Draft Regulations laid before Parliament under paragraph 1(1) of Schedule 7 to the European Union (Withdrawal) Act 2018, for approval by resolution of each House of Parliament.

DRAFT STATUTORY INSTRUMENTS

2019 No. XXX

EXITING THE EUROPEAN UNION
HUMAN TISSUE

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

Made - - - - ***

Coming into force in accordance with regulation 1

The Secretary of State makes these Regulations in exercise of the powers conferred by section 8(1) of, and paragraph 21(b) of Schedule 7 to, the European Union (Withdrawal) Act 2018(**1**).

In accordance with paragraph 1(1) of Schedule 7 to that Act, a draft of this instrument has been laid before Parliament and approved by a resolution of each House of Parliament.

PART 1

Introduction

Citation and commencement

1. These Regulations may be cited as the Human Tissue (Quality and Safety for Human Application) (Amendment) (EU Exit) Regulations 2019 and come into force on exit day.

PART 2

Amendment of primary legislation

Amendment of the Human Tissue Act 2004

2.—(1) The Human Tissue Act 2004(**2**) is amended as follows.

(**1**) 2018 c. 16.
(**2**) 2004 c. 30. Section 46 was amended by S.I. 2011/1043; amendments to section 52 are not relevant to these Regulations.

(2) Omit section 46 (power to give effect to EU obligations).

(3) In section 52 (orders and regulations)—

(a) in subsection (3) omit ", 46(1)";

(b) in subsection (4) for ", 33(3) or (7) or 46(1)" substitute "or 33(3) or (7)";

(c) in subsections (8) and (10) omit "section 46(1);".

PART 2

Amendment of subordinate legislation

Amendment of the Human Tissue (Quality and Safety for Human Application) Regulations 2007

3.—(1) The Human Tissue (Quality and Safety for Human Application) Regulations 2007(**3**) are amended as follows.

(2) Omit regulation 3(**4**) (designation of the competent authority).

(3) In regulation 4(**5**) (references to Directives), in the definition of "the third Directive", for "as amended by Commission Directive 2015/565/EU" substitute "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)".

(4) After regulation 4 (references to Directives), insert—

"**Modifications to the first, second, third and fourth Directives: general**

4A. For the purposes of these Regulations, the first, second, third and fourth Directives are to be read subject to the modifications set out in regulations 4B to 4E.

Modifications to the first Directive

4B.—(1) The modifications to the first Directive are as follows.

(2) Article 8 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(ii) for "on their territory" there were substituted "in the United Kingdom";

(iii) paragraphs 2, 3, 5 and 6 were omitted.

(3) Article 10(1) is to be read as if—

(a) for the reference to "the requirements referred to in Article 28(f)" there were substituted "the requirements referred to in paragraph 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) the reference to the competent authority or authorities were a reference to the Authority;

(c) for "an annual report on these activities" there were substituted "a report on these activities upon request";

(**3**) S.I. 2007/1523, amended by S.I. 2018/335; there are other amending instruments but none is relevant.
(**4**) Regulation 3 was amended by S.I. 2018/335.
(**5**) Relevant amendments to regulation 4 were made by S.I. 2018/335.

(d) the words "This report shall be publicly accessible" were omitted.

(4) Article 14 is to be read as if—

(a) in paragraph 1—

(i) the reference to Member States were a reference to the Authority;

(ii) for "within the scope of this Directive" there were substituted "in accordance with the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 2, the reference to Member States were a reference to the Authority;

(c) in paragraph 3—

(i) the first reference to Member States were a reference to the Authority;

(ii) "in Member States" were omitted.

(5) Article 15 is to be read as if paragraphs 1, 2 and 4 were omitted.

(6) Article 19(5) is to be read as if the words ", in accordance with Article 8" were omitted.

(7) Article 20 is to be read as if, in paragraph 1, the reference to Article 28(h) were a reference to the requirements of Annex 2 of the third Directive listed in paragraph 14 of Schedule 2 to these Regulations.

(8) Article 21 is to be read as if—

(a) in paragraph 4, for "laid down in this Directive" there were substituted "of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 5—

(i) the first reference to Member States were a reference to the Authority;

(ii) the reference to a tissue establishment accredited, designated, authorised or licensed in accordance with Article 6 were a reference to a tissue establishment authorised or licensed in accordance with the provisions of the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006(**6**) or these Regulations;

(iii) for the words "Member States' legislation" there were substituted "legislation".

