Single European Code (SEC) for tissues and cells

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Health and Consumers

SUMMARY

- **New coding requirements for tissues and cells**
- **EU Coding Platform**
- **Calendar for transposition and implementation**
- **Next steps for a TE**

This presentation only reflects the views of its author and does not necessarily reflect the opinion of the European Commission

New coding requirements (1)

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,
  - obligations of the tissue establishments, competent authorities and the European Commission.

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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**

New coding requirements (3)

Format of the SEC

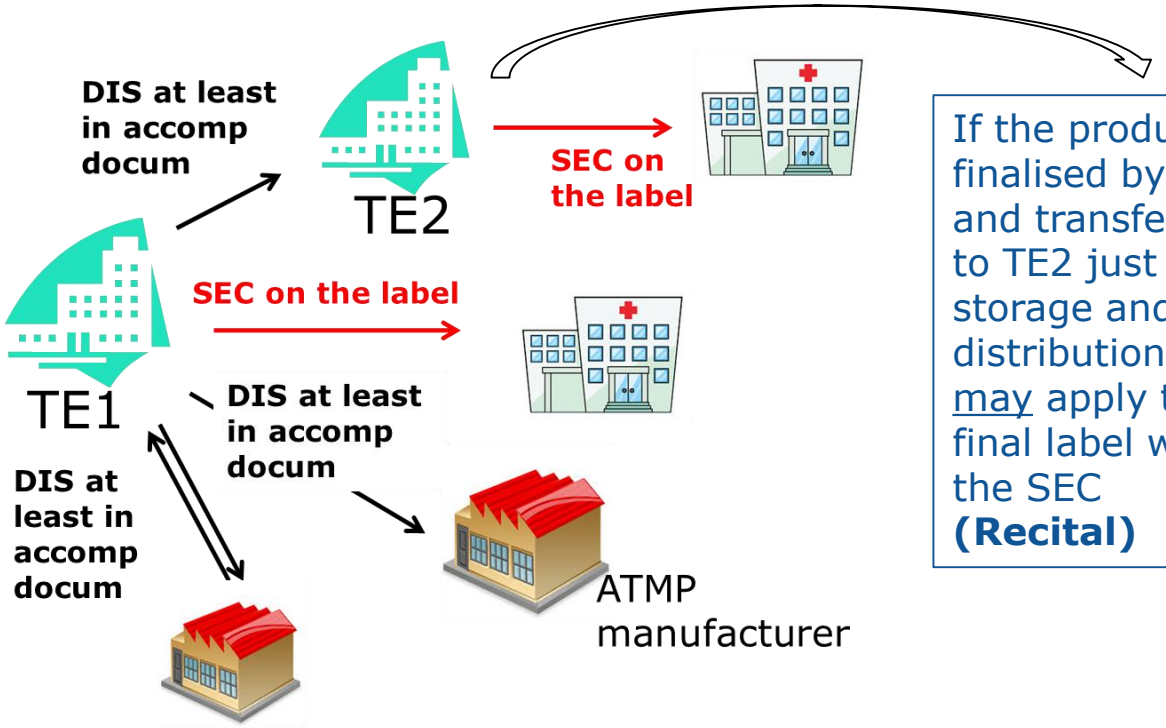
DONATION IDENTIFICATION SEQUENCE (DIS)			PRODUCT IDENTIFICATION SEQUENCE			
TE code		Unique Donation number	Product code		Split number	Expiry date
ISO country identifier	TE number		Product Coding System identifier	Product number		
2 alphabetic characters	6 alpha-numeric characters	13 alpha-numeric characters	1 alphabetic character **E = EUTC** **A = ISBT128** **B = Eurocode**	7 alpha-numeric characters	3 alpha-numeric characters	8 numeric characters

Risk based approach

New coding requirements (4)

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



If the product is finalised by TE1, and transferred to TE2 just for storage and distribution, TE1 may apply the final label with the SEC **(Recital)**

SEC = Single European Code

DIS = donation identification sequence

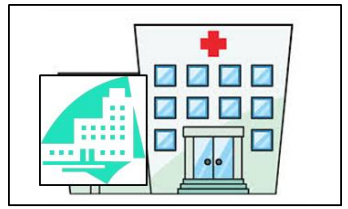
New coding requirements (5)

- **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

New coding requirements (6)

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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;

EUTC
ISBT128
Eurocode

New coding requirements (7)

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.

