



# Coding and Import of Tissues and Cells

## - Refresher and Updates

Richard Forde and Laura Hickey

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**Tissue Establishment Meeting – 4<sup>th</sup> November 2016**

HPRA Offices, Earlsfort Terrace, Dublin 2



## Overview of Presentations

- Coding Directive – 2015/565;
- EU Coding Platform – Publically Available;
- Import Directive – 2015/566;
- Questions – Discussion;



# Single European Code for Tissues and Cells

**Richard Forde – BTO Inspector HPRA**

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**Tissue Establishment Meeting – 4<sup>th</sup> November 2016**

HPRA Offices, Earlsfort Terrace, Dublin 2



## Overview:

- The Single European Code (SEC):  
Legislative Basis;
- Scope of Legislation
- SEC Structure;
- EU Coding Platform;
- Label specifications;
- Next steps



## Single European Code: Legislative Basis.

- Article 25 (2) of Directive 2004/23/EC.  
“The Commission, in cooperation with the Member States, shall design a single European coding system to provide information on the main characteristics and properties of tissues and cells”;



## Single European Code: Legislative Basis

- Directive 2006/86/EC Article 10
  - “A single European identifying code shall be allocated to all donated material at the tissue establishment:
  - To ensure proper identification of the donor;
  - To ensure traceability of all donated material;
  - To provide information on the main characteristics and properties of tissues and cells”



# Single European Code: Legislative Basis

- Directive 2006/86/EC Article 10

The code shall incorporate at least the information set out in Annex VII.

## Information contained in the European Coding System

(a) Donation identification:

- Unique ID number
- Identification of the tissue establishment

(b) Product identification:

- Product code (basic nomenclature)
- Split number (if applicable)
- Expiry date



## Directive 2015/565

- Commission Directive (EU) 2015/565 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells was published on 9 April 2015.
- Implementation required from 29<sup>th</sup> April 2017;





## Scope of Directive 2015/565/EC

### When does the Single European Code need to be applied?

- SEC shall be applied to all tissues and cells that are distributed for human application
- Tissues and cells “released for circulation” to another operator, as a minimum the donation identification sequence shall be applied, at least in the accompanying documentation.



## Exemptions:

- Reproductive cells from partner donation;
- Tissues and cells distributed directly for immediate transplantation to the recipient; as referred to in Article 6(5) of 2004/23/EC;
- Tissues and cells imported into the Union in case of emergency authorised directly by the competent authority as referred to in Article 9(3)b of 2004/23/EC



## Exemptions

- Tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain “within the same centre”;
- Tissues and cells that are imported into the Union, when these tissues 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;



## Transitional period

- Tissues and cells already in storage on 29 October 2016 – exempt – provided they are released for circulation in the Union within 5 years of that date.



## Structure of the SEC

- Alphanumeric code that carries information on the TE, the donation number, the product code, divisions and expiry date in a standard format (ISO format YYYYMMDD)
- It will consist of a donation identification sequence and a product identification sequence.
- New Annex VII of 2006/86/EC



# Structure of Single European Code

Donation Identification Sequence		Product identification Sequence				
TE Code		Unique Donation Number	Product Code		Split Number	Expiry date
ISO Country Code	TE Number		Product Coding System identifier	Product Number		
2 Alphabetic Characters	6 Alpha – numeric Characters	13 alpha-numeric characters	1 alphabetic character <b>E = EUTC</b> <b>A=ISBT128</b> <b>B=Eurocode</b>	7 alpha - numeric characters	3 alpha numeric characters	8 numeric characters



## SEC – Structure

- Donation Identification Sequence:
  - E.g. IE-0TE00X-000000A1234567

### DONATION IDENTIFICATION

ISO country	TE code	Unique donation number (local/national)
2 characters	6 characters (alpha-numeric)	13 characters (alpha-numeric)



## SEC-Structure

- Product Identification Sequence
  - E.g. A000S123-001-20160802
  - E.g. E0000041-002-20160911

### PRODUCT IDENTIFICATION

Product code	Split number	Expiry date
1 symbol + 7 characters (alpha-numeric)	3 characters (alpha-numeric)	8 characters (alpha-numeric)

- A= ISBT128
- B= Eurocode
- E =EUTC





## EU Coding Platform -

- Publically available 6<sup>th</sup> October 2016

<https://webgate.ec.europa.eu/eucoding/>

IT platform hosted by Commission which contains;


1. SEC Look Up;
2. EU Tissue Establishment Compendium;
3. EU Tissue and Cell Product Compendium;
4. Download sample SEC maker file;



