



Information for Competent Authorities and Tissue Establishments on the Implementation of the Single European Code (SEC) for Tissues and Cells

***Disclaimer:** This document aims to assist competent authorities and tissue establishments with the implementation of the requirements on the coding of tissues and cells set out in Directive 2006/86/EC as amended by Directive (EU) 2015/565. It is provided for information purposes only and its contents are not intended to replace consultation of any applicable legal sources or the necessary advice of a legal expert, where appropriate. It should not be considered as a legal interpretation of the legislation. Neither the Commission nor any person acting on its behalf can be held responsible for the use made of this document. This document will be regularly updated to take into account experience and feedback from users.*

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1. Legal requirements

1.1. Format and requirements related to the application of the SEC

The EU Tissue and Cell Directives (Directives 2004/23/EC – Articles 8, 25 and 2006/86/EC – Article 10 as amended) set out the requirement to develop a single European coding system to identify and label tissue and cell products so as to support traceability of tissues and cells in the EU. The minimum set of information to be incorporated in the SEC is set out in Annex VII of Directive 2006/86/EC as amended by Directive (EU) 2015/565¹. Following these amendments, new requirements which cover the full definition of the SEC, indications on its application, as well as obligations of the tissue establishments (TE), competent authorities (CA) and the European Commission have been included in **the amended Directive**.

The "Single European Code" or "SEC" is the unique identifier applied to tissues and cells distributed in the Union. The Single European Code consists of a donation identification sequence and a product identification sequence, as further specified in Annex VII to Directive 2006/86/EC as amended by Directive (EU) 2015/565.

ANNEX VII

THE STRUCTURE OF THE SINGLE EUROPEAN CODE

DONATION IDENTIFICATION SEQUENCE			PRODUCT IDENTIFICATION SEQUENCE			
EU TISSUE ESTABLISHMENT CODE		UNIQUE DONATION NUMBER	PRODUCT CODE		SPLIT NUMBER	EXPIRY DATE (YYYYMMDD)
ISO country code	Tissue establishment 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

Details on the two components of the SEC (the donation identification sequence/SEC-DI and the product identification sequence/SEC-PI) are presented below (see sections 1.1. and 1.3).

The SEC **shall be applied** to all tissues and cells distributed in the EU. For the other situations where tissues and cells are released for circulation (i.e. transfer to another operator for further processing with or without return), as a minimum the donation identification sequence shall be applied at least in the accompanying documentation.

Tissues/cells **imported from third countries for distribution in the EU** should be also labelled with the SEC. The importing TE is responsible for the application of the SEC on the product and in the accompanying documentation (double coding/labelling with both any original code and the SEC).

Tissues and cells in the following situations are **excluded** from the application of the SEC:

- (a) reproductive cells from partner donation;
- (b) tissues and cells distributed directly for immediate transplantation to the recipient, as referred to in Article 6(5) of Directive 2004/23/EC (e.g. haematopoietic stem cells);
- (c) tissues and cells imported into the Union in case of emergency and authorised as such directly by the competent authority or authorities (i.e. according to the definition in Directive (EU) 2015/566, an emergency should be understood as any unforeseen situation in which there is no practical alternative other than to urgently

¹ <http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=OJ:L:2015:093:FULL&from=EN#page=45>

import tissues and cells from a third country into the Union for immediate application to a known recipient or known recipients whose health would be seriously endangered without such an import).

Member States may allow **exemptions** from the application of the SEC for:

- (a) tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre;
- (b) tissues and cells that are imported into the Union, when these tissues and cells 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. Tissue establishments who wish to know whether any such exemptions apply in Member States where they operate are advised to contact the national competent authority or authorities in those Member States.

1.2. DONATION IDENTIFICATION SEQUENCE/SEC-DI

The donation identification sequence is the first part of the Single European Code consisting of the EU tissue establishment code and the unique donation number.

