



# Single European Code (SEC) for tissues and cells

**Unit B4 – Substances of Human Origin Team  
European Commission**

**October 2016**

*Health and  
Consumers*



- **Background**
- **New coding requirements for tissues and cells**
- **Tools for the implementation of the new coding requirements**

## The Treaty of the Functioning of the European Union – article 168



DIRECTIVE 2004/23/EC OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL  
of 31 March 2004

on setting standards of quality and safety for the donation, procurement, testing, processing,  
preservation, storage and distribution of human tissues and cells

COMMISSION DIRECTIVE 2006/17/EC  
of 8 February 2006

implementing Directive 2004/23/EC of the European Parliament and of the Council as regards  
certain technical requirements for the donation, procurement and testing of human tissues and cells

(Text with EEA relevance)

COMMISSION DIRECTIVE 2006/86/EC  
of 24 October 2006

implementing Directive 2004/23/EC of the European Parliament and of the Council as regards  
traceability requirements, notification of serious adverse reactions and events and certain  
technical requirements for the coding, processing, preservation, storage and distribution of  
human tissues and cells

(Text with EEA relevance)





## Directive 2004/23/EC

### *Article 25 - Coding of information*

2. 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.

EC mandate  
restricted to human  
tissue and cells

## Directive 2006/86/EC

### *Article 10 - European coding system*

1. A single European identifying code shall be allocated to all donated material at the tissue establishment, to ensure proper identification of the donor and the traceability of all donated material and to provide information on the main characteristics and properties of tissues and cells. The code shall incorporate **at least the information set out in Annex VII.**



## **Directive 2006/86/EC** **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

## **COMMISSION DIRECTIVE (EU) 2015/565 of 8 April 2015 amending Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells**

- Published on 9 April 2015

<http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32015L0565&from=EN>

- The Directive provides for the full definition of the SEC, indications on its application, as well as obligations of the tissue establishments, competent authorities and the European Commission.

## Definitions

- SEC
  - Donation identification sequence and its components (i.e. EU TE code + unique donation number)
  - Product identification sequence and its components (i.e. product code + split number + expiry date)
- EU Coding Platform
  - EU Tissue Establishment Compendium
  - EU Tissue and Cell Product Compendium
- EUTC
- Released for circulation
- Within the same centre
- Pooling

## Format of the SEC

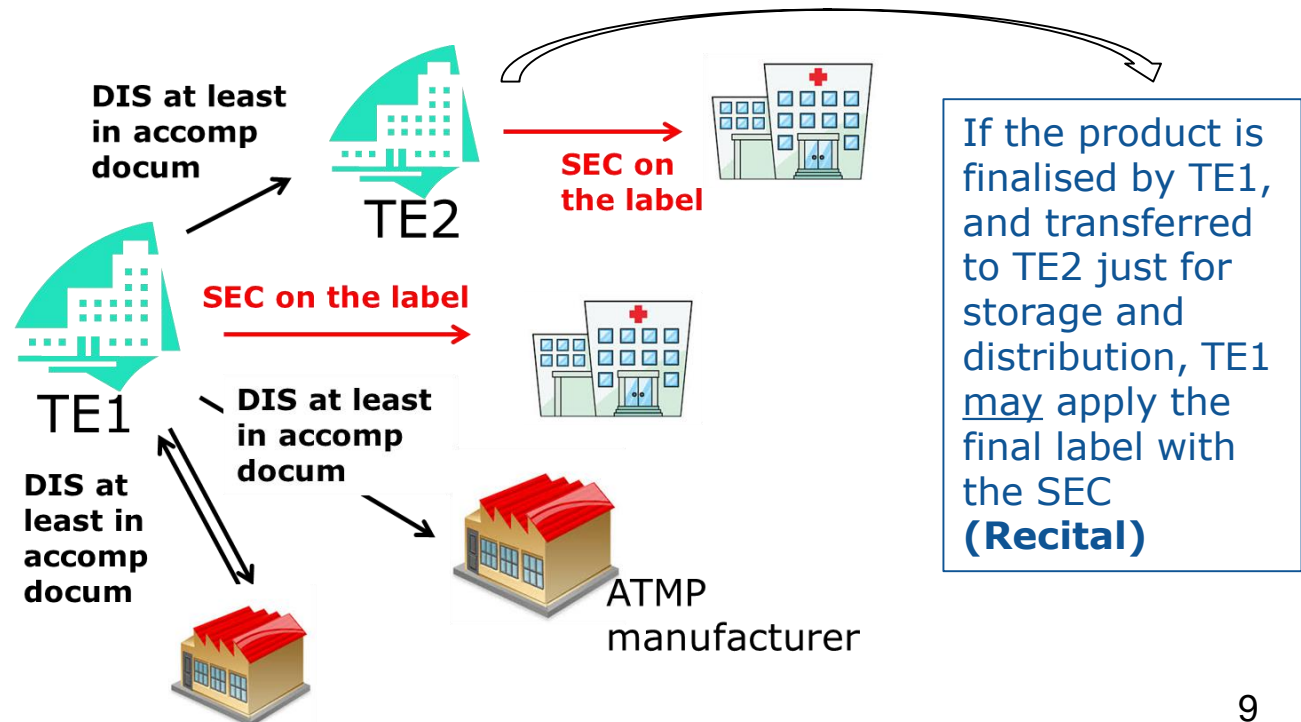
DONATION IDENTIFICATION SEQUENCE (DIS)			PRODUCT IDENTIFICATION SEQUENCE			
TE code		Unique Donation number	Product code		Split number	Expiry date
ISO country identifier	TE number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	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





