Draft Regulations laid before Parliament under paragraph 2(2) of Schedule 2 to the European Communities Act 1972, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2018 No. 0000

HUMAN TISSUE

The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018

Made - - - -	**** 2018*
Coming into force	
for the purposes of regulation 1(3)	**** 2018*
for all other purposes	*1st April 2018*

The Secretary of State is a Minister designated(**1**) for the purposes of section 2(2) of the European Communities Act 1972(**2**) in relation to health protection measures regulating the use of material of human origin.

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

The Secretary of State makes these Regulations in exercise of the powers conferred by section 2(2) of the European Communities Act 1972.

Citation, commencement and interpretation

1.—(1) These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018.

(2) Except as provided by paragraph (3), these Regulations shall come into force on 1st April 2018.

(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 or giving directions to ensure compliance with these Regulations on the commencement date.

(**1**) S.I. 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).

(**2**) 1972 c.68.

(4) In these Regulations—

"the Act" means the Human Tissue Act 2004(**3**);

"the commencement date" means the date specified in paragraph (2);

"the Principal Regulations" means the Human Tissue (Quality and Safety for Human Application) Regulations 2007(**4**).

Amendment of Part 1 of the Principal Regulations

2.—(1) In regulation 2(3) of the Principal Regulations (extent and application), for "import and export", substitute "import into the United Kingdom and export from the United Kingdom".

(2) In regulation 3 of the Principal Regulations (designation of the competent authority), for "the first, second and third Directives", substitute "the first, second, third and fourth Directives".

(3) Regulation 4 of the Principal Regulations (references to Directives) is amended as follows—

(a) at the end of the definition of "the third Directive", insert "as amended by Commission Directive 2015/565/EU(**5**),"; and

(b) after the definition of "the third Directive", insert—

> ""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.".

(4) Regulation 5 of the Principal Regulations (interpretation of other terms) is amended as follows—

(a) in paragraph (1)—

(i) at the appropriate place, insert—

> ""a case of emergency" means any unforeseen situation in which there is no practical alternative other than to urgently import into the United Kingdom 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;";
>
> ""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;";
>
> ""importing licence holder" means a licence holder who is authorised by that licence to import tissues or cells intended for human application into the United Kingdom from a third country;";
>
> ""third country" means a country which is not an EEA state or Gibraltar;";
>
> ""third country premises" means premises—
>
> (a) in a third country; and
>
> (b) on, or from which, a third country supplier, or a person providing services to a third country supplier, procures, tests, processes, stores, distributes or exports tissues or cells that are intended for import into the United Kingdom for human application;";

(**3**) 2004 c.30.
(**4**) S.I. 2007/1523.
(**5**) OJEU L093, 09.04.2015, p43.

""third country supplier" means a person in a third country who has an agreement with an importing licencing holder for exporting tissues or cells intended for import into the United Kingdom for human application;"; and

(ii) omit the definitions of "export" and "import";

(b) in paragraph (2), for "and Article 2 of the third Directive (definitions)", substitute ", Article 2 of the third Directive and Article 2 of the fourth Directive (definitions)";

(c) in paragraph (4)—

(i) for sub-paragraph (a), substitute—

"(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"; and

(ii) in sub-paragraph (b) for "or third" substitute ", third or fourth".

(5) Regulation 6 of the Principal Regulations (references to third party agreements etc) is amended as follows—

(a) in paragraph (1)(a), for "(other than storage)", substitute "(other than storage or import into the United Kingdom from a third country)"; and

(b) in paragraph (2), in the definition of "relevant third party premises", in sub-paragraph (a)—

(i) omit "or to which a third party imports"; and

(ii) after "exports", insert "from the United Kingdom to a third country".

Amendment of Part 2 of the Principal Regulations

3.—(1) Regulation 7 of the Principal Regulations (licensing requirement) is amended as follows—

(a) after paragraph (1), insert—

"(1A) Subject to paragraphs (4) and (5), no person may import into the United Kingdom from a third country tissues or cells that are intended for human application otherwise than under the authority of a licence under Schedule 1.";

(b) in paragraph (2), for "(6)", substitute "(5)";

(c) in paragraph (3)—

(i) omit ", import"; and

(ii) after "export", insert "from the United Kingdom to a third country";

(d) for paragraph (4), substitute—

"(4) The Authority may authorise any person to distribute, import into the United Kingdom from a third country or export from the United Kingdom 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 for the purposes of Article 6(5) of the first Directive.";

(e) for paragraph (5), substitute—

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

(f) omit paragraph (6).

