STATUTORY INSTRUMENTS

2018 No. 335

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

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.".