## European coding system (application of SEC)

- The SEC shall be applied to **all T&C distributed** for human application.
- For the **other situations where tissues and cells are released for circulation**, as a minimum the donation identification sequence (DIS) shall be applied at least in the accompanying documentation



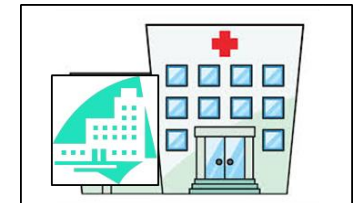
## European coding system

- **Excluded:**

- (a) reproductive cells from partner donation;
- (b) T&C distributed directly for immediate transplantation to the recipient, as referred to in Art. 6(5) of Directive 2004/23/EC;
- (c) T&C imported into the Union in case of emergency authorised directly by the CAs, as referred to in Art. 9(3)b of Directive 2004/23/EC.

- **Potential exemptions** (to be decided by MS!):

- T&C cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre;
- T&C 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 TE authorised for importation



## Requirements for the TEs



- (a) **allocate a SEC** to all tissues and cells requiring application of this code at the latest before their distribution for human application;
- (b) **allocate a donation identification sequence (SEC-DI)** after procuring the tissues and cells, or when receiving them from a procurement organisation, or when importing tissues and cells from a third country supplier.
- (c) **do not alter the SEC-DI** once it is allocated to tissues and cells released for circulation, unless it is necessary to correct an encoding error; any correction requires proper documentation;
- (d) **use one of the permitted product coding systems** and the corresponding tissue and cell product numbers included in the EU Tissue and Cell Product Compendium at the latest before their distribution for human application;

## Requirements for the TEs



- (e) use an **appropriate split number and expiry date**.
- (f) **apply the SEC on the label** of the product concerned in an indelible and permanent manner and mention that code in the relevant accompanying documentation at the latest before its distribution for human application.
- (g) **notify the competent authority or authorities**: when information contained in the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium requires updates, when it observes a situation of significant non-compliance with the requirements relating to the SEC concerning tissues and cells received from other EU tissue establishments;
- (h) **take the necessary measures in case of incorrect application** of the Single European Code on the label.



## Requirements for the CAs

- (a) ensure the **allocation of a unique TE number** to all authorised TEs in its MS.
- (b) decide which **system(s) shall be used for the allocation of unique donation numbers** in their MS (central, local, international allocation systems)
- (c) **monitor and enforce** the full implementation of the SEC in their MS;
- (d) ensure the **validation of the data on the TEs contained in the EU Tissue Establishment Compendium** for their MS and update the Compendium without undue delay in particular in the following situations:
- When a new TE is authorised;
  - When TE information changes or is not correctly recorded in the EU Tissue Establishment Compendium;
  - When the authorisation or licence details of a TE changes

DONATION IDENTIFICATION SEQUENCE (DIS)		
TE code		Unique Donation number
ISO country identifier	TE number	

## Requirements for the CAs



(e) **Alert the CAs of another MS** when they observe incorrect information in the EU Tissue Establishment Compendium relating to the other MS or when they observe a situation of significant non-compliance with the provisions relating to the SEC relating to the other MS;

(f) **Alert the Commission and the other CAs** when in their assessment the EU Tissue and Cell Product Compendium requires an update.

! The application of the SEC does not preclude the additional application of other codes in accordance with MS' national requirements.