# EU Coding Platform

## 1. SEC LookUp

ⓘ Disclaimer   ⓘ User Manuals   ✉ Support   👤 Anonymous   🚪 Logout

 **EU Coding Platform**  
Reference Compendia for the Application of a single European Coding System for Tissues and Cells

**SEC LookUp**   Compendia   TE Management   Admin

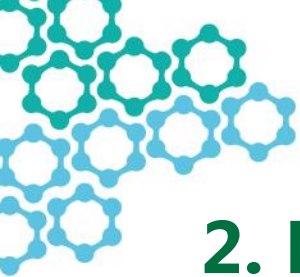
**SEC LookUp**  
Single European Code (SEC) Search  
Download Sample SEC maker file

Full SEC   Donation Identification Sequence   Product Identification Sequence

**Enter code**

Ver 1.1 | developed by **EUROCET128**



## 2. EU TE Compendium

A register of all authorised EU Tissue Establishments detailing;

- Tissue establishment information; (name, address, contact details)
- Authorised activities;
- Tissue and cell type per activity;
- TE code;
  - ISO two country character prefix (IE – Ireland);
  - six character alpha-numeric TE number (assigned by the HPRA – linked with existing national TE number);

**e.g. TE Code for a TE in Ireland: IE 0TE123**

All TE specific information will be associated with this TE code.

Publicly accessible / Search by name of TE or by Code

**Responsibility of HPRA to keep the TE compendium updated**



# 2. EU TE Compendium



## EU Coding Platform

Reference Compendia for the Application of a single European Coding System for Tissues and Cells

SEC LookUp

Compendia

TE Management

Admin

EU Tissue Establishment Compendium

EU TE List

Filter by Activities

EU Tissue and Cell Product Compendium

EUTC

Product List

Product Categories

Overview Tissue Establishments ▸ TE Details

Search

[Back to Full List](#)

EU TE Code	TE Name	City	Country	
			IE-Ireland	
IE0TE030	Beacon CARE Fertility Limited	Dublin 18	Ireland	+
IE0TE019	Biostor Ireland	Co. Wexford	Ireland	+
IE0TE009	Cappagh Bone Bank (Cappagh National Orthopaedic Hospital)	Dublin 11	Ireland	+
R IE0TE004	Clane Fertility Clinic	Clane	Ireland	+
IE0TE007	Cork Fertility Centre	Cork, Limerick, Waterford	Ireland	+
IE0TE001	Cryobiology Laboratory Stem Cell Facility (St. James's Hospital)	Dublin 8	Ireland	+
IE0TE006	Galway Fertility	Galway	Ireland	+
IE0TE005	Galway University Hospitals	Galway	Ireland	+
IE0TE031	Institut Marques Ireland Limited	Co. Kildare	Ireland	+
IE0TE012	Irish Blood Transfusion Service ( National Blood Centre)	Dublin 8	Ireland	+

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1 2 3

10



## 2. EU TE Compendium

**EU Tissue Establishment Compendium**

EU TE List

**Filter by Activities**

**EU Tissue and Cell Product Compendium**

EUTC

Product List

Product Categories

**Filter :**

**Pick Categories: \***

- Cardiovascular, Valves
- Cardiovascular, Vessels
- Mature Cell, Hepatocyte
- Mature Cell, Keratinocyte
- Mature Cell, Pancreatic Islet Cells
- Mature Cell, T Cell (DLI)
- Membrane, Amniotic

**Pick Activities:**

- Procurement </br>
- Donation
- Testing
- Preservation
- Processing
- Storage
- Distribution
- Import

**Tissue Establishment Name:**

**City Name:**

**Pick Countries**

- Austria - AT
- Belgium - BE
- Bulgaria - BG
- Croatia - HR
- Cyprus - CY
- Czech Republic - CZ
- Denmark - DK
- Estonia - EE

**Submit**



## 2. EU TE Compendium - Important

- Familiarise with TE Code;
- Review details (vs) TEA;
- Confirm details with the HPRA;



### 3. EU Tissue and Cell Product Compendium

Register of all tissue and cells circulating in the Union and the respective product under the three permitted coding systems

includes;

- Existing national and international coding systems: **ISBT 128**, **Eurocode**;
- EU Tissue and Cell product codes (**EUTC Code**) that must be used where a national or international system is not in use.

