EUROPEAN COMMISSION
HEALTH AND FOOD DIRECTORATE-GENERAL

Directorate B - Health systems, medical products and innovation
B4 – Medical products: quality, safety, innovation

Single European Code (SEC)

-Questions and answers-

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 is a working document that is regularly updated to take into account experience and feedback from users.

4.5 Could the 'same centre' exemption be applied in the circumstances described in 4.4 if the tissues or cells are used in the same centre where the TE in country B is located?

4.6 Do the TEs carrying out activities that are excluded or exempted from the SEC application, need to be in the TE compendium?

4.7 Can TEs continue using their own coding system as well?

4.8 Where can TEs find the EU product number for their products?

4.9 What should a TE do if one of its products is not mapped to any of the product codes in the EUTC list?

4.10 What should a CA do if it identifies the need for a new product authorisation category in the TE compendium?

4.11 What should a TE do if the EUTC code provides less information than the one provided to users by using their local code?

4.12 Could TEs within one country use different product coding system identifiers (E = EUTC, A = ISBT 128, B = Eurocode) in the SEC (PI) for different product categories or even for the same product?

4.13 What about tissues/cells that do not have an expiry date? What should be entered in the expiry date field?

4.14 How should the application of different expiry dates in different Member States be managed when tissues or cells are distributed between them? (Particularly in the context of ART where expiry dates may be defined under national policies related to ethics).

4.15 Will it be a requirement to present the SEC in a machine-readable format (bar-coded, RFID)?

4.16 Can a TE choose to present the SEC (both donation and product sequences) in a machine-readable format (bar-coded, RFID) even if not required?

4.17 Is there a standard format for a tissue/cell product label?

4.18 A TE is labelling using ISBT128 coding (for donation numbers and product descriptions). How does the implementation of the SEC impact such a TE?

4.19 A TE is labelling using Eurocode (for donation numbers and product descriptions). How does the implementation of the SEC impact such a TE?

4.20 A TE is using a local coding system developed within the TE. How does the implementation of the SEC impact on such a TE?

4.21 If a TE imports tissues/cells from outside the EU should they be relabelled with the SEC?

4.22 When TEs are importing frozen products from a 3rd country, the SEC may need to be applied prior to freezing by the third country TE (as part of their contract with the EU TE) but the third country supplier might not know, at the time of freezing, which TE it will be sending to. How can this be managed?

4.23 If a TE receives finished tissues/cells from another EU Member State for distribution in its own Member State, is there a need to re-label with the SEC?

4.24 Is application of the SEC needed when sending tissues/cells outside the EU?

4.25 If tissues or cells are sent to another TE for processing and distribution, who should apply the SEC?

5.4.

<table>
<tr><th>QUESTION</th><th>ANSWER</th></tr>
<tr><td colspan="2">1. Structure and format of SEC</td></tr>
<tr><td>1.1. What is the Single European Code (SEC)?</td><td>The Single European Code (SEC) is the unique identifier applied to tissues and cells distributed in the European Union. The SEC consists of a donation identification sequence (SEC-DI) and a product identification sequence (SEC-PI).
<table><tr><th colspan="2">Single European Code (SEC)</th></tr><tr><td>Donation identification sequence (SEC-DI)</td><td>Product identification sequence (SEC-PI)</td></tr></table>
The detailed requirements for the implementation of the SEC are included in Directive 2006/86/EC as amended by Directive (EU) 2015/565 adopted in April 2015.
The amending Directive is available in all official EU languages at:
http://eur-lex.europa.eu/legal-content/FR/TXT/?uri=uriserv:OJ.L_.2015.093.01.0043.01.FRA)</td></tr>
<tr><td>1.2. What is the donation identification sequence (SEC-DI)?</td><td>The SEC-DI is the first part of the Single European Code consisting of:
EU tissue establishment code = the unique identifier for accredited, designated, authorised, or licensed tissue establishments in EU. The tissue establishment code consists of an ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium.
unique donation number is 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 (i.e. local allocation by the TE, central allocation by a national body/system, international in case of ISBT128 for countries who adopted ISBT128 as national coding system for tissues and cells).
<table><tr><th colspan="3">SEC-DI</th></tr><tr><th colspan="2">EU TE code</th><th></th></tr><tr><td>ISO Country Code</td><td>TE number</td><td>Unique Donation Number</td></tr><tr><td>2 characters (alphabetic)</td><td>6 characters (alpha/numeric)</td><td>13 characters (alpha/numeric)</td></tr></table></td></tr>
<tr><td>1.3.Can a TE change the SEC-DI?</td><td>NO. The SEC-DI includes important information on the origin of the tissues and cells, therefore, once allocated by a TE, it shall not be changed when the tissues and/or cells are sent to other TEs for processing and/or distributing tissues, unless the tissues or cells are pooled with other donations (see question 4.29).</td></tr>
<tr><td>1.4.How to find the EU TE</td><td>The EU TE code can be obtained from your national CA. It is also available in the EU TE Compendium which is part of the EU Coding</td></tr>
</table>

