STATUTORY INSTRUMENTS

2018 No. 335

HUMAN TISSUE

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

Made - - - -	*5th March 2018*
Coming into force	
for the purposes of regulation 1(3)	*6th March 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.

(4) In these Regulations—

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

(**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.
(**3**) 2004 c.30.

"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;";

""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";

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

(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—

"**Import from the EEA and Gibraltar**

7A.—(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).