Council of the
European Union

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COVER NOTE

From:	European Commission
date of receipt:	12 December 2014
To:	General Secretariat of the Council
Subject:	ANNEXES to the COMMISSION DIRECTIVE ../…/EU of XXX amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

Delegations will find attached document D034434 - Annex 1.

Encl.: D034434 - Annex 1

D034434/04

EN

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)".

(2) 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)’

(3) 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 (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

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 (YYYYMMDD)
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).'