<table>
<tr><td>code?</td><td>Platform (see below) – you can use the search engine to find your TE based on location or tissue type. More information is available in the Q&A related to the application of SEC.</td></tr>
<tr><td>1.5. Can different tissue/cell types from the same donor and donation event be assigned different Unique Donation Numbers?</td><td>YES. If tissues or cells from one donation event are sent to more than one TE then each TE should assign the SEC using its TE code. The unique donation number part of the SEC-DI could be the same for all tissues and cells from that event (e.g. if there is a national donation number allocation system) or could be different if donation numbers are allocated by the TE or internationally.</td></tr>
<tr><td>1.6.What is the product identification sequence (SEC-PI)?</td><td>The SEC-PI is the second part of the Single European Code consisting of:
product code = the identifier for the specific type of tissue and 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 cells product number foreseen in the respective coding system for the product type
split number = 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
expiry date = the date by which the tissues and cells can be applied.
<table><tr><th colspan="2">Product Code</th><th>Split Number</th><th>Expiry Date</th></tr><tr><td>Product Coding System Identifier</td><td>Product number</td><td></td><td></td></tr><tr><td>1 character (alphabetic)</td><td>7 characters (alpha/numeric)</td><td>3 characters (alpha/numeric)</td><td>8 characters (numeric, YYYYMMDD)</td></tr></table></td></tr>
<tr><td>1.7.Can a TE use split numbers to differentiate between different tissues or cells donated</td><td>'Split number' is defined in Directive 2006/86/EU as amended by 2015/565 as 'the number that distinguishes and uniquely identifies tissues and cells having the same unique donation number and the <u>same product code</u> and originating from the same tissue establishment'.

It would not be appropriate, therefore, to use the split number to differentiate between different product types; this should be done using different product codes.</td></tr>
</table>

as part of the same donation event?	
1.8. Can a TE change the SEC-PI for a certain tissue or cell product?	YES. The SEC-PI can be changed depending on the processing activities. However the SEC-DI – once allocated – must remain unchanged except in the case of pooling more than one donation during processing (see question 4.29)
1.9. How to find the appropriate tissue/cell product code?	The tissue and cell product codes are available in the EU Tissue and Cell Product Compendium (https://webgate.ec.europa.eu/eucoding/reports/eugcproduct/index.xhtml), which can be downloaded from the EU Coding Platform. One can also use the search engine to find the corresponding codes to a certain tissue/cell type, depending on the coding system used (e.g. EUTC, ISBT128, Eurocode). More information is available in the section on Q&A related to the application of SEC.
1.10. What is EUTC?	EUTC is a product coding system for tissues and cells developed by the EU consisting of a register of all types of tissues and cells circulating in the Union and their corresponding product codes. This is a high level system, based on the anatomical location of tissue and cells.
1.11. What is ISBT128?	ISBT128 is an international standard for the terminology, identification, coding and labelling of medical products of human origin as defined by WHO (including blood, cell, tissue, milk, and organ products) and managed by ICCBBA. More information is available at https://www.iccbba.org/
1.12. What is Eurocode?	Eurocode is an international non-profit standard for labelling blood products and tissue to enhance security in blood transfusion and tissue transplantation, managed by EUROCODE-International Blood Labelling Systems e.V. More information is available at http://www.eurocode.org/
1.13. How should I use the 'SEC maker' that is available on the Coding Platform?	This is a simple Excel sheet to help users (TEs) to understand how to build the SEC. It is essentially a training tool. Please note that it is not technically possible to enter all zeros for expiry date in the SEC maker although this is allowed the SEC itself (this will be changed in a future version).
1.14. For tissue/cell products that are distributed as single containers	If the sub-containers remain together within the primary container up to the point of use or discard, no split number is needed. If, however, the sub-containers might be separated from each other, stored in different locations/conditions or used in different patients or on different occasions, then they should be considered as primary containers and split numbers should be allocated.

