

F82 Reg. 22A 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), **6(2)**

F83 Words in reg. 22A heading 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(16)(a)** (as substituted by S.I. 2020/1306, regs. 1, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F84 Words in reg. 22A(1)(a) 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(16)(b)** (as substituted by S.I. 2020/1306, regs. 1, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F85 Words in reg. 22A(1)(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(16)(c)** (as substituted by S.I. 2020/1306, regs. 1, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

F86 Words in reg. 22A(1)(c) 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(16)(d)** (as substituted by S.I. 2020/1306, regs. 1, **20**); 2020 c. 1, **Sch. 5 para. 1(1)**

Entry and search in connection with suspected offence

23.—(1) If a justice of the peace is satisfied on sworn information or, in Northern Ireland, on a complaint on oath or, in Scotland, by evidence on oath that there are reasonable grounds for believing—

(a) that an offence under these Regulations is being, or has been, committed on any premises, and

(b) that any of the conditions in paragraph (2) is met in relation to the premises,

he may by signed warrant authorise a duly authorised person to enter the premises, if need be by force, and search them.

(2) The conditions referred to are—

(a) that entry to the premises has been, or is likely to be, refused and notice of the intention to apply for a warrant under this regulation has been given to the occupier;

(b) that the premises are unoccupied;

(c) that the occupier is temporarily absent;

(d) that an application for admission to the premises or the giving of notice of the intention to apply for a warrant under this paragraph would defeat the object of entry.

(3) A warrant under this regulation shall continue in force until the end of the period of 31 days beginning with the day on which it is issued.

(4) The powers exercisable by a justice of the peace under paragraph (1) are also exercisable in Scotland by a sheriff.

Execution of warrants

24.—(1) Entry and search under a warrant under regulation 23 is unlawful if any of paragraphs (2) to (4) and (6) is not complied with.

(2) Entry and search shall be at a reasonable time unless the person executing the warrant thinks that the purpose of the search may be frustrated on an entry at a reasonable time.

(3) If the occupier of the premises to which the warrant relates is present when the person executing the warrant seeks to enter them, the person executing the warrant shall—

(a) produce the warrant to the occupier, and

(b) give him—

(i) a copy of the warrant, and

(ii) an appropriate statement.

(4) If the occupier of the premises to which the warrant relates is not present when the person executing the warrant seeks to enter them, but some other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant shall—

(a) produce the warrant to that other person,

(b) give him—

(i) a copy of the warrant,

(ii) an appropriate statement, and

(c) leave a copy of the warrant in a prominent place on the premises.

(5) In paragraphs (3)(b)(ii) and (4)(b)(ii) the references to an appropriate statement are to a statement in writing containing the information set out in Schedule 3.

(6) If the premises to which the warrant relates are unoccupied, the person executing the warrant shall leave a copy of it in a prominent place on the premises.

(7) Where the premises in relation to which a warrant under regulation 23 is executed are unoccupied, or the occupier is temporarily absent and no other person is present who appears to the person executing the warrant to be in charge of the premises, the person executing the warrant, shall, when leaving the premises, leave them as effectively secured as he found them.

Seizure in the course of inspection or search

25.—(1) A duly authorised person entering and inspecting premises under this Part may seize anything on the premises which he has reasonable grounds to believe may be required for purposes of the Authority's functions relating to the grant, revocation, variation and suspension of licences under Schedule 1 and to the investigation of serious adverse events and serious adverse reactions.

(2) A duly authorised person entering and searching premises under a warrant under regulation 23 may seize anything on the premises which he has reasonable grounds to believe may be required for the purpose of being used in evidence in any proceedings for an offence under these Regulations.

(3) Where a person has power under paragraph (1) or (2) to seize anything, he may take such steps as appear to be necessary for preserving the thing or preventing interference with it.

(4) The power under paragraph (1) or (2) includes power to retain anything seized in exercise of the power for so long as it may be required for the purpose for which it was seized.

(5) Where by virtue of paragraph (1) or (2) a person seizes anything, he shall leave on the premises from which the thing was seized a statement giving particulars of what he has seized and stating that he has seized it.