**ISBT 128**, **Eurocode** and **EUTC Code** will be identified in the SEC by a coding system identifier (A, B and E, respectively)





# 3. EU Tissue and Cell Product Compendium



## EU Coding Platform

Reference Compendia for the Application of a single European Coding System for Tissues and Cells

SEC LookUp

Compendia

TE Management

Admin

EU Tissue  
Establishment  
Compendium

EU TE List

Filter by Activities

**EU Tissue and Cell  
Product Compendium**

*EUTC*

Product List

Product Categories

### EUTC

Product number ^	EUTC Name ↕
1	MEMBRANE, PERICARDIUM
2	<u>CARDIOVASCULAR, VALVE, AORTIC</u>
3	CARDIOVASCULAR, VALVE, MITRAL
4	CARDIOVASCULAR, VALVE, PULMONARY
5	CARDIOVASCULAR, VESSEL, AORTIC
6	CARDIOVASCULAR, VESSEL, ARTERY
7	CARDIOVASCULAR, VESSEL, OTHER
8	CARDIOVASCULAR, VESSEL, VEIN
9	MEMBRANE, AMNIOTIC
10	MEMBRANE, DURA MATER

1-10 out of 77

1 2 3 4 5 6 7 8 10







# 3. EU Tissue and Cell Product Compendium

- EU Tissue Establishment Compendium
- EU TE List
- Filter by Activities
- EU Tissue and Cell Product Compendium**
- EUTC*
- Product List
- Product Categories

EUTC	
Product number ^	EUTC Name ⇅
11	MEMBRANE, FASCIA LATA
12	<u>MUSCULOSKELETAL, BONE, AUDITORY OSSICLE</u>
13	MUSCULOSKELETAL, BONE, CALCANEUS
14	MUSCULOSKELETAL, BONE, CLAVICLE
15	MUSCULOSKELETAL, BONE, CRANIAL PLATE
16	MUSCULOSKELETAL, BONE, FEMORAL
17	MUSCULOSKELETAL, BONE, FIBULAR
18	MUSCULOSKELETAL, BONE, FOOT
19	MUSCULOSKELETAL, BONE, FRAGMENTS
20	MUSCULOSKELETAL, BONE, HAND

Bone  
Cartilage  
Ligament  
Tendon

11-20 out of 77    1 2 3 4 5 6 7 8    10



# 3. EU Tissue and Cell Product Compendium

**EU Tissue Establishment Compendium**

[EU TE List](#)

[Filter by Activities](#)

**EU Tissue and Cell Product Compendium**

*EUTC*

[Product List](#)

[Product Categories](#)

EUTC	
Product number ▲	EUTC Name ▼
51	MUSCULOSKELETAL, TENDON, TIBIALIS
52	<u>OCULAR, CONJUNCTIVAL</u>
53	OCULAR, CORNEAL
55	OCULAR, SCLERAL
56	REPRODUCTIVE, EMBRYO
57	REPRODUCTIVE, OOCYTE
58	REPRODUCTIVE, OVARIAN
59	REPRODUCTIVE, SPERM
60	REPRODUCTIVE, TESTICULAR
61	SKIN, DERMIS

51-60 out of 77    << < 1 2 3 4 5 6 7 8 > >>    10 ▼



# 3. EU Tissue and Cell Product Compendium

- EU Tissue Establishment Compendium
  - EU TE List
  - Filter by Activities
- EU Tissue and Cell Product Compendium**
  - EUTC**
  - Product List
  - Product Categories

EUTC	
Product number ^	EUTC Name ⇅
62	SKIN, FULL
63	SKIN, FULL WITH HYPODERMIS
64	SKIN, OTHER
65	SKIN, SPLIT
72	MATURE CELLS, HEPATOCYTES
74	MATURE CELLS, PANCREATIC ISLET CELLS
76	MATURE CELLS, T CELLS (DLI)
78	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
79	PROGENITOR CELLS, HEMATOPOIETIC, CORD BLOOD
80	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD

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# 3. EU Tissue and Cell Product Compendium

- EU Tissue Establishment Compendium
- EU TE List
- Filter by Activities
- EU Tissue and Cell Product Compendium**
- EUTC
- Product List**
- Product Categories

