
DRAFT STATUTORY INSTRUMENTS

2018 No.

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

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”.