(9) Article 24 is to be read as if—

(a) in paragraph 2, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority.

(10) The Annex is to be read as if—

(a) in paragraph B.1, for "the legislation in force in Member States" there were substituted "the requirements of the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) paragraph B.2 were omitted.

Modifications to the second Directive

4C.—(1) The modifications to the second Directive are as follows.

(**6**) 2006 asp 4.

(2) Article 2 is to be read as if, in paragraph 1, the reference to Member States were a reference to the Authority.

(3) Articles 3, 4 and 5 are to be read as if any reference to the competent authority or authorities were a reference to the Authority.

(4) Annex 1 is to be read as if, in the first paragraph, for "responsible person as defined in Article 17 of Directive 2004/23/EC" there were substituted "designated individual in accordance with regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(5) Annex 2 is to be read as if, in paragraph 2.1 the reference to the competent authority in the Member State were a reference to the Authority.

(6) Annex 3 is to be read as if, in paragraph 3.6, for "in force in Member States" there were substituted "of the Human Tissue (Quality and Safety for Human Application) Regulations 2007".

(7) Annex 4 is to be read as if—

(a) in paragraphs 1.1.1 and 1.2.1, the reference to an authorised person were to—

(i) the designated individual in accordance with regulations 11 and 12 of these Regulations, or

(ii) a person authorised to carry out the specified tasks by—

(aa) the designated individual, or

(bb) the Authority;

(b) in paragraph 1.1.1(a), for "Article 13 of Directive 2004/23/EC" there were substituted "the Human Tissue Act 2004, the Human Tissue (Scotland) Act 2006 or the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph 1.4.4 the reference to the competent authority were a reference to the Authority.

Modifications to the third Directive

4D.—(1) The modifications to the third Directive are as follows.

(2) Annex 1 is to be read as if—

(a) in paragraph A.1—

(i) for "responsible person" there were substituted "designated individual";

(ii) for "as provided in Article 17 of Directive 2004/23/EC there were substituted "in accordance with the requirements of regulations 11(**7**) and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph A.4, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph C.6, for the words from "the requirements of Council" to the end there were substituted "the requirements of the Medical Devices Regulations 2002"(**8**);

(d) in paragraph D.1, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(**7**) Regulation 11 was amended by S.I. 2018/335.
(**8**) S.I. 2002/618.

(e) in paragraph E.1, for "laid down in this Directive" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(f) in paragraph E.8, the reference to the competent authority were a reference to the Authority.

(3) Annex 2 is to be read as if—

(a) in the first paragraph the reference to the competent authority were a reference to the Authority;

(b) in paragraph A, for the words from "the tissues and cells must" to the end there were substituted "tissue establishment procedures must ensure that the licence conditions in paragraph 12 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007 are met";

(c) in paragraph B.3, for the words from "the standards" to the end there were substituted "the requirements of paragraph 13 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(d) in paragraph B.8, the second sentence were omitted;

(e) in paragraph C.2, for "laid down in this Directive" there were substituted "of paragraph 14 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(f) in paragraphs C.4 and C.5, any reference to the responsible person as defined or specified in Article 17 of Directive 2004/23/EC were a reference to the designated individual in accordance with regulations 11 and 12 of these Regulations;

(g) in paragraph D.5, the reference to the competent authority were a reference to the Authority;

(h) in paragraph E.2(h), for "as set out in Articles 5 to 6" there were substituted "in accordance with paragraph 4 of Schedule 2 to the Human Tissue (Quality and Safety for Human Application) Regulations 2007".

Modifications to the fourth Directive

4E.—(1) The modifications to the fourth Directive are as follows.

(2) The Directive is to be read as if references to a third country were references to any country other than the United Kingdom.

(3) Article 2 is to be read as if for "the Union", in each place where it occurs, there were substituted "the United Kingdom".

(4) Article 5(1) is to be read as if—

(a) for "laid down in Directive 2004/23/EC" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) the references to the competent authority or authorities were references to the Authority.

