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

D R A F T S T A T U T O R Y I N S T R U M E N T S

2017 No.00

HUMAN TISSUE

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

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) These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017.

(2) Except as provided by paragraph (3), these Regulations shall come into force on [XX 2017] ("the commencement date").

(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.

(4) In these Regulations—

"the Act" means the Human Tissue Act 2004([3]),

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

([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 as amended.

([3]) 2004 c.30 as amended.

([4]) S.I. 2007/1523.

Amendments to the Regulations relating to the coding of human tissue and cells

—(1) The Regulations are amended as follows.

(2) In regulation 4 (References to Directives), at the end of the definition of "the third Directive" insert "as amended by Commission Directive 2015/565/EU([5]),".

(3) After regulation 20 (Duties of the Authority in relation to serious adverse events and serious adverse reactions), 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 as 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 person who becomes a licence holder on or after the day on which this regulation comes into force, 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.

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

(6) The Authority must arrange for the information to be corrected or updated—

(a) in the case of a correction or update which the Authority considers to be significant, 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.

(7) Paragraph (8) 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.

(8) The Authority must inform the competent authority in the relevant state in question.

(9) 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 authorities in the relevant states.

(10) 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 in any part of the United Kingdom."

(4) In Schedule 2 (Directions for securing compliance with the first, second and third Directives)—

for paragraph 1(b), substitute—

([5]) OJEU L093, 09.04.2015, p43.

"(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).",

after paragraph 1 insert—

"**1A**.—(1) In sub-paragraph 1(b)(iv), the reference to the requirements of paragraph 1(f) of Article 10b of the third Directive includes the requirements of that provision which apply in relation to transitional case tissues or cells by virtue of Article 10d of the third Directive.

(2) For the purposes of sub-paragraph 1A(1) "transitional case tissues or cells" means tissues or cells which are—

(i) in storage on 29 October 2016; and

(ii) are distributed for human application after the end of the period of five years beginning with that date.

1B Directions must require information to be provided to the Authority which the Authority considers appropriate to secure compliance with the requirements of paragraph 1(g) of Article 10b of the third Directive.", and

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

Amendments to the Regulations relating to the import of human tissue and cells

(1) The Regulations are amended as follows.

(2) In regulation 2(3) (Extent and application), for "import and export" substitute "import into the United Kingdom and export from the United Kingdom".

(3) In regulation 3 (Designation of the competent authority), for the words "the first, second and third Directives" substitute "the first, second, third and fourth Directives".

(4) In regulation 4 (References to Directives)—

in the definition of "the second Directive" at the end omit the "and", and

after the definition of the third Directive insert—

", and

the fourth Directive means Commission Directive 2015/566 of 8 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.".

(5) In regulation 5(1) (Interpretation of other terms)—

(a) insert the following definitions in the appropriate alphabetical place—

""importing licence holder" means a licence holder who is authorised 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 intended for import into the United Kingdom for human application;

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

(b) omit the definitions of "export" and "import".

(6) In regulation 5(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)".

(7) In regulation 5(4)(b), after the word "second" omit "or third" and insert ", third or fourth".

(8) In regulation 6(1)(a) (References to third party agreements etc), for "(other than storage)" substitute "(other than storage or import from third countries)".

(9) In regulation 6(2)(a)—

(a) omit the words "or to which a third party imports", and

(b) after the word "exports" insert "from the United Kingdom to a third country".

(10) After regulation 7(1) (Licensing requirement), insert—

"(1A) Subject to paragraph (4), no person shall do an activity to which this paragraph applies otherwise than under the authority of a licence under Schedule 1.

(1B) Paragraph (1A) applies to the import of tissues or cells intended for human application into the United Kingdom from a third country.".

(11) In regulation 7(2), for "paragraphs (4) and (6)" substitute "paragraph (4)".

(12) In regulation 7(3)—

(a) after "distribution" omit ",import", and

(b) after "export" insert "from the United Kingdom to a third country".

(13) In regulation 7(4) for ", import or export" substitute ", import into the United Kingdom from a third country or export from the United Kingdom to a third country".

(14) Omit regulation 7(6).

(15) After regulation 7 insert—

"7A Import from the EEA and Gibraltar

(1) Subject to paragraphs (2) and (3), no person shall import tissues or cells intended for human application into the United Kingdom from an EEA state or Gibraltar.

(2) Paragraph (1) shall not apply where 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.