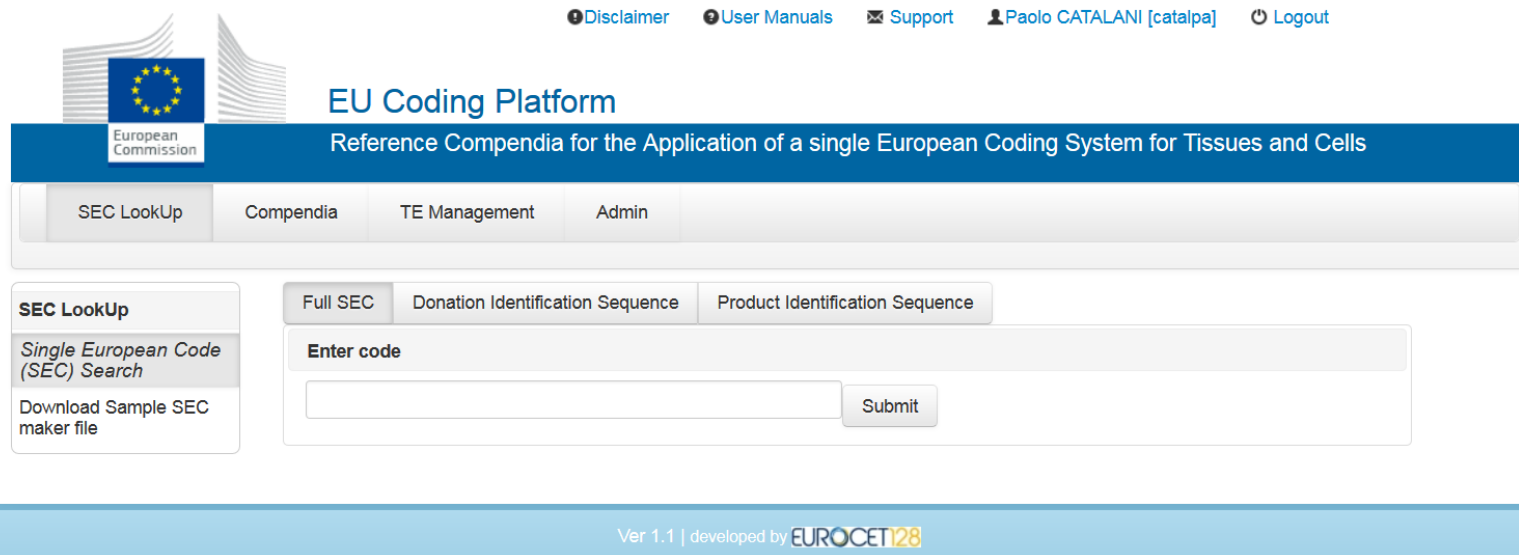
## Accessibility and maintenance of the European coding system



- The Commission shall host and maintain an IT platform (“EU Coding Platform”) which contains:
  - (a) the EU Tissue Establishment Compendium;
  - (b) the EU Tissue and Cell Product Compendium.
- The Commission shall make the EU Coding Platform publicly available before 29 October 2016.
- The Commission shall update when needed the EUTC and ensure the overall update of the EU Tissue and Cell Product Compendium.

## EU Coding Platform <sup>12</sup>

1. EU Tissue Establishment Compendium
2. EU Tissue and Cell Product Compendium
3. Code translator application



The screenshot shows the EU Coding Platform interface. At the top right, there are links for Disclaimer, User Manuals, Support, Paolo CATALANI [catalpa], and Logout. The main header features the European Commission logo and the text "EU Coding Platform Reference Compendia for the Application of a single European Coding System for Tissues and Cells". Below this is a navigation bar with tabs for SEC LookUp, Compendia, TE Management, and Admin. The SEC LookUp tab is active, showing a sub-menu with "SEC LookUp", "Single European Code (SEC) Search", and "Download Sample SEC maker file". The main content area has three tabs: "Full SEC", "Donation Identification Sequence", and "Product Identification Sequence". The "Full SEC" tab is selected, displaying an "Enter code" input field and a "Submit" button. At the bottom, a footer bar indicates "Ver 1.1 | developed by EURO CET128".

<sup>1</sup> <https://webgate.ec.europa.eu/eucoding/>

<sup>2</sup> Developed following a call for tender (EAHC/2011/HEALTH/03) by the Eurocet128 consortium including three organisations: the Italian National Transplant Centre (CNT), ICCBBA, and Artman Technologies.