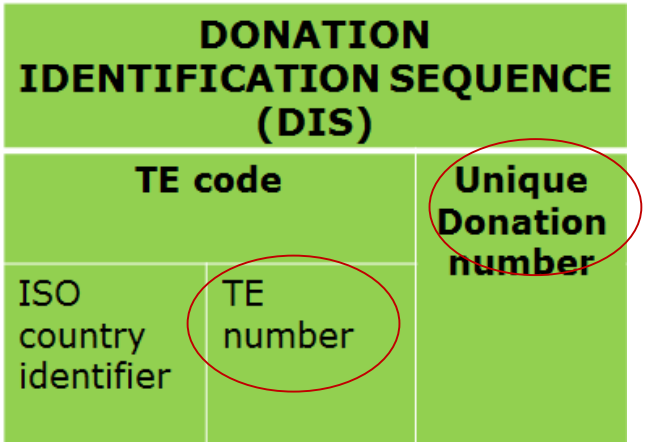
New coding requirements (8)

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

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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.

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Accessibility and maintenance of the European coding system

- The Commission shall host and maintain an IT platform ("EU Coding Platform") which contains:

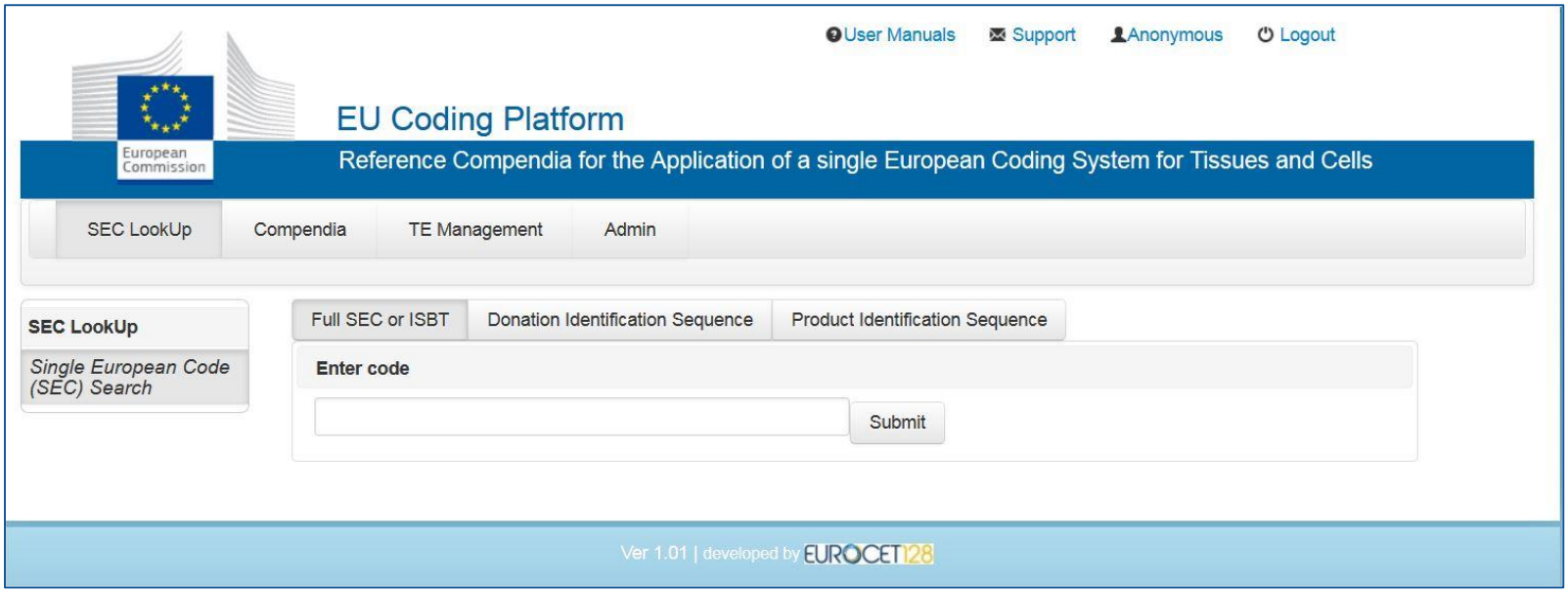
  (a) the EU Tissue Establishment Compendium;

  (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

EU Coding Platform [1][2]