- **EU tissue establishment code** means the unique identifier for accredited, designated, authorised, or licensed tissue establishments in the Union. The tissue establishment code consists of:
 - the ISO country code and
 - the tissue establishment number set out in the EU Tissue Establishment Compendium.
- **Unique donation number** means the unique number attributed to a specific donation of tissues and cells in line with the system in place in each Member State for allocating such numbers. This number that uniquely identifies the donation within that establishment may be allocated locally at the TE (i.e. by applying rules established locally), at national level (i.e. in case of Member States with a central system for allocating donation numbers) or by using an international donation codification system (e.g. for users of ISBT128 or Eurocode).

By combining the unique donation number with a unique identifier for the tissue establishment, an EU-wide unique identification, the donation identification sequence, is obtained.

Example:

If in the EU Tissue Establishment Compendium a Belgian tissue establishment has the number “00A317” and the ISO Country Code is “BE”, the EU TE code to be included in the SEC-DI will always be “BE00A317”.

If this TE assigns a donation number of “491276” to a donation event, then all tissue or cell products prepared by the TE or any other operator from that donation will be labelled with the following SEC-DI: “BE00A317000000491276”. Please note that in order to respect the requirement for the unique donation number (13 characters) the donation number id is padded with zeros.

The SEC-DI sequence is assigned solely by one TE and it identifies the TE which first received the tissues or cells from a procurement organisation (or third country supplier in the case of import from a third country) or which itself carried out the procurement.

The TE must apply the SEC-DI to all tissues and cells prior to distribution for human application or transfer to another operator (i.e. tissue establishment or ATMP manufacturer) for further processing (with or without return) and the donation identification sequence should not subsequently be changed.

If tissues or cells distributed for human application are prepared from more than one donor (i.e. pooling²), a new donation identification sequence shall be allocated, while maintaining the traceability of the original individual donation identification numbers.

1.3. PRODUCT IDENTIFICATION SEQUENCE/SEC-PI

The product identification sequence is the second part of the Single European Code consisting of the product code, the split number and the expiry date.

- **Product code** means the identifier for the specific type of tissue or cell in question. The product code consists of the product coding system identifier indicating the coding system used by the tissue establishment (“E” for the EUTC, “A” for ISBT128, “B” for Eurocode) and the tissues and cell product number foreseen in the respective coding system for the product type. In the SEC-PI only product codes listed in the EU Tissue and Cell Product Compendium can be used.
- **Split number** means the number which distinguishes and uniquely identifies tissues and cells having the same unique donation number and the same product code and originating from the same tissue establishment. Split numbers may be numeric or alphabetic as long as they are unique to each product from a donor that carries the same product code in the SEC. If the split number has less than three characters it should be padded with leading zeros.
- **Expiry date** means the date by which the tissues and cells must be applied; it is expressed in 8 numeric characters including the year, month and date (YYYYMMDD). If the tissues or cells cannot be given an expiry date (e.g. autologous bone marrow) the field should be filled with 8 zeros.

Example:

- A product identified as “Glycerolised Skin” which maps to the EUTC system (coding system “E”) code of “Skin, Full” with EUTC number 62 (see also 4.1. Structure of the Product Compendium) would have the first eight characters of the product identification element of the SEC as “E0000062”. By adding the split number (001) and the expiry date (20161231) the SEC-PI will be: E000006200120161231

- A product identified using ISBT 128 (coding system “A”) with an ISBT 128 product code of S1012 would have the first eight characters of the product identification sequence of the SEC as “A00S1012”. By adding the split number (001) and the expiry date (20161231) the SEC-PI will be: A00S101200120161231

2. THE EU CODING PLATFORM

The EU Coding Platform³ laid down by Directive 2006/86/EC as amended by Directive (EU) 2015/565 is the IT platform hosted by the Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium.

