Transposition Note for Commission Directive (EU) 2015/565 and Directive (EU) 2015/566

This transposition note outlines how the Commission Directives 2015/565/EU and 2015/566/EU are transposed by virtue of two sets of Regulations – The Human Fertilisation and Embryology (Amendment) Regulations 2018 and The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018.

The Human Fertilisation and Embryology (Amendment) Regulations 2018 amend the Human Fertilisation and Embryology Act 1990 ("the 1990 Act"), so far as is necessary to fully implement Commission Directives 2015/565/EU and 2015/566/EU in relation to human reproductive cells ("gametes" i.e. sperm and eggs) and embryos.

The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018 amend the Human Tissue (Quality and Safety for Human Application) Regulations 2007 as regards certain technical requirements for the coding and import of human tissues and cells excluding those in relation to human reproductive cells and embryos.

CODING AND IMPORTATION OF HUMAN TISSUES AND CELLS (EXCLUDING HUMAN REPRODUCTIVE CELLS) INTENDED FOR HUMAN APPLICATION – TRANSPOSITION TABLES

Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

Article	Paragraph	Provision	Transposed by
1	1	Commission Directive 2006/86/EC (1) is hereby amended as follows: In Article 2, the following points (k) to (y) are added: '(k) "Single European Code" or "SEC" means the unique identifier applied to tissues and cells distributed in the Union. The Single European Code consists of a donation identification sequence and a product identification sequence, as further specified in Annex VII to this Directive; (l) "donation identification sequence" means the first part of the Single European Code consisting of the EU tissue establishment code and the unique donation number; (m) "EU tissue establishment code" means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the Union. The tissue establishment code consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium, as further specified in Annex VII to this Directive; (n) "unique donation number" means the unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to this Directive; (o) "product identification sequence" means the second part of the Single European Code consisting of the product code, the split number and the expiry date; (p) "product code" means the identifier for the specific type of	Regulation 2(3)(a) of the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018 ("the 2018 Regulations"), which amends the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ("the 2007 Regulations") to refer to the third Directive as amended by Commission Directive 2015/565/EU.

			tissue and cell in question. The product code consists of the product coding system identifier indicating the coding system used by the tissue establishment (“E” for the EUTC, “A” for ISBT128, “B” for Eurocode) and the tissues and cells product number foreseen in the respective coding system for the product type, as further defined in Annex VII to this Directive; (q) “split number” means the number which distinguishes and uniquely identifies tissues and cells having the same unique donation number and the same product code and originating from the same tissue establishment, as further defined in Annex VII to this Directive; (r) “expiry date” means the date by which the tissues and cells can be applied, as further defined in Annex VII to this Directive; (s) “EU Coding Platform” means the IT platform hosted by the Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium; (t) “EU Tissue Establishment Compendium” means the register of all tissue establishments which are authorised, licensed, designated or accredited by the Member States' competent authority or authorities and which contains the information about these tissue establishments as set out in Annex VIII to this Directive; (u) “EU Tissue and Cell Product Compendium” means the register of all types of tissues and cells circulating in the Union and the respective product codes under the three permitted coding systems (EUTC, ISBT128 and Eurocode); (v) “EUTC” means the product coding system for tissues and cells developed by the Union consisting of a register of all types of tissues and cells circulating in the Union and their corresponding product codes. (w) “released for circulation” means distribution for human application or transfer to another operator, e.g. for further processing with or without	

		return. (x) "within the same centre" means that all steps from procurement to human application are carried out under the same responsible person, quality management system and traceability system, within a healthcare centre comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location; (y) "pooling" means the physical contact or mixing in a single container, of tissues or cells from more than one procurement from the same donor, or from two or more donors.' (1)Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32).	
	2	Article 9 is replaced by the following: *'Article 9* **Traceability** 1.Member States shall ensure that tissues and cells shall be traceable in particular through documentation and the use of the Single European Code from procurement to human application or disposal and vice versa. Tissues and cells used for advanced therapy medicinal products shall be traceable under this Directive at least until transferred to the ATMP manufacturer. 2. Member States shall ensure that tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, using an appropriate and readable storage medium. 3. In case of tissues and cells retrieved from a deceased donor by procurement teams operating for two or more tissue establishments, Member States shall ensure an appropriate traceability system across the procurements.'	Regulation 2(3)(a) of the 2018 Regulations which amends the 2007 Regulations 2007 to refer to the third Directive as amended by Commission Directive 2015/565/EU. Regulation 2(4) of the 2018 Regulations which amends paragraph 2 of Schedule 2 to the 2007 Regulations (directions given by Human Tissue Authority (HTA) relating to traceability).
	3	(3) Article 10 is replaced by the following: *'Article 10* **European coding system** 1.Without prejudice to paragraphs 2 or 3 of	Regulation 2(3)(a) of the 2018 Regulations which amends the 2007 Regulations to refer to the third Directive as amended by Commission

		this Article, a Single European Code shall be applied to all tissues and cells distributed for human application. For the other situations where tissues and cells are released for circulation, as a minimum the donation identification sequence shall be applied at least in the accompanying documentation. 9.4.2015 L 93/45 Official Journal of the European Union EN 2.Paragraph 1 shall not apply to: (a) reproductive cells from partner donation; (b) tissues and cells distributed directly for immediate transplantation to the recipient, as referred to in Article 6(5) of Directive 2004/23/EC; (c) tissues and cells imported into the Union in case of emergency authorised directly by the competent authority or authorities, as referred to in Article 9(3)b of Directive 2004/23/EC. 3.Member States may also allow exemptions from the requirement provided for in paragraph 1 for: (a) tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre; (b) tissues and cells that are imported into the Union, when these tissues and cells remain within the same centre from importation to application, provided that the centre comprises a tissue establishment authorised, designated, accredited, or licensed to carry out importing activities.'	Directive 2015/565/EU and Article 10 is transposed by the requirement for HTA to give directions under paragraph 1(b) of Schedule 2 to the 2007 Regulations as amended by regulation 8(1)(b) of the 2018 Regulations.
	4	(4) The following Articles are inserted: *'Article 10a* **Format of the Single European Code** 1.The Single European Code referred to in Article 10(1) shall comply with the specifications set out in this Article and in Annex VII. 2.The Single European Code shall be in eye-readable format and shall be preceded by the acronym "SEC". The parallel use of other labelling and traceability systems is possible. 3.The Single European Code shall be printed with the Donation Identification Sequence and Product Identification Sequence separated by a single space or as two successive lines.	Regulation 8(1)(b) to the 2018 Regulations which amends paragraph 1(b) of Schedule 2 to the 2007 Regulations (requirement for HTA to give directions to licence holders regarding the Single European Code (SEC)).
	4, cont.	*Article 10b*	Regulation 8(1)(b) to the

		Requirements related to the application of the Single European Code 1.Member States shall ensure that the following minimum requirements are complied with by tissue establishments, including importing tissue establishments as defined by Commission Directive (EU) 2015/566 (*): (a) allocate a Single European Code to all tissues and cells requiring application of this code at the latest before their distribution for human application; (b) allocate a donation identification sequence after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells from a third country supplier. The donation identification sequence shall include: (1) their EU tissue establishment code as assigned in the EU Tissue Establishment Compendium; (2) a unique donation number allocated by the tissue establishment, unless such number is allocated centrally at national level or is a globally unique number as used by the ISBT128 coding system. Where allowed, in case of pooling of tissues and cells, a new donation identification number shall be allocated to the final product; traceability with the individual donations shall be ensured by the tissue establishment in which pooling is carried out; (c) do not alter the donation identification sequence once it is allocated to tissues and cells released for circulation, unless it is necessary to correct an encoding error; any correction requires proper documentation; (d) use one of the permitted product coding systems and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human	2018 Regulations which amends paragraph 1(b) to Schedule 2 to the 2007 Regulations (requirement for HTA to give directions to licence holders regarding the SEC).

