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Import and Coding of Tissues and Cells
- Refresher and Updates

Richard Forde – BTO Inspector HPRA

ICE meeting - 21st October 2016

Overview of Presentation

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- Legislative Overview - Transposition Timelines
- Import Directive – 2015/566
- Coding Directive – 2015/565
- EU Coding Platform – Publically Available
- Regulatory Updates
- Questions - Discussion

Legislative Overview:

- 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.
- Commission 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 was published on 9 April 2015.

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Relevant Timelines

- Transposition required by 29th October 2016; - DoH
- Implementation required from 29th April 2017;

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Import of Tissues and Cells Directive 2015/566

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Import Directive – 2015/566 Background

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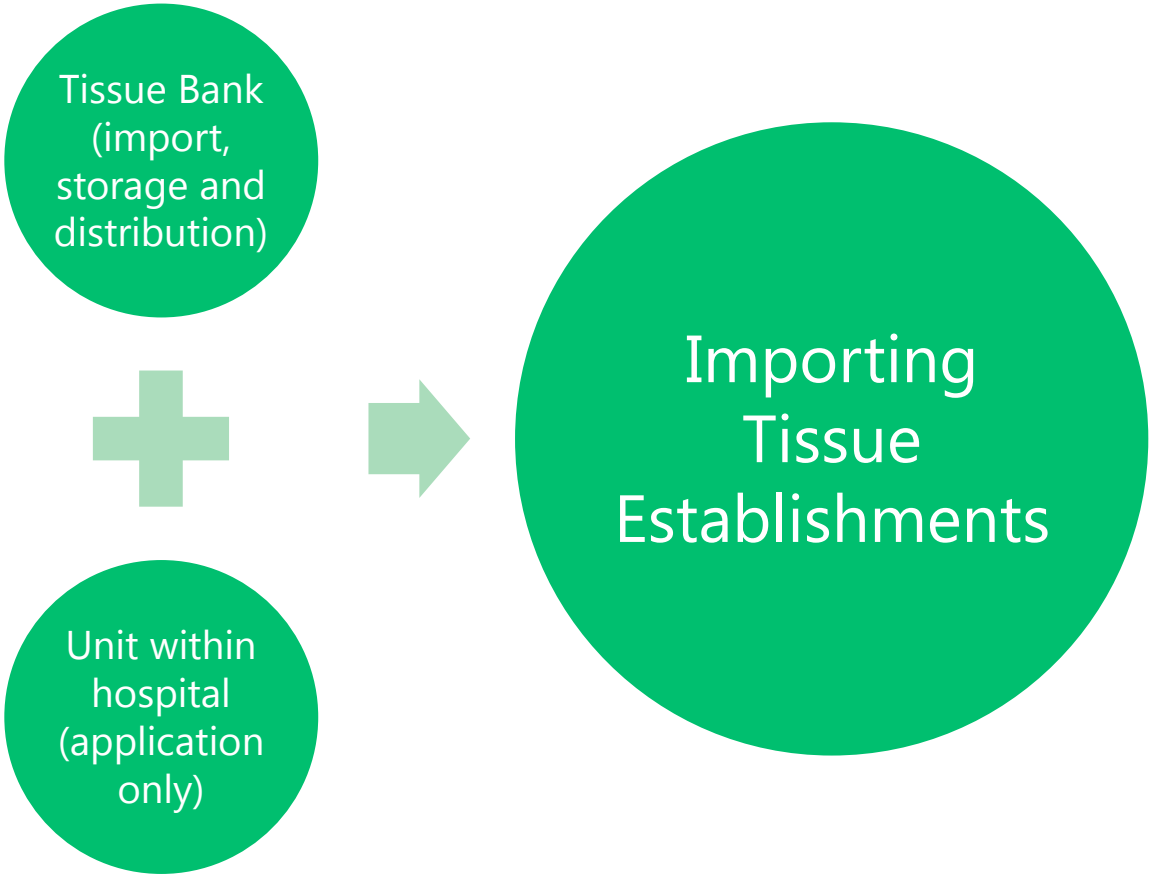
Directive 2004/23/EC requires that imports of tissues and cells are undertaken by authorised TEs.

