STATUTORY INSTRUMENTS

2018 No. 335

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

Amendment of Part 1 of the Principal Regulations

2.—(1) In regulation 2(3) of the Principal Regulations (extent and application), for "import and export", substitute "import into the United Kingdom and export from the United Kingdom".

(2) In regulation 3 of the Principal Regulations (designation of the competent authority), for "the first, second and third Directives", substitute "the first, second, third and fourth Directives".

(3) Regulation 4 of the Principal Regulations (references to Directives) is amended as follows—

(a) at the end of the definition of "the third Directive", insert "as amended by Commission Directive 2015/565/EU(**1**),"; and

(b) after the definition of "the third Directive", insert—

> ""the fourth Directive" means Commission Directive 2015/566 of 8th April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells.".

(4) Regulation 5 of the Principal Regulations (interpretation of other terms) is amended as follows—

(a) in paragraph (1)—

(i) at the appropriate place, insert—

> ""a case of emergency" means any unforeseen situation in which there is no practical alternative other than to urgently import into the United Kingdom from a third country or to export from the United Kingdom to a third country tissues or cells for immediate application to a known recipient whose health would otherwise be seriously endangered;";
>
> ""distribution" in relation to tissues or cells intended for human application means transportation or delivery to any person in or outside the United Kingdom for human application, and related terms are to be interpreted accordingly;";
>
> ""importing licence holder" means a licence holder who is authorised by that licence to import tissues or cells intended for human application into the United Kingdom from a third country;";
>
> ""third country" means a country which is not an EEA state or Gibraltar;";
>
> ""third country premises" means premises—
>
> (a) in a third country; and
>
> (b) on, or from which, a third country supplier, or a person providing services to a third country supplier, procures, tests, processes, stores, distributes

(**1**) OJEU L093, 09.04.2015, p43.

or exports tissues or cells that are intended for import into the United Kingdom for human application;";

""third country supplier" means a person in a third country who has an agreement with an importing licencing holder for exporting tissues or cells intended for import into the United Kingdom for human application;"; and

(ii) omit the definitions of "export" and "import";

(b) in paragraph (2), for "and Article 2 of the third Directive (definitions)", substitute ", Article 2 of the third Directive and Article 2 of the fourth Directive (definitions)";

(c) in paragraph (4)—

(i) for sub-paragraph (a), substitute—

"(a) a person who, from any premises, controls the provision of services for transporting or delivering tissues or cells to any person in or outside the United Kingdom for human application is to be taken to distribute tissues or cells on those premises; and"; and

(ii) in sub-paragraph (b) for "or third" substitute ", third or fourth".

(5) Regulation 6 of the Principal Regulations (references to third party agreements etc) is amended as follows—

(a) in paragraph (1)(a), for "(other than storage)", substitute "(other than storage or import into the United Kingdom from a third country)"; and

(b) in paragraph (2), in the definition of "relevant third party premises", in sub-paragraph (a)—

(i) omit "or to which a third party imports"; and

(ii) after "exports", insert "from the United Kingdom to a third country".