		application; (e) use an appropriate split number and expiry date. For tissues and cells for which no expiry date is defined, the expiry date shall be 00000000 at the latest before their distribution for human application; (f) apply the Single European Code on the label of the product concerned in an indelible and permanent manner and mention that code in the relevant accompanying documentation at the latest before its distribution for human application. The tissue establishment may entrust this task to a third party or third parties, provided the tissue establishment ensures compliance with this Directive, in particular in terms of uniqueness of the code. Where the label size precludes the application of the Single European Code on the label, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation; (g) notify the competent authority or authorities when: (1) information contained in the EU Tissue Establishment Compendium requires an update or correction; (2) the EU Tissue and Cell Product Compendium requires an update; (3) the tissue establishment observes a situation of significant non-compliance with the requirements relating to the Single European Code concerning tissues and cells received from other EU tissue establishments; (h) take the necessary measures in case of incorrect application of the Single European Code on the label.	
		2. Member States shall ensure that the following minimum requirements are applied by all competent authorities: (a) ensure the allocation of a unique tissue establishment number to all tissue establishments authorised, accredited, designated or licensed in its Member State. If a tissue establishment has different physical	Regulation 20A (duties of HTA in relation to application of the SEC), inserted into the 2007 Regulations by regulation 5(2) of the 2018 Regulations.

		locations, but has one system for allocating unique donation numbers, it may be deemed to be one and the same tissue establishment. If a tissue establishment uses two or more systems to allocate unique donation numbers, such an entity shall be allocated separate tissue establishment numbers corresponding to the number of allocation systems used; (b) decide which system or systems shall be used for the allocation of unique donation numbers in their Member State. Permitted systems of allocation include national systems establishing centralised allocation of the nationally unique donation number or systems requiring each tissue establishment to allocate unique donation numbers or international systems that allocate globally unique donation numbers that are compatible with the Single European Code. (c) monitor and enforce the full implementation of the Single European Code in their Member State; (d) ensure the validation of the data on the tissue establishments contained in the EU Tissue Establishment Compendium for their Member State and update the Compendium without undue delay in particular in the following situations: (1) when a new tissue establishment is authorised, designated, accredited, or licensed; (2) when tissue establishment information changes or is not correctly recorded in the EU Tissue Establishment Compendium; (3) when the accreditation, designation, authorisation or licence details of a tissue establishment, as listed in Annex VIII to this Directive, change, including: — accreditation, designation, authorisation or licence for a new tissue or cell type, — accreditation, designation,	

			authorisation or licence for a new prescribed activity, — details of any conditions and or exemptions added to an authorisation, — suspension, in part or in full, of a specific accreditation, designation, authorisation or licence for a particular activity or tissue or cell type; — revocation, in part or in full, of an accreditation, designation, authorisation or licence for a tissue establishment, — situations when a tissue establishment voluntarily ceases, in part or in full, the activity or activities for which it is authorised, accredited, designated or licensed. Without undue delay means in not later than 10 working days for any changes substantially affecting the authorisation, accreditation, designation or licence of the tissue establishments concerned. When a tissue establishment is authorised by two or more competent authorities for different types of tissues and cells or different activities, each competent authority shall update the information relating to those activities for which it is responsible; (e) Alert the competent authorities of another Member State when they observe incorrect information in the EU Tissue Establishment Compendium relating to the other Member State or when they observe a situation of significant non-compliance with the provisions relating to the Single European Code relating to the other Member State;	

		(f) Alert the Commission and the other Competent Authorities when in their assessment the EU Tissue and Cell Product Compendium requires an update. 3.The application of the Single European Code does not preclude the additional application of other codes in accordance with Member States' national requirements.	
	4, cont.	*Article 10c* **Accessibility and maintenance of the European coding system** 1.The Commission shall host and maintain an IT platform ("EU Coding Platform") which contains: (a) the EU Tissue Establishment Compendium; (b) the EU Tissue and Cell Product Compendium. 2.The Commission shall ensure that the information contained in the EU Coding Platform is publicly available before 29 October 2016. 3.The Commission shall update when needed the EUTC and ensure the overall update of the EU Tissue and Cell Product Compendium. The Commission considers that it is necessary that agreements are established with the organisations managing ISBT128 and Eurocode to ensure that updated product codes are regularly made available to the Commission for inclusion in the EU Tissue and Cell Product Compendium. If such organisations do not comply with the terms of the memoranda of understanding, the Commission may suspend, partially or in full, the future use of their respective product codes, having considered the sufficient supply of the concerned type of products in the Member States including a transitional period and having consulted the Member State experts through the Competent Authorities on Substances of Human Origin Expert Group.	No transposition necessary
	4, cont.	*Article 10d* **Transitional period** Tissues and cells already in storage on 29 October 2016 shall be exempted from the obligations relating to the Single European Code, provided the tissues and cells are released for circulation in the Union within five years following that date and under the condition that full traceability is ensured by	Regulation 10 of the 2018 Regulations (transitional arrangements for application of the SEC).

		alternative means. For tissues and cells which remain in storage and which are only released for circulation after the expiry of this five-year period and for which the application of the Single European Code is not possible, in particular because the tissues and cells are stored under deep-freeze conditions, the tissue establishments shall use the procedures applicable to products with small labels as laid down in Article 10b paragraph 1(f). (*)Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissue (OJ L 93, 9.4.2015, p. 56).'	
	5	The Annexes are amended in accordance with Annex I to this Directive. ***Annex I*** *(Annex II to the third Directive amended and Annexes III, IV, VI and VII replaced).* *Annex II – Article 4 – Directions under paragraph 14 of Schedule 2 to the 2007 Regulations* *Annex III – Article 5 – Directions under paragraph 7 of Schedule 2 to the 2007 Regulations* *Annex IV – Article 6 – Directions under paragraph 7 of Schedule 2 to the 2007 Regulations* *Annex VI – Article 9 – Directions under paragraph 1(a) of Schedule 2 to the 2007 Regulations*	Regulation 2(3)(a) of the 2018 Regulations which amends the 2007 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU.
	5, cont.	*Annex VII – Article 10a*	Regulation 8(1)(b) of the 2018 Regulations amending paragraph 1(b) of Schedule 2 to the 2007 Regulations (directions to be given to licence holders by HTA).
	6	A new Annex VIII is added, the text of which is set out in Annex II to this Directive.	New regulation 20A of the 2007 Regulations as inserted by regulation 5(2) of the 2018 Regulations (duties of HTA in relation to the SEC; data to be recorded by HTA in the EU Tissue Establishment Compendium).
2		Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2016 at the latest. They shall forthwith communicate to the Commission the text of those provisions. They shall apply the legislation from 29 April 2017. 9.4.2015 L 93/48 Official Journal of the European Union EN	No transposition necessary