(2) After regulation 7 of the Principal Regulations, insert—

"**7A. Import from the EEA and Gibraltar**

(1) No person may import tissues or cells intended for human application into the United Kingdom from an EEA state or Gibraltar, 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 state, other than the United Kingdom, or in Gibraltar 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 other than the United Kingdom or in Gibraltar 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 state, other than the United Kingdom, or in Gibraltar for the purpose of implementing the first, second or third Directives.".

(3) Regulation 10 of the Principal Regulations (breach of requirement to hold a licence or to act under a third party agreement) is amended as follows—

(a) after paragraph (1), insert—

"(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).";

(b) after paragraph (2) insert—

"(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."; and

(c) in paragraph (3), for "paragraph (1) or (2)", substitute "paragraph (1), (1A), (2) or (2A)".

(4) After regulation 11(4) of the Principal Regulations (preconditions to grant of licence), insert—

"(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); and

(c) 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 into the United Kingdom from a third country of tissues or cells intended for human application;

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

Amendment of Part 3 of the Principal Regulations

4.—(1) Omit regulation 15 of the Principal Regulations (import and export of tissues and cells).

(2) In regulation 16 of the Principal Regulations (directions: compliance with the first, second and third Directives), in each place that it occurs, including in the heading, for "first, second and third Directives", substitute "first, second, third and fourth Directives".

Amendment of Part 4 of the Principal Regulations

5.—(1) In regulation 20(1)(a) of the Principal Regulations (duties of the Authority in relation to serious adverse events and serious adverse reactions), for "import or export", substitute "import into the United Kingdom from a third country or export from the United Kingdom to a third country".

(2) After regulation 20 of the Principal Regulations, insert—

"**20A. Duties of the Authority in relation to application of the Single European Code**

(1) 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.

(3) The Authority must, in relation to each licence holder, arrange for the information specified in Annex VIII to the third Directive to be recorded in the EU Tissue Establishment Compendium.

(4) In relation to a licence holder, the Authority must ensure that the information under paragraph (3) is recorded before the end of the period of 10 working days beginning with 1st April 2018.

(5) In relation to a person who becomes a licence holder on or after 1st April 2018 the Authority must ensure that the information under paragraph (3) is 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) Where this paragraph applies, the Authority must arrange for 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—

"relevant state" means—

(a) an EEA state other than the United Kingdom; or

(b) Gibraltar; and

"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(**6**) in any part of the United Kingdom.

20B. Inspection of third country premises etc

(1) Paragraph (2) applies where—

(a) qualifying tissues or cells are imported into the United Kingdom from a third country by an importing licence holder;

(b) the tissues or cells are distributed in an EEA state, other than the United Kingdom, or in Gibraltar; and

(c) the competent authority in that state or in Gibraltar ("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.

(**6**) 1971 c.80 (section 1(1) and Schedule 1).

(4) For the purposes of ascertaining whether qualifying tissues or cells imported into the United Kingdom 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).

20C. Third country premises and third country suppliers: report of inspections etc

(1) This regulation applies where the European Commission or a competent authority in an EEA state, other than the United Kingdom, or in Gibraltar 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.".

Amendment of Part 5 of the Principal Regulations

6.—(1) After regulation 21 of the Principal Regulations (inspection of documents), insert—

"**21A. Inspection of documents to be held by an importing licence holder**

(1) This regulation applies where—

(a) qualifying tissues or cells are imported into the United Kingdom 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, other than the United Kingdom, or in Gibraltar; and

(c) the competent authority in that state or in Gibraltar 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.".

(2) After regulation 22 of the Principal Regulations (entry and inspection of premises), insert—

"**22A. Importing licence holders: requests for inspections**

(1) This regulation applies where—

(a) any licensed activity in relation to qualifying tissues or cells imported into the United Kingdom 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, other than the United Kingdom, or in Gibraltar; and

(c) the competent authority in that state or in Gibraltar 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.".

