STATUTORY INSTRUMENTS

2020 No. 1306

EXITING THE EUROPEAN UNION

HUMAN TISSUE

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

Made - - - - 18th November 2020

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by sections 8(1) and 8C of the European Union (Withdrawal) Act 2018(**a**) and section 41(1) of the European Union (Withdrawal Agreement) Act 2020(**b**).

A draft of this instrument has been approved by a resolution of each House of Parliament, in accordance with paragraphs 1 and 8F(**c**) of Schedule 7 to the European Union (Withdrawal) Act 2018.

Citation and commencement

1. These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2020 and come into force immediately before IP completion day.

Amendment of the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019

2. The Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019(**d**) are amended as follows.

(**a**) 2018 c. 16. The European Union (Withdrawal) Act 2018 was amended by the European Union (Withdrawal Agreement) Act 2020 (c. 1); section 8C was inserted by section 21 of that Act.
(**b**) 2020 c. 1.
(**c**) Paragraph 8F was inserted by paragraph 51 of Schedule 5 to the 2020 Act.
(**d**) S.I. 2019/481.

Insertion of regulation 3(1A)

3. After regulation 3(1) insert—

"(1A) In regulation 2(3)(**a**) (extent and application), for "import into the United Kingdom" substitute "import from third countries".".

Substitution of regulation 3(2)

4. For regulation 3(2) substitute—

"(2) In regulation 3 (designation of the competent authority), after "is designated" insert ", in relation to Northern Ireland,".".

Substitution of regulation 3(3)

5. For regulation 3(3) substitute—

"(3) In regulation 4 (references to Directives), in the definition of "the third Directive", for the words from "tissues and cells" to the end substitute—

"tissues and cells—

(a) in relation to Great Britain, as it had effect immediately before 29th April 2015 (the date on which the amendments made by Commission Directive 2015/565/EU came into force); and

(b) in relation to Northern Ireland, as amended by Commission Directive 2015/565/EU;".".

Amendment of regulation 3(4)

6. In regulation 3(4)—

(a) in regulation 4A as inserted by that provision (modifications to the first, second, third and fourth Directives: general), after "these Regulations," insert "as they apply in relation to Great Britain,";

(b) in regulation 4B as inserted by that provision (modifications to the first Directive)—

(i) for paragraph (2) substitute—

"(2) Article 8 is to be read as if—

(a) in paragraph 1, the reference to Member States were a reference to the Authority;

(b) in paragraph 1, for "on their territory" there were substituted "in Great Britain";

(c) paragraphs 2, 3, 5 and 6 were omitted.";

(ii) for paragraph (4)(b) substitute—

"(b) in paragraph 2, for "they" there were substituted "the Authority";";

(c) in regulation 4E as inserted by that provision (modifications to the fourth Directive)—

(i) in paragraph (3), for "the United Kingdom" substitute "Great Britain";

(ii) in paragraph (5), before sub-paragraph (a), insert—

"(za) in paragraph 1, the reference to the competent authority or authorities were a reference to the Authority;";

(iii) in paragraph (6)(a)(i), for "the United Kingdom" substitute "Great Britain".

(**a**) S.I. 2007/1523. Relevant amendments were made by S.I. 2018/335; there are other amending instruments but none is relevant.

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.".".

Insertion of regulation 3(5A)

8. After paragraph 3(5) insert—

"(5A) In regulation 6(1)(a) (references to third party agreements etc) omit "into the United Kingdom".".

Substitution of regulation 3(6)

9. For regulation 3(6) substitute—

"(6) In regulation 7 (licensing requirement)—

(a) in paragraph (1A), omit "into the United Kingdom";

(b) for paragraph (4) substitute—

"(4) The Authority may authorise any person to distribute, import from a third country or export to a third country tissues or cells directly from where the procurement takes place to an organisation responsible for human application for immediate human application where that authorisation relates to tissues or cells specified by the Authority.";

(c) in paragraph (5) omit "into the United Kingdom".".