		When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	
3		This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	No transposition necessary
4		The Directive is addressed to the Member States	No transposition necessary

Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells

Article	Paragraph	Provision	Transposed by
1	1	This Directive shall apply to the import into the Union of: (a) human tissues and cells intended for human application; and (b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other Union legislation.	Already implemented by Regulation 2(3) of the Human Tissue (Quality and Safety for Human Application) Regulations 2007 ("the 2007 Regulations").
	2	Where the human tissues and cells to be imported are intended to be used exclusively in manufactured products which are covered by other Union legislation, this Directive shall only apply to the donation, procurement and testing which takes place outside of the Union as well as to contributing to ensuring traceability from donor to recipient and vice versa.	Already implemented by Regulation 2(3) of the 2007 Regulations.
	3	This Directive shall not apply to: (a) the import of tissues and cells referred to in Article 9(3)(a) of Directive 2004/23/EC which are directly authorised by the competent authority or authorities; (b) the import of tissues and cells referred to in Article 9(3)(b) of Directive 2004/23/EC which are directly authorised in case of emergencies; (c) blood and blood components as defined by Directive 2002/98/EC; (d) organs or parts of organs, as defined in Directive 2004/23/EC.	*(a)* - Already implemented by Regulation 7(4) and (5) of the 2007 Regulations. *(b)* - Already implemented by Regulation 7(4) and (5) of the 2007 Regulations. *(c)* - Regulation 5(1) of the 2007 Regulations, definition of "cells" does not include blood or blood components. *(d)* - Definition of cells is when not bound by any form of connective tissue and "tissue" does not include "organs or parts of organs".
2		For the purposes of this Directive, the following definitions apply: (a) 'emergency' means any unforeseen situation in which there is no practical alternative other than to urgently import tissues and cells from a third country into the Union for	No transposition necessary. Terms already covered and defined in body of 2007 Regulations.

		immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import; (b) 'importing tissue establishment' means a tissue bank or a unit of a hospital or another body established within the Union which is a party to a contractual agreement with a third country supplier for the import into the Union of tissues and cells coming from a third country intended for human application; (c) 'one-off import' means the import of any specific type of tissue or cell which is for the personal use of an intended recipient or recipients known to the importing tissue establishment and the third country supplier before the importation occurs. Such an import of any specific type of tissue or cell shall normally not occur more than once for any given recipient. Imports from the same third country supplier taking place on a regular or repeated basis shall not be considered to be 'one-off imports'; (d) 'third country supplier' means a tissue establishment or another body, established in a third country, which is responsible for the export to the Union of tissues and cells it supplies to an importing tissue establishment. A third country supplier may also carry out one or more of the activities, which take place outside of the Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the Union.	
3	1	Without prejudice to Article 1(3), Member States shall ensure that all imports of tissues and cells from third countries are undertaken by importing tissue establishments accredited,	Regulation 7(1A) of the 2007 Regulations as inserted by the Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2018

		designated, authorised or licensed by a competent authority or authorities for the purposes of these activities.	("the 2018 Regulations"). Implements the obligation of the first Directive that only imports from third countries require authorisation, i.e. licensing, by the Human Tissue Authority ("HTA").
	2	The competent authority or authorities, having obtained the information set out in Annex I to this Directive and, having verified that the importing tissue establishment complies with the requirements of this Directive, shall accredit, designate, authorise or license the importing tissue establishment to import tissues and cells and indicate any conditions which apply such as any restrictions of the types of tissues and cells to be imported or the third country suppliers to be used. The competent authority or authorities shall issue the accredited, designated, authorised or licensed importing tissue establishment with the certificate set out in Annex II to this Directive.	Regulation 11(4A)(b) of the 2007 Regulations as inserted by regulation 3(4) of the 2018 Regulations (pre-conditions to grant of a licence authorising import to reflect the requirements of the fourth Directive). Paragraph 5 of Schedule 3 to the Human Tissue Act 2004 (the power to grant a licence subject to conditions) as applied to licences under Schedule 1 by regulation 8 of the 2007 Regulations. Paragraph 5A of Schedule 1 to the 2007 Regulations (relating to characteristics of licences), as inserted by regulation 7(2) of the 2018 Regulations.
	3	The importing tissue establishment shall not undertake any substantial changes to its import activities without the prior written approval of the competent authority or authorities. In particular, any changes to the type of tissues and cells imported, the activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells or the third country suppliers used shall be considered as substantial changes. Where an importing tissue establishment undertakes a one-off import of tissues or cells originating from a third country supplier not covered by its existing accreditation, designation, authorisation or licence, such an import shall not be considered as a substantial change if the importing tissue establishment is authorised to import the same type of tissues or cells from another third country supplier or suppliers.	Para 15 of Schedule 2 to the 2007 Regulations (directions to be given by HTA relating to updated information) as inserted by regulation 8(1)(g) of the 2018 Regulations.
	4	The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation, or licence, in part or in full, of an	See Schedule 3 Human Tissue Act 2004 as applied to licences under Schedule 1 by regulation 8 of the 2007 Regulations - power to revoke

		importing tissue establishment if, in particular, inspections or other control measures demonstrate that such an establishment no longer meets the requirements of this Directive.	or suspend or to vary a condition of the licence where the Authority ceases to be satisfied that the person to whom the licence is granted or the DI are suitable or the DI has failed to discharge his duties or where there has been any other material change of circumstance. Paragraph 7(2)(h) of Schedule 3 to the 2007 Regulations, inserted by regulation 9(4)(b) of the 2018 Regulations, which provides that the Authority may revoke the licence otherwise than on application if it ceases to be satisfied as to the suitability of third country premises.
4	1	Member States shall ensure that the competent authority or authorities organise inspections and other control measures of importing tissue establishments and, where appropriate, their third country suppliers and that importing tissue establishments carry out appropriate controls in order to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC. The interval between inspections of any given importing tissue establishment shall not exceed 2 years.	*Member State control measures* - Regulation 21(1) and 22(1) of the 2007 Regulations; existing powers to inspect documents and premises to which a licence relates. Regulation 20B(4) of the 2007 Regulations inserted by regulation 5(2) of the 2018 Regulations; relating to inspecting third country premises and documents held by third country suppliers. *Importing establishment control measures* - Existing powers to revoke or suspend a licence or to vary conditions – see Schedule 3 Human Tissue Act 2004 as applied to licences under Schedule 1 by regulation 8 of the 2007 Regulations. Importing Tissue Establishments must comply with directions given by the Authority under regulation 16 and Schedule 2 to the 2007 Regulations as amended by the 2018 Regulations. *Inspection intervals* - Regulation 22(2) of the 2007 Regulations.
	2	Such inspections shall be carried out by officials representing the competent authority or authorities who shall: (a) be empowered to inspect importing tissue establishments and, where appropriate, the	Regulation 22(1) of the 2007 Regulations (entry and inspection of premises in respect of which a licence is in force). *(a)* - Regulation 20B(4) (inspection of third country premises and

