



Single European Code for Tissues and Cells

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Overview:

- The Single European Code (SEC): Legislative Basis;
- Eurocet 128 Consortium;
- EU Coding Platform;
- The structure of the SEC;
- How to construct the SEC?
- Label specifications;
- When will the SEC apply? - Exemptions
- Next steps
- Some Worked Examples.



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

- Amending Directive 2006/86/EC as regards certain technical requirements for the coding of tissues and cells
- Published Official Journal of European Union 8th April 2015;
- Entered into force 28th April 2015;
- 18 month transposition deadline (29th October 2016);
- full implementation required 6 months post transposition (29th April 2017).



Implementation of SEC: Eurocet 128 Consortium

ITALIAN NATIONAL TRANSPLANT CENTRE

  
www.eurocet.org

ARTMAN TECHNOLOGIES | **ICCBBA**

  
www.artman.eu | www.iccbba.org



For further info:
WWW.EUROCET128.EU

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Eurocet 128 Consortium - Objective

- To build the “EU coding platform” –
 - IT platform hosted by Commission which contains;
 1. EU Tissue Establishment Compendium
 2. EU Tissue and Cell Product Compendium;
 3. A translator application to assist searches of both compendia .



1. EU Tissue Establishment 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: IE0TE123

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

Publicly accessible / Search by name of TE or by Code



EU Tissue Establishment Compendium

- Currently being updated
- Data to be recorded in the EU TE Compendium – new Annex VIII of Directive 2006/86/EC
- Any substantial changes to authorisation will require updating on TE Compendium (HPRA responsibility)



2. 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)



EU T&C Product Compendium

- Currently mapping all ISBT 128 and Eurocode tissue and cell codes to their corresponding EUTC Codes;
- EUTC High level descriptions;
 - OCULAR, CORNEAL
- ISBT 128 – more detailed –method of preservation / sterilisation etc. is coded
 - CORNEA, Anterior and Posterior Layers / left / Hypothermic storage



EU T&C Product Compendium - Example

EUTC Code	EUTC Product description	ISBT 128 code	ISBT 128 product description	
53	Ocular, Cornea	V0003	Cornea	Right , hypothermic storage
		V0004	Cornea	Left, hypothermic storage
		V0005	Cornea	Anterior and posterior layers, left, hypothermic storage
		V0006	Cornea	Anterior and posterior layers, right, hypothermic storage
		V0007	Cornea	Corneoscleral disc, left, organ culture, nutrient
		V0008	Cornea	Corneoscleral disc, right, organ culture, nutrient
		ETC.....		