**Product List**

Search

Coding System	Product number	Product Name	Product Characteristics	Product Code	EUTC Name
E - EUTC					muscl
E - EUTC	12	MUSCULOSKELETAL, BONE, AUDITORY OSSICLE		E0000012	MUSCULOSKELETAL, BONE, AUDITORY OSSICLE
E - EUTC	13	MUSCULOSKELETAL, BONE, CALCANEUS		E0000013	MUSCULOSKELETAL, BONE, CALCANEUS
E - EUTC	14	MUSCULOSKELETAL, BONE, CLAVICLE		E0000014	MUSCULOSKELETAL, BONE, CLAVICLE
E - EUTC	15	MUSCULOSKELETAL, BONE, CRANIAL PLATE		E0000015	MUSCULOSKELETAL, BONE, CRANIAL PLATE
E - EUTC	16	MUSCULOSKELETAL, BONE, FEMORAL		E0000016	MUSCULOSKELETAL, BONE, FEMORAL
E - EUTC	17	MUSCULOSKELETAL, BONE, FIBULAR		E0000017	MUSCULOSKELETAL, BONE, FIBULAR
E - EUTC	18	MUSCULOSKELETAL, BONE, FOOT		E0000018	MUSCULOSKELETAL, BONE, FOOT
E - EUTC	19	MUSCULOSKELETAL, BONE, FRAGMENTS		E0000019	MUSCULOSKELETAL, BONE, FRAGMENTS
E - EUTC	20	MUSCULOSKELETAL, BONE, HAND		E0000020	MUSCULOSKELETAL, BONE, HAND
E - EUTC	21	MUSCULOSKELETAL, BONE, HUMERAL		E0000021	MUSCULOSKELETAL, BONE, HUMERAL

1-40 out of 40    1    100



# 3. EU Tissue and Cell Product Compendium

**EU Tissue Establishment Compendium**

EU TE List

Filter by Activities

**EU Tissue and Cell Product Compendium**

EUTC

*Product List*

Product Categories

Product List

Search

Coding System	Product number	Product Name	Product Characteristics	Product Code	EUTC Name
E - EUTC	78	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW		E0000078	PROGENITOR CELLS, HEMATOPOIETIC, BONE MARROW
E - EUTC	79	PROGENITOR CELLS, HEMATOPOIETIC, CORD BLOOD		E0000079	PROGENITOR CELLS, HEMATOPOIETIC, CORD BLOOD
E - EUTC	80	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD		E0000080	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
E - EUTC	81	PROGENITOR CELLS, HEMATOPOIETIC, UNSPECIFIED		E0000081	PROGENITOR CELLS, HEMATOPOIETIC, UNSPECIFIED

1-4 out of 4    1    100

XLS PDF CSV





# 3. EU Tissue and Cell Product Compendium

<b>EU Tissue Establishment Compendium</b>
EU TE List
Filter by Activities
<b>EU Tissue and Cell Product Compendium</b>
EUTC
<i>Product List</i>
Product Categories

N = 1127

Product List					
Search					
<input type="text"/>					
Coding System	Product number	Product Name	Product Characteristics	Product Code	EUTC Name
A - ISBT 1					prog
A - ISBT 128	S0197	HPC, APHERESIS	NS/XX/rt Open 4th container extensive Mot	A00S0197	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0198	HPC, APHERESIS	NS/XX/rt Open Plasma added 1st container extensive Mot	A00S0198	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0199	HPC, APHERESIS	NS/XX/rt Open Plasma added 2nd container extensive Mot	A00S0199	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0200	HPC, APHERESIS	NS/XX/rt Open Plasma added 3rd container extensive Mot	A00S0200	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0201	HPC, APHERESIS	NS/XX/rt Open Plasma added 4th container extensive Mot	A00S0201	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0214	HPC, APHERESIS	DMSO/XX/<-120C Open container extensive Cry	A00S0214	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0215	HPC, APHERESIS	DMSO/XX/<-120C Open container extensive Cry	A00S0215	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD
A - ISBT 128	S0216	HPC, APHERESIS	DMSO/XX/<-120C Open container extensive Cry	A00S0216	PROGENITOR CELLS, HEMATOPOIETIC, PERIPHERAL BLOOD