		activities of any third country suppliers; (b) evaluate and verify the procedures and activities carried out in importing tissue establishments and the facilities of third country suppliers that are relevant to ensuring the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC; (c) examine any documents or other records that are relevant for this evaluation and verification.	documents held by a third country supplier) of the 2007 Regulations, as inserted by regulation 5(2) of the 2018 Regulations. *(b)* - Regulation 26(2) of the 2007 Regulations (supplementary powers in relation to the power to enter and search premises) and 20B(7) of the same as inserted by regulation 5(2) of the 2018 Regulations. *(c)* - Regulation 21(1) of the 2007 Regulations (relating to the inspection of documents relevant to compliance with the Regulations) and 20B(4) of the same as inserted by regulation 5(2) of the 2018 Regulations (inspection of documents held by a third country supplier).
	3	Member States shall, upon a duly justified request from another Member State or the Commission, provide information on the results of inspections and other control measures relating to importing tissue establishments and third country suppliers.	Regulation 20C of the 2007 Regulations as inserted by regulation 5(2) of the 2018 Regulations.
	4	Member States into which tissues and cells are imported shall, upon a duly justified request from another Member State into which imported tissues and cells are subsequently distributed, consider carrying out inspections or other control measures on importing tissue establishments and the activities of any third country suppliers. The Member State in which the importing tissue establishment is located shall decide on the appropriate measures to take following consultation with the Member State which made such a request.	Regulation 20B(1) of the 2007 Regulations as inserted by regulation 5(2) of the 2018 Regulations.
	5	Where an on-site inspection takes place following such a request, the competent authority or authorities of the Member State in which the importing tissue establishment is located shall agree with the competent authority or authorities of the Member State which made such a request on whether and how the Member State which made such a request shall participate in the inspection. The final decision on any	Regulation 20B(2) of the 2007 Regulations as inserted by regulation 5(2) of the 2018 Regulations.

		such participation shall rest with the Member State in which the importing tissue establishment is located. The reasons for any decision to refuse such participation shall be explained to the Member State which made such a request.	
5	1	1. Importing tissue establishments, having taken measures to ensure that any imports of tissues and cells meet standards of quality and safety equivalent to the ones laid down in Directive 2004/23/EC and that imported tissues and cells can be traced from the donor to the recipient and vice versa, shall apply for an accreditation, designation, authorisation or licence as an importing tissue establishment by: (a) providing to the competent authority or authorities the required information and documentation as set out in Annex I to this Directive; (b) making available and, when requested by the competent authority or authorities, providing the documentation listed in Annex III to this Directive.	Regulation 11(4A) of the 2007 Regulations (pre-conditions to grant of import licence), as inserted by regulation 3(4) of the 2018 Regulations.
	2	Member States may choose to not apply the documentation requirements of Annex I, part F and Annex III to this Directive to one-off imports as defined in Article 2 of this Directive, provided they have suitable national measures in place to regulate such imports. Those national measures shall ensure the following: (a) traceability from donor to recipient and vice versa; and (b) imported tissues and cells are not applied to anyone other than their intended recipients.	Regulation 11(4B) of the 2007 Regulations (pre-conditions to grant of import licence) as inserted by regulation 3(4) of the 2018 Regulations. *(a) & (b)* - paragraph 1(a) of Schedule 2 to the 2007 Regulations, directions given to licence holders by HTA.
6	1	Importing tissue establishments shall seek the prior written approval of the competent authority or authorities for any planned substantial changes to their import activities, and in particular those substantial changes described in Article 3(3), and inform the competent authority or authorities of their decision to cease their import activities in part or	Paragraph 15 of Schedule 2 to the 2007 Regulations (directions given by HTA relating to updated information) inserted by regulation 8(1)(g) of the 2018 Regulations.

		in full.	
	2	Importing tissue establishments shall notify, without delay, the competent authority or authorities of any suspected or actual serious adverse events or reactions, reported to them by third country suppliers and which may influence the quality and safety of the tissues and cells they import. The information laid out in Annexes III and IV to Directive 2006/86/EC shall be included in such notifications.	Paragraph 4A of Schedule 2 to the 2007 Regulations (directions given by HTA regarding notification) inserted by regulation 8(1)(f) of the 2018 Regulations.
	3	The importing tissue establishment shall notify, without delay, the competent authority or authorities of: (a) any revocation or suspension, in part or full, of a third country supplier's authorisation to export tissues and cells; and (b) any other decision taken for reasons of non-compliance by the competent authority or authorities of the country in which the third country supplier is based and which may be relevant to the quality and safety of imported tissues and cells.	Paragraph 15 of Schedule 2 to the 2007 Regulations (directions given by HTA relating to third country suppliers) inserted by regulation 8(1)(g) of the 2018 Regulations.
7	1	Importing tissue establishments shall have in place written agreements with third country suppliers where any of the activities of donation, procurement, testing, processing, preservation, storage or export to the Union of tissues and cells to be imported into the Union are carried out outside of the Union. Member States may choose to not apply this requirement to one-off imports as defined in Article 2 of this Directive, provided they have suitable national measures in place to regulate such an imports. Those national measures shall ensure the following: (a) traceability from donor to recipient and vice versa; and (b) imported tissues and cells are not applied to anyone other than their intended recipients.	Regulation 11(4A)(d) to (f) and 11(4B)(c) of the 2007 Regulations (pre-conditions to grant of import licence) inserted as inserted by regulation 3(4) of the 2018 Regulations. *(a) & (b)* - Paragraph 1(a) of Schedule 2 to the 2007 Regulations (directions given by HTA relating to traceability).
	2	The written agreement between the importing tissue establishment and the third country supplier shall specify the	Regulation 11(4A)(e) of the 2007 Regulations inserted by regulation 3(4) of the 2018 Regulations (pre-

		quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC. In particular, the written agreement shall include, as a minimum, the contents listed in Annex IV to this Directive.	conditions to grant of import licence).
	3	The written agreement shall establish the right of the competent authority or authorities to inspect the activities, including the facilities, of any third country suppliers during the duration of the written agreement and for a period of 2 years following its termination.	Regulation 11(4A)(e) of the 2007 Regulations inserted by regulation 3(4) of the 2018 Regulations (pre-conditions to grant of import licence).
	4	Importing tissue establishments shall provide copies of written agreements with third country suppliers to the competent authority or authorities as part of their application for accreditation, designation, authorisation or licensing.	Regulation 11(4A)(f) of the 2007 Regulations as inserted by regulation 3(4) of the 2018 Regulations (pre-conditions to grant of import licence).
8	1	Importing tissue establishments shall keep a record of their activities, including the types and quantities of tissues and cells imported, and on their origin and destination. This record shall also include the same information for any one- off imports carried out. The annual report referred to in Article 10(1) of Directive 2004/23/EC shall include information about those activities.	Paragraph 3 of Schedule 2 to the 2007 Regulations as amended by regulation 8(1)(e) of the 2018 Regulations (directions given by HTA relating to reporting obligations).
	2	The competent authority or authorities shall include importing tissue establishments in the publicly accessible register of tissue establishments laid down in Article 10(2) of Directive 2004/23/EC.	Regulation 18 of the 2007 Regulations (register of licences).
	3	Information on the accreditations, designations, authorisations or licences of importing tissue establishments shall also be made available through the network of registers referred to in Article 10(3) of Directive 2004/23/EC.	Regulation 18 of the 2007 Regulations.
9		1. Member States shall adopt and publish laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2016 at the latest. They shall forthwith communicate to the Commission the text of those provisions.	No transposition necessary

		They shall apply the legislation from 29 April 2017. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. 2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	
10		This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	No transposition necessary
11		The Directive is addressed to the Member States	No transposition necessary
Annex I			Regulation 11(4A)(b) and 11(4B)(b) inserted by regulation 3(4) of the 2018 Regulations (pre-conditions to grant of import licence).
Annex II			Paragraph 5A of Schedule 1 inserted by regulation 7(2) of the 2018 Regulations (characteristics of licences – the certificate issued by the HTA must be in the form set out in Annex II.
Annex III			Regulation 11 (4A)(c) inserted by regulation 3(4) of the 2018 Regulations (pre-conditions to grant of import licence).
Annex IV			Regulation 11(4A)(e) inserted by regulation 3(4) of the 2018 Regulations (pre-conditions to grant of import licence).