(5) Article 6 is to be read as if—

(a) in paragraph 2—

(i) the reference to the competent authority or authorities were a reference to the Authority;

(ii) the words from "The information laid out" to the end were omitted;

(b) in paragraph 3—

(i) the first reference to the competent authority or authorities were a reference to the Authority;

(ii) the reference to the competent authority or authorities in subparagraph (b) were a reference to the authority in the third country concerned responsible for regulating tissue establishments in that country.

(6) Article 7 is to be read as if—

(a) in paragraph 1—

(i) in the first subparagraph, for "the Union", in each place where it occurs, there were substituted "the United Kingdom";

(ii) for the second subparagraph, there were substituted "This requirement does not apply to one-off imports as defined in regulation 11(4C)(a) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 provided that the requirements in regulation 11(4B) of those regulations are met.";

(b) in paragraph 2, for "laid down in Directive 2004/23/EC" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph 3, the reference to the competent authority or authorities were a reference to the Authority;

(d) in paragraph 4, the reference to the competent authority or authorities were a reference to the Authority.

(7) Article 8(1) is to be read as if the word "annual" were omitted.

(8) Annex 1 is to be read as if—

(a) in paragraph A.4, for "TE compendium code" there were substituted "reference number previously allocated to the tissue establishment by the Authority";

(b) in paragraph B.4, the reference to the Responsible Person were a reference to the designated individual in accordance with regulations 11 and 12 of these Regulations;

(c) in paragraph C.2, the words "(where applicable, in accordance with the EU generic list)" were omitted;

(d) in paragraph F.3, the references to a third country competent authority or authorities were references to the authority in the third country responsible for regulating tissue establishments in that country.

(9) Annex 3 is to be read as if—

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

(b) in paragraph A.1, for "as laid down in Directive 2004/23/EC" there were substituted "in accordance with regulations 11 and 12 of the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(c) in paragraph A.3, the words "applying the Single European Code," were omitted;

(d) in paragraph B.7, the reference to a third country competent authority or authorities were a reference to the authority in the third country responsible for regulating tissue establishments in that country.

(10) Annex 4 is to be read as if—

(a) in paragraph 1, for "laid down in Directive 2004/23/EC" there were substituted "required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007";

(b) in paragraph 4, the reference to a third country competent authority or authorities were a reference to the authority in the third country responsible for regulating tissue establishments in that country;

(c) in paragraph 5, the reference to the competent authority or authorities were a reference to the Authority;

(d) in paragraph 7, for "EU data protection rules" there were substituted "data protection legislation within the meaning of section 3(9) of the Data Protection Act 2018"(**9**);

(e) in paragraph 8, for the words from "requirements" to the end there were substituted "quality and safety standards required by the Human Tissue (Quality and Safety for Human Application) Regulations 2007".".

(5) In regulation 5(**10**) (interpretation of other terms)—

(a) in paragraph (1)—

(i) after the definition of "the 2004 Act" insert—

"the Authority" means the Human Tissue Authority(**11**);";

(ii) for the definition of "third country", substitute—

""third country" means any country other than the United Kingdom;";

(iii) after the definition of "third party agreement" insert—

""tissue establishment" means a tissue bank or a unit of a hospital or another body which procures, tests, processes, preserves, stores or distributes human tissues and cells;";

"traceability" means the ability to—

(a) identify and locate tissues and cells during any step from procurement to use for human application and disposal;

(b) identify the donor and recipient of particular tissues and cells;

(c) identify any person who has carried out any activity in relation to particular tissues and cells; and

(d) identify and locate all relevant data relating to products and materials coming into contact with particular tissues and cells and which can affect their quality and safety.";

(b) for paragraph (4)(b), for the words from "is a reference to" to the end, substitute "is to be read as a reference to a requirement which that provision is expressed as requiring to be imposed (ignoring the fact that the Directives do not form part of domestic law)."

(6) In regulation 7(**12**) (licensing requirement), in paragraph (4) omit "for the purposes of Article 6(5) of the first Directive.".

(7) Omit regulation 7A(**13**) (import from the EEA and Gibraltar).

(8) In regulation 10(**14**) (breach of requirement to hold a licence or to act under a third party agreement)—

(a) omit paragraph (2A);

(b) in paragraph (3) for ", (2) or (2A)" substitute "or (2)".