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)



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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 – applies to the donation, procurement & testing of human T&C which takes place outside the of the EU.

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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.

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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 that 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)

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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.

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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.

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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.

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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.

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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 Party 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.

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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

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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
There are no further entries in this section	There are no further entries in this section	There are no further entries in this section	There are no further entries in this section					

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.

*** specify if site performing activity is third country supplier or sub- contractor

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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, repackage label, external package 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.

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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.

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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;

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

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Single European Code for Tissues and Cells

Richard Forde – BTO Inspector HPRA

ICE meeting - 21st October 2016

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Overview:

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

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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";

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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.

Scope of Directive 2015/565/EC

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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 at least the donation identification sequence shall be applied.

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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

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Exemptions

- Tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain in 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;**

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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

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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 – numeri Characters	13 alpha-numeric characters	1 alphabetic character **E = EUTC** **A=ISBT128** **B=Eurocode**	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. A000S123-001-20140802
  - E.g. E0000041-002-20140911

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 -

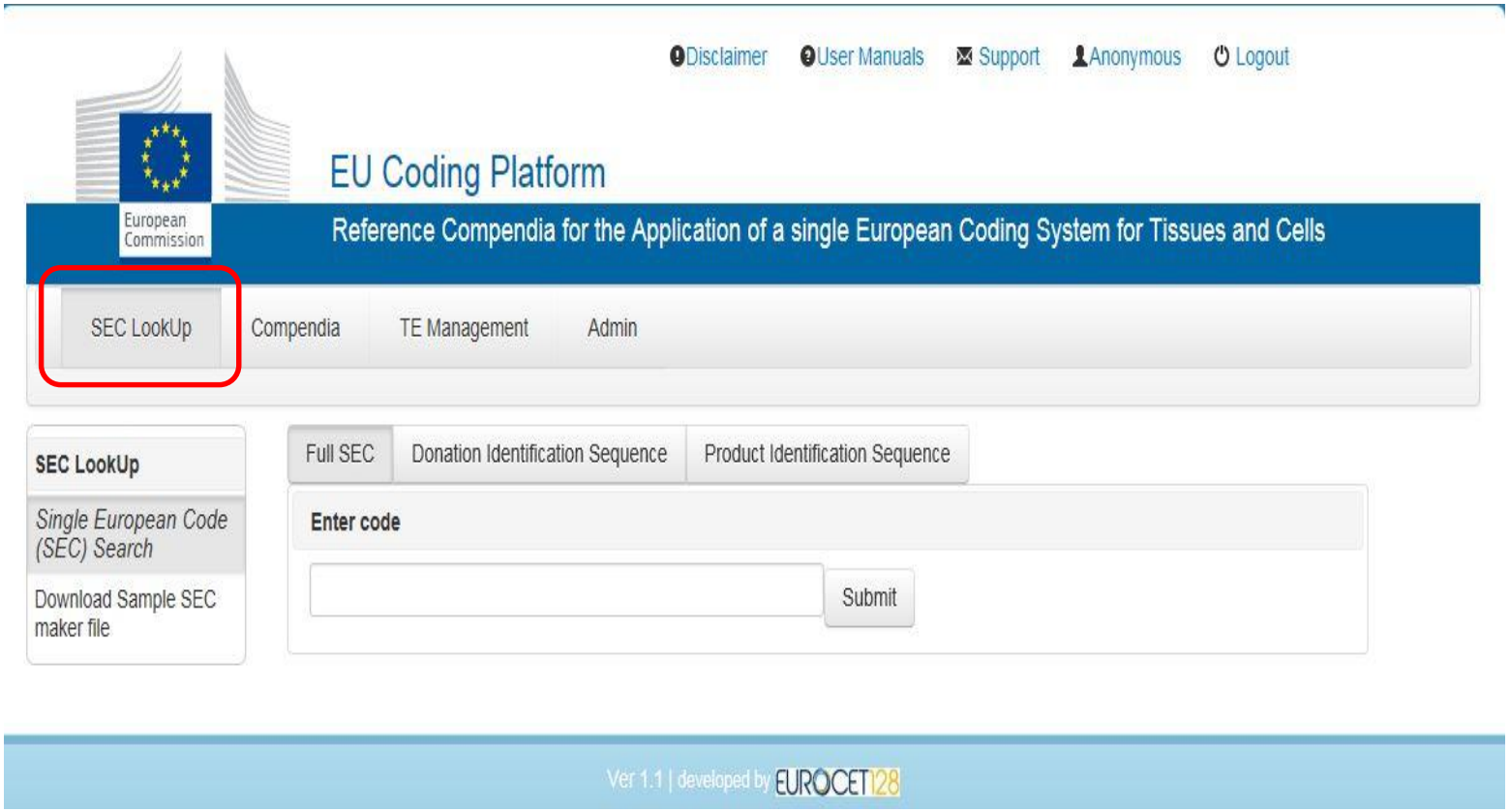
- Publically available 6th October 2016

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

  IT platform hosted by Commission which contains;

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

EU Coding Platform
1. SEC LookUp



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

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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	

2. EU TE Compendium

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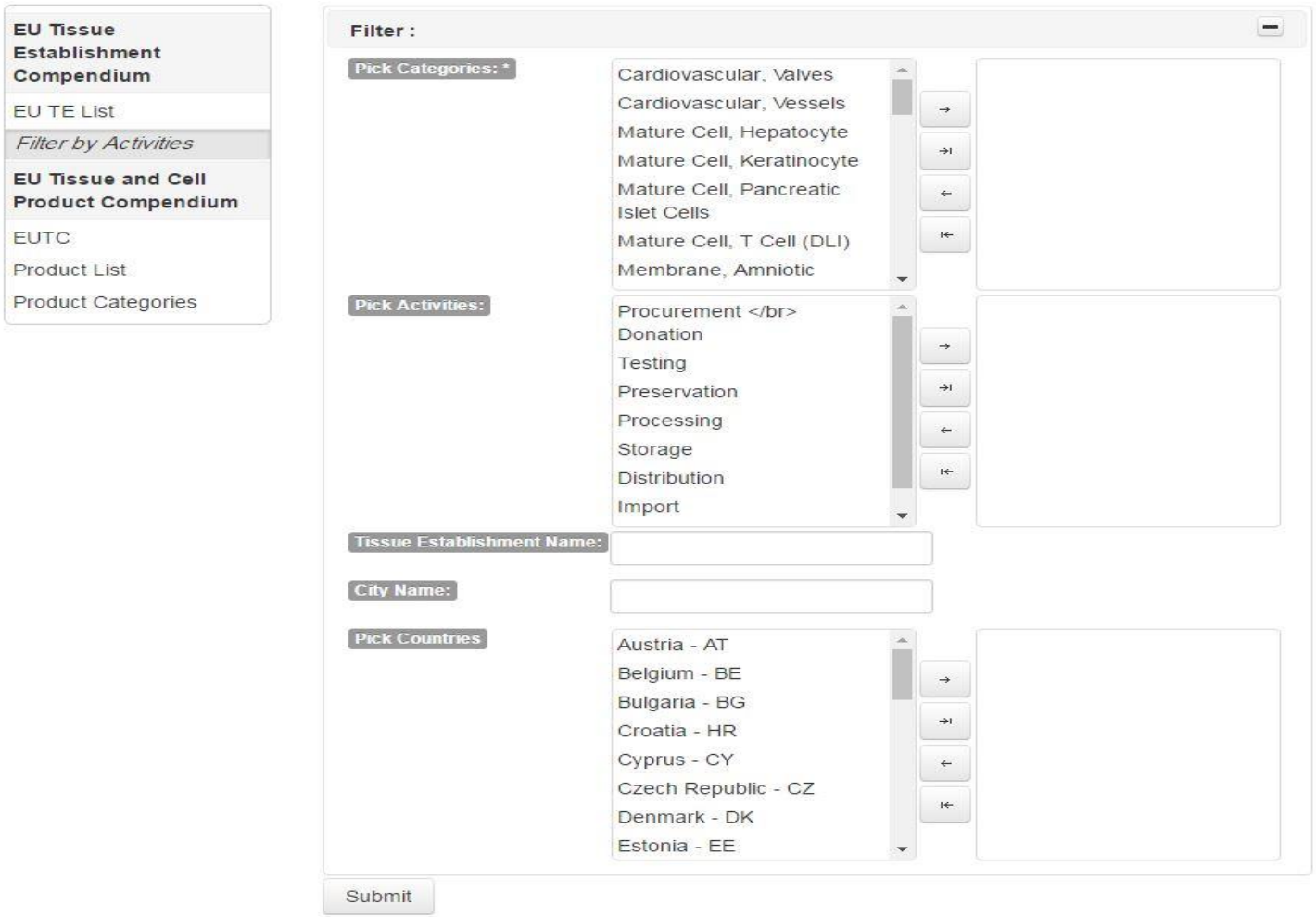