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CODING AND IMPORTATION OF HUMAN REPRODUCTIVE CELLS (SPERM, EGGS AND EMBRYOS) INTENDED FOR HUMAN APPLICATION – TRANSPOSITION TABLES

Commission Directive (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

Article	Paragraph	Provision	Transposed by
1	1	Commission Directive 2006/86/EC (1) is hereby amended as follows: In Article 2, the following points (k) to (y) are added: '(k) "Single European Code" or "SEC" means the unique identifier applied to tissues and cells distributed in the Union. The Single European Code consists of a donation identification sequence and a product identification sequence, as further specified in Annex VII to this Directive; (l) "donation identification sequence" means the first part of the Single European Code consisting of the EU tissue establishment code and the unique donation number; (m) "EU tissue establishment code" means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the Union. The tissue establishment code consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium, as further specified in Annex VII to this Directive; (n) "unique donation number" means the unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers, as further specified in Annex VII to this Directive; (o) "product identification sequence" means the second part of the Single European Code consisting of the product code, the split number and the expiry date; (p) "product code" means the identifier for the specific type of	Section 1A of the Human Fertilisation and Embryology Act 1990 ("the 1990 Act") is amended by regulation 3(2) of the Human Fertilisation and Embryology (Quality and Safety) Regulations 2018 ("the 2018 Regulations") to refer to the third Directive as amended by Commission Directive 2015/565/EU thereby adding points (k) to (y) to Article 2 of the third Directive, which are requirements relating to the Single European Code.

			tissue and cell in question. The product code consists of the product coding system identifier indicating the coding system used by the tissue establishment (“E” for the EUTC, “A” for ISBT128, “B” for Eurocode) and the tissues and cells product number foreseen in the respective coding system for the product type, as further defined in Annex VII to this Directive; (q) “split number” means the number which distinguishes and uniquely identifies tissues and cells having the same unique donation number and the same product code and originating from the same tissue establishment, as further defined in Annex VII to this Directive; (r) “expiry date” means the date by which the tissues and cells can be applied, as further defined in Annex VII to this Directive; (s) “EU Coding Platform” means the IT platform hosted by the Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium; (t) “EU Tissue Establishment Compendium” means the register of all tissue establishments which are authorised, licensed, designated or accredited by the Member States' competent authority or authorities and which contains the information about these tissue establishments as set out in Annex VIII to this Directive; (u) “EU Tissue and Cell Product Compendium” means the register of all types of tissues and cells circulating in the Union and the respective product codes under the three permitted coding systems (EUTC, ISBT128 and Eurocode); (v) “EUTC” means the product coding system for tissues and cells developed by the Union consisting of a register of all types of tissues and cells circulating in the Union and their corresponding product codes. (w) “released for circulation” means distribution for human application or transfer to another operator, e.g. for further processing with or without	

		return. (x) "within the same centre" means that all steps from procurement to human application are carried out under the same responsible person, quality management system and traceability system, within a healthcare centre comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location; (y) "pooling" means the physical contact or mixing in a single container, of tissues or cells from more than one procurement from the same donor, or from two or more donors.' (1)Commission Directive 2006/86/EC of 24 October 2006 implementing Directive 2004/23/EC of the European Parliament and of the Council as regards traceability requirements, notification of serious adverse reactions and events and certain technical requirements for the coding, processing, preservation, storage and distribution of human tissues and cells (OJ L 294, 25.10.2006, p. 32).	
	2	Article 9 is replaced by the following: *'Article 9* **Traceability** 1.Member States shall ensure that tissues and cells shall be traceable in particular through documentation and the use of the Single European Code from procurement to human application or disposal and vice versa. Tissues and cells used for advanced therapy medicinal products shall be traceable under this Directive at least until transferred to the ATMP manufacturer. 2. Member States shall ensure that tissue establishments and organisations responsible for human application shall retain the data set out in Annex VI for at least 30 years, using an appropriate and readable storage medium. 3. In case of tissues and cells retrieved from a deceased donor by procurement teams operating for two or more tissue establishments, Member States shall ensure an appropriate traceability system across the procurements.'	Section 1A of the 1990 Act is amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU. Article 9 is transposed by paragraph 1 of Schedule 3A (traceability).
	3	(3) Article 10 is replaced by the following: *'Article 10* **European coding system** 1.Without prejudice to paragraphs 2 or 3 of	Section 1A of the 1990 Act is amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission

		this Article, a Single European Code shall be applied to all tissues and cells distributed for human application. For the other situations where tissues and cells are released for circulation, as a minimum the donation identification sequence shall be applied at least in the accompanying documentation. 9.4.2015 L 93/45 Official Journal of the European Union EN 2.Paragraph 1 shall not apply to: (a) reproductive cells from partner donation; (b) tissues and cells distributed directly for immediate transplantation to the recipient, as referred to in Article 6(5) of Directive 2004/23/EC; (c) tissues and cells imported into the Union in case of emergency authorised directly by the competent authority or authorities, as referred to in Article 9(3)b of Directive 2004/23/EC. 3.Member States may also allow exemptions from the requirement provided for in paragraph 1 for: (a) tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre; (b) tissues and cells that are imported into the Union, when these tissues and cells remain within the same centre from importation to application, provided that the centre comprises a tissue establishment authorised, designated, accredited, or licensed to carry out importing activities.'	Directive 2015/565/EU and Article 10 (European coding system) is transposed by section 24(12)(b) as substituted by regulation 4(2) of the 2018 Regulations.
	4	(4) The following Articles are inserted: *'Article 10a* **Format of the Single European Code** 1.The Single European Code referred to in Article 10(1) shall comply with the specifications set out in this Article and in Annex VII. 2.The Single European Code shall be in eye-readable format and shall be preceded by the acronym "SEC". The parallel use of other labelling and traceability systems is possible. 3.The Single European Code shall be printed with the Donation Identification Sequence and Product Identification Sequence separated by a single space or as two successive lines.	Section 1A of the 1990 Act is amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU. Article 10a is transposed by section 24(12)(c) as substituted by regulation 4(2) of the 2018 Regulations.
	4, cont.	*Article 10b*	Section 1A of the 1990 Act is

		Requirements related to the application of the Single European Code 1.Member States shall ensure that the following minimum requirements are complied with by tissue establishments, including importing tissue establishments as defined by Commission Directive (EU) 2015/566 (*): (a) allocate a Single European Code to all tissues and cells requiring application of this code at the latest before their distribution for human application; (b) allocate a donation identification sequence after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells from a third country supplier. The donation identification sequence shall include: (1) their EU tissue establishment code as assigned in the EU Tissue Establishment Compendium; (2) a unique donation number allocated by the tissue establishment, unless such number is allocated centrally at national level or is a globally unique number as used by the ISBT128 coding system. Where allowed, in case of pooling of tissues and cells, a new donation identification number shall be allocated to the final product; traceability with the individual donations shall be ensured by the tissue establishment in which pooling is carried out; (c) do not alter the donation identification sequence once it is allocated to tissues and cells released for circulation, unless it is necessary to correct an encoding error; any correction requires proper documentation; (d) use one of the permitted product coding systems and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human	amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU. Article 10b is transposed by section 24(12)(d) as substituted by regulation 4(2) of the 2018 Regulations.