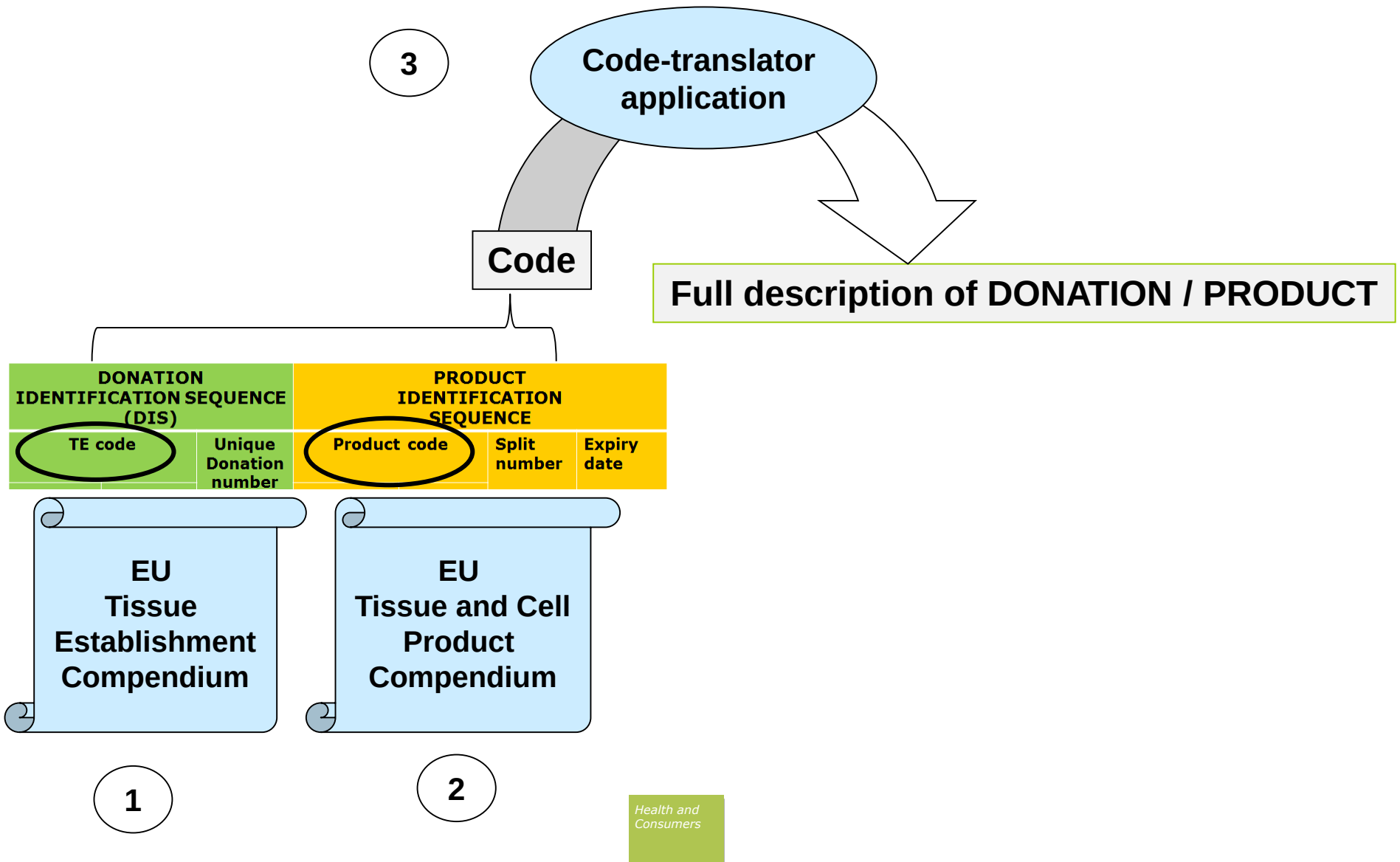
1. EU Tissue Establishment Compendium
2. EU Tissue and Cell Product Compendium
3. Code translator application