- **EU Tissue Establishment Compendium** is the register of all tissue establishments which are authorised, licensed, designated or accredited by the Member States' competent authority or authorities and which contains the information about these tissue establishments along with their corresponding TE codes. The EU TE Compendium is hosted by the EC and maintained by the MS CAs. Each CA is

² “Pooling” means the physical contact or mixing in a single container, of tissues or cells from more than one procurement from the same donor, or from two or more donors (Directive (EU) 2015/565 amending Directive 2006/86/EC).

³ This database was developed following a service contract awarded by the European Commission to the Eurocet 128 consortium including three organisations: the Italian National Transplant Centre (CNT), ICCBBA, which maintains the ISBT 128 coding standard for human substances, and Artman Technologies, a software company.

responsible for the accuracy of the entries of the TEs that they have authorised (or licensed, designated or accredited) and for keeping these entries up-to-date.

For traceability purposes, one EU TE code may cover all physical locations of a TE which uses one system for allocating unique donation numbers across these different locations. If a TE includes services which procure, process and distribute different types of tissues and cells using separate donation number allocation systems, these entities should be allocated different codes in the EU TE Compendium. It is the responsibility of the CAs to identify such TEs and take the appropriate measures for their correct identification in the EU TE Compendium.

Example:

If a hospital department includes, for example, both heart valve and cord blood banking services under a single Responsible Person and authorised by a single CA, but the donation number allocation systems for their two services are different, it is critical that two separate TE codes are allocated to ensure the uniqueness of each SEC-DI sequence. It is the task of CAs to identify such situations and make a request to the Commission for the assignment of separate TE numbers in the EU TE Compendium for these services.

- **EU Tissue and Cell Product Compendium** is the register of all types of tissues and cells circulating in the Union and the respective product codes under the three permitted coding systems (EUTC, ISBT128 and Eurocode).

The EU Coding Platform also includes a translator for decoding the EU tissue establishment code and the product code.

2.1. THE EU TISSUE ESTABLISHMENT COMPENDIUM

The EU TE Compendium carries information on all authorised, licensed, designated or accredited TEs⁴ in the EU.

In line with the definition of 'tissue establishment' in Directive 2004/23/EC, all establishments fulfilling this definition and authorised, licensed, designated or accredited by the appropriate national CA(s) (e.g. tissue banks, ART centres and haematopoietic stem cell laboratories) are included in this compendium.

Some exclusions / exemptions from the requirement to apply the SEC are defined in the relevant EU legislation, but TEs that carry out excluded / exempted activities are, nonetheless, included in the TE Compendium so that the provisions of Article 10(3) of Directive 2004/23/EC⁵ are also met by this instrument.

Importing tissue establishments which only import or only import and distribute tissues or cells are also included in the Compendium.

Centres that carry out only donation, and/or testing, and/or procurement (i.e. procurement organisations⁶), as well as centres that only carry out clinical application (i.e. organisations responsible for human application), are not included in the Compendium.

⁴ "Tissue establishment" means a tissue bank or a unit of a hospital or another body where activities of processing, preservation, storage or distribution of human tissues and cells are undertaken. It may also be responsible for procurement or testing of tissues and cells (Article 3(o) of Directive 2004/23/EC)

⁵ Directive 2004/23/EC, Article 10.3 "Member States and the Commission shall establish a network linking the national tissue establishment registers".

The data set to be included for each TE is presented below:

