STATUTORY INSTRUMENTS

2007 No. 1523

The Human Tissue (Quality and Safety for Human Application) Regulations 2007

PART 5

INSPECTION, ENTRY, SEARCH AND SEIZURE

[F1Inspection of documents to be held by an importing licence holder [F2, Northern Ireland]

21A.—(1) This regulation applies where—

(a) qualifying tissues or cells are imported into **[**F3Northern Ireland**]** 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 F4...; and

(c) the competent authority in that state F5... 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.**]**

Textual Amendments

F1 Reg. 21A inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018 (S.I. 2018/335), regs. 1(2)(3), **6(1)**

F2 Words in reg. 21A heading inserted (31.12.2020) by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(15)(a)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 21A(1)(a) substituted (31.12.2020) by The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(15)(b)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Words in reg. 21A(1)(b) omitted (31.12.2020) by virtue of The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(15)(c)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Words in reg. 21A(1)(c) omitted (31.12.2020) by virtue of The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481), regs. 1, **3(15)(d)** (as substituted by S.I. 2020/1306, regs. 1, **19**); 2020 c. 1, **Sch. 5 para. 1(1)**

Changes to legislation:
There are currently no known outstanding effects for the The Human Tissue (Quality and Safety for Human Application) Regulations 2007, Section 21A.