



STATUTORY INSTRUMENTS.

S.I. No. 32 of 2019

EUROPEAN COMMUNITIES (HUMAN TISSUES AND CELLS
TRACEABILITY REQUIREMENTS, NOTIFICATION OF SERIOUS
ADVERSE REACTIONS AND EVENTS AND CERTAIN TECHNICAL
REQUIREMENTS) (AMENDMENT) REGULATIONS 2019

S.I. No. 32 of 2019

European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) (Amendment) Regulations 2019

I, Simon Harris, Minister for Health, in exercise of the powers conferred on me by section 3 of the European Communities Act 1972 (No. 27 of 1972) and for the purpose of giving effect to Commission Directive (EU) 2015/565 of 8 April 2015¹ amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells, hereby make the following regulations:

Citation

1. These Regulations may be cited as the European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) (Amendment) Regulations 2019.

Definitions

2. In these Regulations -

“Principal Regulations” means the European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007 (S.I. No. 598 of 2007);

“Regulations of 2006” means the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006).

¹ OJ No. L 93, 9.4.2015, p. 43.

Amendment of Regulation 3 of Principal Regulations

3. Regulation 3 of the Principal Regulations is amended -

- (a) in paragraph (1), by the insertion of the following definitions:

“ ‘Coding Directive’ means Commission Directive (EU) 2015/565 of 8 April 2015² amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells;

‘donation identification sequence’ means the first part of the Single European Code consisting of the EU tissue establishment code and the unique donation number;

‘EU tissue establishment code’ means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the European Union which consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium referred to in Schedule 7;

‘EU Tissue and Cell Product Compendium’ means the register of all types of tissues and cells circulating in the European Union and the respective product codes under the 3 permitted coding systems (EUTC, ISBT128 and Eurocode);

‘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 referred to in Schedule 8;

‘EUTC’ means the product coding system for tissues and cells developed by the European Union consisting of a register of all types of tissues and cells circulating in the European Union and their corresponding product codes;

‘expiry date’ means the date by which the tissues and cells can be applied as referred to in Schedule 7;

‘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 2 or more donors;

‘product code’ means the identifier for the specific type of tissue and cell in question which consists of -

- (a) the product coding system identifier indicating the coding system used by the tissue

² OJ No. L 93, 9.4.2015, p. 43.

establishment (‘E’ for the EUTC, ‘A’ for ISBT128, ‘B’ for Eurocode), and

- (b) the tissues and cells product number foreseen in the respective coding system for the product type referred to in Schedule 7;

‘product identification sequence’ means the second part of the Single European Code consisting of the product code, the split number and the expiry date;

‘Regulations of 2006’ means the European Communities (Quality and Safety of Human Tissues and Cells) Regulations 2006 (S.I. No. 158 of 2006);

‘released for circulation’ means distribution for human application or transfer to another operator, (including for further processing with or without return);

‘Single European Code’ or ‘SEC’ means the unique identifier applied to tissues and cells distributed in the European Union and consists of a donation identification sequence and a product identification sequence referred to in Schedule 7;

‘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 referred to in Schedule 7;

‘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 referred to in Schedule 7;

‘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 authorised tissue establishment and an organisation responsible for human application at the same location;”, and

- (b) by the insertion of the following paragraphs after paragraph (3):

“(4) A word or expression used in these Regulations that is also used in the Coding Directive has, unless the contrary intention appears, the same meaning in these Regulations that it has in the Coding Directive.

(5) Subject to paragraph (6), in these Regulations, a reference to a tissue establishment shall include a reference to an importing tissue establishment.

(6) Paragraph (5) shall not apply to a tissue establishment referred to in -

- (a) Regulation 3(1), in the definition of “procurement organisation”,
- (b) Regulation 7(a) or (c),
- (c) Regulation 12,
- (d) Regulation 20(2),
- (e) Schedule 1 at Part D5, or
- (f) Schedule 2 at Part B or Part C3.”.

Traceability

4. The Principal Regulations are amended by the substitution of the following Regulation for Regulation 20:

- “20. (1) A tissue establishment shall ensure that -
- (a) tissues and cells are traceable, in particular through documentation and the use of the Single European Code from procurement to human application or disposal and vice versa, and
 - (b) tissues and cells used for advanced therapy medicinal products are traceable under these Regulations at least until they are transferred to the advanced therapy medicinal product manufacturer.
- (2) Where tissues and cells are retrieved from a deceased donor by procurement teams which operate for 2 or more tissue establishments, each tissue establishment shall ensure robust traceability links between the donation identification numbers allocated by each of the tissue establishments concerned.”.