# Tools for SEC implementation



3

Code-translator application

Code

Full description of DONATION / PRODUCT

DONATION IDENTIFICATION SEQUENCE (DIS)		PRODUCT IDENTIFICATION SEQUENCE		
TE code	Unique Donation number	Product code	Split number	Expiry date

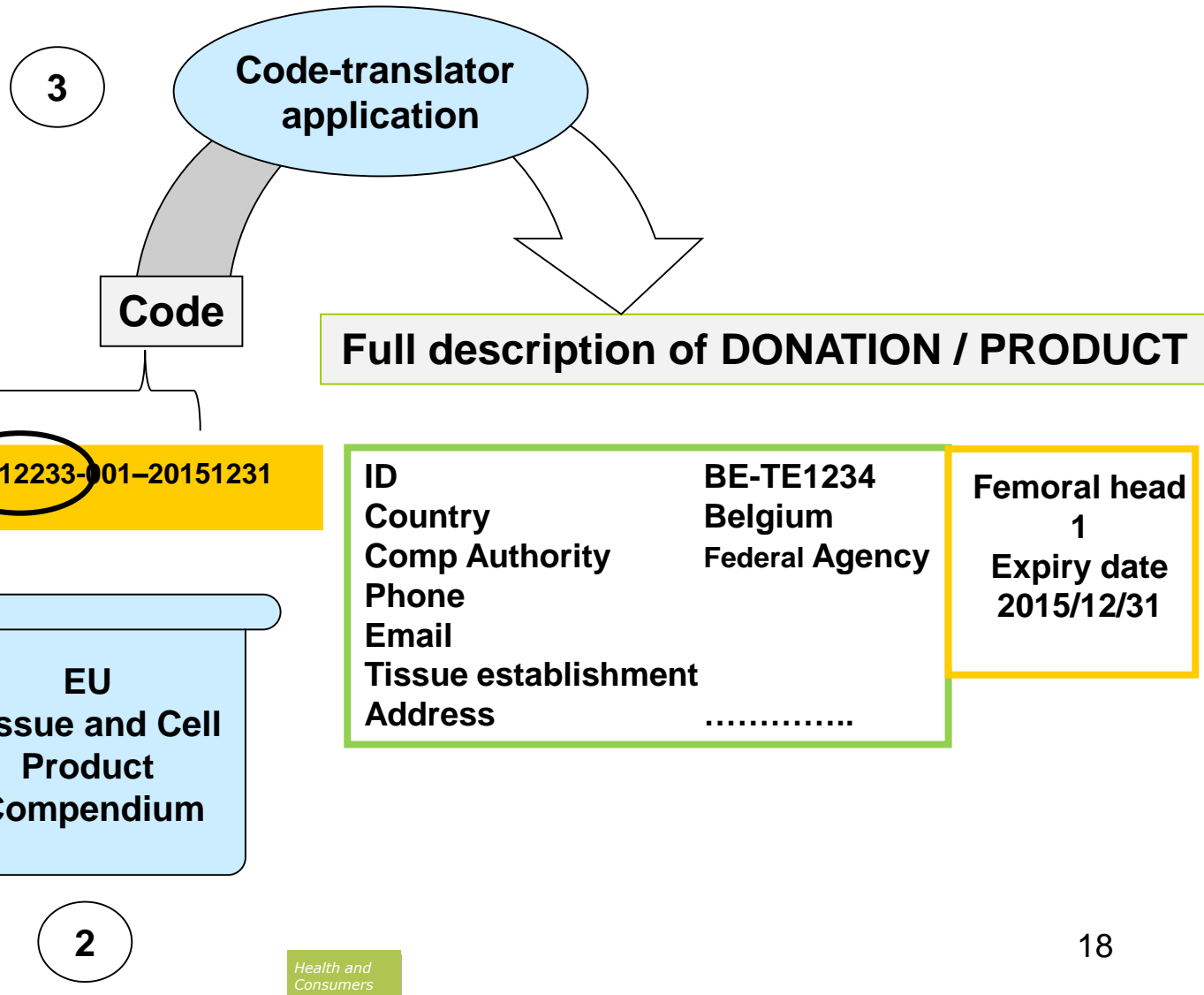
EU Tissue Establishment Compendium

EU Tissue and Cell Product Compendium

1

2

# Tools for SEC implementation



Member States are required to transpose the provisions of Directive (EU) 2015/565 into their national legislation by **29 October 2016**.

Member States should apply the requirements on the SEC from **29 April 2017**.

## Transitional period

According to Article 10d in Directive (EU) 2015/565, tissues and cells already in storage on 29 October 2016 shall be exempted from the obligations relating to the SEC, provided the tissues and cells are released for circulation in the Union within five years following that date (i.e. until 29 October 2021) and under the condition that full traceability is ensured by alternative means.