NAME OF THE FIELD	FIELD DESCRIPTION
National identifier code <i>(if existing)</i>	This is the identification code of the TE assigned nationally by the CA and used in the system of national traceability, where applicable.
International identifier code <i>(if existing)</i>	This is the identification code assigned to the TE internationally (e.g. ISBT128) and used in the labelling system of the TE.
Name of TE	Official name of the TE as shown on the authorisation. It identifies the TE within the hospital / institute, where applicable.
Name of Institute/Hospital <i>(if applicable)</i>	Name of institution / hospital when the TE is within such an institute.
Number and street	Street number and name in legally registered address of TE site (where the Responsible Person can be contacted).
City	Name of city where TE is located (in the national language) (where the Responsible Person can be contacted).
Country	Name of country where TE is located.
Postal code	Legally registered address of TE site (where the Responsible Person can be contacted).
Phone and Fax	Telephone and fax number at the site where the Responsible Person can be contacted.
Email	Functional email address of the TE.
Website	TE webpage
Authorising Competent Authority	The authority (ies) that inspect(s) and accredit(s), designate(s), authorise(s) or license(s) the TE for compliance with the EU tissue and cell legislation. (The entry may be, for example, 'Regional Health Authority', 'Länder Authority' or 'Health Authority of the Autonomous Community').
National Competent Authority responsible for maintenance of the EU Tissue Establishment Compendium <i>(if different from above)</i>	The national authority that maintains and updates the entries for that Member State in the EU Tissue Establishment Compendium.
Name of authorisation/licence/designation/ accreditation holder <i>(if existing)</i>	When the structure that hosts the TE (e.g. hospital/clinic) is the holder of the authorisation/licence/designation/ accreditation rather than the TE unit or department itself.

⁶ "Procurement organisation" means a health care establishment or a unit of a hospital or another body that undertakes the procurement of human tissues and cells and that may not be accredited, designated, authorised or licensed as a tissue establishment (Article 1(h) of Directive 2006/17/EC)

Type of authorisation/licence/designation/accreditation	<input type="radio"/> Based on desk-based document review OR Self certification of compliance <input type="radio"/> Based on site inspection (Note: if both have taken place, only the site inspection is to be ticked as this supercedes the other type of authorisation)
Type of tissues/cells:	List of tissues/cells for which the TE is authorised/licenced/designated/accredited.
Type of HPC	Specify type of HPC: Autologous, allogeneic related , allogeneic unrelated.
Type of reproductive cells	Specify type of reproductive cell services: Partner, Non-partner.
Type of activity:	Type of activity(ies) carried out and authorised in the TE from those foreseen in Directive 2004/23/EC (processing, preservation, storage or distribution of human tissues and cells). Also includes whether the TE is authorised for Import or Export. If the TE is also responsible for procurement or testing of tissues and cells this is also indicated.

The EU Tissue Establishment Compendium entries for each EU Member State are maintained and updated in due time by the responsible national CA.

2.1.1. OBTAINING INFORMATION ABOUT A TE

The EU TE Compendium provides several ways to find information.

It is possible to search for a TE on the basis of:

- EU TE code (ISO Country identifier together with the TE number) taken from the SEC-DI carried on a tissue or cell product;
- TE name;
- Authorised tissues/cells or activities.

It is also possible to list all authorised, licensed, designated or accredited tissue establishments in one Member State.

More details regarding the application modules for look-up and reports are provided online via the User Manual available in the EU Coding Platform.

2.1.2. TE REQUESTS FOR CHANGES TO THEIR ENTRY IN THE EU TE COMPENDIUM

It is important that the EU TE Compendium contains accurate and complete information. TEs should check that the information entered for their organisation is correct and up-to-date, and notify the relevant CA of any corrections or changes that they consider are required.

2.1.3. CA UPDATING OF THE EU TE COMPENDIUM

When a TE's authorisation status changes, (e.g. a new activity or tissue/cell type is authorised or an authorisation for an activity is suspended or revoked) or when details change or are not correctly recorded in the EU TE Compendium, the CA must update the status in the EU TE Compendium to ensure that clinical users, TEs and CAs that are consulting the EU TE Compendium can be confident that the information shown is accurate and up-to-date.

National CAs must nominate a contact person and a substitute who will be given credentials for secure access to the EU TE Compendium hosted by the European Commission. An IT User Manual describing how records can be updated or modified is available in the application itself. CAs should provide training to new individuals who are given responsibility for maintaining their entries in the EU TE Compendium.