Single European Code

5. The Principal Regulations are amended by the substitution of the following Regulation for Regulation 22:

- “22. (1) Subject to paragraphs (2) and (3), a Single European Code shall be applied to all tissues and cells distributed for human application.
- (2) Where tissues and cells are released for circulation other than in accordance with paragraph (1), at a minimum the donation identification sequence shall be applied in the accompanying documentation.
- (3) Paragraphs (1) and (2) shall not apply to:
- (a) reproductive cells from partner donation;
 - (b) tissues and cells distributed directly for immediate transplantation to the recipient in

- accordance with Regulation 6(13) of the Regulations of 2006;
- (c) tissues and cells imported into the European Union in case of emergency authorised directly by the Health Products Regulatory Authority under Regulation 15(4)(b) of the Regulations of 2006;
 - (d) tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre;
 - (e) tissues and cells that are imported into the European Union, when these tissues and cells remain within the same centre from importation to application, provided that the centre comprises an importing tissue establishment authorised by the Health Products Regulatory Authority to carry out importing activities.”.

Insertion of Regulations 23 to 27

6. The Principal Regulations are amended by the insertion of the following Regulations after Regulation 22:

“Format of Single European Code

23. (1) The Single European Code shall -

- (a) comply with this Regulation and Schedule 8,
- (b) be in eye-readable format,
- (c) be preceded by the acronym ‘SEC’, and
- (d) be printed with the donation identification sequence and product identification sequence separated by a single space or as 2 successive lines.

(2) Nothing in these Regulations shall be construed as prohibiting the parallel use of other labelling and traceability systems in accordance with the Single European Code.

Allocation of Single European Code

24. (1) A tissue establishment –

- (a) shall allocate a Single European Code to all tissues and cells requiring application of this code before their distribution for human application,
- (b) shall 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,

- (c) shall not alter the donation identification sequence once it is allocated to tissues and cells released for circulation unless the alteration is necessary to correct an encoding error, and where such an error is corrected, the tissue establishment shall maintain a record of the correction,
 - (d) shall 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 the distribution for human application, and
 - (e) shall use an appropriate split number and expiry date for tissues and cells and where no expiry date is defined the expiry date shall be 00000000 at the latest before their distribution for human application.
- (2) A donation identification sequence shall include -
 - (a) the EU tissue establishment code as established in the EU Tissue Establishment Compendium, and
 - (b) a unique donation number allocated by the tissue establishment unless the number is a globally unique number as used by the ISBT128 coding system.
- (3) Where the pooling of tissues and cells is permitted -
 - (a) a new donation identification number shall be allocated to the final product, and
 - (b) the tissue establishment in which the pooling is carried out shall ensure the traceability of individual donations.
- (4) A tissue establishment shall apply the Single European Code on the label of the product concerned in an indelible and permanent manner and specify that code in the relevant accompanying documentation prior to the distribution for human application.
- (5) Where the label size does not allow the application of the Single European Code on the label, the code shall be clearly linked to tissues and cells packaged with such a label through the accompanying documents.
- (6) A tissue establishment shall take the necessary measures in consultation with the Health Products Regulatory Authority in the case of incorrect application of the Single European Code on the label.
- (7) A tissue establishment may entrust a third party to apply the Single European Code in accordance with paragraph (4), provided that the establishment ensures that the third party complies with these Regulations, in particular in terms of uniqueness of the code.
- (8) A tissue establishment shall notify the Health Products Regulatory Authority when -

- (a) information contained in the EU Tissue Establishment Compendium requires an update or correction,
- (b) the EU Tissue and Cell Product Compendium requires an update, and
- (c) that 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.

Allocation of tissue establishment number

25. (1) The Health Products Regulatory Authority shall allocate a unique tissue establishment number to all tissue establishments authorised in the State.

(2) Where a tissue establishment has different physical locations in the State, but has one system for allocating unique donation numbers, it may be deemed to be one and the same tissue establishment.

(3) Where a tissue establishment uses 2 or more systems for allocating unique donation numbers, such an establishment shall be allocated separate tissue establishment numbers corresponding to the number of allocation systems used.

EU Tissue Establishment Compendium

26. (1) The Health Products Regulatory Authority shall validate the data on the tissue establishments established in the State that are contained in the EU Tissue Establishment Compendium.