Substitution of regulation 3(7)

10. For regulation 3(7) substitute—

"(7) In regulation 7A (import from the EEA and Gibraltar)—

(a) for the heading substitute "Import into Northern Ireland from the EEA";

(b) in paragraph (1), in the words before sub-paragraph (a)—

(i) for "the United Kingdom" substitute "Northern Ireland";

(ii) omit "or Gibraltar";

(c) in sub-paragraph (a) omit ", other than the United Kingdom, or in Gibraltar";

(d) in sub-paragraph (b)(i) omit "other than the United Kingdom or in Gibraltar";

(e) in sub-paragraph (b)(ii) omit ", other than the United Kingdom, or in Gibraltar".".

Omission of regulation 3(8)

11. Omit regulation 3(8).

Substitution of regulation 3(9)

12. For regulation 3(9) substitute—

"(9) In regulation 11 (preconditions to grant of licence)—

(a) for paragraph (4B)(c), and the "and" immediately preceding it, substitute—

"(c) in relation to Great Britain, the applicant has provided the Authority with any information or documents as may be specified by the Authority for the purposes of demonstrating—

(i) traceability; and

(ii) that the import is a one-off import within the meaning of paragraph (4C); and

(d) in relation to Northern Ireland, the applicant has provided the Authority with any information or documents as may be specified by the Authority for the purposes of securing compliance with the requirements of Articles 5(2) and 7(1) of the fourth Directive (requirements in relation to one off imports).";

(b) in paragraph (4C)(b) omit "into the United Kingdom".".

Amendment of regulation 3(10)

13. In regulation 3(10)—

(a) for paragraph (a) substitute—

"(a) for the heading substitute "Directions: Great Britain";";

(b) in paragraph (b), after "these Regulations" insert ", as they apply in relation to Great Britain".

Insertion of regulation 3(10A)

14. After regulation 3(10) insert—

"(10A) After regulation 16 (directions: Great Britain) insert—

"Directions: compliance with first, second, third and fourth Directives as they apply in relation to Northern Ireland

16A.—(1) In relation to Northern Ireland, the Authority shall give directions to licence holders or designated individuals under section 23(1) of the 2004 Act, as applied by regulation 8, in accordance with Schedule 2 for the purpose of securing compliance with the requirements of the first, second, third and fourth Directives.

(2) In relation to Northern Ireland, the Authority shall give such other directions to licence holders or designated individuals under section 23(1) of that Act, as applied by regulation 8, as it considers necessary for securing compliance by licence holders and third parties with any requirements of the first, second, third and fourth Directives.".".

Amendment of regulation 3(11)

15. In regulation 3(11)—

(a) for paragraph (a) substitute—

"(a) in paragraph (1)—

(i) for sub-paragraph (a) substitute—

"(a) any person in the United Kingdom carrying-on procurement, testing, processing, storage, distribution, import or export of tissue or cells intended for human application,";

(ii) for sub-paragraphs (c) and (d) (but not the words following sub-paragraph (d)), substitute—

"(c) in relation to Northern Ireland, the competent authorities in EEA states; and

(d) in relation to Northern Ireland, the European Commission,";";

(b) for paragraph (b) substitute—

"(b) for paragraph (3) substitute—

"(3) In relation to Northern Ireland, the duty under paragraph (2) includes a duty to investigate any serious adverse event or serious adverse reaction which has occurred in Northern Ireland, and to carry out appropriate control measures, at the request of a competent authority in an EEA state.".".

Substitution of regulation 3(12)

16. For regulation 3(12) substitute—

"(12) In regulation 20A (duties of the Authority in relation to application of the Single European Code)—

(a) in the heading, after "the Single European Code" insert "in relation to Northern Ireland";

(b) in paragraph (1), for "The Authority" substitute "In relation to Northern Ireland, the Authority";

(c) for paragraph (3) substitute—

"(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.";

(d) omit paragraph (4);

(e) for paragraph (5) substitute—

"(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.";

(f) in paragraph (7), for the words before sub-paragraph (a) substitute—

"Where this paragraph applies, the Authority must take steps to enable the information to be corrected or updated—";

(g) in paragraph (11), for the definition of "relevant state", substitute—

""relevant state" means an EEA state;".".