		application; (e) use an appropriate split number and expiry date. For tissues and cells for which no expiry date is defined, the expiry date shall be 00000000 at the latest before their distribution for human application; (f) apply the Single European Code on the label of the product concerned in an indelible and permanent manner and mention that code in the relevant accompanying documentation at the latest before its distribution for human application. The tissue establishment may entrust this task to a third party or third parties, provided the tissue establishment ensures compliance with this Directive, in particular in terms of uniqueness of the code. Where the label size precludes the application of the Single European Code on the label, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation; (g) notify the competent authority or authorities when: (1) information contained in the EU Tissue Establishment Compendium requires an update or correction; (2) the EU Tissue and Cell Product Compendium requires an update; (3) the tissue establishment observes a situation of significant non-compliance with the requirements relating to the Single European Code concerning tissues and cells received from other EU tissue establishments; (h) take the necessary measures in case of incorrect application of the Single European Code on the label.	
		2. Member States shall ensure that the following minimum requirements are applied by all competent authorities: (a) ensure the allocation of a unique tissue establishment number to all tissue establishments authorised, accredited, designated or licensed in its Member State. If a tissue establishment has different physical	Section 1A of the 1990 Act is amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU. New section 8ZB of the 1990 Act is inserted by regulation 4(1) of the 2018 Regulations to transpose the requirements of

		locations, but has one system for allocating unique donation numbers, it may be deemed to be one and the same tissue establishment. If a tissue establishment uses two or more systems to allocate unique donation numbers, such an entity shall be allocated separate tissue establishment numbers corresponding to the number of allocation systems used; (b) decide which system or systems shall be used for the allocation of unique donation numbers in their Member State. Permitted systems of allocation include national systems establishing centralised allocation of the nationally unique donation number or systems requiring each tissue establishment to allocate unique donation numbers or international systems that allocate globally unique donation numbers that are compatible with the Single European Code. (c) monitor and enforce the full implementation of the Single European Code in their Member State; (d) ensure the validation of the data on the tissue establishments contained in the EU Tissue Establishment Compendium for their Member State and update the Compendium without undue delay in particular in the following situations: (1) when a new tissue establishment is authorised, designated, accredited, or licensed; (2) when tissue establishment information changes or is not correctly recorded in the EU Tissue Establishment Compendium; (3) when the accreditation, designation, authorisation or licence details of a tissue establishment, as listed in Annex VIII to this Directive, change, including: — accreditation, designation, authorisation or licence for a new tissue or cell type, — accreditation, designation,	Article 10b(2).

			authorisation or licence for a new prescribed activity, — details of any conditions and or exemptions added to an authorisation, — suspension, in part or in full, of a specific accreditation, designation, authorisation or licence for a particular activity or tissue or cell type; — revocation, in part or in full, of an accreditation, designation, authorisation or licence for a tissue establishment, — situations when a tissue establishment voluntarily ceases, in part or in full, the activity or activities for which it is authorised, accredited, designated or licensed. Without undue delay means in not later than 10 working days for any changes substantially affecting the authorisation, accreditation, designation or licence of the tissue establishments concerned. When a tissue establishment is authorised by two or more competent authorities for different types of tissues and cells or different activities, each competent authority shall update the information relating to those activities for which it is responsible; (e) Alert the competent authorities of another Member State when they observe incorrect information in the EU Tissue Establishment Compendium relating to the other Member State or when they observe a situation of significant non-compliance with the provisions relating to the Single European Code relating to the other Member State;	

		(f) Alert the Commission and the other Competent Authorities when in their assessment the EU Tissue and Cell Product Compendium requires an update. 3.The application of the Single European Code does not preclude the additional application of other codes in accordance with Member States' national requirements.	
	4, cont.	*Article 10c* **Accessibility and maintenance of the European coding system** 1.The Commission shall host and maintain an IT platform ("EU Coding Platform") which contains: (a) the EU Tissue Establishment Compendium; (b) the EU Tissue and Cell Product Compendium. 2.The Commission shall ensure that the information contained in the EU Coding Platform is publicly available before 29 October 2016. 3.The Commission shall update when needed the EUTC and ensure the overall update of the EU Tissue and Cell Product Compendium. The Commission considers that it is necessary that agreements are established with the organisations managing ISBT128 and Eurocode to ensure that updated product codes are regularly made available to the Commission for inclusion in the EU Tissue and Cell Product Compendium. If such organisations do not comply with the terms of the memoranda of understanding, the Commission may suspend, partially or in full, the future use of their respective product codes, having considered the sufficient supply of the concerned type of products in the Member States including a transitional period and having consulted the Member State experts through the Competent Authorities on Substances of Human Origin Expert Group.	No transposition necessary
	4, cont.	*Article 10d* **Transitional period** Tissues and cells already in storage on 29 October 2016 shall be exempted from the obligations relating to the Single European Code, provided the tissues and cells are released for circulation in the Union within five years following that date and under the condition that full traceability is ensured by	Section 1A of the 1990 Act is amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU. (Regulation 6 of the 2018 Regulations).

		alternative means. For tissues and cells which remain in storage and which are only released for circulation after the expiry of this five-year period and for which the application of the Single European Code is not possible, in particular because the tissues and cells are stored under deep-freeze conditions, the tissue establishments shall use the procedures applicable to products with small labels as laid down in Article 10b paragraph 1(f). (*)Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissue (OJ L 93, 9.4.2015, p. 56).'	
	5	The Annexes are amended in accordance with Annex I to this Directive. *Annex I (Annex II to the Directive 206/86/EC (third Directive) amended and Annexes III, IV, VI and VII replaced).* *Annex II – Article 4 of third Directive* *Annex III – Article 5 of third Directive* *Annex IV – Article 6 of third Directive* *Annex VI – Article 9 of third Directive* *Annex VII – Article 10a of the third Directive*	Section 1A of the 1990 Act is amended by regulation 3(2) of the 2018 Regulations to refer to the third Directive as amended by Commission Directive 2015/565/EU. *Annex II* - Paragraph 11(b) of Schedule 3A to the 1990 Act *Annex III* - Paragraph 3 of Schedule 3A to the 1990 Act. *Annex IV* - Paragraph 3 of Schedule 3A to the 1990 Act *Annex VI* - Paragraph 1 of Schedule 3A to the 1990 Act (Schedule 3A concerns licence conditions which refer to the relevant Articles of the third Directive). Section 8ZB(3) of the 1990 Act as inserted by regulation 4(1) of the 2018 Regulations.
	6	A new Annex VIII is added, the text of which is set out in Annex II to this Directive.	Directions issued by the Human Fertilisation and Embryology Authority ("HFEA") under subsection 12(c) of section 24 of the 1990 Act as inserted by regulation 4(2) of the 2018 Regulations. Section 8ZB(3) of the 1990 Act as inserted by regulation 4(1) of the 2018 Regulations (data to be recorded by HFEA in the EU Tissue Establishment Compendium).
2		Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2016 at the latest. They shall	No transposition necessary

		forthwith communicate to the Commission the text of those provisions. They shall apply the legislation from 29 April 2017. 9.4.2015 L 93/48 Official Journal of the European Union EN When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	
3		This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	No transposition necessary
4		The Directive is addressed to the Member States	No transposition necessary