(2) The Health Products Regulatory Authority shall, as soon as practicable, update the EU Tissue Establishment Compendium in relation to the following:

- (a) the authorisation of a new tissue establishment;
- (b) when information relating to a tissue establishment changes or is not recorded correctly in the EU Tissue Establishment Compendium;
- (c) when the particulars of an authorisation of a tissue establishment listed in Schedule 8 changes, including -
 - (i) authorisation for a new tissue or cell type,
 - (ii) authorisation for a new prescribed activity or a new importing activity,
 - (iii) details of any conditions and or exemptions added to an authorisation,
 - (iv) suspension of an authorisation for a tissue establishment whether in part or in full,
 - (v) revocation of an authorisation for a tissue establishment whether in part or in full, and

- (vi) where a tissue establishment voluntarily ceases the activity or activities for which it is authorised whether in part or in full.

(3) In this Regulation, “as soon as practicable” means, in relation to any changes substantially affecting the authorisation of the tissue establishment concerned, not later than 10 working days.

Alerts

27. The Health Products Regulatory Authority shall alert -

- (a) the competent authority of a Member State when it observes -
 - (i) incorrect information in the EU Tissue Establishment Compendium relating to that Member State, or
 - (ii) a situation of significant non-compliance with the provisions relating to the Single European Code relating to that Member State, and
- (b) the Commission and competent authorities of Member States when, in the assessment of the Health Product Regulatory Authority, the Compendium requires an update.

Transitional provisions

28. (1) Regulation 20 and Regulations 22 to 27 shall not apply to tissues and cells in storage on or before 29 October 2016 if such tissues and cells are released for circulation in the European Union on or before 29 October 2021 and full traceability is ensured by alternative means.

(2) Where -

- (a) tissues and cells remain in storage and are released for circulation after 29 October 2021, and
- (b) the Single European Code cannot be applied, in particular because the tissues and cells are stored under deep-freeze conditions,

a tissue establishment shall use the procedures applicable to products with small labels in accordance with Regulation 24(4), (5) and (7).”.

Amendments to Schedules to Principal Regulations

7. The Principal Regulations are amended -

- (a) in Part E of Schedule 2 titled “Final Labelling for Distribution” -
 - (i) in paragraph (1) -
 - (I) by the substitution, in subparagraph (f), of “BIOLOGICAL HAZARD;” for “BIOLOGICAL HAZARD.”,

- (II) by the insertion of the following subparagraph after subparagraph (f):
 - “(g) Single European Code as applicable to the tissues and cells being distributed for human application or the donation identification sequence as applicable to the tissues and cells released for circulation, other than distributed for human application.”, and
- (III) by the substitution of “information under paragraphs (d), (e) and (g) above” for “information under paragraphs (d) and (e) above”, and
- (ii) in paragraph (2) -
 - (I) by the substitution, in subparagraph (i), of “oxide etc);” for “oxide etc).”, and
 - (II) by the insertion of the following subparagraph after subparagraph (i):
 - “(j) for imported tissues and cells, the country of procurement and the exporting country (if different from the procurement country).”,
- (b) by the substitution of Schedule 1 to these Regulations for Schedule 3,
- (c) by the substitution of Schedule 2 to these Regulations for Schedule 4,
- (d) by the substitution of Schedule 3 to these Regulations for Schedule 6,
- (e) by the substitution of Schedule 4 to these Regulations for Schedule 7, and
- (f) by the insertion of Schedule 5 to these Regulations after Schedule 7.

Amendment of Regulations of 2006

- 8. The Regulations of 2006 are amended -
 - (a) in Regulation 2(1) -
 - (i) in the definition of “inspection”, by the substitution of “these Regulations and the Regulations of 2007” for “these Regulations”, and
 - (ii) by the insertion of the following definition:
 - “ ‘Regulations of 2007’ means the European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse

Reactions and Events and Certain Technical Requirements) Regulations 2007 (S.I. No. 598 of 2007) (amended by the European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) (Amendment) Regulations 2019 (S.I. No. 32 of 2019));” and

- (b) in Regulation 19, by the substitution of “these Regulations and the Regulations of 2007” for “these Regulations” in each place that it occurs.

Schedule 1**NOTIFICATION OF SERIOUS ADVERSE REACTIONS****PART A****Rapid notification for suspected serious adverse reactions**

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Reporting date (year/month/day)
Individual affected (recipient or donor)
Date and place of procurement or human application (year/month/day)
Unique donation identification number
Date of suspected serious adverse reaction (year/month/day)
Type of tissues and cells involved in the suspected serious adverse reaction
Single European Code of tissues or cells involved in the suspected serious adverse reaction (if applicable)
Type of suspected serious adverse reaction(s)

PART B

Conclusions of Serious Adverse Reactions Investigation

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Confirmation date (year/month/day)
Date of serious adverse reaction (year/month/day)
Unique donation identification number
Confirmation of serious adverse reaction (Yes/No)
Single European Code of tissues or cells involved in the confirmed serious adverse reaction (if applicable)
Change of type of serious adverse reaction (Yes/No) If YES, specify
<p>Clinical outcome (if known)</p> <ul style="list-style-type: none"> — Complete recovery — Minor sequelae — Serious sequelae — Death
Outcome of the investigation and final conclusions
Recommendations for preventive and corrective actions