Powers: supplementary

26.—(1) Any power under this Part to enter and inspect or search any premises includes power to take such other persons and equipment as the person exercising the power reasonably considers necessary.

(2) Any power under regulation 22 or 23 to inspect or search any premises includes, in particular—

(a) power to inspect any equipment found on the premises,

(b) power to inspect and take copies of any records found on the premises,

(c) in the case of premises in respect of which a licence under Schedule 1 is in force, power to observe the carrying-on on the premises of the licensed activity, and

(d) in the case of relevant third party premises in respect of which a third party agreement is in force, power to observe the carrying-on on the premises of the activity carried on pursuant to such agreement.

(3) Any power under this Part to enter, inspect or search premises includes power to require any person to afford such facilities and assistance with respect to matters under that person's control as are necessary to enable the power of entry, inspection or search to be exercised.

Requirements when exercising power of inspection or search

27.—(1) A person's right to exercise a power under this Part is subject to his producing evidence of his entitlement to exercise it, if required.

(2) As soon as reasonably practicable after having exercised a power under this Part to inspect or search premises, the duly authorised person shall—

(a) prepare a written report of the inspection or search, and

(b) if requested to do so by the appropriate person, give him a copy of the report.

(3) In paragraph (2), the "appropriate person" means—

(a) in relation to premises in respect of which a licence is in force, the designated individual;

(b) in relation to any relevant third party premises, the occupier.

[F87(4) **[**F88In relation to Northern Ireland, paragraph (5) applies if the European Commission or a competent authority in an EEA state requires the Authority to provide it with a copy of a report or information on—**]**

(a) any inspection under regulation 21 or 21A of records or documents;

(b) any inspection under regulation 22 of premises to which a licence held by an importing licence holder relates or which are relevant third party premises in relation to an importing licence holder.**]**

[F87(5) Where this paragraph applies, the Authority must give a copy of the report or information to the person requesting it, unless the Authority considers that it would be inappropriate to do so in the particular circumstances of the case.**]**

Textual Amendments

F87 Reg. 27(4)(5) 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), **6(3)**

F88 Words in reg. 27(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(17)** (as substituted by S.I. 2020/1306, regs. 1, **21**); 2020 c. 1, **Sch. 5 para. 1(1)**

Enforcement

28.—(1) A person commits an offence if—

(a) he fails without reasonable excuse to comply with a requirement **[**F89under regulation 21, 21A or**]** regulation 26(3), or

(b) he intentionally obstructs the exercise of any right under this Part.

(2) A person guilty of an offence under this regulation is liable on summary conviction to a fine not exceeding level 5 on the standard scale.

Textual Amendments

F89 Words in reg. 28(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), **6(4)**

Meaning of duly authorised person

29. In this Part, "duly authorised person", in the context of any provision, means a person authorised by the Authority to act for the purposes of that provision.

PART 6

AMENDMENTS TO THE 2004 ACT

Remit of the Authority

30.—(1) Section 14 (remit) of the 2004 Act is amended as follows.

(2) At the end of subsection (1) insert—

"(h) the procurement, processing, preservation, testing, storage, distribution, import or export of tissue or cells, in so far as those activities are activities to which regulation 7(1) or (2) of the 2007 Regulations applies and are not within the remit of the Authority by virtue of paragraphs (a) to (g).".

(3) After subsection (2) insert—

"(2A) Expressions used in paragraph (h) of subsection (1) and in the 2007 Regulations have the same meaning in that paragraph as in those Regulations; and the reference to activities to which regulation 7(1) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.".

Exclusion from licensing requirement of section 16

31.—(1) Section 16 of the 2004 Act is amended as follows.

(2) After subsection (2), insert—

"(2A) This section does not apply to the procurement, testing, processing, preservation, storage, distribution, import or export of tissue and cells intended for human application in so far as those activities are activities to which regulation 7(1) or (2) of the 2007 Regulations applies.

(2B) Expressions used in subsection (2A) and in the 2007 Regulations have the same meaning in that subsection as in those Regulations; and the reference to activities to which regulation 7(1) or (2) of those Regulations applies is to be read subject to regulation 2(3) of those Regulations.".

