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 (Text with EEA relevance)

Article 1

Scope

1 This Directive shall apply to the coding, processing, preservation, storage and distribution of:

a human tissues and cells intended for human applications; and

b manufactured products derived from human tissues and cells intended for human applications, where those products are not covered by other directives.

2 The provisions of Articles 5 to 9 of this Directive, concerning traceability and the reporting of serious adverse reactions and events shall also apply to the donation, procurement and testing of human tissues and cells.

Article 2

Definitions

For the purposes of this Directive, the following definitions apply:

(a) '*reproductive cells*' means all tissues and cells intended to be used for the purpose of assisted reproduction;

(b) '*partner donation*' means the donation of reproductive cells between a man and a woman who declare that they have an intimate physical relationship;

(c) '*quality system*' means the organisational structure, defined responsibilities, procedures, processes, and resources for implementing quality management and includes all activities which contribute to quality, directly or indirectly;

(d) '*quality management*' means the coordinated activities to direct and control an organisation with regard to quality;

(e) '*Standard Operating Procedures'(SOPs)* means written instructions describing the steps in a specific process, including the materials and methods to be used and the expected end product;

(f) '*validation*' (or '*qualification*' in the case of equipment or environments) means establishing documented evidence that provides a high degree of assurance that a specific process, piece of equipment or environment will consistently produce a product meeting its predetermined specifications and quality attributes; a process is validated to evaluate the performance of a system with regard to its effectiveness based on intended use;

(g) '*traceability*' means the ability to locate and identify the tissue/cell during any step from procurement, through processing, testing and storage, to distribution to the

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recipient or disposal, which also implies the ability to identify the donor and the tissue establishment or the manufacturing facility receiving, processing or storing the tissue/cells, and the ability to identify the recipient(s) at the medical facility/facilities applying the tissue/cells to the recipient(s); traceability also covers the ability to locate and identify all relevant data relating to products and materials coming into contact with those tissues/cells;

(h) '*critical*' means potentially having an effect on the quality and/or safety of or having contact with the cells and tissues;

(i) '*procurement organisation*' means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment;

(j) '*organisations responsible for human application*' means a health care establishment or a unit of a hospital or another body which carries out human application of human tissues and cells**[**F1**;]**

(k) '***[**F2***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 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;

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(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.**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

F2 Inserted by 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 (Text with EEA relevance).

Article 3

Requirements for the accreditation, designation, authorisation or licensing of tissue establishments

A tissue establishment must comply with the requirements set out in Annex I.

Article 4

Requirements for the accreditation, designation, authorisation, licensing of tissue and cell preparation processes

Preparation processes at the tissue establishments must comply with the requirements set out in Annex II.

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Article 5

Notification of serious adverse reactions

1 Member States shall ensure that:

a procurement organisations have procedures in place to retain the records of tissues and cells procured and to notify tissue establishments without delay of any serious adverse reactions in the living donor which may influence the quality and safety of tissues and cells;

b organisations responsible for human application of tissues and cells have procedures in place to retain the records of tissues and cells applied and to notify tissue establishments without delay of any serious adverse reactions observed during and after clinical application which may be linked to the quality and safety of tissues and cells;

c tissue establishments that distribute tissue and cells for human application provide information to the organisation responsible for human application of tissues and cells about how that organisation should report serious adverse reactions as referred to in (b).

2 Member States shall ensure that tissue establishments:

a have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse reactions as referred to in paragraph 1(a) and (b);

b have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

3 Member States shall ensure that:

a the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex III;

b tissue establishments notify the competent authority of the actions taken with respect to other implicated tissues and cells that have been distributed for human applications;

c tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex III.

Article 6

Notification of serious adverse events

1 Member States shall ensure that:

a procurement organisations and tissue establishments have procedures in place to retain the records and to notify tissue establishments without delay of any serious adverse events that occur during procurement which may influence the quality and/or safety of human tissues and cells;

b organisations responsible for human application of tissues and cells have procedures in place to notify tissue establishments without delay of any serious adverse events that may influence the quality and safety of the tissues and cells;

c tissue establishments provide to the organisation responsible for human application information about how that organisation should report serious adverse events to them that may influence the quality and safety of the tissues and cells.

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2 In the case of assisted reproduction, any type of gamete or embryo misidentification or mix-up shall be considered to be a serious adverse event. All persons or procurement organisations or organisations responsible for human application performing assisted reproduction shall report such events to the supplying tissue establishments for investigation and notification to the competent authority.

3 Member States shall ensure that tissue establishments:

a have procedures in place to communicate to the competent authority without delay all relevant available information about suspected serious adverse events as referred to in paragraph 1(a) and (b);

b have procedures in place to communicate to the competent authority without delay the conclusion of the investigation to analyse the cause and the ensuing outcome.

4 Member States shall ensure that:

a the responsible person referred to in Article 17 of Directive 2004/23/EC notifies the competent authority of the information included in the notification set out in Part A of Annex IV;

b tissue establishments evaluate serious adverse events to identify preventable causes within the process;

c tissue establishments notify the competent authority of the conclusion of the investigation, supplying at least the information set out in Part B of Annex IV.

Article 7

Annual reports

1 Member States shall submit to the Commission an annual report, by 30 June of the following year, on the notification of serious adverse reactions and events received by the competent authority. The Commission shall submit to the competent authorities of Member States a summary of the reports received. The competent authority shall make this report available to tissue establishments.

2 Data transmission shall comply with the data exchange format specifications as set out in Annex V, part A and B, and shall provide all the information necessary to identify the sender and maintain its reference data.

Article 8

Communication of information between competent authorities and to the Commission

Member States shall ensure that their competent authorities communicate to each other and to the Commission such information as is appropriate with regard to serious adverse reactions and events, in order to guarantee that adequate actions are taken.

I[F1] 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

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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.**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

[F1 Article 10

European coding system

1 Without prejudice to paragraphs 2 or 3 of 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.

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.**]**

Textual Amendments

F1 Substituted by 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 (Text with EEA relevance).

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[F2 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.

Textual Amendments

F2 Inserted by 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 (Text with EEA relevance).

Article 10b

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[(1)]:

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 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;

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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 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,

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- — 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.

Textual Amendments

F2 Inserted by 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 (Text with EEA relevance).

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

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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.

Textual Amendments

F2 Inserted by 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 (Text with EEA relevance).

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 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).**]**

Textual Amendments

F2 Inserted by 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 (Text with EEA relevance).

Article 11

Transposition

1 Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by 1 September 2007, at the latest. They shall forthwith communicate to the Commission the text of those provisions and a correlation table between those provisions and this Directive.

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with Article 10 of this Directive, by 1 September 2008.

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.

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Article 12

Entry into force

This Directive shall enter into force on the 20th day following its publication in the *Official Journal of the European Union*.

Article 13

Addressees

This Directive is addressed to the Member States.

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(1) **[**[F2]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).**]**

Textual Amendments

F2 Inserted by 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 (Text with EEA relevance).