(3) After regulation 27(3) of the Principal Regulations (requirements when exercising power of inspection or search) insert—

"(4) Paragraph (5) applies if the European Commission or a competent authority in an EEA state, other than the United Kingdom, or in Gibraltar requests 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.

(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.".

(4) In regulation 28(1)(a) of the Principal Regulations (enforcement), for "under regulation 21 or" substitute "under regulation 21, 21A or".

Amendment of Schedule 1 to the Principal Regulations

7.—(1) In paragraph 2 of Schedule 1 to the Principal Regulations (characteristics of licences), for "7(1) or (2)", substitute "7(1), (1A) or (2)".

(2) After paragraph 5 of Schedule 1 to the Principal Regulations, insert—

"**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 certificate in the form set out in Annex II to the fourth Directive.".

Amendment of Schedule 2 to the Principal Regulations

8.—(1) Schedule 2 to the Principal Regulations (directions for securing compliance with the first, second and third directives) is amended as follows—

(a) for the heading substitute—

"Directions for securing compliance with the first, second, third and fourth Directives";

(b) for paragraph 1(b) (traceability and coding system), substitute—

"(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).";

(c) after paragraph 1, insert—

"**1A.** 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.";

(d) for paragraph 2, substitute—

"**2.** 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).";

(e) at the end of paragraph 3 (reporting obligations), insert "and Article 8(1) (register of importing tissue establishments) of the fourth Directive";

(f) after paragraph 4 (serious adverse events and serious adverse reactions), insert—

"**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).";

(g) after paragraph 14 (requirements for holding a licence under Schedule 1 for tissue and cell preparation processes), insert—

"**15. Updated information**

(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 into the United Kingdom 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).

16. 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).".

Amendments to the Act relating to the import of tissues or cells

9.—(1) The Act is amended as follows.

(2) In section 14 (remit of Human Tissue Authority)—

(a) in subsection (1)(h)—

(i) omit the word "preservation,"; and

(ii) after the words "regulations 7(1)" insert ", (1A)"; and

(b) in subsection (2A) after the words "regulation 7(1)" insert ", (1A)".

(3) In section 16 (licence requirement)—

(a) in subsection (2A)(**7**)—

(i) omit the words ", preservation" and "intended for human application"; and

(ii) after the words "regulation 7(1)" insert ", (1A)"; and

(b) in subsection (2B)(**8**) after the words "regulation 7(1)" insert ", (1A)".

(4) In paragraph 7(2) of Schedule 3 (revocation of licence otherwise than on application)—

(a) omit "or" at the end of paragraph (f); and

(b) after paragraph (g) insert—

"or

(h) it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that tissues or cells imported from a third country by an importing licence holder meet standards of quality and safety equivalent to those laid down in the 2007 Regulations.".

(**7**) Inserted by the Human Tissue (Quality and Safety for Human Application) Regulations 2007/1523, Part 6, regulation 31(2).
(**8**) Inserted by the Human Tissue (Quality and Safety for Human Application) Regulations 2007/1523, Part 6, regulation 31(2).

(5) After paragraph 7(2) of Schedule 3 insert—

"(3) For the purposes of sub-paragraph (2)(h), "importing licence holder", "third country" and "third country premises" have the same meaning as in the 2007 Regulations.".

Transitional arrangements

10.—(1) Paragraph (2) applies in relation to any licence granted under Schedule 1 to the Principal Regulations (licences for the purposes of regulation 7) that—

(a) is in force immediately before the commencement date;

(b) authorises the licence holder ("the relevant licence holder") to carry out qualifying imports; and

(c) in respect of which the relevant licence holder notifies the Authority of his intention to carry out further qualifying imports after the commencement date.

(2) Where this paragraph applies and the conditions in paragraph (3) are met—

(a) the licence must, from the commencement date, be treated as a licence granted under Schedule 1 to the Principal Regulations, as amended by these Regulations, authorising activities to which regulation 7(1A) of the Principal Regulations (licensing requirement) applies;

(b) the relevant licence holder in relation to that licence must be treated as an importing licence holder for the purposes of the Principal Regulations; and

(c) the Authority must provide the relevant licence holder in relation to that licence with a certificate in the form set out in Annex II to the fourth Directive.