The CAs are responsible for ensuring the validation of the data on the tissue establishments contained in the EU Tissue Establishment Compendium for their Member State and update the EU TE 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 Directive 2006/86/EC as amended, 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 not later than 10 working days for any changes substantially affecting the authorisation, accreditation, designation or licence of the tissue establishments concerned.

Each CA has access rights to change information relating only to those entries for which it is responsible. To facilitate an efficient updating of the EU TE Compendium, it is recommended that the function of updating be delegated by the entity that officially issues the licence to the operational unit responsible for inspection in those MS where these are not the same entities. In countries where inspection and authorisation is a regional responsibility, the national CA responsible for the maintenance of the EU TE Compendium will need to establish an efficient communication and co-ordination procedure with the regional authorities to ensure that modifications to TE entries are made within the required timeframe.

2.2. THE EU TISSUE AND CELL PRODUCT COMPENDIUM

The EU Tissue and Cell Product Compendium is the register of all types of tissues and cells circulating in the Union and the respective product codes under the three permitted coding systems (EUTC, ISBT128 and Eurocode).

- **EUTC** is the product coding system for tissues and cells developed by the Union consisting of a register of all types of tissues and cells circulating in the Union and their corresponding product codes.
- **ISBT128** is an international product coding system developed and managed by ICCBBA⁷.
- **Eurocode** is an international product coding system developed and managed by Eurocode-IBLS e.V.⁸.

TEs need to ensure that every tissue or cell product that they distribute carries a SEC containing the correct SEC-PI.

EUTC codes are associated with high-level descriptions of human tissue and cell products. Information such as the method of preservation or sterilisation is not coded. Centres using the EUTC in the SEC should continue including this information (e.g. details related to the processing and/or preservation methods) in the accompanying documentation or on the label in line with their national requirements.

CAs and TEs may also use the EU Tissue and Cell Product Compendium to look up information on tissues and cells distributed from another EU Member State.

2.2.1. USING THE EU TISSUE AND CELL PRODUCT COMPENDIUM

The full list of the tissues and cells product codes to be used is available to view or download from the EU Coding Platform on the European Commission website⁹. In practice, three lists are available for each of the three coding systems allowed, in which the following information is displayed: coding system, product number, product name, product characteristics, product code and mapping to the corresponding EUTC code (for ISBT128 and Eurocode-coded products).

Examples of headers for the tissue and cell product lists corresponding to the three coding systems

Coding System	Product number	Product Name	Product Characteristic	Product Code	EUTC Name
E - EUTC	1	MEMBRAN E, PERICARDIUM		E0000001	MEMBRAN E, PERICARDIUM

Coding System	Product number	Product Name	Product Characteristic	Product Code	EUTC Name
A - ISBT 128	S0295	HPC, MARROW	NS/XX/rt Open Plasma added 4th container extensive	A00S0295	PROGENITOR CELLS, HEMATOP OIETIC, BONE MARROW

⁷ <https://www.iccbba.org/>

⁸ <http://www.eurocode.org/>

⁹ The hyperlink will be included in the document a few months before the transposition deadline

Coding System	Product number	Product Name	Product Characteristic	Product Code	EUTC Name
B - Eurocode IBLS	702001	Tissue/Amnion	2to25/PAA/other/CleanR/Transpl/VSTis	B0702001	MEMBRANE, AMNIOTIC

2.2.2. REQUESTING A NEW ENTRY IN THE EU TISSUE AND CELL PRODUCT COMPENDIUM

If an individual TE is using EUTC and intends to distribute a new tissue/cell product, they should contact their national CA as soon as possible, and if the new product does not map to one of the existing product types in the EU Tissue and Cell Product Compendium, the national CA (on behalf of the respective TE) is responsible for requesting a new EUTC code from the European Commission¹⁰. As the descriptors are high-level, requests for new EUTC codes are not expected to be frequent. However, TEs that are developing novel products not currently in the EU Tissue and Cell Product Compendium should take into consideration that, during the R&D phase, a request for the new code should be submitted to ensure availability when the product is to be distributed.

