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Essential Information for Tissue Establishments on the Implementation of the Single European Code for Tissues and Cells

QUESTION	ANSWER
1. What is Eurocet 128?	Eurocet 128 is a Service Contract that was awarded by the European Commission (EC) to a consortium of 3 organisations. The consortium includes: • The Italian National Transplant Centre (CNT), which maintains the Eurocet Registry; • ICCBBA, which maintains the ISBT 128 coding standard for human substances, and • Artman Technologies, a software company.
2. What is the objective of Eurocet 128?	The aim was to build the tools that will support the traceability of human tissues and cells (T&C) applied to patients in the EU through the implementation of a Single European Coding (SEC) System. The tools comprise 2 compendia and a code translator. One compendium is the list of authorized EU Tissue Establishments (TEs) with their authorized activities and their EU codes; the other is a list of EU tissue/cell product codes and descriptions. An electronic code translator allows users to immediately establish both the TE of origin and the EU description of the material; the compendia and translator will be publicly accessible on the EU Coding Platform, hosted by the European Commission. The codes listed in these compendia will be used by TEs to construct the SEC that will need to appear on their tissue/cell products.
3. What is the difference between Eurocet and Eurocet 128?	These are two separate and distinct organizations and activities. Eurocet is an information platform with registries of Competent Authorities (CAs) and TEs in the EU. Member States (MS) collaborate voluntarily by providing annual data on activity in this field. The platform is hosted and managed by CNT. . Eurocet 128 is a Service Contract that has used the experience and contacts developed by Eurocet to build compendia that will be hosted by the EC to support the implementation of the SEC System for T&C.
4. What is the difference between ISBT 128 and Eurocet 128	These are two separate and distinct organizations and activities. ISBT 128 is an international standard for coding and labelling of substances of human origin. Eurocet 128 is a Service Contract which will use the coding experience of ISBT 128 to build compendia that will be hosted by the EC to support the implementation of the SEC System for T&C.

5. What is the Single European Code?

The SEC is the unique identifier to be applied to tissues and cells released for circulation in the European Union. It was foreseen in Article 10 of Directive 2006/86/EC, and its structure incorporates the information laid down in Annex VII of that Directive. Its detailed structure was defined and agreed by the National Competent Authorities for Tissues and Cells together with the European Commission. It is a standard fixed-length alphanumeric code comprising information concerning the donation (donation identification sequence) and the tissue or cell product (product identification sequence).

The format of the SEC has been established as follows:

Donation Identification Sequence (SEC DI)

TE Code		
ISO Country Code	TE number	Unique Donation Number
2 characters (alphabetic)	6 characters (alpha/numeric)	13 characters (alpha/numeric)

Product Identification Sequence (SEC PI)

Product Code			
Product Coding System Identifier	Product number	Split Number	Expiry Date
1 character (alphabetic)	7 characters (alpha/numeric)	3 characters (alpha/numeric)	8 characters (numeric, YYYYMMDD)

6. Will it be mandatory to display the SEC on every tissue/cell label?

In general yes; finished products will need to carry a SEC, although there will be some exceptions. Gametes and embryos exclusively for application in partners are excluded by the current legislation. Some other specific exemptions will be defined, e.g. it is likely that for products distributed directly for immediate application to the recipient ('direct distribution' as defined in Article 6(5) of Directive 2004/23/EC) the application of the SEC will not be required. Furthermore, it is likely that Member States will be able to make exemptions for tissues or cells donated, processed and/or stored and used clinically in the same centre or imported and applied in a centre where both the importing TE and the healthcare facility that applies the tissues or cells are located. These exemptions will be established through an EU legal instrument that will need to be transposed into national legislation by EU MS.