Substitution of regulation 3(13)

17. For regulation 3(13) substitute—

"(13) In regulation 20B (inspection of third country premises etc.)—

(a) in the heading, at the end insert ", Northern Ireland";

(b) in paragraph (1)(a), for "the United Kingdom" substitute "Northern Ireland";

(c) in paragraph (1)(b) omit ", other than the United Kingdom, or in Gibraltar";

(d) in paragraph (1)(c) omit "or in Gibraltar";

(e) in paragraph (4), for "the United Kingdom" substitute "Northern Ireland".".

Substitution of regulation 3(14)

18. For regulation 3(14) substitute—

"(14) In regulation 20C (third country premises and third country suppliers: report of inspections etc.)—

(a) in the heading, at the end insert ", Northern Ireland";

(b) in paragraph (1)—

(i) after "This regulation applies" insert "in relation to Northern Ireland";

(ii) omit ", other than the United Kingdom, or in Gibraltar".".

Substitution of regulation 3(15)

19. For regulation 3(15) substitute—

"(15) In regulation 21A (inspection of documents to be held by an importing licence holder)—

(a) in the heading, at the end insert ", Northern Ireland";

(b) in paragraph (1)(a), for "the United Kingdom" substitute "Northern Ireland";

(c) in paragraph (1)(b) omit ", other than the United Kingdom, or in Gibraltar";

(d) in paragraph (1)(c) omit "or in Gibraltar".".

Substitution of regulation 3(16)

20. For regulation 3(16) substitute—

"(16) In regulation 22A (importing licence holders: requests for inspections)—

(a) in the heading, at the end insert ", Northern Ireland";

(b) in paragraph (1)(a), for "the United Kingdom" substitute "Northern Ireland";

(c) in paragraph (1)(b) omit ", other than the United Kingdom, or in Gibraltar";

(d) in paragraph (1)(c) omit "or in Gibraltar".".

Substitution of regulation 3(17)

21. For regulation 3(17) substitute—

"(17) In regulation 27 (requirements when exercising power of inspection or search), for the words before paragraph (4)(a) substitute—

"In relation to Northern Ireland, paragraph (5) applies if the European Commission or a competent authority in an EEA state requires the Authority to provide it with a copy of a report or information on—".".

Omission of regulation 3(18)

22. Omit regulation 3(18).

Amendment of regulation 3(19)

23. In regulation 3(19)—

(a) in regulation 34ZA as inserted by that regulation—

(i) in the heading, at the end insert ", Great Britain";

(ii) for paragraph (6) substitute—

"(6) In this regulation "appropriate authority" means—

(a) in relation to England, the Secretary of State;

(b) in relation to Wales—

(i) the Welsh Ministers; or

(ii) the Secretary of State acting with the consent of the Welsh Ministers;

(c) in relation to Scotland—

(i) the Scottish Ministers; or

(ii) the Secretary of State acting with the consent of the Scottish Ministers;

(d) for the whole of Great Britain, the Secretary of State acting with the consent of the Welsh Ministers and the Scottish Ministers.";

(b) in regulation 34ZB as inserted by that regulation omit paragraph (3);

(c) in regulation 34ZC as inserted by that regulation omit paragraph (4).

Substitution of regulation 3(20)

24. For regulation 3(20) substitute—

"(20) In Schedule 1 (licences), in paragraph 5A for "certificate" to the end substitute—

"certificate—

(a) of authority in relation to Great Britain, in such form as the Authority considers appropriate,

(b) in relation to Northern Ireland, in the form set out in Annex II to the fourth Directive.".".