The Commission has established agreements with the organisations managing ISBT128 and Eurocode to ensure that updates of their product' lists are regularly made available to the EC for inclusion in the EU Tissue and Cell Product Compendium. Therefore, TEs using ISBT128 or Eurocode should be able to find the new product numbers corresponding to these coding systems without any further requests to their national CA.

3. BUILDING THE SINGLE EUROPEAN CODE

3.1. BUILDING A SINGLE EUROPEAN CODE FOR A TISSUE/CELL PRODUCT

To build a SEC the following elements are required:

- **Donation Identification Sequence**
 - The EU TE code in the EU TE Compendium (two character ISO country code for the relevant country + the tissue establishment number);
 - The unique donation identification number (allocated at central or local level, depending on national requirements).
- **Product Identification Sequence**
 - The coding system to be used for tissue and cell product identification, in line with the national legislation following the transposition of the Directive (EU) 2015/565;
 - Product code from the EU TC Product Compendium;
 - Split number. The split number is an alphabetic or numeric or alpha-numeric sequence that uniquely identifies this particular product from any other bearing the same product code from the same donor.

3.2. CREATING THE SEC

The rules for creating the SEC will depend on the coding system in use. There are three options for building the code.

¹⁰ Requests should be addressed to SANTE-EUCODING@ec.europa.eu

3.2.1. USING AN EUTC CODE

The correct EUTC Product Code must be selected. Due to its high-level terminology, several products may map to the same EUTC code.

The SEC is created as follows:

Donation Identification Sequence

- Two character ISO country code;
- TE number as assigned in the EU TE Compendium;
- National Donation Identification Number (padded with leading zeros to 13 characters).

Product Identification Sequence

- Coding System Identifier for EUTC (letter E);
- Product Code from the EUTC List padded to seven characters with leading zeros;
- Three character split number;
- Expiration date in YYYYMMDD format.

Example (EUTC):

A TE in Italy with identifier R207 does not use a current coding system and intends using the EUTC code. They require a code for SKIN, SPLIT. They search the Product Compendium looking for EUTC Codes used in their country. They find that the appropriate EUTC term is Skin, Split and this has a code of '65'. The donation number is 10479 and the product is split 003 and expires on 31 July 2018

<i>Two character ISO country code</i>	<i>IT</i>
<i>TE number as assigned in the EU TE Compendium</i>	<i>00R207</i>
<i>Donation Identification Number assigned by the TE (if needed padded to 13 characters with leading zeros)</i>	<i>0000000010479</i>
<i>Coding System Identifier for EUTC</i>	<i>E</i>
<i>EUTC Code padded to seven characters with five leading zeros</i>	<i>0000065</i>
<i>Three character split number</i>	<i>003</i>
<i>Expiration date in YYYYMMDD format</i>	<i>20180731</i>

This gives a SEC of: IT00R2070000000010479 E000006500320180731

3.2.2. USING ISBT 128

The entire list of ISBT 128 product codes for tissues and cells have been uploaded into the Product Compendium and should be regularly updated by ICCBBA.

The SEC is created as follows:

Donation Identification Sequence

- Two character ISO country code;
- TE number as assigned in the EU TE Compendium;
- ISBT 128 Donation Identification Number (13 characters).

Product Identification Sequence

- Coding System Identifier for ISBT 128 (letter A);
- ISBT 128 Product Description Code padded to seven characters with two leading zeros;
- Three character split number (for tissues use the three digit ISBT 128 division number, for cellular therapy use the two character division identifier with a leading zero);
- Expiration date in YYYYMMDD format.

Example (ISBT 128):

A UK TE with identifier '547' uses ISBT 128 product codes and requires a code for SKIN, FULL THICKNESS WITH HYPODERMIS. They search the Product Compendium looking for ISBT 128 codes used in the UK. 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 2018.