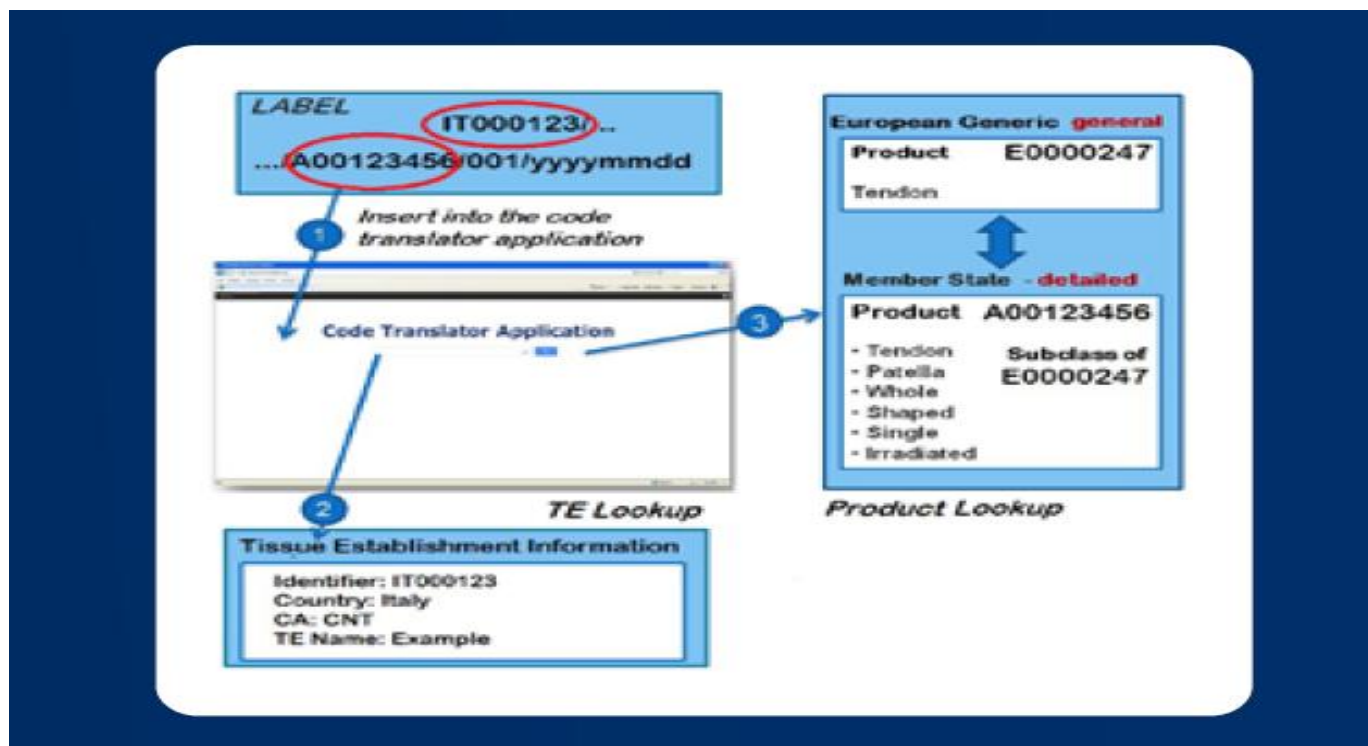
EU T&C Product Compendium

- 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);



3. Translator application tool

A translator application will be developed that will allow searches of both compendia – construct SEC





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 – numerics 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



How to construct SEC

- 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)



How to construct SEC

- 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








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;
- If label size precludes inclusion of SEC – accompanying documentation.
- **Note:** for imports – country of procurement (exporting country) must be on final label for distribution (amended Annex II – Part E of 2006/86/EC)



Example: ISBT 128 Label with SEC

 G9999 14 123456 S <input checked="" 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
HPC, APHERESIS Other Additives Present Mobilized See Attached Documentation for Details Approx _____ mL containing 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

<p>Tissue Establishment Name and Address</p> <p>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</p>  <p>01397 12/12D</p> <p>SEC: XX000048000000S101397 E000002100120140802</p>
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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.



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 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;



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.



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, distribution, and import;
- Review of IT systems, label designs and printing systems to accommodate the SEC;



Thank you





SEC Worked Examples

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17th June 2015



Scenario 1 – EU Generic Code

- A TE in Ireland with TE number TE033 does not use a current coding system (ISBT128 or Eurocode) and intends using the EU Generic Product List.
- They require a code for Cornea. They search the EU Tissue and Cell product compendium looking for EUTC. They find that Cornea maps to the EU Generic Term “Ocular, Corneal” and this has a code of ‘78’.
- The unique donation number is 10479, the product is not split and expires on 31 July 2014

SEC IE0TE0330000000010479

E000007800020140731



Scenario 2 - ISBT 128

- An Irish TE (TE035) uses ISBT 128 product codes and requires a code for SKIN, FULL THICKNESS WITH HYPODERMIS.
- They check the product compendium looking for ISBT128 codes. They find that T0326 is the ISBT 128 Product Description Code for this product. The donation number is G999913765432 and the product is split 007 and expires on 31 July 2014

SEC IE0TE035G999913765432

A00T032600720140731



Scenario 3 - Import

- **Tissues/cells imported from third countries** for distribution in the EU should be also labelled with the SEC by the importing TE
- For the donation identification:
 - the codes for country and TE will be the ones corresponding to the importing TE.
 - the donation identification number should be a new one, allocated by the importing TE unless the supplier is using ISBT 128.
 - If the supplier is using ISBT 128 the globally unique donation number should be retained.
- For the product identification:
 - The product identification number of the product should map to the EU generic codes or ISBT product codes in the EU Product compendium.



Scenario 3 - import

- Generis Tissue Bank in the USA supplies tissue to a TE in Ireland (TE0041). The TE receives a pack containing an Achilles tendon with bone block identified with serial number 02485061327 and product code 67104 expiring on June 24, 2015.
- The TE assigns the next available donation number from its own number allocation sequence which is 705721, and determines that the appropriate EU Generic product code for Achilles tendon with bone block is 41 (MS/TENDON/ACHILLES). As they will only use this donation number for one product they can use a division number of '000'.
- The SEC is assigned on the label as:
SEC IE0TE0410000000705721 E000004100020150624.
Country of Procurement: USA



Scenario 4: “Released for circulation”

- A TE in Ireland with TE number TE033 does not use a current coding system (ISBT128 or Eurocode) and intends using the EU Generic Product List.
- They require a code for Hepatocytes. Which are procured for distribution to an ATMP manufacturer.
- They search the EU Tissue and Cell product compendium looking for EUTC. They find that Hapatocyte maps to the EU Generic Term “Mature Cell, Hepatocyte” and this has a code of ‘72’.
- The unique donation number is 10659, the product is not split and expires on 31 July 2014.
- Tissues and cells “released for circulation” to ATMP manufacturer at least the donation identification sequence shall be applied (and retained).
- SEC IE0TE0330000000010659



Thank you

