EUROPEAN
COMMISSION

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COMMISSION DIRECTIVE ../…/EU

of XXX

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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THE EUROPEAN COMMISSION,

Having regard to the Treaty on the Functioning of the European Union,

Having regard to Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells, and in particular Article 28 thereof,

Whereas:

(1) Directive 2004/23/EC requires that Member States ensure the traceability of human tissues and cells from the donor to the recipient and vice-versa.

(2) In order to facilitate traceability it is necessary to establish a unique identifier applied to tissues and cells distributed in the Union ("Single European Code") providing information on the main characteristics and properties of those tissues and cells.

(3) In order to ensure a uniform implementation of the Single European Code throughout the Union, obligations of the Member States competent authorities and of the tissue establishments for the application of the Single European Code should be set out. Only this approach will guarantee a consistent and coherent application of the code in the Union.

(4) Traceability from donor to recipient and vice-versa should be ensured through coding of tissues and cells and through accompanying documentation. At the recipient end, the Single European Code provides information on the donation and on the tissue establishment responsible for the procurement of tissues and cells. At the donor end, the tissue establishment responsible for the procurement of tissues and cells may track the tissues and cells distributed for human application by requesting the next operators in the chain to provide data related to the use of the tissues and cells based on the donation identification elements of the Single European Code as contained in the accompanying documentation.

(5) A Single European Code allowing for donation and product identification should be allocated to all tissues and cells distributed for human application, including those imported from third countries. Member States may allow certain exemptions from the application of the code.

(6) Where tissues and cells are excluded or exempted from the application of the Single European Code, the Member States should ensure that appropriate traceability of these tissues and cells is guaranteed throughout the entire chain from donation and procurement to human application.

(7) In situations where tissues and cells are released for circulation, other than for distribution, such as transfer to another operator for further processing with or without return, as a minimum the donation identification sequence should be applied at least in the accompanying documentation. Where tissues and cells are transferred from a tissue establishment to another operator just for storage and/or for further distribution, the tissue establishment may already apply the Single European Code on their final label in addition to the donation identification sequence which should be applied at least in the accompanying documentation.

(8) 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 procurements. This may be ensured by developing a central system for the allocation of the unique donation numbers for each donation event recorded at national level, or by requiring all tissue establishments to ensure the appropriate links between the donation identification numbers allocated by each tissue establishment procuring or receiving tissue and cells originating from the same deceased donor.

(9) The format of the Single European Code should be harmonised in order to facilitate its application by small and large establishments, whilst allowing some flexibility for establishments to continue using existing codes.

(10) The Commission should ensure the implementation of the Single European Code by providing the appropriate tools to the Member States competent authorities and tissue establishments. The Member States competent authorities should update the register for tissue establishments, reflecting any changes in tissue establishment accreditations, designations, authorisations, or licenses and the Commission should ensure the update of the register of the tissues and cells whenever new products need to be included. For this the Commission should consult a group of experts, in particular experts nominated by the Member States competent authorities.

(11) For the donation identification sequence in the Single European Code, the importing tissue establishment should use the tissue establishment code allocated to it in the EU Tissue Establishment Compendium and should allocate a unique donation number if the donation number on the imported product is not globally unique.

(12) A transitional regime for tissues and cells already in storage at the end of the transposition period should be introduced.

(13) This Directive does not prevent Member States from maintaining or introducing more stringent measures relating to coding of tissues and cells, provided that the provisions of the Treaty are met.

(14) The measures provided for in this Directive are in accordance with the opinion of the Committee established by Article 29 of Directive 2004/23/EC,

HAS ADOPTED THIS DIRECTIVE:

Article 1

Directive 2006/86/EC is hereby amended as follows:

(1) In Article 2, the following points (k) to (y) are added:

(k) “tissues and cells” means all substances of human origin falling within the scope of this Directive as set out in Article 1 paragraph 1;

(l) “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;

(m) “donation identification sequence” means the first part of the Single European Code consisting of the tissue establishment code and the unique donation number;

(n) “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;

(o) “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;

(p) “product identification sequence” means the second part of the Single European Code consisting of the product code, the split number and the expiry date;

(q) “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;

(r) “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;

(s) “expiry date” means the date by which the tissues and cells can be applied, as further defined in Annex VII to this Directive;

(t) “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;

(u) “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;

(v) “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);

(w) “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.

(x) “released for circulation” means distribution for human application or transfer to another operator e.g. for further processing with or without return.

(y) “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 facility comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location;

(z) “pooling” means …

Comentario [MR(SANCO)1]: Suggestions welcomed

(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.

   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.”

(3) Article 10 is replaced by the following:

“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 tissue 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 after direct authorisation by the competent authority or authorities.

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 healthcare facility from importation to application, provided that the healthcare facility comprises the tissue establishment authorised, designated, accredited, or licensed to carry out importing activities."

(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.

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 Directive xxxx/xx/EU:

(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:

(i) their EU tissue establishment code as assigned in the EU Tissue Establishment Compendium;

(ii) 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. 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;

(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 their 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:

(i) information contained in the EU Tissue Establishment Compendium requires an update or correction,

(ii) the EU Tissue and Cell Product Compendium requires an update,

(iii) 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.

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:

i. When a new tissue establishment is authorised, designated, accredited, or licensed;

ii. When tissue establishment information changes or is not correctly recorded in the EU Tissue Establishment Compendium;

iii. 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.

Undue delay means in not later than ten 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.”

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.

3. The Commission shall update when needed the EUTC and ensure the overall update of the EU Tissue and Cell Product Compendium. The Commission shall establish memorandums of understanding 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 memorandums of understanding, the Commission may suspend, partially or in full, the use of their respective product codes, having consulted the Member State experts through the Competent Authorities of Substances of Human Origin Expert Group.

Article 10d

Transitional period

Tissues and cells in storage on […][1] 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)."

(5) The Annexes are amended in accordance with Annex I to this Directive.

(6) A new Annex VIII is added, the text of which is set out in Annex II to this Directive."

Article 2

[1] date of expiry of the transposition period

Member States shall bring into force the laws, regulations and administrative provisions necessary to comply with this Directive by […][2] at the latest. They shall forthwith communicate to the Commission the text of those provisions. They shall apply the legislation from […][3]

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.

Article 3

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

Article 4

This Directive is addressed to the Member States.

Done at Brussels,

For the Commission
The President
[…]

[Choose between the two options, depending on the person who signs.]

On behalf of the President
[…]
[Position]

[2] 18 months following entry into force of this Directive
[3] 6 months after the transposition deadline.

ANNEX I

The Annexes to Directive 2006/86/EC are amended as follows:

(1) Annex II, Part E, is amended as follows:

(a) In point 1 the following point (g) is added:

"(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";

(b) The second subparagraph of point 1 is replaced by the following:

"If any of the information under points (d), (e) and (g) above cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together."

(c) In point 2, the following point (j) is added:

"(j) for imported tissues and cells, the country of procurement and the exporting country (if different from the procurement country)".

(a) Annexes III and IV are replaced by the following:

'Annex III

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
Clinical outcome (if known) - Complete recovery - Minor sequelae - Serious sequelae - Death
Outcome of the investigation and final conclusions
Recommendations for preventive and corrective actions"

Annex IV

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)'

4. Annexes VI and VII are replaced by the following:

‘Annex VI

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 (if applicable)

- 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

B. 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)”

Annex VII

THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			**PRODUCT IDENTIFICATION SEQUENCE**			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONA-TION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE
ISO country code	Tissue establish-ment 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’

ANNEX II

‘Annex VIII

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 email 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 license 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 license 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).’