# 3. EU Tissue and Cell Product Compendium

EU Tissue  
Establishment  
Compendium

EU TE List

Filter by Activities

EU Tissue and Cell  
Product Compendium

EUTC

Product List

*Product Categories*

## Product Categories

Search

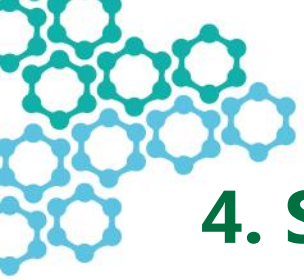
EUTC Product number ▲	EUTC Name ⇅ <input type="text"/>	TE Dataset Category ⇅ <input type="text"/>	SARE Category ⇅ <input type="text"/>	EU Coding Platform Categ <input type="text"/>
1	MEMBRANE, PERICARDIUM	Membrane, Pericardium	Other Tissues or Cells	Other tissue
2	CARDIOVASCULAR, VALVE, AORTIC	Cardiovascular, Valves	Heart Valves	Heart Valve
3	CARDIOVASCULAR, VALVE, MITRAL	Cardiovascular, Valves	Heart Valves	Heart Valve
4	CARDIOVASCULAR, VALVE, PULMONARY	Cardiovascular, Valves	Heart Valves	Heart Valve
5	CARDIOVASCULAR, VESSEL, AORTIC	Cardiovascular, Vessels	Vessels	Blood Vessel
6	CARDIOVASCULAR, VESSEL, ARTERY	Cardiovascular, Vessels	Vessels	Blood Vessel
7	CARDIOVASCULAR, VESSEL, OTHER	Cardiovascular, Vessels	Vessels	Blood Vessel
8	CARDIOVASCULAR, VESSEL, VEIN	Cardiovascular, Vessels	Vessels	Blood Vessel
9	MEMBRANE, AMNIOTIC	Membrane, Amniotic	Amniotic membrane	Amniotic membranes
10	MEMBRANE, DURA MATER	Membrane, Dura Mater	Other Tissues or Cells	Other tissue



### 3. EU Tissue and Cell Product Compendium

- ICCBBA regularly updates the ISBT 128 product code database, but does not have the authority to update this in the product compendium –
- responsibility of Commission - in consultation with expert sub group (MS CA / ICCBA / Eurocode);





## 4. SEC Maker File

Download from the website

<https://webgate.ec.europa.eu/eucoding/>








# Specifications for Product labels

- Eye readable format;
- Must be preceded by the text SEC
- As a single line of characters – with DIS and PIS separated by a single space  
or two successive lines;
- Printed;
- Where possible the SEC must appear on the affixed label of the product;
- **Note: If label size precludes inclusion of SEC – accompanying documentation.**
- For imports – country of procurement (exporting country) must be on final label for distribution (amended Annex II – Part E of 2006/86/EC)



**HPRA**  
An tÚdarás Rialála Táirgí Sláinte  
Health Products Regulatory Authority

# Example: ISBT 128 Label with SEC

 G9999 14 123456 8 <input type="checkbox"/> 7 Collection Center or Registry City, Country Postal Code	 4700 O Rh Positive
Collection Date/Time  0140221055 22 JAN 2014 10:55 Do Not Irradiate Do Not Use Leukoreduction Filters	For Use by Intended Recipient Only Related Donor, 1st or 2nd Degree SMITH, GERALD R Donor # W0001 123654987 Date of Birth: 22 JUL 1962
 S1134400 DESIGNATED	 0140241055 Expiration Date/Time : 24 JAN 2014 10:55
<b>HPC, APHERESIS</b> Other Additives Present Mobilized See Attached Documentation for Details Approx _____ mL containng approx _____ mL Citrate Store at 1 to 10 C	Intended Recipient: SMITH, ROGER R MRN: 123456789 Date of Birth: 07 JUL 1963 Processing Laboratory Name 2nd Line of Name City, Country, Postal Code
SEC: GB0G9999G999914123456 A00S113400020140124	



## Example: Generic Label with SEC

### **Tissue Establishment Name and Address**

Expiry Date: 02-08-2014

Surface Area: 674 cm

Thickness: 600 micron

Type of Tissue: Glycerolised Skin (store at -80C)(T1)

Package Number: S101397-12/12D



01397-12/12D

SEC: XX000048000000S101397 E000002100120140802



## Next steps for TE's

- Familiarise with legislation – **Note:** changes to Annexes of 2006/86/EC – labelling / SARE reporting / traceability data
- Identification of when and if you will need to apply the SEC;
- Plan for the modification of procedures and documentation relevant to labelling, storage, and import;
- Review of IT systems, label designs and printing systems to accommodate the SEC;
- **Familiarise with EU Coding Platform;**



**Thank you**





# Import of Tissues and Cells

**Directive 2015/566 – Implementing Directive 2004/23/EC as regards the procedures for verifying the equivalent standards of quality and safety of imported tissues and cells**

**Laura Hickey – BTO Inspector HPRA**

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**TE Meeting – 4<sup>th</sup> November 2016**



## **Directive 2015/566**

Implementation required from 29<sup>th</sup> April  
2017;





# Import Directive – 2015/566

## Background

Directive 2004/23/EC requires that imports of tissues and cells are undertaken by authorised TEs.

