DRAFT STATUTORY INSTRUMENTS

2018 No.

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

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).