with multiple sub-containers inside, is it necessary to allocate split numbers to the sub-containers?	
2. **EU Coding Platform**	
2.1. What is the EU Coding Platform?	The EU Coding Platform is the IT platform hosted by the Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium and a code-translator application which allows "translating" the numbers in the SEC into detailed information. https://webgate.ec.europa.eu/eucoding/lookup/compendium/secdipi.xhtml The EU Coding Platform is the main tool for the implementation of the coding requirements of Directive 2006/86/EC as amended by Directive (EU) 2015/565 and was developed by a service contract awarded to a consortium of three organisations under the name Eurocet128.
2.2. What is the difference between the EU Coding Platform and Eurocet 128?	Eurocet 128 was the consortium which was awarded a service contract by the European Commission (EC) for building the tools for the implementation of the SEC. The consortium included three organisations for building the tools for the implementation of the SEC (i.e. EU Coding Platform = EU TE Compendium + EU Tissue and Cell Product Compendium + code-translator application). The consortium included: • The Italian National Transplant Centre (CNT), which maintains the Eurocet Registry (collecting data on transplantation and ART activities submitted voluntarily by EU and non-EU countries); • ICCBBA, which maintains the ISBT 128 coding standard for human substances, and • Artman Technologies, a software company. The contract ended in July 2014 with the transfer of the compendia and the code translator to the European Commission, which has the responsibility to host, maintain and update it.
2.3. What are the costs to access the EU Coding	Access to the EU Coding Platform is public and free of charge. The link to the platform will be published at: http://ec.europa.eu/health/blood_tissues_organs/tissues/index_en.htm

Platform?	
2.4. When will the EU Coding Platform become available?	The EU Coding Platform was made available to users in October 2016.
2.5. What software is needed for accessing the EU Coding Platform?	Access to the EU Coding Platform does not require any special software.
2.6. When will a TE use the EU TE compendium?	The EU TE Compendium will be useful for EU TEs to assist them in identifying TEs in other Member States and confirming their authorisation status.
2.7. Who is responsible for the TE information in the TE compendium?	All data and information on TEs is entered directly by national CAs who have been given access privileges and who must ensure that the information is up to date.
2.8. What do the terms "suspended" and "revoked" in the TE compendium mean?	"Revoked" means the authorisation of a TE or a tissue or cell preparation process in a TE has been withdrawn by a CA (see Article 6 paragraph 4 of Directive 2004/23/EC); "Suspended" means a temporary withdrawal of an authorisation, of a TE or a tissue or cell preparation process by a CA until identified non-compliances have been corrected and verified.
2.9. What should a TE do if the information regarding the TE authorisation, contact details and/or data in the EU TE Compendium is not accurate?	If this occurs the TE should contact its CA immediately and request a modification to the data.
2.10. How can a CA make corrections to	Most entries can be corrected by the CAs directly however, some fields, such as categories of tissue and cell for authorisation, can only be changed by an administrator in the European Commission.