(**9**) 2018 c.12.
(**10**) Relevant amendments to regulation 5 were made by S.I. 2018/335.
(**11**) The Human Tissue Authority was established by section 13(1) of the Human Tissue Act 2004 c.30.
(**12**) Regulation 7(4) was substituted by S.I. 2018/335.
(**13**) Regulation 7A was inserted by S.I. 2018/335.
(**14**) Regulation 10 was amended by S.I. 2018/335.

(9) In regulation 11(**15**) (preconditions to grant of licence), for subparagraph (c) of paragraph (4B) substitute—

"(c) 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)."

(10) In regulation 16(**16**) (directions: compliance with the first, second, third and fourth Directives)—

(a) in the heading, omit ":compliance with the first, second, third and fourth Directives";

(b) in paragraphs (1) and (2), for "the first, second, third and fourth Directives" substitute "these Regulations";

(c) after paragraph (2), insert—

"(3) In this regulation, the references to securing compliance with these Regulations includes a reference to securing compatibility with the principles set out in Article 12 of the first Directive as modified by section 32(3B) of the 2004 Act.".

(11) In regulation 20(**17**) (duties of the Authority in relation to serious adverse events and reactions)—

(a) in paragraph (1) omit subparagraphs (c) and (d);

(b) omit paragraph (3).

(12) Omit regulation 20A(**18**) (duties of the Authority in relation to application of the Single European Code).

(13) Omit regulation 20B(**19**) (inspection of third country premises etc.).

(14) Omit regulation 20C(**20**) (third country premises and third country suppliers: report of inspections etc.).

(15) Omit regulation 21A(**21**) (inspection of documents to be held by an importing licence holder).

(16) Omit regulation 22A(**22**) (importing licence holders: requests for inspections).

(17) In regulation 27(**23**) (requirements when exercising power of inspection or search) omit paragraphs (4) and (5).

(18) In regulation 28(**24**) (enforcement) in subparagraph (1)(a), omit ", 21A".

(19) Before regulation 34 (but after the heading "General") (offences by bodies corporate) insert—

"**Powers to make regulations in relation to standards of quality and safety**

34ZA.—(1) The appropriate authority may by regulations make provision specifying requirements to be met for the purposes of ensuring traceability.

(**15**) Regulation 11 was amended by S.I. 2018/335.
(**16**) Regulation 16 was amended by S.I. 2018/335.
(**17**) Regulation 20 was amended by S.I. 2018/335.
(**18**) Regulation 20A was inserted by S.I. 2018/335.
(**19**) Regulation 20B was inserted by S.I. 2018/335.
(**20**) Regulation 20C was inserted by S.I. 2018/335.
(**21**) Regulation 21A was inserted by S.I. 2018/335.
(**22**) Regulation 22A was inserted by S.I. 2018/335.
(**23**) Regulation 27 was amended by S.I. 2018/335.
(**24**) Regulation 28(1)(a) was amended by S.I. 2018/335.

(2) The appropriate authority may by regulations make provision in relation to the notification of serious adverse events and reactions (whether to the Authority or such other person as may be specified in the regulations).

(3) The appropriate authority may by regulations make provision specifying requirements to be met for the purposes of verifying that standards of quality and safety equivalent to those required by these Regulations apply in relation to imports by tissue establishments of tissues and cells from third countries.

(4) The appropriate authority may by regulations prescribe technical requirements in relation to the following—

(i) the licensing or authorisation of tissue establishments;

(ii) the procurement of tissues or cells;

(iii) selection criteria for the donor of tissues or cells;

(iv) laboratory tests required for donors;

(v) procedures for the reception of tissues and cells at the tissue establishment;

(vi) the tissue and cell preparation process;

(vii) tissue and cell processing, storage and distribution;

(viii) the direct distribution to the recipient of specific tissues and cells.

(5) The provision that may be made in regulations under paragraphs (1) to (4) includes provision amending regulations 4A to 4E to modify, or further modify, the provisions of the second, third and fourth Directives as they apply by virtue of these Regulations.