Interpretation of Part 2 of the 2004 Act

32. In section 41 (interpretation of Part 2) of the 2004 Act, before the definition of "anatomical specimen" insert—

""the 2007 Regulations" means the Human Tissue (Quality and Safety for Human Application) Regulations 2007;".

Applications under Schedule 3 to the 2004 Act

33. In paragraph 13(1) of Schedule 3 to the 2004 Act, after "Schedule", insert " and Schedule 1 to the 2007 Regulations ".

PART 7

GENERAL

[F90Powers to make regulations in relation to standards of quality and safety, Great Britain

34ZA.—(1) The appropriate authority may by regulations make provision specifying requirements to be met for the purposes of ensuring traceability.

(2) The appropriate authority may by regulations make provision in relation to the notification of serious adverse events and reactions (whether to the Authority or such other person as may be specified in the regulations).

(3) The appropriate authority may by regulations make provision specifying requirements to be met for the purposes of verifying that standards of quality and safety equivalent to those required by these Regulations apply in relation to imports by tissue establishments of tissues and cells from third countries.

(4) The appropriate authority may by regulations prescribe technical requirements in relation to the following—

(i) the licensing or authorisation of tissue establishments;

(ii) the procurement of tissues or cells;

(iii) selection criteria for the donor of tissues or cells;

(iv) laboratory tests required for donors;

(v) procedures for the reception of tissues and cells at the tissue establishment;

(vi) the tissue and cell preparation process;

(vii) tissue and cell processing, storage and distribution;

(viii) the direct distribution to the recipient of specific tissues and cells.

(5) The provision that may be made in regulations under paragraphs (1) to (4) includes provision amending regulations 4A to 4E to modify, or further modify, the provisions of the second, third and fourth Directives as they apply by virtue of these Regulations.

(6) In this regulation "appropriate authority" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales—

(i) the Welsh Ministers; or

(ii) the Secretary of State acting with the consent of the Welsh Ministers;

(c) in relation to Scotland—

(i) the Scottish Ministers; or

(ii) the Secretary of State acting with the consent of the Scottish Ministers;

(d) for the whole of Great Britain, the Secretary of State acting with the consent of the Welsh Ministers and the Scottish Ministers.

Textual Amendments

F90 Regs. 34ZA-34ZC 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(19)** (as amended by S.I. 2020/1306, regs. 1, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**

Scope and nature of powers

34ZB.—(1) Regulations made by the Secretary of State or the Welsh Ministers under regulation 34ZA are to be made by statutory instrument.

(2) For regulations made under regulation 34ZA by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010 (Scottish statutory instruments).

(3) . . . . . .

(4) Any power in regulation 34ZA to make regulations includes a power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.

Textual Amendments

F90 Regs. 34ZA-34ZC 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(19)** (as amended by S.I. 2020/1306, regs. 1, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**

Scrutiny of regulations

34ZC.—(1) A statutory instrument containing regulations made by the Secretary of State under regulation 34ZA may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

(2) A statutory instrument containing regulations made by the Welsh Ministers may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.

(3) Regulations made by the Scottish Ministers under regulation 34ZA are subject to the affirmative procedure (see section 29 of the Interpretation and Legislative Reform (Scotland) Act 2010).

(4) . . . . . .]

Textual Amendments

F90 Regs. 34ZA-34ZC 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(19)** (as amended by S.I. 2020/1306, regs. 1, **23**); 2020 c. 1, **Sch. 5 para. 1(1)**

Offences by bodies corporate

34.—(1) Where an offence under these Regulations is committed by a body corporate and is proved to have been committed with the consent or connivance of or to be attributable to any neglect on the part of—

(a) any director, manager, secretary or other similar officer of the body corporate, or

(b) any person who was purporting to act in any such capacity,

he (as well as the body corporate) commits the offence and shall be liable to be proceeded against and punished accordingly.

(2) Where the affairs of a body corporate are managed by its members, paragraph (1) applies in relation to the acts and defaults of a member in connection with his functions of management as if he were a director of the body corporate.