7. When will it be mandatory to show the SEC on tissue/cell products?	It is anticipated that the SEC will be required from 2016. The exact date will be specified in the legal instrument.
8. Can we continue to use our own coding system as well?	Yes. Existing labelling and coding can continue to be used, but in addition the SEC will need to be added to the label, and TEs will need to ensure a clear mapping between their local coding system and the SEC. In some cases, it will be possible for existing codes to be incorporated in the SEC.
9. How do I know what number to use for the donation number part of the SEC?	The donation identifier (DI) comprises three elements. The first is the two character country identifier as specified in ISO 3166-1 alpha-2. The second element is identifier number for the TE as listed in the TE Compendium (6 characters). The third part is the unique donation number for each donation (13 digits); the number can be created at local, regional, national or international level, taking into account any requirements of existing national traceability systems. Where existing numbers are incorporated in the SEC but are shorter than the specified length, leading zeros are used. For example, a donation from a TE in Italy with a TE identifier of 207 and a local donation number of 12206 would have a European donation identifier of IT0002070000000012206.
10. Where should the donation identification sequence appear?	The donation identification sequence will be required to appear as part of the SEC on final product labels, and will need to be retained in TE records to map to the local identifiers. It may also be used more widely, e.g. on procured and in-process tissues/cells, blood samples, donor documentation, processing records etc.
11. Where will I find the EU product number for my products?	A Product number will be incorporated in every SEC. These product numbers will be maintained in the EU Tissue and Cell Product which has been constructed and will be publicly available. The codes available will be: a) EU Tissue and Cell Codes (EUTC) b) ISBT 128 Product Codes c) Eurocode. Only codes appearing in the Compendium may be used.
12. What should I do if one of my products does not map to any of the products in the EUTC list?	New codes can be requested if there is not a suitable code in the compendium. ISBT 128 codes and Eurocode codes will be added routinely once they appear in those Product Databases. Requests for new codes to be added to the Compendium should be submitted to the EC.
13. What should I do if the EUTC code provides less information than we normally provide to users?	The EUTC list describes products at a generic level. The EUTC may be used in addition to your existing labelling information. You should continue to provide the additional information.

14. My TE stores tissues/cells that do not have an expiry date. What should I enter in the expiry date field?	Where it is permitted for a product to not have an expiry date, you should enter 8 zeros in the expiry date field.
15. Will it be a requirement to present the SEC in a machine-readable format (bar-coded, RFID)?	There is currently no requirement to provide a machine-readable format. Any future requirement for a machine-readable format would require a standard format be agreed and followed.
16. Will there be a standard format for a tissue/cell product label?	No, the only requirement will be that the SEC appears on the label. See examples of how the code should appear on an ISBT 128 label, a Eurocode label and on a national/local label in Figures 1 to 3 below.
17. Can I choose to present the SEC (both donation and product sequences) in a machine-readable format (bar-coded, RFID) even if not required?	There is nothing to prevent a TE presenting the SEC in a machine readable format, but because the format is not standardised it will be of limited value and would have to be changed with any future introduction of a standard format.
18. I am currently labelling using ISBT 128 coding (for donation numbers and product descriptions). How will the implementation of the SEC impact on me?	You will be able to continue to use your existing ISBT 128 labelling, but you will need to add the human-readable SEC to the label of final products. The ISBT 128 donation identification number will form the third element of the donation number within the SEC. The ISBT 128 Product Code can be placed directly into the product code field, and the division number into the splits field. See illustration in Figure 1 below.
19. I am currently labelling using a national coding system (for donation numbers and product descriptions). How will the implementation of the SEC impact on me?	You will be able to continue to use your existing national coding system for labelling, but you will need to add the human-readable SEC to the label. You will determine the appropriate way to map the donation number, and divisions into the SEC in agreement with your CA. Your product codes can be mapped into the SEC if your national system uses ISBT 128 or Eurocode.
20. I am currently using a local coding system developed within our own TE. How will the implementation of the SEC impact on me?	You will be able to continue to use your existing local coding system for labelling, but you will have to add the SEC to each final product label. However, you will **not** be able to use your local product codes in the construction of the SEC. You will have to determine the appropriate EUTC code that matches your product and you will also need to control division numbers used in the SEC so that uniqueness of all the products that fall within the EUTC code is ensured. If you have any problems during the mapping process, you should contact your CA who will refer the issue to the EC.