(3) Paragraph (1) shall not apply where-

(a) the import 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

(b) the import follows the procurement of those tissues and 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.".

(16) After regulation 10(1) (Breach of requirement to hold a licence or to act under a third party agreement), 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).".

(17) After regulation 10(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 one of the exceptions set out in regulation 7A(2)(a) or (b) applies.".

(18) In regulation 10(3), for the words "paragraph (1) or (2)" substitute "paragraph (1), (1A), (2) or (2A)".

(19) After regulation 11(4) (Preconditions to grant of licence), insert—

"(4A) In the case of an application for a licence to make a qualifying import (other than a one-off import), 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 the Authority with any documents falling within paragraph (i),

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

(e) any written agreement mentioned in paragraph (d) complies with the requirements of Articles 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 paragraph (e).

(4B) In the case of an application for a licence to make a qualifying import which is a one-off import, 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, in relation to tissues or cells, is to tissues or cells imported for the purposes of providing services to a particular person or persons-

(i) on one occasion only, or

(ii) where the Authority is satisfied that [it] [would be expedient/ is necessary][to treat the import as a one off import] for clinical reasons,, on more than one occasion.

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

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

(20) Omit Regulation 15 (Import and export of tissues and cells).

(21) In regulation 16 (Directions: compliance with the first, second and third Directives), for every reference to the "first, second and third Directives", including in the heading, substitute "first, second, third and fourth Directives".

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

(23) After regulation 20A (Duties of the Authority in relation to the application of the Single European Code), [as inserted by regulation 2(3) of these regulations], insert—

"20B. Inspections of third country premises etc.

(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 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 carry out any of the following activities—

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

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

(iii) exercising the Authority's powers under paragraph 7(2) of Schedule 3 to the Act to revoke a licence held by an importing licence holder,

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

(v) exercising the Authority's powers under paragraph 9(1) of Schedule 3 to the Act to suspend a licence held by an importing licence holder, and

(vi) other appropriate control measures.

(2) If the Authority considers that it would be appropriate in the circumstances to carry out the activity in question, the Authority must carry out that activity.

(3) Before an inspection of any premises is carried out in pursuance of paragraph (2) the Authority must—

(a) make arrangements with the requesting authority for it to participate in the inspection, or

(b) notify the requesting authority that the Authority has decided that it is not appropriate for the requesting 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 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 documents 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) References in this regulation to carrying out an inspection of any premises include, in particular—

(a) inspecting any equipment found on the premises,

(b) inspecting and taking copies of any relevant documents or records found on the premises, and

(c) observing the carrying on 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 document" means a document 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" means the competent authority which made the request under paragraph (1) for the Authority to arrange for an inspection of the premises to be carried out.

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 Act 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) If the Authority considers that it would be appropriate in the circumstances for the Authority to provide the report or information in question to the person requesting it, the Authority must provide that report or information to the person.".

(24) After regulation 21(inspection of documents) insert—

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

(2) If the Authority considers that it would be appropriate in the circumstances for the inspection in question to be carried out, the Authority must arrange for an inspection of the documents in question to be carried out by a duly authorised person.

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

(4) Where relevant documents are stored in any 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 document" 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.".

(25) After regulation 22 (entry and inspection of premises) insert—

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

(1) This regulation applies where—

(a) any licensed activity is carried out in relation to qualifying tissues or cells imported into the United Kingdom from a third country 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) If the Authority considers that it would be appropriate in the circumstances for the inspection in question to be carried out, 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.

(3) Before an inspection is carried out in pursuance of paragraph (2), the Authority must—

(a) make arrangements with the requesting authority for it to participate in the inspection, or

(b) notify the requesting authority that the Authority has decided that it is not appropriate for the requesting authority to participate in the inspection and give reasons for that decision.

(4) 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.".

(26) After regulation 27(3) 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) If the Authority considers that it would be appropriate in the circumstances for it to give a copy of the report or information to the person requesting it, the Authority must give a copy of that report or information to the person.".

(27) After paragraph 5 of Schedule 1, 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.".

(28) In paragraph 2 of Schedule 1 (Characteristics of licences), for the words "any of the activities to which regulation 7(1) or (2) applies" substitute "any of the activities to which regulation 7(1), (1A) or (2) applies.".