(3) Where an offence under these Regulations is committed by a Scottish partnership and is proved to have been committed with the consent or connivance of a partner, or to be attributable to any neglect on the part of a partner, he (as well as the partnership) commits the offence and shall be liable to be proceeded against and punished accordingly.

(4) In paragraph (3), "partner" includes a person purporting to act as a partner.

Transitional arrangements: storage licences

35.—(1) This regulation applies where, immediately before the commencement date, a licence granted under Schedule 3 to the 2004 Act authorises the carrying-on of the activity described in section 16(2)(e)(ii) of the 2004 Act for use for transplantation.

(2) A licence referred to in paragraph (1) shall, from the commencement date, also be treated as a licence granted pursuant to Schedule 1 to these Regulations in respect of the storage of tissue or cells for human application and shall authorise the carrying-on of the activities to which regulation 7(2) applies.

(3) Where any premises to which a licence referred to in paragraph (1) relates have not been inspected on behalf of the Authority since the licence was granted, the Authority shall arrange for such premises to be inspected on its behalf before the end of the period of two years beginning with the commencement date.

Signed by authority of the Secretary of State for Health

Rosie Winterton
Minister of StateDepartment of Health

SCHEDULE 1

Regulation 7

Licences for the purposes of regulation 7

Power to grant licence

1. The Authority may on application grant a licence for the purposes of regulation 7.

Characteristics of licences

2. A licence under this Schedule may authorise the carrying-on of any of the activities to which regulation **[**[F91]7(1), (1A) or (2)**]** applies.

Textual Amendments

F91 Words in Sch. 1 para. 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), **7(1)** (with reg. 10)

3. A licence—

(a) shall designate an individual as the designated individual, and

(b) shall not authorise the licensed activities to be carried on under the supervision of more than one such individual.

4. A licence —

(a) shall specify the premises (other than relevant third party premises) where the licensed activity is authorised to be carried on, and

(b) shall not authorise the licensed activity to be carried on on premises (other than relevant third party premises in the case of activities to which regulation 7(2) applies) at different places.

5. It shall be a condition of a licence under this Schedule—

(a) that the licensed activities shall be carried on only under the supervision of the designated individual;

(b) that the licensed activity shall be carried on only on the premises specified in the licence or, in the case of activities to which regulation 7(2) applies, on relevant third party premises.

[[F92]**5A.** Where the Authority grants a licence under this Schedule authorising the carrying on of the activities to which regulation 7(1A) applies, it must provide the designated individual in relation to that licence with a **[**[F93]certificate—

(a) of authority in relation to Great Britain, in such form as the Authority considers appropriate,

(b) in relation to Northern Ireland, in the form set out in Annex II to the fourth Directive.**]]**

Textual Amendments

F92 Sch. 1 para. 5A 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), **7(2)** (with reg. 10)

F93 Words in Sch. 1 para. 5A 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(20)** (as substituted by S.I. 2020/1306, regs. 1, **24**); 2020 c. 1, **Sch. 5 para. 1(1)**

Fees

6. In determining the amounts of any fees to be charged under paragraph 13 of Schedule 3 to the 2004 Act, as applied by regulation 8, the Authority shall have regard to its costs in connection with the consideration of applications for licences under this Schedule.

[F94]SCHEDULE 2

Regulation 16

[[F95]Directions for securing compliance with the first, second, third and fourth Directives**]**

Textual Amendments

F94 Sch. 2 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(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F95 Sch. 2 heading 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), **8(1)(a)**

Traceability and coding system

[[F96]**1.** In relation to Great Britain, directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure, in relation to traceability, compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).**]**

Textual Amendments

F96 Sch. 2 para. 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(21)(a)** (as amended by S.I. 2020/1306, regs. 1, **25(a)**); 2020 c. 1, Sch. 5 para. 1(1)

[[F97]**1ZA.** In relation to Northern Ireland, directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure—

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and

(b) in relation to the coding of information, compliance with—

(i) the requirements of paragraph 1 of Article 25 of the first Directive (coding of information);

(ii) the requirements of paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article;