2. EU TE Compendium - Important

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

3. EU Tissue and Cell Product Compendium

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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

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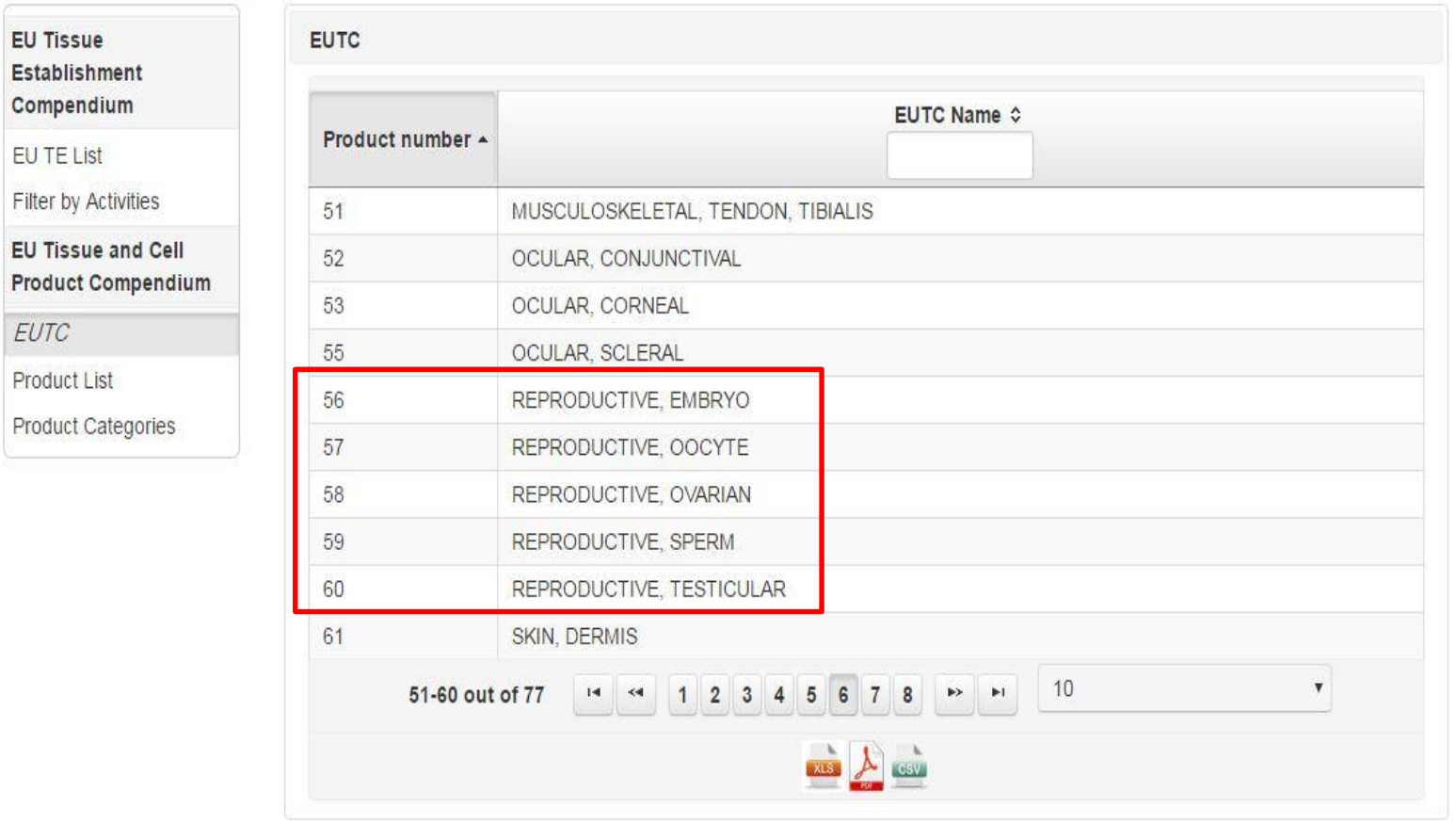

