STATUTORY INSTRUMENTS

2020 No. 1306

The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020

Amendment of regulation 3(5)

7. In regulation 3(5)—

(a) after paragraph (a)(i) insert—

"(ia) in the definition of "a case of emergency" omit "into the United Kingdom";

(ib) in the definition of "importing licence holder" omit "into the United Kingdom";";

(b) in paragraph (a)(ii), for the substituted definition of "third country" substitute—

""third country" means—

(a) in relation to the import of tissues or cells into, or the export of tissues and cells from, Great Britain, a country other than the United Kingdom;

(b) in relation to the import of tissues or cells into Northern Ireland, a country other than Northern Ireland or an EEA state; and

(c) in relation to the export of tissues or cells from Northern Ireland, a country other than the United Kingdom or an EEA state;";

(c) after paragraph (a)(ii) insert—

"(iia) for the definition of "third country premises" substitute—

""third country premises", in relation to Northern Ireland, means premises in a country other than Northern Ireland or an EEA state on or from which a third country supplier procures, tests, processes, stores, distributes or exports tissues or cells that are intended for import into Northern Ireland for human application;";

(iib) for the definition of "third country supplier" substitute—

""third country supplier" means—

(a) in relation to tissues or cells intended for import into Great Britain for human application, a person in a country other than the United Kingdom who has an agreement with an importing licence holder for exporting such tissues or cells to Great Britain; and

(b) in relation to tissues or cells intended for import into Northern Ireland for human application, a person in a country other than Northern Ireland or an EEA state who has an agreement with an importing licence holder for exporting such tissues or cells to Northern Ireland;";";

(d) for paragraph (b) substitute—

"(b) for paragraph (4)(b) substitute—

"(b) any reference in these Regulations to a requirement of any provision of the first, second, third or fourth Directive—

(i) in the application of these Regulations in relation to Great Britain, is to be read as a reference to a requirement which that provision would require to be imposed if the provision formed part of the law of England and Wales or Scotland;

(ii) in the application of these Regulations in relation to Northern Ireland, is to be read as a reference to a requirement which that provision requires to be imposed in relation to the procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application.”.”.