(3) For the purposes of paragraph (2), the conditions in respect of which the Authority must be satisfied are—

(a) the relevant licence holder has taken any measures as may be specified by the Authority in directions 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 under the Principal Regulations.

(b) the relevant licence holder has provided to the Authority—

(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); and

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

(c) the relevant licence holder has—

(i) made available for inspection by the Authority any documents listed in Parts A and B to Annex III to the fourth Directive (availability and provision of documentation by importing tissue establishments); and

(ii) provided the Authority with any documents falling within paragraph (i) that are requested by the Authority;

(d) the relevant licence holder has entered into a written agreement with any third country supplier that complies with the requirements of Articles 7(2) and (3) of the fourth Directive (written agreements); and

(e) the relevant licence holder has provided the Authority with a copy of any written agreement mentioned in sub-paragraph (d).

(4) Paragraph (5) applies in relation to any licence granted under Schedule 1 to the Principal Regulations —

(a) that is in force immediately before the commencement date;

(b) that authorises the licence holder ("the applicable licence holder") to carry out qualifying imports; and

(c) in respect of which the applicable licence holder notifies the Authority of his intention to carry out qualifying imports which are one-off imports after the commencement date.

(5) Where the circumstances in paragraph (6) are met—

(a) that licence must, from the commencement date, be treated as a licence granted under Schedule 1 to the Principal Regulations, as amended by these Regulations, authorising activities to which regulation 7(1A) of the Principal Regulations applies;

(b) the applicable licence holder in relation to that licence must be treated as an importing licence holder for the purposes of the Principal Regulations; and

(c) the Authority must provide the applicable licence holder in relation to that licence with a certificate in the form set out in Annex II to the fourth Directive.

(6) The circumstances are where the Authority is satisfied that—

(a) the applicable licence holder has taken any measures specified by the Authority in directions for the purpose of ensuring that any qualifying tissues or cells imported from a third country will meet standards of quality and safety equivalent to those under the Principal Regulations;

(b) the applicable licence holder has provided to the Authority the information set out in Parts A to E of Annex I to the fourth Directive (information to be provided by importing tissue establishments); and

(c) the applicable licence holder has provided the Authority with any information or documents as may be specified by the Authority in directions 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).

(7) For the purposes of this regulation—

(a) "the Authority", "importing licence holder", "third country", "third country supplier" and "the fourth Directive" have the same meaning as in the Principal Regulations as amended by these Regulations;

(b) 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 known to the relevant licence holder and the third country supplier before the import occurs, and which, in relation to any given recipient, occurs only once, except where the 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 the Principal 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;

(c) "qualifying import" means the import into the United Kingdom from a third country of tissues or cells intended for human application; and

(d) "qualifying tissues or cells" means tissues or cells intended for human application.

(8) Paragraph (9) applies where—

(a) tissues or cells intended for human application are in storage on 29th October 2016; and

(b) those tissues or cells are transported or delivered to any person on or before 29th October 2021.

(9) Where this paragraph applies, regulation 8(1)(b) and (c) does not apply.

(10) Paragraph (11) applies in respect of tissues or cells intended for human application which either—

(a) were in storage on 29th October 2016, and are transported or delivered to any person on or after 30th October 2021; or

(b) were placed into storage after 29th October 2016, and are in storage on the commencement date (irrespective of when they are transported or delivered to any person).

(11) Where this paragraph applies—

(a) regulation 8(1)(b) does not apply, and

(b) directions must specify the systems which are to be adopted for the identification of tissues or cells to which this paragraph applies, that the Authority considers appropriate to secure compliance with the requirements of paragraph 1(f) of Article 10b of the third Directive (requirements as to labelling).

Signed by authority of the Secretary of State for Health.

Name
Parliamentary Under-Secretary of State,
Department of Health

Date

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations amend the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ("the Principal Regulations") to implement Directive 2015/565 of the European Commission ("the coding Directive"), laying down technical requirements for the coding of human tissues and cells. These Regulations also further amend the Principal Regulations and the Human Tissue Act 2004 ("the Act") to implement Directive 2015/566 of the European Commission ("the fourth Directive"), setting out procedures for verifying standards of quality and safety of imported tissues and cells. The coding Directive and the fourth Directive are implemented in so far as they apply to gametes and embryos by the Human Fertilisation and Embryology (Amendment) Regulations 2018 which amend the Human Fertilisation and Embryology Act 1990.