3. EU Tissue and Cell Product Compendium

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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 (E - EUTC)	Product numb	Product Name	Product Characteristic	Product Code	EUTC Name (reproductive)
E - EUTC	56	REPRODUCTIVE, EMBRYO		E0000056	REPRODUCTIVE, EMBRYO
E - EUTC	57	REPRODUCTIVE, OOCYTE		E0000057	REPRODUCTIVE, OOCYTE
E - EUTC	58	REPRODUCTIVE, OVARIAN		E0000058	REPRODUCTIVE, OVARIAN
E - EUTC	59	REPRODUCTIVE, SPERM		E0000059	REPRODUCTIVE, SPERM
E - EUTC	60	REPRODUCTIVE, TESTICULAR		E0000060	REPRODUCTIVE, TESTICULAR

1-5 out of 5 | 1 | 10

XLS PDF CSV

3. EU Tissue and Cell Product Compendium

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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 (A - ISBT 1)	Product numb	Product Name	Product Characteristi	Product Code	EUTC Name (reproductive)
A - ISBT 128	R0001	OVARIAN TISSUE	Autologous|For further processing	A00R0001	REPRODUCTIVE, OVARIAN
A - ISBT 128	R0002	OVARIAN TISSUE	Autologous|Cryopreserv	A00R0002	REPRODUCTIVE, OVARIAN
A - ISBT 128	R0003	TESTICULAR TISSUE	Autologous|For further processing|Cryopreserv	A00R0003	REPRODUCTIVE, TESTICULAR
A - ISBT 128	R0004	SPERM	Ejaculated	A00R0004	REPRODUCTIVE, SPERM
A - ISBT 128	R0005	SPERM	Autologous|Extracted	A00R0005	REPRODUCTIVE, SPERM
A - ISBT 128	R0006	TESTICULAR TISSUE	Autologous	A00R0006	REPRODUCTIVE, TESTICULAR
A - ISBT 128	R0007	OVARIAN TISSUE	Autologous	A00R0007	REPRODUCTIVE, OVARIAN
A - ISBT 128	R0008	OOCYTE		A00R0008	REPRODUCTIVE, OOCYTE
A - ISBT 128	R0009	EMBRYO		A00R0009	REPRODUCTIVE, EMBRYO
A - ISBT 128	R0010	EMBRYO	Allogeneic|For further processing	A00R0010	REPRODUCTIVE, EMBRYO