(iii) the requirements of Article 10a of the third Directive (format of the Single European Code); and

(iv) the requirements of paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).**]**

Textual Amendments

F97 Sch. 2 para. 1ZA 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(21)(aa)** (as inserted by S.I. 2020/1306, regs. 1, **25(b)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F98]**1A. [**[F99]In relation to Northern Ireland, directions**]** must require information that the Authority considers appropriate to secure compliance with the requirements of paragraph 1(g) of Article 10b of the third Directive to be provided to the Authority.**]**

Textual Amendments

F98 Sch. 2 para. 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), **8(1)(c)** (with reg. 10)

F99 Words in Sch. 2 para. 1A 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(21)(b)** (as substituted by S.I. 2020/1306, regs. 1, **25(c)**); 2020 c. 1, **Sch. 5 para. 1(1)**

Directions given for the purposes of paragraph 1(a) must include directions requiring designated individuals to ensure that third parties responsible for human application retain the information listed in Annex VI to the third Directive (minimum data to be kept in accordance with Article 9(2).**]**

Textual Amendments

F100 Sch. 2 para. 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), **8(1)(d)**

Reporting obligations

3. Directions under paragraph 2(4)(c) to (e) of Schedule 3 to the 2004 Act (as applied by regulation 8) shall specify the information to be recorded, the form in which it is to be recorded, the period for which such information is to be kept and the persons to whom any specified information is to be provided for the purpose of securing compliance with the requirements of Article 10(1) (register of tissue establishments and reporting obligations) of the first Directive **[**[F101]and Article 8(1) (register of importing tissue establishments) of the fourth Directive**]**.

Textual Amendments

F101 Words in Sch. 2 para. 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), **8(1)(e)**

Serious adverse events and serious adverse reactions

4. [[F102]In relation to Great Britain, directions shall**]** require licence holders to adopt such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

[[F103]as the Authority considers appropriate**]**.

Textual Amendments

F102 Words in Sch. 2 para. 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(21)(c)(i)** (as substituted by S.I. 2020/1306, regs. 1, **25(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F103 Words in Sch. 2 para. 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(21)(c)(ii)** (as substituted by S.I. 2020/1306, regs. 1, **25(d)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F104]**4ZA.** In relation to Northern Ireland, directions shall require licence holders to adopt such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.**]**

Textual Amendments

F104 Sch. 2 para. 4ZA 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(21)(ca)** (as inserted by S.I. 2020/1306, regs. 1, **25(e)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F105]**4A.** Directions must require that importing licence holders are required to—

(a) notify the Authority of any serious adverse events or serious adverse reactions notified to the importing licence holder by that person's third country supplier (including events or reactions which that supplier suspects are serious adverse events or reactions); and

(b) provide any information specified in the direction which the Authority requires for the purposes of securing compliance with the requirements of Article 6(2) of the fourth Directive (updated information).**]**

Textual Amendments

F105 Sch. 2 para. 4A 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), **8(1)(f)**

Third party agreements and termination of licensed activities

5. For the purpose of securing compliance with the requirements of Article 21(5) (tissue and cell storage conditions) and Article 24 (relations between tissue establishments and third parties) of the first Directive, directions shall specify the requirements that must be met in relation to the termination of storage activities authorised by the licence and in relation to third party agreements.

Procurement and use of tissue or cells

6. Directions shall specify the requirements to be met by all licence holders authorised to procure tissue or cells to secure compliance with the requirements (including as to staff training, written

agreements with staff, standard operating procedures, and appropriate facilities and equipment) laid down in Article 2 (requirements for the procurement of human tissues and cells) of the second Directive.