Schedule 2

NOTIFICATION OF SERIOUS ADVERSE EVENTS

PART A

Rapid notification for suspected serious adverse events

Tissue establishment				
EU tissue establishment code (if applicable)				
Report identification				
Reporting date (year/month/day)				
Date of serious adverse event (year/month/day)				
Serious adverse event, which may affect quality and safety of tissues and cells due to a deviation in:	Specification			
	Tissues and cells defect	Equipment failure	Human error	Other (specify)
Procurement				
Testing				
Transport				
Processing				
Storage				
Distribution				
Materials				
Others (specify)				

PART B

Conclusions of Serious Adverse Events investigation

Tissue establishment
EU tissue establishment code (if applicable)
Report identification
Confirmation date (year/month/day)
Date of serious adverse event (year/month/day)
Root cause analysis (details)
Corrective measures taken (details)

Schedule 3
Minimum data to be kept in accordance with Article 9(2)

A. BY TISSUE ESTABLISHMENTS

- (1) Donor identification
- (2) Donation identification that will include at least:
 - Identification of the procurement organisation (including contact details) or the tissue establishment
 - Unique donation number
 - Date of procurement
 - Place of procurement
 - Type of donation (e.g. single v multi-tissue; autologous v allogenic; living v deceased)
- (3) Product identification that will include at least:
 - Identification of the tissue establishment
 - Type of tissue and cell/product (basic nomenclature)
 - Pool number (in case of pooling)
 - Split number (if applicable)
 - Expiry date (if applicable)
 - Tissue/cell status (i.e. quarantined, suitable for use, etc.)
 - Description and origin of the products, processing steps applied, materials and additives coming into contact with tissues and cells and having an effect on their quality and/or safety.
 - Identification of the facility issuing the final label
- (4) Single European Code (if applicable)
- (5) Human application identification that will include at least:
 - Date of distribution/disposal
 - Identification of the clinician or end-user/facility

A. BY ORGANISATIONS RESPONSIBLE FOR HUMAN
APPLICATION

- (1) Identification of the supplier tissue establishment
- (2) Identification of the clinician or end-user/facility
- (3) Type of tissues and cells
- (4) Product identification
- (5) Identification of the recipient
- (6) Date of application

(7) Single European Code (if applicable)

Schedule 4**THE STRUCTURE OF THE SINGLE EUROPEAN CODE**

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters'

Schedule 5

Data to be recorded in the EU Tissue Establishment Compendium

- A. Tissue establishment information
 - 1. Name of the tissue establishment
 - 2. National or international code of tissue establishment
 - 3. Name of the organisation in which the tissue establishment is located (if applicable)
 - 4. Address of the tissue establishment
 - 5. Publishable contact details: functional e-mail address, phone and fax
- B. Details on the authorisation, accreditation, designation, or license of the tissue establishment
 - 1. Name of the authorising, accrediting, designating or licensing competent authority or authorities
 - 2. Name of the national competent authority or authorities responsible for maintenance of the EU Tissue Establishment Compendium
 - 3. Name of the authorisation, accreditation, designation or licence holder (if applicable)
 - 4. Tissues and cells for which the authorisation, accreditation, designation or license was granted
 - 5. Activities actually carried out for which the authorisation, accreditation, designation or licence was granted
 - 6. Status of the authorisation, accreditation, designation or license (authorised, suspended, revoked, in part or in full, voluntary cessation of activities)
 - 7. Details of any conditions and exemptions added to the authorisation (if applicable).⁷



GIVEN under my Official Seal,
5 February 2019

SIMON HARRIS,
Minister for Health.

Explanatory Note

(This note is not part of the instrument and does not purport to be a legal interpretation)

These Regulations give effect to Commission Directive (EU) 2015/565 of 08 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells.

The Regulations provide procedures for ensuring the traceability of human tissues and cells from the donor to the recipient and vice versa. The Regulations provide that a unique identifier known as the Single European Code should be applied to all tissues and cells distributed for human application. The Regulations further provide that the Health Products Regulatory Authority will assign a unique tissue establishment number to all authorised, accredited, designated or licensed tissue establishments and importing tissue establishments.

The Regulations amend the European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) Regulations 2007 (S.I. No. 598 of 2007).

The Regulations may be cited as the European Communities (Human Tissues and Cells Traceability Requirements, Notification of Serious Adverse Reactions and Events and Certain Technical Requirements) (Amendment) Regulations 2019.

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