Regulation 2(1) amends references to "import and export" in regulation 2 of the Principal Regulations.

Regulation 2(2) amends regulation 3 of the Principal Regulations and appoints the Human Tissue Authority as the competent authority for the purposes of the fourth Directive.

Regulation 2(3) amends regulation 4 of the Principal Regulations to ensure that all references in those Regulations to the "third Directive" include amendments made to that Directive by the coding Directive and inserts a definition of the fourth Directive.

Regulation 2(4) amends regulation 5 of the Principal Regulations to insert new definitions to reflect amendments made to implement the fourth Directive and, in particular, it introduces the concepts of an "importing licence holder", "third country", "third country premises" and "third country supplier". Regulation 2(4) also includes a definition of "distribution" to clarify that the term only captures the transportation or delivery of tissues or cells intended for human application to the place where those tissues or cells will be used in human application.

Regulation 3(1)(a) amends regulation 7 of the Principal Regulations to require that, subject to the exemptions set out in paragraphs (4) and (5), anyone who imports tissues or cells intended for human application into the United Kingdom from a country which is not an EEA state or Gibraltar (i.e. from a "third country") must have a licence from the Authority to do so.

Regulation 3(1)(d) and (e) amend regulation 7(4) and (5) of the Principal Regulations to clarify the certain circumstances when the Authority can directly authorise, as opposed to requiring a licence for, the distribution, import into the United Kingdom from a third country, or export from the United Kingdom to a third country, of tissues or cells intended for human application.

Regulation 3(2) inserts new regulation 7A into the Principal Regulations, which prohibits import from an EEA state or Gibraltar unless the import is from a regulated tissue establishment, or from the person who is approved to procure those tissues or cells where certain conditions are satisfied.

Regulations 2(4)(a)(ii), 2(5), 3(1)(b),(c) and (f), 3(3)(a) to (c), 5(1), 7(1) and 9(2) and (3) make amendments which are consequential on the changes made by regulations 3(1)(a) and (2).

Regulation 3(3)(a) amends regulation 10 of the Principal Regulations to provide that it is a criminal offence to import tissues or cells intended for human application from a third country without a licence. Regulation 3(3)(b) further amends regulation 10 to provide that it is a criminal offence to import tissues or cells intended for human application from an EEA state or Gibraltar unless the circumstances set out in new regulation 7A apply. Regulation 3(3)(c) makes an amendment that is consequential upon these changes.

Regulation 3(4) amends regulation 11 of the Principal Regulations so that the Authority cannot grant a licence to import tissues or cells for human application from a third country unless they are satisfied that the applicant has complied with the requirements of the fourth Directive by providing specified information and documentation to the Authority. The information and documentation may have been provided with a previous application provided the Authority is satisfied the information and documentation is up to date. Provision is also made to enable the Authority to waive some or all of the documentation requirements in relation to one-off imports.

Regulation 4(1) omits regulation 15 of the Principal Regulations, which is no longer required.

Regulations 4(2) and 8(1) amend regulation 16 and Schedule 2 to the Principal Regulations to require the Authority to give directions to licence holders to secure compliance with the requirements of the fourth Directive and the coding Directive. These include directions in relation to the application of the Single European Code ("SEC") to tissues and cells intended for human application to identify them and to ensure their traceability from donor to recipient, notification of serious adverse events and reactions, the provision of updated information to the Authority, and the review of written agreements between the importing licence holder and any third country supplier.

Regulation 5(2) inserts new regulation 20A into the Principal Regulations to require the Human Tissue Authority ("the Authority") to take certain steps to ensure compliance with requirements imposed by the coding Directive relating to the application of the SEC.

Regulation 5(2) also inserts new regulation 20B into the Principal Regulations to make provision for the Authority to arrange for an inspection of third country premises, or relevant documents held by a third country supplier, or to carry out control measures in relation to an importing licence holder, if the Authority considers that it would be appropriate to do so following a request from a competent authority in an EEA state other than the UK, or in Gibraltar, in whose country the tissues or cells are subsequently distributed. Where a competent authority in another EEA state or in Gibraltar requests an inspection, arrangements must be made for the participation of that authority in the inspection, or reasons given why participation is not appropriate. Provision is also made in new regulation 20B for the Authority to arrange for an inspection of third country premises or relevant documents held by a third country supplier for the purposes of ascertaining whether tissues or cells imported into the United Kingdom for human application from a third country meet standards of quality and safety equivalent to those laid down in the Regulations.