21. If I import tissues/cells from outside the EU should they be relabelled with the SEC?	The imported products must be labelled with the SEC before distribution to the clinical user. The original label should not be covered by a new label. You should add a label to each product that shows the SEC. You should construct the SEC using your ISO country identifier, your TE code, a unique donation number allocated by your donation numbering system and a product code taken from the EU compendium (EUTC, ISBT 128 or Eurocode). This additional label will indicate that your TE is responsible for having ensured that the safety and quality of the products are equivalent to EU requirements. If the imported tissues/cells will be applied clinically in the healthcare facility to which your TE belongs, and where it is located, there may be the possibility for an exemption from the requirement to apply the SEC.
22. If I receive finished tissues/cells from another EU MS for distribution in my MS, do I need to re-label with the SEC?	No. As every MS must implement the system, the tissues/cells should arrive already labelled in line with the requirements. You should include this requirement in any collaborative agreements with TEs in other MS.
23. If I am sending tissues/cells outside the EU do I need to add the SEC?	Yes. These products should be distributed with identical labels to those applied on products for EU distribution.
24. If I send tissues or cells to another TE for processing and distribution, should I apply the SEC or should they?	It is likely that the legal instrument will require that the tissues or cells that you send to the second TE be allocated at least the Donation Identification Sequence part of the SEC (it should appear as a minimum in the accompanying documentation) and that this should appear **unchanged** on the final products distributed by the second TE, together with a Product Identification Sequence allocated by the second TE.
25. If I send tissues or cells for processing by a third party and return to my TE for distribution, should I apply the SEC?	It is likely that the legal instrument will require that the tissues or cells that you send to the third party be allocated the Donation Identification Sequence part of the SEC (as a minimum appearing in the accompanying documentation).
26. If I send tissues or cells to an ATMP manufacturing facility for processing into an ATMP and subsequent distribution, should I apply the SEC?	It is likely that the legal instrument will require that the tissues or cells that you send to the ATMP facility be allocated the Donation Identification Sequence part of the SEC (as a minimum appearing in the accompanying documentation).
27. Will I need to relabel products that are already in frozen inventory?	The legal instrument will define the requirements to follow in situations where it is not possible to label products already frozen. It is likely that, in these circumstances, the SEC will be required only on associated documentation, unambiguously linked to the product.

28. What will I do if there is not enough room on my product to add the SEC to the label?	The legal instrument will define the requirements to follow in situations where it is not possible to add the SEC to very small products. It is likely that, in these circumstances, the SEC will be required only on associated documentation, unambiguously linked to the product.
29. How will I access the compendia?	The Compendia and code translator have been provided to the EC for hosting and maintenance. There will be public, on-line, read-only access to the data held in both compendia.
30. When will I use the EU TE compendium?	The compendium will be useful for EU TEs to assist them in identifying TEs in other MS and confirming their authorization status.
31. When will I use the EU Product Compendium?	The compendium will be useful for EU TEs to assist them in finding EUTC codes to insert on their product labels and in understanding how the product descriptions on products from other countries match to their codes.
32. How will my TE be entered in the EU TE compendium?	Your CA will have secure access to the compendium and will provide all the required details of your TE. They will update your authorization status for each activity (by tissue/cell type) for which you are authorized, on a real time basis.
33. What should I do if the information I find for my TE is not accurate?	If this occurs you should contact your CA immediately and request a modification to the data.
34. What should I be doing to prepare for implementation of the SEC?	TEs should now be preparing their implementation plans for this change. In particular, they should: • In consultation with their CAs, identify the product coding system they will be using, and prepare reference tables to indicate how each of their products will be identified using a code from the European compendium. • Develop procedures and controls to ensure that each product carries a unique SEC through the assignment of split numbers to distinguish products carrying the same donation number and product code. • Review their label designs and printing systems to accommodate the European identification code.