Commission Directive (EU) 2015/566 of 8 April 2015 implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells

Article	Paragraph	Provision	Transposed by
1	1	This Directive shall apply to the import into the Union of: (a) human tissues and cells intended for human application; and (b) manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other Union legislation.	Implementation for via: - The Human Fertilisation & Embryology Act 1990 ("the 1990 Act"), as amended by - The Human Fertilisation and Embryology (Quality and Safety) Regulations 2018 ("the 2018 Regulations"), The use of gametes or embryos in manufactured products is prohibited.
	2	Where the human tissues and cells to be imported are intended to be used exclusively in manufactured products which are covered by other Union legislation, this Directive shall only apply to the donation, procurement and testing which takes place outside of the Union as well as to contributing to ensuring traceability from donor to recipient and vice versa.	Not transposed, the use of gametes or embryos in manufactured products is prohibited.
	3	This Directive shall not apply to: (a) the import of tissues and cells referred to in Article 9(3)(a) of Directive 2004/23/EC which are directly authorised by the competent authority or authorities; (b) the import of tissues and cells referred to in Article 9(3)(b) of Directive 2004/23/EC which are directly authorised in case of emergencies; (c) blood and blood components as defined by Directive 2002/98/EC; (d) organs or parts of organs, as defined in Directive 2004/23/EC.	*(a)* - This direct authorisation provision was not implemented in 2007. Reproductive cells (Gamete (sperm and eggs) and embryos) are not tissues needed for emergency use to safeguard the health of a patient. There are no circumstances where direct authorisation for import would be applicable *(b)* – Reproductive cells are not supplied in emergency situations. *(c)* – Not applicable to reproductive cells *(d)* – Not applicable to reproductive cells
2		For the purposes of this Directive, the following definitions apply: (a) 'emergency' means any unforeseen situation in which there is no practical alternative other than to urgently import tissues and cells from a third	*Emergency* - definition not transposed. *Importing tissue establishment* – definition not transposed. *One-off import* - regulation 5(2) of the 2018 Regulations

		country into the Union for immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import; (b) 'importing tissue establishment' means a tissue bank or a unit of a hospital or another body established within the Union which is a party to a contractual agreement with a third country supplier for the import into the Union of tissues and cells coming from a third country intended for human application; (c) 'one-off import' means the import of any specific type of tissue or cell which is for the personal use of an intended recipient or recipients known to the importing tissue establishment and the third country supplier before the importation occurs. Such an import of any specific type of tissue or cell shall normally not occur more than once for any given recipient. Imports from the same third country supplier taking place on a regular or repeated basis shall not be considered to be 'one-off imports'; (d) 'third country supplier' means a tissue establishment or another body, established in a third country, which is responsible for the export to the Union of tissues and cells it supplies to an importing tissue establishment. A third country supplier may also carry out one or more of the activities, which take place outside of the Union, of donation, procurement, testing, processing, preservation, storage or distribution of tissues and cells imported into the Union.	*Third country supplier* – regulation 3(4)(6) of the 2018 Regulations
3	1	Without prejudice to Article 1(3), Member States shall ensure that all	Sections 3 & 4 of the 1990 Act (licence requirements) taken with s.

		imports of tissues and cells from third countries are undertaken by importing tissue establishments accredited, designated, authorised or licensed by a competent authority or authorities for the purposes of these activities.	24(4). The Human Fertilisation and Embryology Authority ("HFEA") authorises imports by way of issuing directions to a person to whom a licence applies.
	2	The competent authority or authorities, having obtained the information set out in Annex I to this Directive and, having verified that the importing tissue establishment complies with the requirements of this Directive, shall accredit, designate, authorise or license the importing tissue establishment to import tissues and cells and indicate any conditions which apply such as any restrictions of the types of tissues and cells to be imported or the third country suppliers to be used. The competent authority or authorities shall issue the accredited, designated, authorised or licensed importing tissue establishment with the certificate set out in Annex II to this Directive.	Section 24(4AA) and, (4AB) and paragraphs 1(a) – (c) and 2(a) and (b) of Schedule 3AA of the 1990 Act inserted by the 2018 Regulations, concerning the directions to be given by the HFEA (Regulation 5(4)(b) and 5(6)).
	3	The importing tissue establishment shall not undertake any substantial changes to its import activities without the prior written approval of the competent authority or authorities. In particular, any changes to the type of tissues and cells imported, the activities undertaken in third countries which may have an influence on the quality and safety of imported tissues and cells or the third country suppliers used shall be considered as substantial changes. Where an importing tissue establishment undertakes a one-off import of tissues or cells originating from a third country supplier not covered by its existing accreditation, designation, authorisation or licence, such an import shall not be considered as a substantial change if the importing tissue establishment is authorised to import the same type of tissues or cells from another third country supplier or suppliers.	Section 24(4AC) and paragraph 3(a) of Schedule 3AA of the 1990 Act inserted by the 2018 Regulations, concerning the directions to be given by the HFEA (Regulation 5(4)(b) and 5(6).
	4	The competent authority or authorities may suspend or revoke the accreditation, designation, authorisation, or licence, in part or in full, of an importing tissue establishment if, in particular,	Subsections 18(2)(c) and (j) (relating to third country premises and inserted by regulation 5(3) of the 2018 Regulations) & s. 19C of the 1990 Act, grounds to revoke or suspend a licence.

		inspections or other control measures demonstrate that such an establishment no longer meets the requirements of this Directive.	
4	1	Member States shall ensure that the competent authority or authorities organise inspections and other control measures of importing tissue establishments and, where appropriate, their third country suppliers and that importing tissue establishments carry out appropriate controls in order to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC. The interval between inspections of any given importing tissue establishment shall not exceed 2 years.	*Control measures* - Section 38A and paragraph 3(1) of Schedule 3B to the 1990 Act relating to existing powers of inspection. Section 15B(4) of the 1990 Act inserted by the 2018 Regulations relating to inspections of third country premises (Regulation 5(2)). *Inspection intervals* - Paragraph 4(1) of Schedule 3B to the 1990 Act which requires two yearly inspections for premises to which a licence relates.
	2	Such inspections shall be carried out by officials representing the competent authority or authorities who shall: (a) be empowered to inspect importing tissue establishments and, where appropriate, the activities of any third country suppliers; (b) evaluate and verify the procedures and activities carried out in importing tissue establishments and the facilities of third country suppliers that are relevant to ensuring the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC; (c) examine any documents or other records that are relevant for this evaluation and verification.	*(a)* - Section 38A (powers of inspection etc.) and paragraph 3(1) of Schedule 3B (inspection of statutory records) to the 1990 Act, in relation to those to whom a licence relates and Section 15B(4) of the 1990 Act as inserted by the 2018 Regulations (Regulation 5(2)), in relation to third country premises and documents. *(b)* - Paragraph 8(2)(a) and (c) of Schedule 3B to the 1990 Act. Section 15B(8)(a) and (c) of the 1990 Act as inserted by the 2018 Regulations (Regulation 5(2)). *(c)* - Paragraph 8(2)(b) of Schedule 3B to the 1990 Act. Section 15B(8)(b) of the 1990 Act as inserted by the 2018 Regulations (Regulation 5(2)).
	3	Member States shall, upon a duly justified request from another Member State or the Commission, provide information on the results of inspections and other control measures relating to importing tissue establishments and third country suppliers.	Section 15C of the 1990 Act inserted by the 2018 Regulations (Regulation 5(2)).