Regulation 5(2) also inserts new regulation 20C into the Principal Regulations to make provision for the Authority to provide a copy of a report or information on any inspection of third country premises or relevant documents carried out under new regulation 20B, as well as information on the exercise of control measures in relation to an importing licence holder, where it considers it appropriate to do so, following a request from the European Commission or a competent authority in an EEA state other than the United Kingdom, or in Gibraltar.

Regulation 6(1) inserts new regulation 21A into the Principal Regulations to make provision for the Authority to inspect documents held by an importing licence holder who has imported tissues or cells intended for human application into the United Kingdom from a third country where there is a request from a competent authority in an EEA state or Gibraltar into whose country the tissues or cells have subsequently been or will be distributed, and where the Authority considers that it would be appropriate to do so.

Regulation 6(2) inserts new regulation 22A into the Principal Regulations to make provision for the Authority to inspect the premises of an importing licence holder following a request from a competent authority in an EEA state, other than the UK, or in Gibraltar into whose country tissues or cells are subsequently distributed, where the Authority considers that it would be appropriate to do so. Provision is also made for the competent authority making the request to participate in any inspection, or for the Authority to give reasons as to why such participation is not appropriate.

Regulation 6(3) amends regulation 27 of the Principal Regulations to make provision for the Authority to give a copy of a report or information on any inspection of records or documents carried

out under regulation 21 or 21A of the Principal Regulations, or on any inspection of premises under regulation 22 of the Principal Regulations to the European Commission or a competent authority in an EEA state, other than the UK, or Gibraltar at their request, where the Authority considers that it would be appropriate to do so. Regulation 6(4) amends regulation 28 of the Principal Regulations to make it an offence to fail without reasonable excuse to comply with a requirement under new regulation 21A.

Regulation 7(2) amends Schedule 1 to the Principal Regulations to require that when the Authority grants a licence authorising the import into the United Kingdom of tissues or cells intended for human application from a third country, it must provide the designated individual in relation to that licence with a certificate in the form set out in Annex II to the fourth Directive.

Regulation 9(2) and (3) amend the Act in consequence of the amendments made to the Principal Regulations. Regulation 9(4) amends paragraph 7 of Schedule 3 to the Act to enable the Authority to revoke a licence where it is not satisfied that any third country premises are suitable for carrying out activities in a manner which secures that tissues or cells imported from a third country will meet standards of safety and quality equivalent to those laid down in the Principal Regulations.

Regulation 10 makes transitional provision in relation to any licence that is in force immediately before the commencement date, where that licence authorises the import into the United Kingdom of tissues or cells intended for human application from a third country. This regulation provides that if the Authority is satisfied that the information and documents required by the fourth Directive have been provided by the licence holder (including those required for one-off imports, where applicable), the licence will be treated as a licence granted under the Principal Regulations as amended, and as authorising activities to which the new regulation 7(1A) applies. Provision is also made to clarify that the licence holder for that licence is to be treated as the importing licence holder for the purposes of the Principal Regulations, as amended. The Authority must provide the licence holder with a certificate in the form set out in Annex II to the fourth Directive.

Regulation 10(9) provides that where tissues or cells are in storage on 29th October 2016 and are transported or delivered to any person before the end of 29th October 2021, the new requirements in the Principal Regulations relating to the SEC, inserted by regulation 8(1)(b) and (c) of these Regulations, will not apply to those tissues or cells.

Regulation 10(11) provides that where tissues or cells were in storage on 29th October 2016 and are transported or delivered to any person on or after 30th October 2021, or where they were placed into storage after 30th October 2016 and are transported or delivered to any person at any time thereafter, the Authority will issue directions requiring application of the rules applicable to small labels in the coding Directive, namely that the SEC must be unambiguously linked to those tissues or cells through the accompanying documentation.

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 Health Ethics Team (Blood, Organ and Tissue Donation), Department of Health, 6th Floor, 39 Victoria Street, London SW1H 0EU.