7. **[**[F106]In relation to Great Britain, directions shall**]** be given—

(a) for the purpose of securing that procurement organisations comply with the requirements of the Annex to the first Directive (information to be provided on the donation of tissue or cells), and

(b) for the purpose of securing that procurement organisations and organisations responsible for human application of tissue or cells comply with **[**[F107]the requirements of these Regulations in relation to notification of serious adverse reactions and notification of serious adverse events.**]**

Textual Amendments

F106 Words in Sch. 2 para. 7 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(21)(d)(i)** (as substituted by S.I. 2020/1306, regs. 1, **25(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

F107 Words in Sch. 2 para. 7(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(21)(d)(ii)** (as substituted by S.I. 2020/1306, regs. 1, **25(f)**); 2020 c. 1, **Sch. 5 para. 1(1)**

[[F108]**7A.** In relation to Northern Ireland, directions shall be given—

(a) for the purpose of securing that procurement organisations comply with the requirements of the Annex to the first Directive (information to be provided on the donation of tissue or cells), and

(b) for the purpose of securing that procurement organisations and organisations responsible for human application of tissue or cells comply with the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.**]**

Textual Amendments

F108 Sch. 2 para. 7A 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(21)(e)** (as inserted by S.I. 2020/1306, regs. 1, **25(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**

8. In giving directions for the purposes of paragraph 7, the Authority shall, in particular, impose a requirement on designated individuals to ensure that records are retained, and the Authority and tissue establishments are notified without delay, of any serious adverse event and any serious adverse reaction.

Selection criteria and laboratory tests required for donors of tissues and cells

9. In relation to donors of tissues or cells who are deceased at the time of donation, directions shall impose requirements in respect of the selection criteria for such donors, in accordance with—

(a) in relation to all such donors, point 1.1 (general criteria for exclusion), and

(b) in relation to such donors who are children, point 1.2 (additional exclusion criteria for deceased child donors),

of Annex I (selection criteria for donors of tissue or cells) to the second Directive.

10. In relation to donors of tissues or cells who are alive at the time of donation, directions shall impose requirements in respect of the selection criteria for such donors, in accordance with—

(a) in relation to autologous donors, point 2.1 (autologous living donor),

(b) in relation to allogeneic donors, point 2.2 (allogeneic living donor),

of Annex I to the second Directive.

11. Directions shall, in respect of all donors of tissues or cells, deal with the biological tests to be performed and carried out, in accordance with the requirements of section 1 (biological tests required for donors) and section 2 (general requirements to be met for determining biological markers) of Annex II (laboratory tests required for donors) to the second Directive.

Donation and procurement procedures and reception at the tissue establishment

12. In respect of—

(a) donation and procurement procedures, and

(b) the reception of tissue and cells at premises specified in a licence under Schedule 1,

directions shall be given for the purpose of securing compliance with the requirements of Article 15(3) (selection, evaluation and procurement) and Article 19(4) to (6) (tissue and cell reception) of the first Directive and with the requirements laid down in the provisions of the second Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the second Directive
1. **Donation and procurement procedures**	
Consent and donor identification (record of consent, method of identification, donor interview)	Annex IV, point 1.1
Donor evaluation: other than autologous donors (assessment of donor's medical and behavioural information and physical examinations)	Annex IV, point 1.2
Procurement procedures for tissue and cells (requirements relating to procurement procedures and instruments)	Annex IV, point 1.3
Donor documentation (record of donor and the procurement)	Annex IV, point 1.4
Packaging (requirements as to packaging and shipping containers)	Annex IV, point 1.5
Labelling of the procured tissue and cells (minimum labelling requirements)	Annex IV, point 1.6
Labelling of the shipping container (minimum labelling requirements)	Annex IV, point 1.7
2. **Reception of tissue and cells at the tissue establishment**	
Verification upon arrival (procedures for verification and requirement for quarantine until verification)	Annex IV, point 2.1 to 2.3
Registration of data	Annex IV, point 2.4

Requirements for holding a licence under Schedule 1

13. Directions shall be given for the purpose of securing compliance with the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Organisation and management (requirements as to organisational structure, management systems, and third party agreements)	Annex I, Part A
Personnel (number, competence, responsibilities and training)	Annex I, Part B
Equipment and materials (appropriate for use, validation, maintenance, and specifications)	Annex I, Part C
Facilities and premises (suitability, environment, storage, and maintenance)	Annex I, Part D
Documentation and records (standard operating procedures, document control, record reliability)	Annex I, Part E
Quality review (quality management system, investigations, corrective action, and reviews)	Annex I, Part F

Requirements for holding a licence under Schedule 1 for tissue and cell preparation processes

14. In respect of tissue and cell preparation processes, directions shall be given for the purpose of securing compliance with—

(a) the requirements of Article 20(2) and (3) (tissue and cell processing) and Article 21(2) to (4) of the first Directive, and

(b) the requirements laid down in the provisions of the third Directive listed in the right-hand column, the subject-matter of which are described in the left-hand column in respect of those provisions.