Amendment of regulation 3(21)

25. In regulation 3(21)—

(a) in sub-paragraph (a), in paragraph 1 as substituted by that provision, for "Directions" substitute "In relation to Great Britain, directions";

(b) after sub-paragraph (a) insert—

"(aa) after paragraph 1 insert—

"**1ZA.** In relation to Northern Ireland, directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure—

(a) in relation to traceability, compliance with the requirements of Article 8 (traceability) of the first Directive and Article 9 (traceability) of the third Directive, and

(b) in relation to the coding of information, compliance with—

(i) the requirements of paragraph 1 of Article 25 of the first Directive (coding of information);

(ii) the requirements of paragraph 1 of Article 10 of the third Directive (European coding system), subject to any exemption specified in the directions in accordance with paragraph 3 of that Article;

(iii) the requirements of Article 10a of the third Directive (format of the Single European Code); and

(iv) the requirements of paragraph 1(a) to (f) and (h) of Article 10b of the third Directive (requirements related to the application of the Single European Code).";";

(c) for sub-paragraph (b) substitute—

"(b) in paragraph 1A, for "Directions" substitute "In relation to Northern Ireland, directions";";

(d) for sub-paragraph (c) substitute—

"(c) in paragraph 4—

(i) for "Directions shall" substitute "In relation to Great Britain, directions shall";

(ii) for the words from "are necessary" to the end substitute "as the Authority considers appropriate;";

(e) after sub-paragraph (c) insert—

"(ca) after paragraph 4 insert—

"**4ZA.** In relation to Northern Ireland, directions shall require licence holders to adopt such—

(a) systems to report, investigate, register and transmit information about serious adverse events and serious adverse reactions, and

(b) accurate, rapid and verifiable procedures for recalling from distribution any product which may be related to a serious adverse event or serious adverse reaction,

as are necessary to secure compliance with the requirements of Article 11 (notification of serious adverse events and reactions) of the first Directive and Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.";";

(f) for paragraph (d) substitute—

"(d) in paragraph 7—

(i) in the words before sub-paragraph (a), for "Directions shall" substitute "In relation to Great Britain, directions shall";

(ii) in sub-paragraph (b), for "the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive" substitute "the requirements of these Regulations in relation to notification of serious adverse reactions and notification of serious adverse events.";";

(g) after paragraph (d) insert—

"(e) after paragraph 7 insert—

"**7A.** In relation to Northern Ireland, directions shall be given—

(a) for the purpose of securing that procurement organisations comply with the requirements of the Annex to the first Directive (information to be provided on the donation of tissue or cells), and

(b) for the purpose of securing that procurement organisations and organisations responsible for human application of tissue or cells comply with the requirements of Article 5 (notification of serious adverse reactions) and Article 6 (notification of serious adverse events) of the third Directive.";

(f) in paragraph 15(5), in the definition of "qualifying import", omit "into the United Kingdom".".

Amendment of regulation 4

26. In regulation 4(1)—

(a) in the words before sub-paragraph (a), for "exit day" substitute "IP completion day";

(b) in sub-paragraphs (a) and (b), for "the United Kingdom" substitute "Great Britain".

Edward Argar
Minister of State,
18th November 2020 Department of Health and Social Care

EXPLANATORY NOTE

(This note is not part of the Regulations)

These Regulations are made in exercise of the powers in sections 8(1) and 8C of the European Union (Withdrawal) Act 2018 (c.16) in order to address failures of retained EU law to operate effectively and other deficiencies (in particular under sections 8(2)(a), (b), (c), (f) and (g) of that Act) arising from the withdrawal of the United Kingdom from the European Union, and in order to give effect to the Protocol on Ireland/Northern Ireland in the withdrawal agreement, respectively.

They amend the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 (S.I. 2019/481) so as to enable the provision amended by those Regulations to continue to operate effectively in light of the Ireland/Northern Ireland Protocol following IP completion day.

An impact assessment has not been produced for this instrument as no, or no significant, impact on the private or voluntary sector is foreseen.

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