STATUTORY INSTRUMENTS

2007 No. 1523

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

PART 4

OBLIGATIONS OF THE AUTHORITY

[F1Duties of the Authority in relation to application of the Single European Code [F2in relation to Northern Ireland]

20A.—(1) **[**F3In relation to Northern Ireland, the Authority**]** must allocate to each licence holder one or more unique numbers to be the tissue establishment number or numbers in relation to that licence holder in accordance with Annex VII and paragraph 2(a) of Article 10b of the third Directive.

(2) Any number allocated under paragraph (1) must be in the format specified in Annex VII to the third Directive.

[F4(3) In relation to Northern Ireland, the Authority must take steps to enable the information specified in Annex VIII to be recorded in the EU Tissue Establishment Compendium in relation to each licence holder.**]**

F5(4) . . . . . .

[F6(5) The Authority must take the steps mentioned in paragraph (3) to enable the information mentioned in that paragraph to be recorded before the end of the period of 10 working days beginning with the day on which the person becomes a licence holder.**]**

(6) Paragraph (7) applies if the Authority becomes aware that any information recorded under paragraph (3) was incorrectly recorded or requires updating.

(7) **[**F7Where this paragraph applies, the Authority must take steps to enable the information to be corrected or updated—**]**

(a) in the case of a correction or update that the Authority considers to be a significant change to the information recorded under paragraph (3), before the end of the period of 10 working days beginning with the day on which the Authority became aware that the information was incorrectly recorded or required updating;

(b) in any other case, as soon as is reasonably practicable.

(8) Paragraph (9) applies if the Authority becomes aware that—

(a) any information recorded in the EU Tissue Establishment Compendium in respect of a tissue establishment in a relevant state was incorrectly recorded or requires updating; or

(b) a tissue establishment in a relevant state has not complied with the requirements of the laws or other measures adopted in that state for the purpose of implementing paragraph 1 of Article 10b of the third Directive and the non-compliance is significant.

(9) Where this paragraph applies, the Authority must inform the competent authority in the relevant state in question of the information to be corrected or updated or the non-compliance in question.

(10) If the Authority becomes aware that the information recorded in the EU Tissue and Cell Product Compendium requires updating, it must inform the European Commission and the competent authority in the relevant state.

(11) In this regulation—

[[F8]"relevant state" means an EEA state;**]**

"working day" means any day other than—

(a) a Saturday or Sunday;

(b) Christmas Day or Good Friday; or

(c) a day which is a bank holiday under the Banking and Financial Dealings Act 1971 in any part of the United Kingdom.**]**

Textual Amendments

F1 Regs. 20A-20C 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), **5(2)**

F2 Words in reg. 20A 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(12)(a)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F3 Words in reg. 20A(1) 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(12)(b)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F4 Reg. 20A(3) 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(12)(c)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F5 Reg. 20A(4) 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(12)(d)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F6 Reg. 20A(5) 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(12)(e)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F7 Words in reg. 20A(7) 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(12)(f)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 2020 c. 1, **Sch. 5 para. 1(1)**

F8 Words in reg. 20A(11) 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(12)(g)** (as substituted by S.I. 2020/1306, regs. 1, **16**); 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 20A.