errors in the TE compendium?	As a general principle, once a TE code or a product code has been used, or a TE has been shown as active and authorised, it should never be removed. This is also valid for the authorisation categories. This ensures traceability for tissues or cells that might already have been labelled with a SEC using the TE or product code and distributed in the EU or elsewhere.
2.11. Why is there a distinction between authorisations for "allogeneic related" and "allogeneic unrelated" in the TE compendium?	The terms 'allogeneic use' and 'autologous use' are defined in Directive 2004/23/EC In some Member States, centres that only carry out autologous and allogeneic related are authorised in a different way to those that also carry out allogeneic unrelated. However, any Member State that does not differentiate in this way should indicate in the TE compendium that both types of authorisation apply.
2.12. What is meant by the term 'fertility preservation' in the detail of the TE compendium?	Fertility preservation is one of the categories for which a TE can be authorised. It refers to the storage of gametes, testicular and ovarian tissues, for patients' own future intended use.
2.13. Does "reproductive cells" include all the ART tissues and cells, such as embryos, ovarian and testicular tissue?	Legal: Art 2(a) of 2006/86/EC defines reproductive cells as "all tissues and cells intended to be used for the purpose of assisted reproduction". When these reproductive cells are intended to be used for partner treatments the SEC exclusion applies, even if the partner is not identified at the time of the donation, unless more stringent rules are applied at a national level.
2.14. When will a TE use the EU Tissue and Cell Product Compendium ?	The EU Tissue and Cell Product 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.
2.15. How do the	Each of the EUTC codes is mapped to one of Product Categories for authorisations in the TE compendium. A TE should only use codes that

authorisation categories in the TE compendium relate to the EUTC product codes?	map to a Product Category for which it is authorised. The mapping can be consulted on the Coding Platform: https://webgate.ec.europa.eu/eucoding/reports/eugcproduct/index2.xhtml
3. Calendar of transposition and implementation of Directive (EU) 2015/565 regarding certain technical requirements for coding of tissues and cells	
3.1. What is the deadline for transposing Directive (EU) 2015/565 and what is its practical significance?	Directive (EU) 2015/565 shall be transposed i.e. its provisions incorporated into the national legislation of all EU Member States, by 29 October 2016. The Directive allows the Member States the discretion to allow certain exemptions from the requirements, so tissue establishments involved in implementing the requirements related to the SEC should contact their competent authority and enquire about the status of national transposing regulations.
3.2. When will the requirements of this Directive become applicable across the EU?	The application of requirements related to the application of SEC will become mandatory from 29 April 2017 onwards.
3.3. Is application of the SEC mandatory for tissues/cells distributed between 29 October 2016 and 29 April 2017?	NO. 29 October 2016 is just the deadline for transposition into national legislation. See the answer to questions 3.1 and 3.2 above.
3.4. Is there a transitional period?	YES. According to Article 10d of Directive 2006/86/EC as amended by 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 they are released for either distribution for human application or to another operator (e.g. ATMP manufacturer) within five years following that date (i.e. until 29 October 2021) and under the condition that full traceability is ensured by alternative means. National requirements may apply regarding ensuring full traceability.
3.5. Is application of the SEC mandatory for	NO. See transition period (see also the answer to question 3.3 above).

tissues/cells in storage before 29 October 2016 and distributed on 30 April 2017?	
3.6. Is application of the SEC mandatory for tissues/cells in storage before 29 October 2016 but distributed after 29 October 2021?	YES, when distributed after 29 October 2021(not if distributed before that date) due to the expiry of the transitional period (5 years from 29 October 2016).
3.7. Is application of the SEC mandatory for tissues/cells processed and prepared for either storage or distribution for human application after 29 April 2017?	YES. For deep-frozen tissues/cells, if the SEC is not applied before storage, re-labelling will be mandatory at the moment of distribution.
3.8. Is application of the SEC mandatory for tissues/cells procured and processed between 29 October 2016 and 29 April 2017?	If the tissues or cells are procured and processed between 29 October 2016 (deadline for transposition into national legislation) and 29 April 2017 (deadline for implementation across EU), the application of the SEC depends on the moment of their release for clinical application: - If released before 29 April 2017, the application of SEC is not mandatory; - If released on/after 29 April 2017, SEC must be applied.
3.9. What steps should a TE follow to ensure correct application of the coding	In particular, TEs should: • Obtain their TE code from their CA • Be informed on how the legislation has been transposed in their Member State, in particular which exemptions have been transposed (see below)