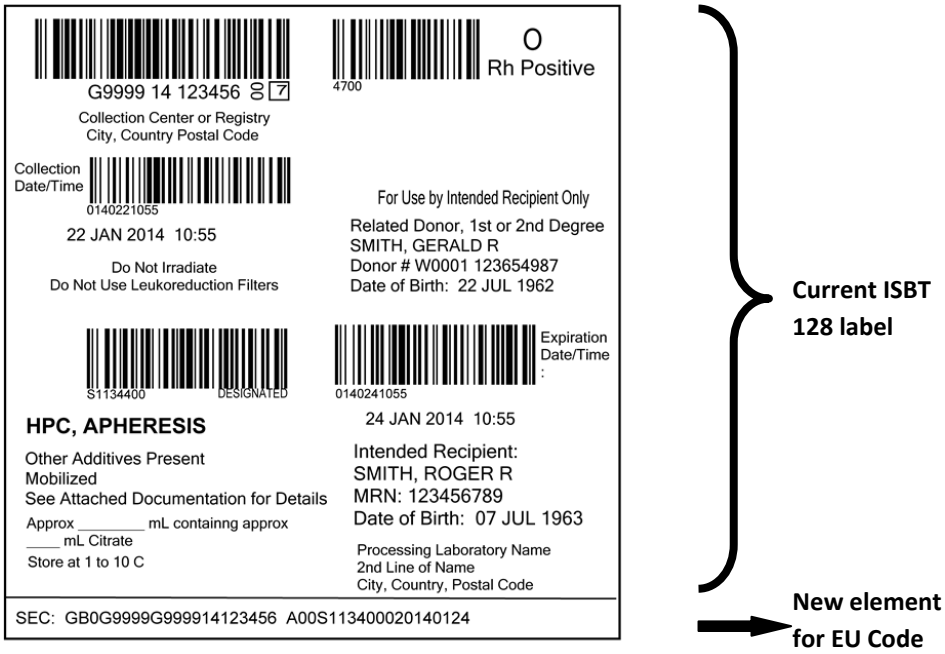

Figure 1: Addition of the EU code to an ISBT 128 label (invented data)

Figure 2: Addition of the EU code to a Eurocode label (German system, invented data)

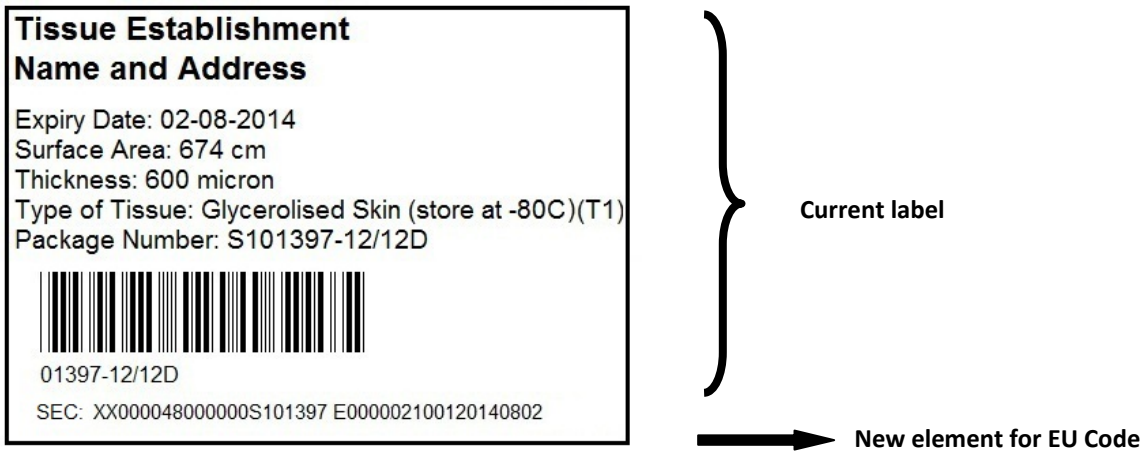

Figure 3: Addition of the EU code to a local label