(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) in relation to Northern Ireland—

(i) the Department of Health in Northern Ireland; or

(ii) the Secretary of State acting with the consent of that Department;

(e) for the whole of the United Kingdom, the Secretary of State acting with the consent of the Welsh Ministers, the Scottish Ministers and the Department of Health in Northern Ireland.

Scope and nature of powers

34ZB.—(1) Regulations made by the Secretary of State or the Welsh Ministers under regulation 34ZA are to be made by statutory instrument.

(2) For regulations made under regulation 34ZA by the Scottish Ministers, see section 27 of the Interpretation and Legislative Reform (Scotland) Act 2010(**25**) (Scottish statutory instruments).

(**25**) 2010 asp 10.

(3) Any power of the Department of Health in Northern Ireland to make regulations under regulation 34ZA is exercisable by statutory rule for the purposes of the Statutory Rules (Northern Ireland) Order 1979(**26**).

(4) Any power in regulation 34ZA to make regulations includes a power to make—

(a) different provision for different purposes;

(b) consequential, supplementary, incidental, transitional, transitory or saving provision.

Scrutiny of regulations

34ZC.—(1) A statutory instrument containing regulations made by the Secretary of State under regulation 34ZA may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, each House of Parliament.

(2) A statutory instrument containing regulations made by the Welsh Ministers may not be made unless a draft of the instrument has been laid before, and approved by a resolution of, the National Assembly for Wales.

(3) Regulations made by the Scottish Ministers under regulation 34ZA are subject to the affirmative procedure (see section 29 of the Interpretation and Legislative Reform (Scotland) Act 2010).

(4) Regulations made under regulation 34ZA by the Department of Health in Northern Ireland may not be made unless a draft of the regulations has been laid before and approved by resolution of the Northern Ireland Assembly".

(20) In Schedule 1(**27**) (licences) in paragraph 5A for "in the form set out in Annex II to the fourth Directive" substitute "of authority in such form as the Authority considers appropriate".

(21) In Schedule 2(**28**) (directions for securing compliance with the first, second, third and fourth Directives)—

(a) for paragraph 1 substitute—

"**1.** Directions shall require that licence holders adopt such systems as the Authority considers appropriate to secure, in relation to traceability, compliance with the requirements of Article 8 of the first Directive (traceability) and Article 9 of the third Directive (traceability).";

(b) omit paragraph 1A;

(c) in paragraph 4, for the words from "are necessary" to the end substitute "the Authority considers appropriate";

(d) in paragraph 7, in subparagraph (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.".

PART 4

Transitional Provision

4.—(1) For a period of six months beginning with exit day the requirements of the provisions listed in paragraph (2) do not apply to—

(**26**) S.I. 1979/1573 (NI 12).
(**27**) Paragraph 5A of Schedule 1 was inserted by S.I. 2018/335.
(**28**) Schedule 2 was amended by S.I. 2018/335.

(a) an import of tissues or cells into the United Kingdom from an EEA state or Gibraltar;

(b) an export of tissues or cells from the United Kingdom into an EEA state or Gibraltar,

provided that the Authority is satisfied that the import or, as the case may be, export meets the requirements of traceability and standards of quality and safety equivalent to those laid down in the Regulations.

(2) The provisions referred to in paragraph (1) are—

(a) regulation 11(4A) to (4C) of the Regulations.

(b) Schedule 2 to the Regulations.

(3) In this regulation—

(a) "the Regulations" means the Human Tissue (Quality and Safety for Human Application) Regulations 2007; and

(b) the terms "the Authority", "cells", "tissue" and "traceability" have the same meanings as they have in the Regulations.

Signed by authority of the Secretary of State for Health and Social Care.

Name
Address — Parliamentary Under-Secretary of State,
Date — 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 conferred by section 8(1) 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 section 8(2)(a), (b), (c), (f) and (g)) arising from the withdrawal of the United Kingdom from the European Union.

These Regulations make amendments to legislation concerning human tissue and cells intended for use in human application, including stem cells and cell lines grown outside the body. These Regulations do not apply to reproductive cells, embryos grown outside the human body, organs and blood. In particular, they amend legislation relating to technical requirements for the storage, procurement, testing, processing or distribution of tissues and cells into, and their export from, the United Kingdom. Part 2 amends primary legislation. Part 3 amends subordinate legislation and Part 4 makes transitional provision.

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