Two character ISO country code	GB
TE number as assigned In the EU TE Compendium	000547
ISBT 128 Donation Identification Number (13 characters)	G999913765432
Coding System Identifier for ISBT 128	A
ISBT 128 Product Description Code padded to seven characters with two leading zeros	00T0326
Three character split number	007
Expiry date in YYYYMMDD format	20180731

This gives a SEC of: GB000547G999913765432 A00T032600720180731

3.2.3. USING EUROCODE

The entire list of Eurocode product codes for tissues and cells have been uploaded into the Product Compendium and should be regularly updated by Eurocode. If code(s) required is/are not listed, TEs should confirm with the organisation managing the Eurocode system that they are present in their product list and if not, ask their CA to request that they be added to the EU Tissue and Cell Product Compendium.

The SEC is created as follows:

Donation Identification Sequence

- Two character ISO country code;
- TE number as assigned by CA padded to six characters;
- Eurocode Donation Identification Number (padded with leading zeros to 13 characters).

Product Identification Sequence

- Coding System Identifier for Eurocode (letter B);
- Eurocode Product Description Code padded to seven characters with leading zeros;
- Three character split number;
- Expiration date in YYYYMMDD format.

Example (Eurocode):

A DE TE with identifier '102' uses Eurocode product codes and requires a code for AMNIOTIC MEMBRANE. They search the product compendium looking for Eurocode codes. They find that 702001 is the Eurocode Product Description Code for this product. The donation number is 0000012312312 and the split number is 001 and expires on 31 July 2018.

Two character ISO country code	DE
TE number as assigned In the EU TE Compendium	000102
Donation Identification Number (13 characters)	0000012312312
Coding System Identifier for Eurocode	B
Eurocode Product Description Code padded to seven characters with one leading zero	0702001
Three character split number	001
Expiry date in YYYYMMDD format	20180731

This gives a SEC of: DE0001020000012312312 B070200100120180731

3.2.4. APPLYING THE SEC FOR TISSUES/CELLS IMPORTED FROM THIRD COUNTRIES

Without prejudice to the exclusions / potential exemptions explained in chapter 1, tissues/cells imported from third countries for distribution in the EU must be labelled with the SEC. The importing TE is responsible for the application of the SEC on the product and in the accompanying documentation (double coding/labelling with both the original code and the SEC is possible). In such cases:

- For the SEC-DI:
 - the codes for country and TE number will be the ones corresponding to the importing TE;
 - the donation identification number shall be allocated by the importing TE according to the national system in place in the EU Member State in which the importing TE is located. Where an international coding system was used (e.g. ISBT128), the original donation identification number may be retained.
- For the SEC-PI: the product identification number of the product should map to the EUTC or other international or national codes included in the EU Tissue and Cell Product Compendium (ISBT 128, Eurocode).

In addition, for imported tissues and cells, the country of procurement and the exporting country (if different from the procurement country) have to be indicated either on the label or in the accompanying documentation.

The importing TE is also responsible for storing all the information needed for ensuring the appropriate traceability from donor to recipient for imported tissues/cells.

Example 1:

Generis Tissue Bank in the USA supplies tissue to its subsidiary in Belgium for distribution in the EU. The Belgian EU TE code is 00J427. The subsidiary receives a pack containing an achilles tendon with bone block identified with serial number 02485061327 and product code 67104 expiring on June 24, 2025. The subsidiary assigns the next available donation number from its own number allocation sequence which is 705721, and determines that the appropriate EUTC 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/split number of '000'. They therefore assign the SEC as:

BE00J4270000000705721 E000004100020250624

In their own TE records they ensure that the mapping between the SEC and the original identifiers from the supplier is maintained.