	Relevant provisions of the third Directive
Reception of tissue and cells at the tissue establishment	Annex II, Part A
Processing of tissue and cells (validation, documentation and evaluation of critical procedures)	Annex II, Part B
Storage and release of tissue and cells (criteria to be complied with, including standard operating procedure)	Annex II, Part C
Distribution and recall of tissue and cells (criteria to be complied with, including procedures to be adopted)	Annex II, Part D
Final labelling of tissue and cells containers for distribution (information to be shown on container label or in accompanying documentation)	Annex II, Part E
External labelling of the shipping container (information to be shown on label on shipping container)	Annex II, Part F

[F109Updated information

15.—(1) Directions must require that importing licence holders must not make any substantial changes in connection with any qualifying import made by that licence holder unless the requirement in sub-paragraph (2) or (3) is met.

(2) The requirement of this sub-paragraph is where the substantial change would require the variation of a condition of the licence authorising the qualifying import—

(a) the importing licence holder has made an application to the Authority to vary the licence under paragraph 8(2) of Schedule 3 to the 2004 Act, as applied by regulation 8, to reflect the change; and

(b) the Authority has made that variation.

(3) The requirement in this sub-paragraph is where the substantial change does not fall within sub-paragraph (2), the Authority has approved the change in writing.

(4) Directions must require that importing licence holders must notify the Authority—

(a) if the licence holder ceases to make qualifying imports; and

(b) of any changes in circumstances of the importing licence holder's third country supplier of which the importing licence holder is aware.

(5) In this paragraph—

"changes of circumstances" means any changes in circumstances of the description specified in the direction in question in accordance with the provision made in Article 6(3) of the fourth Directive (notification of revocation of third country's authorisation);

"qualifying import" means the import [F110]... from a third country of tissues or cells intended for human application;

"qualifying tissues or cells" means tissues or cells intended for human application; and

"substantial changes" means changes of the description specified in the direction in question in accordance with the provision as to the meaning of substantial changes made in Article 3(3) of the fourth Directive (requirements where substantial changes made to import activities).**]**

Textual Amendments

F109 Sch. 2 paras. 15, 16 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), **8(1)(g)**

F110 Words in Sch. 2 para. 15(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(21)(f)** (as inserted by S.I. 2020/1306, regs. 1, **25(g)**); 2020 c. 1, **Sch. 5 para. 1(1)**; 2020 c. 1, **Sch. 5 para. 1(1)**

[[F109]**Written agreements**

16. Directions must specify the requirements to be made by all importing licence holders to secure compliance with the requirements of Article 7 of the fourth Directive (written agreements).**]**

Textual Amendments

F109 Sch. 2 paras. 15, 16 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), **8(1)(g)**

SCHEDULE 3

Regulation 24

Appropriate statements

An appropriate statement for the purposes of regulation 24 must contain the following information—

(a) a statement that the duly authorised person has been authorised by the Authority for the purposes of regulation 23;

(b) a statement that the duly authorised person's rights of entry and search are subject to his producing evidence of his entitlement to exercise them, if required;

(c) a statement that the duly authorised person is entitled, if need be, to enter the premises by force;

(d) a description of the duly authorised person's powers under regulation 25(2) to (4) of inspection and seizure of property;

(e) a description of the requirement under paragraph 25(5) for the duly authorised person to leave a statement giving particulars of what he has seized and stating that he has seized it;

(f) a description of the powers of the duly authorised person—

(i) under regulation 26(1), to bring with him such other persons and equipment as he considers necessary;

(ii) under regulation 26(2), to inspect equipment and inspect and take copies of records, and in the case of premises in respect of which a licence under Schedule 1 is in force, or relevant third party premises in respect of which a third party agreement is in force, to observe the carrying-on of licensed activity or activity pursuant to such agreement;

(g) a description of the duly authorised person's obligations under regulation 27(2) to prepare a written report of the search and, if requested to do so by the appropriate person, give him a copy of the report;

(h) a statement that a person commits an offence under regulation 28 if—

(i) he fails without reasonable excuse to comply with a requirement under regulation 26(3), or

(ii) he intentionally obstructs the exercise of any right under Part 5.