	4	Member States into which tissues and cells are imported shall, upon a duly justified request from another Member State into which imported tissues and cells are subsequently distributed, consider carrying out inspections or other control measures on importing tissue establishments and the activities of any third country suppliers. The Member State in which the importing tissue establishment is located shall decide on the appropriate measures to take following consultation with the Member State which made such a request.	Paragraphs 1A and 4A of Schedule 3B to the 1990 Act as inserted by the 2018 Regulations (Regulation 5(8) and (9)). Section 15B of the 1990 Act inserted by the 2018 Regulations (Regulation 5(2)).
	5	Where an on-site inspection takes place following such a request, the competent authority or authorities of the Member State in which the importing tissue establishment is located shall agree with the competent authority or authorities of the Member State which made such a request on whether and how the Member State which made such a request shall participate in the inspection. The final decision on any such participation shall rest with the Member State in which the importing tissue establishment is located. The reasons for any decision to refuse such participation shall be explained to the Member State which made such a request.	Section 15B of the 1990 Act inserted by the 2018 (Regulation 5(2)).
5	1	1. Importing tissue establishments, having taken measures to ensure that any imports of tissues and cells meet standards of quality and safety equivalent to the ones laid down in Directive 2004/23/EC and that imported tissues and cells can be traced from the donor to the recipient and vice versa, shall apply for an accreditation, designation, authorisation or licence as an importing tissue establishment by: (a) providing to the competent authority or authorities the required information and documentation as set out in Annex I to this Directive; (b) making available and, when requested by the competent authority or authorities, providing the documentation listed in Annex III to this	Section 24(4AA) and (4AB) and paragraphs 1(a) to (d) and 2(a) and (b) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations. (Regulation 5(4)(b) and (6)).

		Directive.	
	2	Member States may choose to not apply the documentation requirements of Annex I, part F and Annex III to this Directive to one-off imports as defined in Article 2 of this Directive, provided they have suitable national measures in place to regulate such imports. Those national measures shall ensure the following: (a) traceability from donor to recipient and vice versa; and (b) imported tissues and cells are not applied to anyone other than their intended recipients.	Section 24(4AB) and paragraph 2(c) of the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).
6	1	Importing tissue establishments shall seek the prior written approval of the competent authority or authorities for any planned substantial changes to their import activities, and in particular those substantial changes described in Article 3(3), and inform the competent authority or authorities of their decision to cease their import activities in part or in full.	Section 24(4AC) and paragraph 3(a) and (b) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations. (Regulation 5(4)(b) and (6)).
	2	Importing tissue establishments shall notify, without delay, the competent authority or authorities of any suspected or actual serious adverse events or reactions, reported to them by third country suppliers and which may influence the quality and safety of the tissues and cells they import. The information laid out in Annexes III and IV to Directive 2006/86/EC shall be included in such notifications.	Section 24(4AC) and paragraph 3(c) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations. (Regulation 5(4)(b) and (6)).
	3	The importing tissue establishment shall notify, without delay, the competent authority or authorities of: (a) any revocation or suspension, in part or full, of a third country supplier's authorisation to export tissues and cells; and (b) any other decision taken for reasons of non-compliance by the competent authority or authorities of the country in which the third country supplier is based and which may be relevant to the quality and safety of imported tissues	Section 24(4AC) and paragraph 3(d) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).

		and cells.	
7	1	Importing tissue establishments shall have in place written agreements with third country suppliers where any of the activities of donation, procurement, testing, processing, preservation, storage or export to the Union of tissues and cells to be imported into the Union are carried out outside of the Union. Member States may choose to not apply this requirement to one-off imports as defined in Article 2 of this Directive, provided they have suitable national measures in place to regulate such an imports. Those national measures shall ensure the following: (a) traceability from donor to recipient and vice versa; and (b) imported tissues and cells are not applied to anyone other than their intended recipients.	Section 24(4AA) and (4AB) and paragraphs 1(e) and 2(c) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by 2018 Regulations (Regulation 5(4)(b) and (6)).
	2	The written agreement between the importing tissue establishment and the third country supplier shall specify the quality and safety requirements to be met to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported with the standards laid down in Directive 2004/23/EC. In particular, the written agreement shall include, as a minimum, the contents listed in Annex IV to this Directive.	Section 24(4AA)and paragraph 1(e) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).
	3	The written agreement shall establish the right of the competent authority or authorities to inspect the activities, including the facilities, of any third country suppliers during the duration of the written agreement and for a period of 2 years following its termination.	Section 24(4AA) and paragraph 1(e) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).
	4	Importing tissue establishments shall provide copies of written agreements with third country suppliers to the competent authority or authorities as part of their application for accreditation, designation, authorisation or licensing.	Section 24(4AA) and paragraph 1(f) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).
8	1	Importing tissue establishments shall keep a record of their activities, including the types and quantities of tissues and cells imported, and on their origin and destination. This record shall also include the same information	This seems to have been implemented by the Register kept by HFEA, section 31A of the 1990 Act and the duty to communicate re serious adverse events and reactions, section 8A.

		for any one- off imports carried out. The annual report referred to in Article 10(1) of Directive 2004/23/EC shall include information about those activities.	
	2	The competent authority or authorities shall include importing tissue establishments in the publicly accessible register of tissue establishments laid down in Article 10(2) of Directive 2004/23/EC.	Section 31A of the 1990 Act.
	3	Information on the accreditations, designations, authorisations or licences of importing tissue establishments shall also be made available through the network of registers referred to in Article 10(3) of Directive 2004/23/EC.	Section 31A(3) of the 1990 Act.
9		1. Member States shall adopt and publish laws, regulations and administrative provisions necessary to comply with this Directive by 29 October 2016 at the latest. They shall forthwith communicate to the Commission the text of those provisions. They shall apply the legislation from 29 April 2017. When Member States adopt those provisions, they shall contain a reference to this Directive or be accompanied by such a reference on the occasion of their official publication. Member States shall determine how such reference is to be made. 2. Member States shall communicate to the Commission the text of the main provisions of national law which they adopt in the field covered by this Directive.	No transposition necessary
10		This Directive shall enter into force on the twentieth day following that of its publication in the *Official Journal of the European Union*.	No transposition necessary
11		The Directive is addressed to the Member States	No transposition necessary
Annex I			Section 24(4AA) and (4AB) and paragraphs (b) and (c) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations

			(Regulation 5(4)(b) and (6)).
Annex II			Section 24(4AD) of the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b).
Annex III			Section 24(4AA) and (4AB) and paragraphs 1(d) and 2(c) of Schedule 3AA to the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).
Annex IV			Section 24(4AA) and paragraph 1(e) of the 1990 Act, concerning directions to be given by HFEA, as inserted by the 2018 Regulations (Regulation 5(4)(b) and (6)).

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