(29) Schedule 2 is amended as follows—

(a) For the heading substitute—

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

(b) In paragraph 3 (Reporting obligations), after "Article 10(1) (register of tissue establishments and reporting obligations) of the first Directive" insert "and Article 8(1) (register of importing tissue establishments) of the fourth Directive.";

(c) After paragraph 4 insert—

"**4A.** Directions shall require that importing licence holders must—

(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).";

(d) After paragraph 14 insert—

"**15. Updated information**

(a) Directions shall require that importing licence holders must not make any substantial changes in connection with any qualifying import made by that licence holder unless the requirements in paragraph (b) or (c) are met.

(b) Where the substantial change would require the variation of a condition of the licence authorising the qualifying import, the requirements are that—

(i) 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

(ii) the Authority has made that variation.

(c) Where the substantial change does not fall within paragraph (b), the requirement is that the Authority has approved the change in writing.

(d) Directions shall require that importing licence holders must—

(i) notify the Authority if the licence holder ceases to make qualifying imports, and

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

(e) 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)"; and

(e) After paragraph 15 insert—

"**16. Written agreements**

Directions shall specify the requirements to be met by all importing licence holders to secure compliance with the requirements of Article 7 (written agreements) of the fourth Directive.".

Amendments to the Regulations relating to implementation of the first Directive

—(1) The Regulations are amended as follows.

(2) In regulations 5(4), for the whole of paragraph (a) substitute—

"(a) a person who, from any premises, controls the provision of services for transporting tissues or cells to any organisation responsible for human application is to be taken to distribute tissues or cells on those premises; and".

(3) In regulation 7(5) for the whole paragraph substitute—

"(5) The Authority may not authorise distribution, import or export under paragraph (4) unless—

(a) the authorisation relates to tissues or cells specified for the purposes of Article 6(5) of the first Directive, or

(b) the Authority is satisfied—

(i) that the case is one of emergency, and

(ii) that the tissues or cells to be distributed, imported or exported are of a type that has been approved by the Authority for use in accordance with paragraph (4).".

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

—(1) The Act is amended as follows.

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

in subsection (1)(h)—

omit the word "preservation,", and

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

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

(3) In section 16 (licence requirement)—

in subsection (2A)—

omit the words ", preservation" and "intended for human application", and

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

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

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

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

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.".

(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

–(1) Paragraph (2) applies in relation to any licence that—

is in force immediately before the commencement date; and

authorises the licence holder ("the relevant licence holder") to carry out a qualifying import (which is not a one-off import).

Where the circumstances in paragraph (3) are met—

the licence shall, from the commencement date, be treated as a licence granted under Schedule 1 of the Regulations authorising activities to which regulation 7(1A) of the Regulations applies,

the relevant licence holder in relation to that licence shall be treated as an importing licence holder for the purposes of the Regulations, and

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.

The circumstances are where the Authority is satisfied that—

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 laid down in the Regulations,

the relevant 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

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

the relevant licence holder has—

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

if requested by the Authority, provided the Authority with any documents falling within paragraph (i),

the relevant licence holder has entered into a written agreement with any third country supplier,

any written agreement mentioned in paragraph (d) complies with the requirements of Articles 7(2) and (3) of the fourth Directive (written agreements), and

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

Paragraph (5) applies in relation to any licence that—

is in force immediately before the commencement date, and

authorises the licence holder ("the relevant licence holder") to carry out a qualifying import which is a one-off import.

Where the circumstances in paragraph (6) are met—

that licence shall, from the commencement date, be treated as a licence granted under Schedule 1 of the Regulations authorising activities to which regulation 7(1A) of the Regulations applies,

the relevant licence holder in relation to that licence shall be treated as an importing licence holder for the purposes of the Regulations, and

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.

The circumstances are where the Authority is satisfied that—

the relevant licence holder has taken any measures specified by the Authority in directions fore 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 the Regulations,

the relevant licence holder has provide 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

the relevant 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).

For the purposes of this regulation—

references to the Regulations are to the Human Tissue (Quality and Safety for Human Application) Regulations 2007, as amended by these regulations,

"the Authority", "importing licence holder", "third country", "third country supplier" and "the fourth Directive" have the same meaning as in the Regulations,

a reference to a one-off import, in relation to tissues or cells, is to tissues or cells imported for the purposes of providing services to a particular person or persons-

on one occasion only, or

where the Authority is satisfied that [it] [would be expedient/ is necessary][to treat the import as a one off import] for clinical reasons,, on more than one occasion,

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

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

—(1) Paragraph (2) applies where—

tissues or cells are in storage on the commencement date; and

those tissues or cells are distributed for human application before the end of the period of 5 years beginning with the 29th October 2016.