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations implement in part 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, as well as Commission Directive 2006/17/EC and Commission Directive 2006/86/EC laying down technical requirements in relation to Directive 2004/23/EC ("the Directives"). These Regulations impose safety and quality requirements in relation to human tissue and cells intended for human application, including stem cells and cell lines grown outside the body. These Regulations do not apply to reproductive cells, embryos outside the human body, organs and blood.

These Regulations extend to the whole of the United Kingdom, except Part 6 which does not extend to Scotland.
Regulation 3 appoints the Human Tissue Authority ("the Authority") as the competent authority for the purposes of the Directives.
Regulation 7 prohibits the storage of tissue or cells, which are intended to be applied in or on a human, otherwise than under a licence granted under Schedule 1 to these Regulations. It also prohibits the procurement, testing, processing, distribution, import or export of such tissue or cells otherwise than under a licence, or under an agreement with a licence holder which complies with certain requirements of the Directives. Regulation 11 makes it an offence to breach such prohibition and provides for maximum penalties. Schedule 1 provides for the grant of licences and regulation 8 applies a number of provisions of the Human Tissue Act 2004 ("the 2004 Act") to such licences, including the procedures to be followed in respect of an application for a licence and powers to impose fees. These provisions, as well as other relevant provisions of the 2004 Act (regulation 9), are extended to Scotland in so far as they relate to the activities covered by these Regulations. Regulation 7(4) provides power for the Authority to authorise any person to distribute, import or export tissue or cells directly from where procurement takes place for immediate transplantation to humans.
Regulation 11 imposes preconditions to the grant of licences. Regulation 12 imposes a duty on the individual designated under a licence with responsibility for supervising the licensed activities to ensure that only suitable persons participate in carrying-on the activities, that suitable practices are used in doing so, and that the conditions of the licence and of agreements with third parties in relation to such activities are complied with.
Regulation 13 imposes restrictions on the disclosure of information obtained under the Regulations. Regulation 14 makes it an offence to breach such restrictions and imposes maximum penalties.
Regulations 15 and 16 make provision in relation to the giving of directions by the Authority in relation to the import or export of tissue or cells and in relation to the carrying-on of licensed activities. In particular, licence holders are required to comply with directions given by the Authority in accordance with Schedule 2 to the Regulations for the purpose of securing compliance with the requirements of the Directives.
Regulations 17 to 20 impose obligations on the Authority, including requirements to keep registers of licences and of serious occurrences affecting donors and recipients of tissue or cells, and to notify other EEA states of such occurrences.
Regulations 21 to 29 and Schedule 3 provide for enforcement and related matters, including powers of inspection. Regulations 30 to 33 make consequential amendments to the Human Tissue Act 2004.
Regulation 34 provides that an officer of a body corporate, or a partner in a Scottish partnership, commits an offence when it is proved that such body or partnership committed an offence under these Regulations with the consent or connivance of that officer or partner, or it was attributable to neglect on his part.
Regulation 35 makes transitional provision in relation to licences under the 2004 Act which authorised the storage of material (other than blood) which has come from a human body for use for transplantation. Such licences shall also be treated as licences under Schedule 1 to these Regulations on the commencement date (5 July 2007).
A Regulatory Impact Assessment and a Transposition Note have been prepared for these Regulations and a copy of each has been placed in the library of each House of Parliament. Copies of the Regulatory Impact Assessment and the Transposition Note can be obtained from the Organ and Tissue Transplantation Team, Department of Health, Room 611, 6th floor North, Wellington House, 133-155 Waterloo Road, London SE1 8UG.

Status:
Point in time view as at 31/12/2020.

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