requirements?	• In consultation with their CAs, clarify the allocation of the donation identification number (e.g. by the TE itself, national central allocation system, using ISBT128 or Eurocode donation number). • 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 EU Tissue and Cell Product 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 inclusion of the SEC
4. Application of SEC	
4.1. Will it be mandatory to display the SEC on every tissue/cell label?	Some tissue and cells are excluded from the application of the SEC (see the answer to question 4.2.) According to Directive 2006/86/EC as amended by Directive (EU) 2015/565, Member States may also allow exemptions when they transpose the Directive into their national legislation (see the answer to question 4.3.) Apart from those exceptions, in principle YES, the SEC shall be applied to all tissues and cells distributed for human application (i.e. transplantation and assisted reproductive technologies procedures). For the other situations where tissues and cells are released for circulation (e.g. 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. For example, when sending bone to a third party for irradiation, SEC-DI should be applied at least in the accompanying documentation. Where the label size precludes the application of the SEC, the code shall be unambiguously linked to tissues and cells packaged with such a label through the accompanying documentation. It should also be noted that Annex II of Directive 2006/86/EC (as amended by Directive 2015/565) specifies that *'if any of the information under points (d) (e) or (g)* (point g refers to the requirement for the SEC) *cannot be included on the primary container label, it must be provided on a separate sheet accompanying the primary container. This sheet must be packaged with the primary container in a manner that ensures that they remain together*'.

4.2. Which tissues and cells are excluded from the application of the SEC?	The following tissues and cells 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 and Article 6 of Directive 2006/17/EC (e.g. haematopoietic stem cells; TEs should check the transposition of "immediate transplantation" in their national legislation); (c) tissues and cells imported into the Union in case of emergency and authorised as such directly by the competent authority or authorities, as referred to in Article 9(3)b of Directive 2004/23/EC. See also 4.3.
4.3. Which tissues and cells may be exempted from the application of the SEC?	Member States may allow exemptions for: (a) tissues and cells other than reproductive cells for partner donation, when these tissues and cells remain within the same centre (e.g. for ART establishments authorised for non-partner donation activities, when the donated gametes and embryos are used only in patients treated in the clinic/hospital having the same location with the ART establishment). (b) tissues and cells that are imported into the EU, 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. (e.g. for tissue establishments located in clinics/hospitals, when importing cells from non-EU countries to be used for patients treated in the clinic/hospital having the same location with the tissue establishment). ! Tissue establishments should contact their National CA to know if any of these exemptions apply to the activities in their TE/country.
4.4. Is the SEC required when tissues or cells are procured in Member State A and processed, stored and distributed by a TE in Member State B?	Yes, it is. The TE in Member State B is the first TE to receive the tissues or cells and should apply the SEC using its TE code.
4.5. Could the 'same centre' exemption be applied in the	If the procurement falls under the same Responsible Person, within the same quality management system and traceability system (either as it is carried out by employees of the TE or via a third party agreement)

circumstances described in 4.4 if the tissues or cells are used in the same centre where the TE in country B is located?	then it could be considered under the same centre exclusion. This can only apply if the MS 'Member State B' has chosen to transpose the same centre exemption into its national legislation.
4.6. Do the TEs carrying out activities that are excluded or exempted from the SEC application, need to be in the TE compendium?	YES, they need to be in the TE compendium. The TE compendium also aims to fulfil the obligation of Article 10 part 3 of Directive 2004/23/EC by establishing an EU network of authorised TEs registries.
4.7. Can TEs continue using their 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.
4.8. Where can TEs find the EU product number for their products?	A tissue and cell product number will be incorporated in every SEC. These product numbers will be maintained in the EU Tissue and Cell Product Compendium which has been constructed and will be publicly available, free of charge. Only codes appearing in the EU Tissue and Cell Product Compendium shall be used.
4.9. What should a TE do if one of its products is not mapped to any of the product codes in the EUTC list?	New codes can be requested if there is not a suitable code in the EU Tissue and Cell Product Compendium. ISBT 128 codes and Eurocode codes will be added routinely once provided to the Commission. Requests for new EUTC codes to be added to the Compendium should be submitted to the national Competent Authorities, who shall communicate these requests to the European Commission.
4.10. What should a CA do if it identifies the need for a new product authorisation category in the TE compendium?	The form for submission of a request for a new product code (see 4.8) includes a field where the CA should indicate the need for a new product authorisation category to which that code should map.