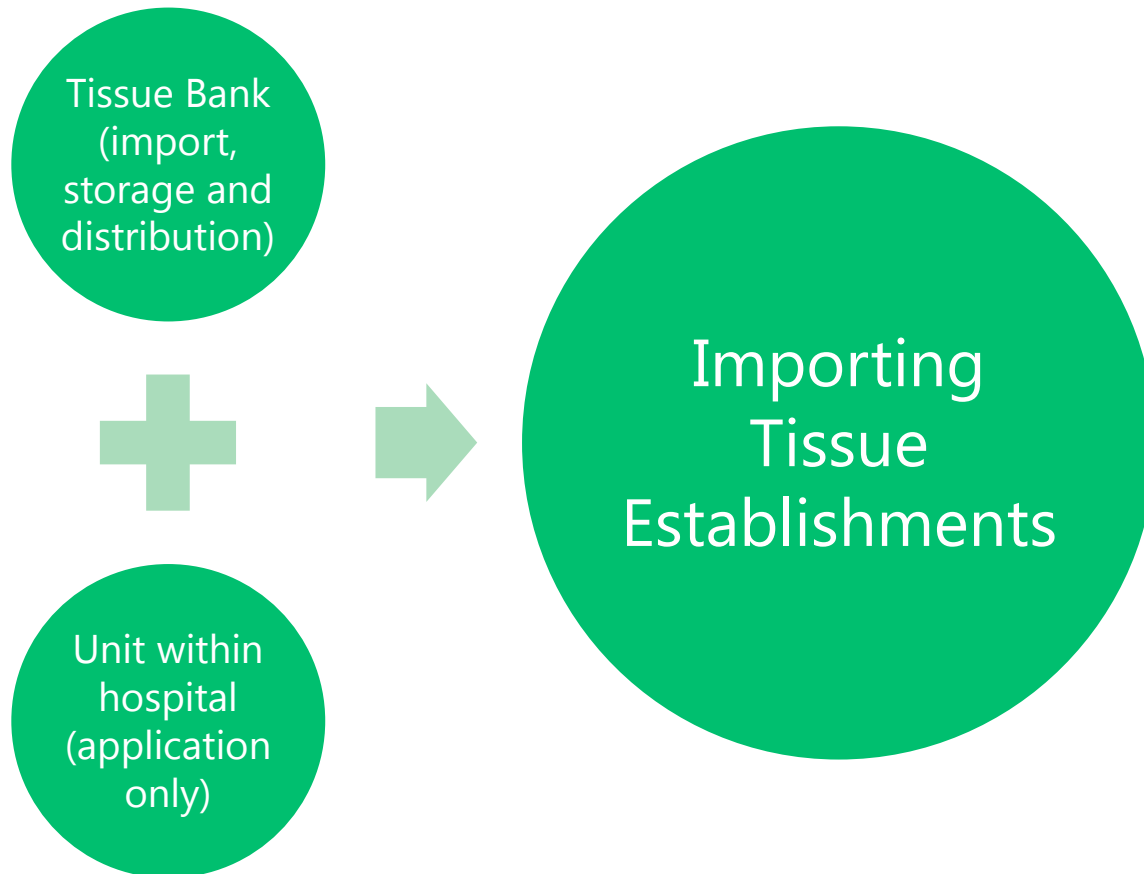
Directive 2004/23/EC requires that MS and TEs ensure that imports of T&C meet the standards of quality and safety laid down in 2004/23/EC.

And calls for the establishment of procedures to verify the equivalency of the quality and safety standards of imported tissues and cells.

Directive 2015/566 lays down these procedures.



# Importing Tissue Establishments (ITEs)





## Background

### Aims:

To establish authorisation and inspection schemes for ITEs mirroring the process in place for tissues and cells within the EU;

To establish procedures to be followed by importing TEs (ITEs) in their relations with third country suppliers (TCSs).



## Scope of Directive 2015/566/EC

- **Applies to import of all human tissues and cells for human application in the EU;**
- Applies to manufactured products derived from human T&C intended for human application – where these products are not covered by other EU Legislation;
- ATMPs – T&C's imported intended for use in manufactured product- applies to the donation, procurement & testing of human T&C which takes place outside the of the EU.



## Scope of Directive 2015/566/EC

### Exemptions:

- The import of tissues and cells as referred to in Article 9(3) of Directive 2004/23/EC as regards authorisation of 'direct distribution' and 'in the case of emergencies'.
- Brokerage Services – organisation party to a contract with a TCS to facilitate the import of T&C but not the import itself – the receiving organisation (hospital, TE etc) is considered to be the importing TE.



