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)

I[F1] 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;

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,

— 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

F1 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).

(1) **[**[F1]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

F1 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).