Regulations 2(4)(a), (b) [and (c)] of these Regulations shall not apply.

—(1) Paragraph (2) applies to any tissues or cells that—

(a) were placed in storage after 29th October 2916,

(b) are in storage on the commencement date, and

(c) are distributed for human application after the period of five years beginning with the 29th October 2016.

(2) Any tissues or cells falling within paragraph (1) shall be treated as "transitional case tissues or cells" for the purposes of paragraph 1(b) and 1A of Schedule 2 to the Regulations, as amended by these regulations.

Signed by authority of the Secretary of State for Health

Name

Address Parliamentary Under Secretary of State for Health

Date Department of Health

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 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. The regulations also further amend the 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.

Regulation 2(2) amends regulation 4 of the Regulations to ensure that all references in the Regulations to the "third Directive" include amendments made to that Directive by the coding Directive.

Regulation 2(3) inserts new regulation 20A into the 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 a Single European Code ("the SEC") to tissues and cells intended for human application. The SEC will be used to identify tissues and cells and to ensure their traceability from donor to recipient. Regulation 2(4) amends Schedule 2 to the Regulations to require the Authority to direct licence holders to secure compliance with requirements set out in the coding Directive relating to the SEC.

Regulations 3(2), and (4) to (9) amend various definitions in the Regulations to reflect further amendments made to implement the fourth Directive. They also insert new definitions into the Regulations. In particular, regulation 3(5) introduces the concepts of an "importing licence holder", "third country", "third country premises" and "third country supplier". Regulation 3(3) amends regulation 3 of the Regulations and appoints the Authority as the competent authority for the purposes of the fourth Directive.

Regulation 3(10) amends regulation 7 of the Regulations to require that anyone who imports tissues and 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(15) inserts new regulation 7A into the 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 3(11) to (14), (22) and (28) make amendments which are consequential on the changes made by regulations 3(10) and (15).

Regulation 3(16) amends regulation 10 of the Regulations to provide that it is a criminal offence to import tissues and cells intended for human application from a third country without a licence. Regulation 3(17) 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(18) makes an amendment that is consequential on these changes.

Regulation 3(19) amends regulation 11 of the 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. Provision is also made to enable the Authority to waive some or all of the documentation requirements in relation to one off imports.

Regulation 3(20) deletes regulation 15 of the Regulations, which is no longer required.

Regulations 3(21) and (29) amend regulation 16 and Schedule 2 to the Regulations to require the Authority to give directions to licence holders to secure compliance with the requirements of the fourth Directive. These include directions in relation to the 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 3(23) inserts new regulation 20B into the 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 3(23) also inserts new regulation 20C into the 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 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 a state other than the United Kingdom or in Gibraltar.

Regulation 3(24) inserts new regulation 21A into the 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 distributed, and where the Authority considers that it would be appropriate to do so.

Regulation 3(25) inserts new regulation 22A into the Regulations to make provision for the Authority to inspect the premises of an importing licence holder following a request from a competent authority in another 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 3(26) amends regulation 27 of the 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 Regulations, or on any inspection of premises under regulation 22 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 3(27) amends Schedule 1 to the 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 4(2) amends the interpretation provisions in the Regulations to clarify that the term "distribution" only captures transportation and delivery to the place where tissues and cells will be used in human application]. Regulation 4(3) amends regulation 7 of the Regulations to allow the Authority to directly authorise 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 without a licence in certain circumstances.

Regulations 5(2) and (3) amend the Act in consequence of the amendments made to the Regulations. Regulation 5(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 in the 2007 Regulations.

Regulation 6 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. Regulation 6 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), that the licence will be treated as a licence granted under the 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 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 7 provides that where tissues or cells are in storage on the commencement date, and are distributed for human application before the end of five years beginning 29th October 2016, the new requirements in the Regulations relating to the SEC, inserted by regulation 2(4) of the regulations, will not apply to those tissues or cells.

Regulation 8 provides that where tissues or cells were placed in storage after 29th October 2016, are in storage on the commencement date, and are distributed within 5 years of 29th October 2016 the requirements of the third Directive relating to coding, as amended by the coding Directive, should be limited to those applicable to products with small labels, as laid down in Article 10b paragraph 1(b) of the third Directive.

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 Blood, Organ and Tissue Donation, Transplantation and Trafficking Team, Department of Health, Room 101, Richmond House, 79 Whitehall, London SW1A 2NS.