1-10 out of 37 | 1 2 3 4 | 10

3. EU Tissue and Cell Product Compendium

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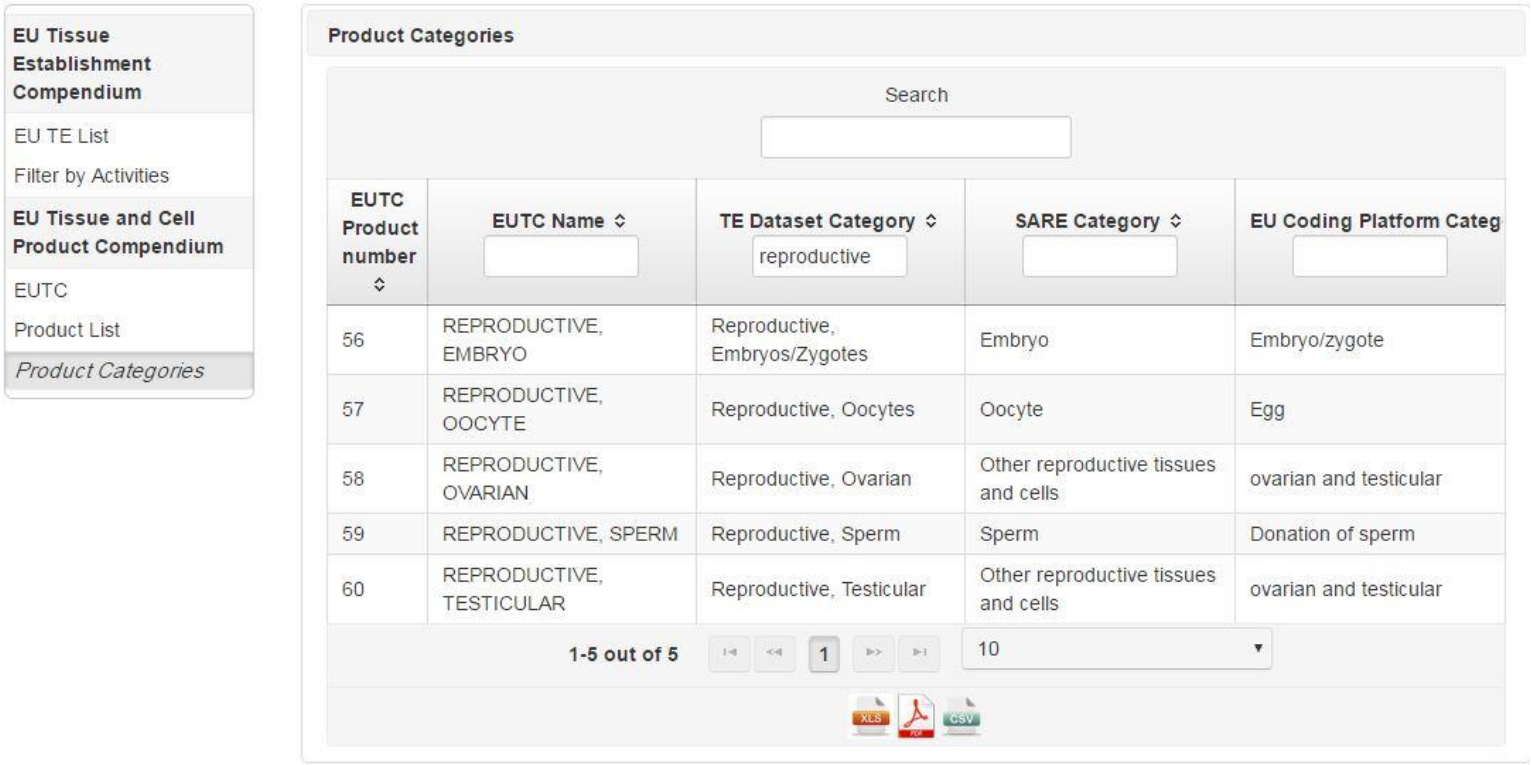

EU T&C Product Compendium

- 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

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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)

What does this mean for ART Clinics?

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- Partner Reproductive Cells – Exempt
- Apply SEC - Non partner gametes or embryos – distributed outside of clinic;
- Imported non-partner gametes and embryos used at the importing TE will not be required to use the Single European Code – unless Distributed

Major implication for ART Clinics?

- Receipt of non partner gametes / embryos.
- Contact your third part suppliers;
- SEC to be referenced in SAE/R reporting (Donor Blocks);
- SEC to be retained for 30 years;
- Essential to confirm the method by which suppliers intend to apply SEC / what coding system / how split numbers are applied;

Next steps for ART TE's

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- 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, **distribution (NB: acceptance procedures),** and import;
- Review of IT systems, label designs and printing systems to accommodate the SEC;
- Familiarise with EU Coding Platform;

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Thank you