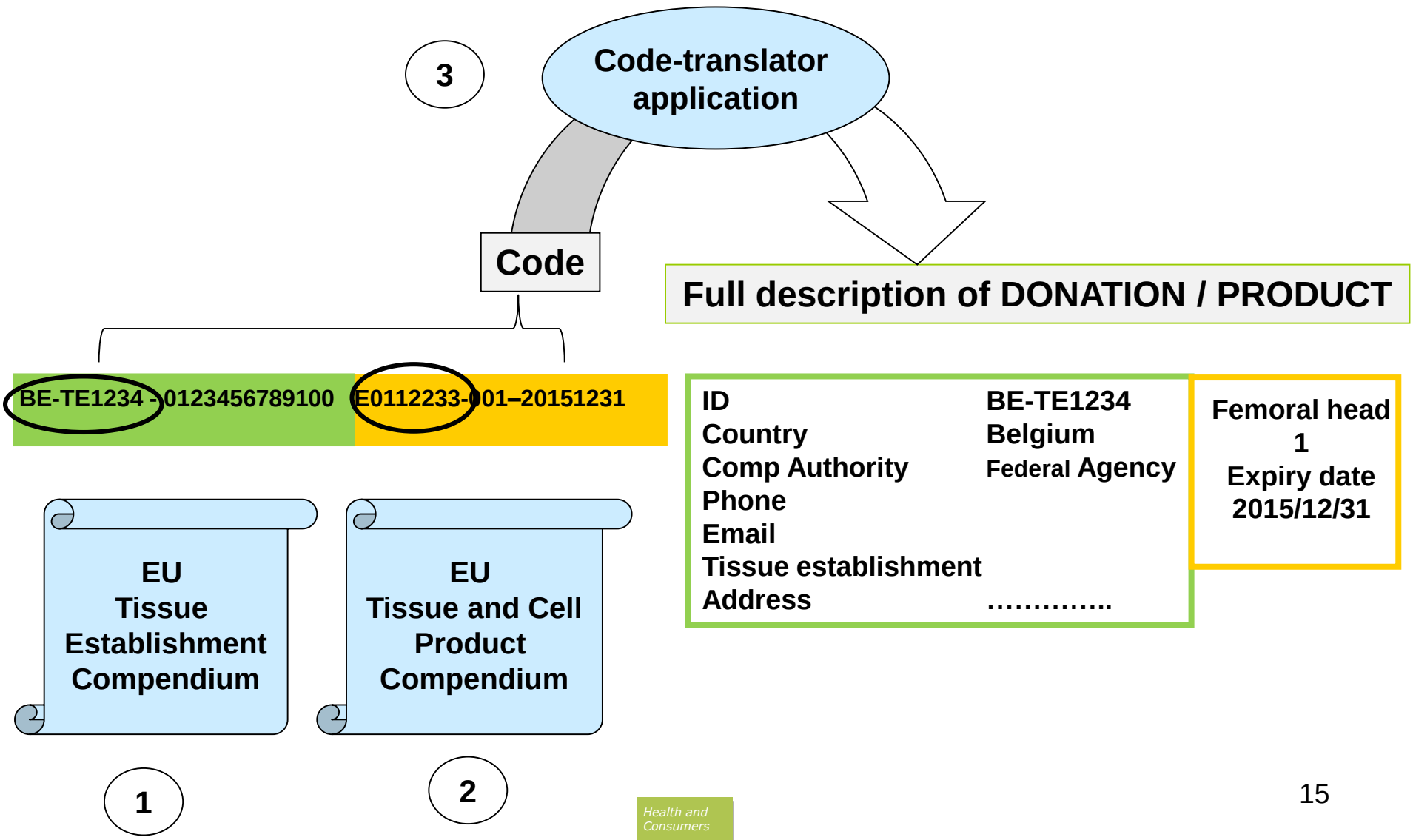
[1] Developed following a call for tender (EAHC/2011/HEALTH/03) by the Eurocet128 consortium including three organisations: the Italian National Transplant Centre (CNT), ICCBBA, and Artman Technologies.

[2] Will become available in 2016

EU Coding Platform



EU Coding Platform



Transposition and 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.