## New Definitions

- 'Emergency'
- 'Importing Tissue Establishment' (ITE)
- 'Third Country Supplier' (TCS)
- 'One – Off Import'
  - The import of any specific tissue or cell which is for the personal use of an intended recipient(s) known to the importing TE and the TCS before the importation occurs.
  - Shall not (normally) occur more than once. If it occurs on a regular or repeated basis shall not be considered 'one-off'.
- (Currently captured by HPRA using 'Non-Routine Import Procedure')



# Obligations on Competent Authorities

## Authorisation of ITEs:

- Ensure that imports of T&C are only undertaken by authorised TEs;
- Obtain the information from ITEs set out in Annex I of this Directive;
- Issue to the ITE a certificate as set out in Annex II to this Directive;
- Establish a system for approval of changes to import activities undertaken by ITEs.



# Obligations on Competent Authorities

## Inspections and other Control Measures:

- Organise inspections and other control measures of ITEs and *where appropriate their 'third country suppliers;*
- Evaluate and verify the procedures and activities carried out.....to ensure the equivalency of the quality and safety standards of the tissues and cells to be imported....
- Provide information when requested on such inspection and control measures to the Commission and other MS;
- Co-operate with the Competent Authorities in other MS to which the imported T&C are likely to be distributed.





## Obligations on Importing Tissue Establishments

- Verify that the standards of quality and safety of the tissues and cells they import into the EU are equivalent to the standards laid down in Directive 2004/23/EC;
- Provide certain information and documentation when requested to the CAs;
- Establish written agreements with TCS;
- Audit TCS – strongly encouraged as part of verification process.



## Obligations on Importing Tissue Establishments

- Provide to the CA the information and requested documentation set out in Annex 1 to this Directive;
- Make available to the CA when requested, the information set out in Annex III to this Directive;
- Seek the approval of the CA for any planned substantial changes to import activities;
- Notify the CA of SAREs reported to them by the TCS which may influence the quality and safety of the T&C imported.
- Notify the CA of any suspension or revocation of a TCS authorisation to export T&C and any other decision relating to non-compliance taken by a CA where the TCS is based which may influence the quality and safety of the imported T&C.



## Obligations on Importing Tissue Establishments

### Written Agreements:

- Must be in place with TCS;
- Must specify the quality and safety requirements to be met to ensure the equivalency of the T&C imported with the requirements of Directive 2004/23/EC;
- Shall include as a minimum the contents listed in Annex IV to this Directive;
- Shall establish the right of the CA to inspect the activities and facilities of the TCS during the duration of the agreement and for 2 years following its termination;
- Shall provide copies of the agreements with TCS to the CA.



## Obligations on Importing Tissue Establishments

### Registers:

- ITEs shall keep a record of their activities including the types and quantities of T&C imported and on their origin and destination;
- This information shall be contained with TE Annual Report.



## Annex I

- Minimum requirements concerning the information and documentation to be provided by importing tissue establishment applicants when applying to be accredited, designated, authorised or licensed for the purpose of import activities.
- Part A – General Information on the Importing TE
- Part B – Contact Details of the ITE
- Part C – Details of the Tissues and Cells to be Imported
- Part D – Location of Activities
- Part E – Details of Third Country Suppliers
- Part F – Documentation to accompany application



# Annex I

## F. Documentation to Accompany the Application

1. A copy of the written agreement with the third country supplier(s).
2. A detailed description of the flow of imported tissues and cells from their procurement to their reception at the importing tissue establishment.
3. A copy of the third country supplier's export authorisation certificate or, where a specific export authorisation certificate is not issued, certification from the relevant third country competent authority or authorities authorising the third country supplier's activities in the tissue and cells sector including exports. This documentation shall also include the contact details of the third country competent authority or authorities. In third countries where such documentation is not available, alternative forms of documentation shall be provided such as reports of audits of the third country supplier.



