



Human Fertilisation and Embryology Act 1990

1990 CHAPTER 37

The Human Fertilisation and Embryology Authority, its functions and procedure

[^{F1}8ZB [^{F2}Duties of the Authority in relation to the Single European Code: Northern Ireland]

- (1) The Authority [^{F3}in relation to Northern Ireland,] must allocate to each holder of a relevant licence, one or more unique numbers as 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 subsection (1) must be in the format specified in Annex VII.
- [^{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 holder of a relevant licence.]
- ^{F5}(4)
- [^{F6}(5) The Authority must take the steps mentioned in subsection (3) to enable the information mentioned in that subsection to be recorded before the end of the period of 10 working days beginning with the day on which the person becomes the holder of a relevant licence.]
- (6) Subsection (7) applies if the Authority becomes aware that any information recorded under subsection (3) was incorrectly recorded or requires updating.
- (7) [^{F7}The Authority must take steps to enable the information to be corrected or updated] —
 - (a) in the case of a correction or update which the Authority considers to be a significant change to the information recorded under subsection (3), before the end of the period of 10 working days beginning with the day on which

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- 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) Subsection (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) The Authority must inform the competent authority in the relevant state 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 section—
- “Annex VII” means Annex VII to the third Directive,
 - “Annex VIII” means Annex VIII to the third Directive,
 - “EU Tissue and Cell Product Compendium” and “EU Tissue Establishment Compendium” have the same meaning as in Article 2 of the third Directive,
 - “relevant licence” means a licence granted under any of the following provisions of Schedule 2—
 - (a) paragraph 1,
 - (b) paragraph 1A,
 - (c) paragraph 2, so far as authorising the storage of gametes or embryos intended for human application,
 - (d) paragraph 3, so far as authorising activities in connection with the derivation from embryos of stem cells that are intended for human application,
 - [^{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** S. 8ZB inserted (6.3.2018 for specified purposes, 1.4.2018 in so far as not already in force) by [The Human Fertilisation and Embryology \(Amendment\) Regulations 2018 \(S.I. 2018/334\)](#), regs. 1(3), [4\(1\)](#)
- F2** S. 8ZB heading substituted (31.12.2020) by [S.I. 2019/482](#), [reg. 2\(6\)\(a\)](#) (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, [7](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))
- F3** Words in s. 8ZB(1) inserted (31.12.2020) by [S.I. 2019/482](#), [reg. 2\(6\)\(b\)](#) (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020 \(S.I. 2020/1307\)](#), regs. 1, [7](#)); 2020 c. 1, [Sch. 5 para. 1\(1\)](#))

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- F4** S. 8ZB(3) substituted (31.12.2020) by S.I. 2019/482, **reg. 2(6)(c)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1307), regs. 1, 7); 2020 c. 1, **Sch. 5 para. 1(1)**
- F5** S. 8ZB(4) omitted (31.12.2020) by S.I. 2019/482, **reg. 2(6)(d)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1307), regs. 1, 7); 2020 c. 1, **Sch. 5 para. 1(1)**
- F6** S. 8ZB(5) substituted (31.12.2020) by S.I. 2019/482, **reg. 2(6)(e)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1307), regs. 1, 7); 2020 c. 1, **Sch. 5 para. 1(1)**
- F7** Words in s. 8ZB(7) substituted (31.12.2020) by S.I. 2019/482, **reg. 2(6)(f)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1307), regs. 1, 7); 2020 c. 1, **Sch. 5 para. 1(1)**
- F8** Words in s. 8ZB(11) substituted (31.12.2020) by S.I. 2019/482, **reg. 2(6)(g)** (as substituted by [The Human Fertilisation and Embryology \(Amendment\) \(EU Exit\) Regulations 2020](#) (S.I. 2020/1307), regs. 1, 7); 2020 c. 1, **Sch. 5 para. 1(1)**

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