SEC info on Europa website

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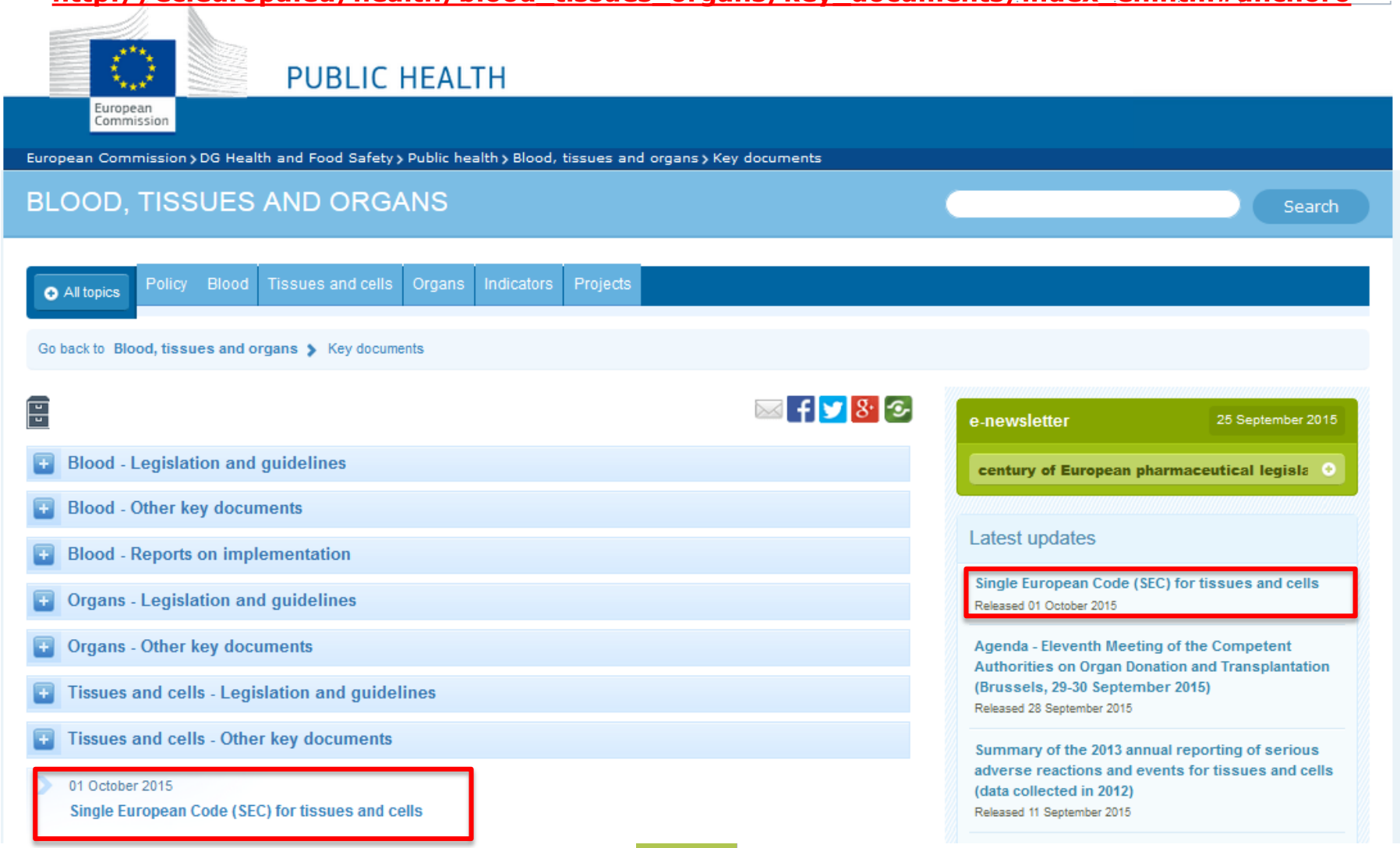
http://ec.europa.eu/health/blood_tissues_organs/key_documents/index_en.htm#anchor6



SEC info on Europa website

http://ec.europa.eu/health/blood_tissues_organs/docs/tissues_single_european_code_en.pdf

SINGLE EUROPEAN CODE (SEC) FOR TISSUES AND CELLS

1. Legal requirements

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

The Directive introduces the obligation for tissue establishments to affix a **"Single European Code" or "SEC"** on tissues and cells distributed for clinical application in the EU. The Directive also sets out the requirements for its application (including exceptions) and general obligations of the tissue establishments, competent authorities and the European Commission.

The **"Single European Code" or "SEC"** is a unique identifier that consists of two elements, a donation identification sequence, essentially indicating the origin of the tissue or cells, and a product identification sequence, essentially classifying the type of tissue or cells. Further details are specified in Annex VII to the Directive (see below).

Next steps

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In practice, as a TE

- Contact your Competent Authority!

- Visit regularly the Europa website for more info

Soon available: FAQ, PPT, Manual for CA and TE

+ Hyperlink to the EU Coding Platform

- If user of ISBT128 or Eurocode - request information on the support provided for the implementation of the requirements on SEC

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Thank you

http://ec.europa.eu/health/blood_tissues_organs/policy/index_en.htm