Example 2;

A Tissue Bank in the USA which uses ISBT 128 identification supplies tissue to a tissue bank in Portugal for distribution in the EU. The Portuguese EU TE code is 000215. The Portuguese TE receives a pack containing ground bone identified with donation identification number W000014287126, product code T0183, and division/split number of 074 expiring on Dec 31, 2018. The Portuguese TE retains the ISBT 128 Donation Identification Number, Product Code and Division/Split number, and assigns the SEC as:

PT000215W000014287126 A00T018307420181231

In their own TE records they ensure that the mapping between the SEC and the original identifiers from the supplier is maintained.

However, Member States may also allow exemptions from the application of the SEC for tissues and cells that are imported into the Union (see section 1.1).

3.2.5. APPLYING THE SINGLE EUROPEAN CODE TO A PRODUCT LABEL

The SEC must appear in eye readable format (a minimum of 6pt font is recommended). It must be preceded by the text “SEC:” to identify it as the Single European Code.

It may be presented:

- **as a single line of characters** with the Donation Identifier Sequence and Product Identifier Sequence separated by a gap:

SEC: IT00R2070000000010479 E000006500320140731

Or;

- **as two successive lines:**

SEC: IT00R2070000000010479

E000006500320140731

While there is no requirement to provide the SEC in a machine-readable format, there is nothing to prevent a TE presenting the SEC in a machine-readable format in addition to the obligatory eye-readable format.

Wherever possible the SEC must be applied in a permanent manner to the label of the product and in the relevant accompanying documentation. Where label size precludes the inclusion of the SEC label, the SEC must appear on accompanying documentation and be secured in such a manner that the SEC remains clearly and unambiguously associated with the product to which it relates. In particular embryo and sperm straws do not need to be labelled but the SEC must be included in the accompanying documentation.

Examples

Example ISBT128 label

 G9999 14 123456 8 7	 T300
Tissue Bank City, Country, Postal Code	FIT FOR CLINICAL USE
 T0416003	 0163662359
SKIN, SPLIT Not Meshed Frozen	Expiry Date: 2016-12-31
Container 3	If stored at -20 C or colder
SEC: GB0GY120G999914123456 A00T041600320161231	

Example Eurocode label

 !TDE0001151300000011114	 !C 20120731 – donation date
	 !E20170731 – expiry date
Human Fascia, allogeneic, freeze-dried Zul.-Nr.:3004180.00.00	
 !P732001	Fascia lata, 1 piece, 20x100 mm (f-d) Connective tissue from fascia Graft of human origin, freeze-dried
Storage temperature: <+25°C Prescription only! Tissue for transplantation. Pharmaceutical product. Keep away from children!	
Name and address of manufacturer	
SEC: DE0001151300000011114 B073200100120170731	

Example – Local label

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

4. OBTAINING INFORMATION ABOUT A PRODUCT FROM ITS SINGLE EUROPEAN CODE

The SEC provides information on both the TE and the tissue or cell product. Information that can be obtained includes:

- Country in which the TE is located;
- Identification of the TE in that country (TE number);
- Donation identification number;
- Product coding system;
- Product number within that system;
- Division/split number;
- Expiry date;

By entering the code into the look-up tool it will be possible to obtain contact information and the authorisation status of the tissue establishment, and the description of the product.

Example:

A product with the SEC **BE00A3170000000491276 E000006200120181231** provides the following information:

- Country in which the TE is located: *BE*;
- Number of the TE in that country: *00A317*, which corresponds to the Skin Bank in Belgium;
- Donation identification number: *0000000491276*;
- Product coding system: *E*, which corresponds to the EUTC system;
- Product number within that system: *0000062*, which corresponds to "Glycerolised Skin";
- Division/split number: *001*;
- Expiry date: *2018-12-31*.

5. RECORDS TO BE RETAINED TO ENSURE TRACEABILITY USING THE SINGLE EUROPEAN CODE

TEs distributing tissues and cells will need to retain the SEC in their records and associate it with any internal identifiers used to track the product back to the donor and to all critical procurement, processing and storage documentation. The same records need to be retained for ensuring the traceability of imported tissues and cells.