## Annex II

- Certificate of Accreditation, Designation, Authorisation or Licence to be issued by the competent authority or authorities to importing tissue establishments.
- This can be added as an appendix to the current TEA for those TEs undertaking the import of T&C from third countries;
- **Updating TEA;**



# Updating TEA

## PART 6 – IMPORT OF HUMAN TISSUES AND CELLS

Imported Tissue / Cell			Prescribed Activity Performed in Third Country					
Tissue / Cell	Type	Third Country Site***	Donation	Procurement	Testing	Processing	Preservation	Storage
<b>There are no further entries in this section</b>	<b>There are no further entries in this section</b>	<b>There are no further entries in this section</b>	<b>There are no further entries in this section</b>					
<p>In accordance with Regulation 15 (4) of S.I. 158 of 2006, the HPRA may directly authorise the import or export of a) tissues and cells referred to in Regulation 6 (13) and b) certain tissues and cells, in case of emergency. Regulation 6 (13) states that the HPRA may authorise the direct distribution of specific tissues and cells from where the procurement is carried out to a healthcare establishment for immediate transplantation.</p> <p>*** specify if site performing activity is third country supplier or sub- contractor</p>								





## Annex III

- Minimum requirements concerning the documentation to be made available to the competent authority or authorities by tissue establishments intending to import tissues and cells from third countries – when requested



## Annex III

### A. Documentation relating to the importing tissue establishment

1. A job description of the Responsible Person and details of his/her relevant qualifications and training record as laid down in Directive 2004/23/EC;
2. A copy of the primary label, repackaging label, external packaging and transport container;
3. A list of relevant and up-to-date versions of standard operating procedures (SOPs) relating to the establishment's import activities including SOPs on applying the Single European Code, reception and storage of imported tissues and cells at the importing tissue establishment, management of adverse events and reactions, management of recalls and traceability from donor to recipient.



## Annex III

### B. Documentation relating to the third country supplier or suppliers

1. A detailed description of the criteria used for donor identification and evaluation, information provided to the donor or donor family, how consent is obtained from the donor or donor family and whether the donation was voluntary and unpaid or not;
2. Detailed information on the testing centre(s) used by third country suppliers and the tests performed by such centres;
3. Detailed information on the methods used during the processing of the tissues and cells including details of the validation for the critical processing procedure;
4. A detailed description of the facilities, critical equipment and materials and criteria used for quality control and control of the environment for each activity carried out by the third country supplier;
5. Detailed information on the conditions for release of tissues and cells by the third country supplier or suppliers;
6. Details of any sub-contractors used by the third country suppliers including the name, location and activity undertaken;
7. A summary of the most recent inspection of the third country supplier by the third country competent authority or authorities including the date of the inspection, type of inspection and main conclusions;
8. A summary of the most recent audit of the third country supplier carried out by, or on behalf of, the importing tissue establishment;
9. Any relevant national or international accreditation.



## Annex IV

- Minimum requirements concerning the contents of written agreements between importing tissue establishments and their third country suppliers.



## Annex IV

1. Detailed information on the specifications of the importing tissue establishment aimed at ensuring that the quality and safety standards laid down in Directive 2004/23/EC are met and the mutually agreed roles and responsibilities of both parties in ensuring that imported tissues and cells are of equivalent standards of quality and safety;
2. A clause ensuring that the third country supplier provides the information set out in Annex III B to this Directive to the importing tissue establishment;
3. A clause ensuring that the third country supplier informs the importing tissue establishment of any suspected or actual serious adverse events or reactions which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;
4. A clause ensuring that the third country supplier informs the importing tissue establishment of any substantial changes to its activities, including any revocation or suspension, in part or in full, of its authorisation to export tissue and cells or other such decisions of non-compliance by the third country competent authority or authorities, which may influence the quality and safety of tissues and cells imported or to be imported by the importing tissue establishment;



## Annex IV

5. A clause guaranteeing the competent authority or authorities the right to inspect the activities of the third country supplier, including on-site inspections, should it wish to do so as part of its inspection of the importing tissue establishment. The clause should also guarantee the importing tissue establishment the right to regularly audit its third country supplier;
6. The agreed conditions to be met for the transport of tissues and cells between the third country supplier and importing tissue establishment;
7. A clause ensuring that donor records relating to imported tissues and cells are kept by the third country supplier or its sub-contractor, in line with EU data protection rules, for 30 years following procurement and that suitable provision is made for their retention should the third country supplier cease to operate;
8. Provisions for the regular review and, where necessary, revision of the written agreement including in order to reflect any changes in the requirements of the EU quality and safety standards laid out in Directive 2004/23/EC;
9. A list of all standard operating procedures of the third country supplier relating to the quality and safety of imported tissues and cells and a commitment to provide these on request.



## Next Steps for TEs

- Review the Directive in detail especially the Annexes
- Discuss additional requirements with your TCS
- It is likely that a lot of this information is already available to you.
- Update SOPs, Quality Manual, written agreements etc.

