
DRAFT STATUTORY INSTRUMENTS

2018 No.

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

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

- 9.—(1) The Act is amended as follows.
- (2) In section 14 (remit of Human Tissue Authority)—
- (a) in subsection (1)(h)—
- (i) omit the word “preservation,”; and
- (ii) after the words “regulations 7(1)” insert “, (1A)”; and
- (b) in subsection (2A) after the words “regulation 7(1)” insert “, (1A)”.
- (3) In section 16 (licence requirement)—
- (a) in subsection (2A)(1)—
- (i) omit the words “, preservation” and “intended for human application”; and
- (ii) after the words “regulation 7(1)” insert “, (1A)”; and
- (b) in subsection (2B)(2) after the words “regulation 7(1)” insert “, (1A)”.
- (4) In paragraph 7(2) of Schedule 3 (revocation of licence otherwise than on application)—
- (a) omit “or” at the end of paragraph (f); and
- (b) 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.”.