4.11. What should a TE do if the EUTC code provides less information than the one provided to users by using their local code?	The EUTC list describes products at a generic level and it should be seen as one element for providing traceability of tissues and cells. The EUTC may be used in addition to your existing labelling information, and additional information can be provided on both label and accompanying documentation.
4.12. Could TEs within one country use different product coding system identifiers (E = EUTC, A = ISBT 128, B = Eurocode) in the SEC (PI) for different product categories or even for the same product?	YES. TEs within one country can use different product coding systems for any product or category of products, as long as this is permitted by the national rules. The different coding systems are mapped in the EU Coding platform to help to identify products coded with different systems.
4.13. What about tissues/cells that do not have an expiry date? What should be entered in the expiry date field?	In such situations you should enter 8 zeros in the expiry date field.
4.14. How should the application of different expiry dates in different Member States be managed when tissues or cells are distributed between them? (Particularly in the context of	It will be inevitable that there will be differing expiry periods defined in different Member States and possibly even in different TEs within the same Member State. In some cases this will be based on validation of packaging, for example, and in others because of ethical rules. To provide further clarification, additional information could be included in the accompanying documentation to describe: • Date of donation or fertilisation (in the case of ART) • Expiry period allocated in the originating country • Rationale for the allocation of the expiry period • Statement that the expiry may need adjustment if the tissues or cells are being stored or used in another MS with different rules.

ART where expiry dates may be defined under national policies related to ethics).	
4.15. 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. Directive 2006/86/EC as amended by Directive (EU) 2015/565 requires SEC to be in eye-readable format and to be preceded by the acronym "SEC".
4.16. Can a TE 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 in addition to the mandatory eye-readable format.
4.17. 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. The SEC shall be printed with the SEC-DI and the SEC-PI separated by a single space or as two successive lines. Note that the space should not be used when using the search function on the Coding Platform. (See examples of how the code could appear on an ISBT 128 label, a Eurocode label and on a national/local label in section 5 of this document.)
4.18. A TE is currently labelling using ISBT128 coding (for donation numbers and product descriptions). How will the implementation of the SEC impact such a TE?	The TE will be able to continue using its existing ISBT128 labelling, but it will need to add the eye-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 ISBT128 Product Code can be placed directly into the product code field, and the division number into the split number field. Please check ICCBBA website for more information on the support provided to ISBT128 users for the implementation of SEC and where an ICCBBA tool/programme to help ISBT 128 users generate a SEC for their products is available. https://www.iccbba.org/lookup-tools/sec-builder

4.19. A TE is currently labelling using Eurocode (for donation numbers and product descriptions). How will the implementation of the SEC impact such a TE?	The TE will be able to continue using its existing Eurocode labelling, but it will need to add the human-readable SEC to the label of final products. The Eurocode donation identification number will form the third element of the donation number within the SEC. The Eurocode Product Code can be placed directly into the product code field, and the division number into the split number field. For reference: http://www.eurocode.org/guides/index.html
4.20. A TE is currently using a local coding system developed within the TE. How will the implementation of the SEC impact on such a TE?	A TE will be able to continue using an existing local coding system for labelling, but will have to add the SEC to each final product label. However, the TE will not be able to use its local product codes in the construction of the SEC. The TE will have to determine the appropriate EUTC code that matches to its product and 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 a TE has any problems during the mapping process, it should contact its CA who will refer the issue to the EC.
4.21. If a TE imports tissues/cells from outside the EU should they be relabelled with the SEC?	The imported tissues and cells must be labelled with the SEC before distribution. The original label should not be covered by a new label, but a label that shows the SEC should be added to each product. This additional label will indicate that the importing TE is responsible for having ensured that the safety and quality of the products are equivalent to EU requirements. The SEC should be constructed using the ISO country identifier and the TE code of the importing TE, a unique donation number allocated by the importing TE and a product code taken from the EU Tissue and Cell Product Compendium (i.e. EUTC, ISBT 128 or 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. If the imported tissues/cells are to be applied clinically in the healthcare facility to which the importing TE belongs, and where it is located, there may be the possibility for an exemption from the requirement to apply the SEC (see the answer to question 4.3).

	The importing TE is also responsible for ensuring the traceability of all imported tissues and cells back to the donor.
4.22. When TEs are importing frozen products from a 3rd country, the SEC may need to be applied prior to freezing by the third country TE (as part of their contract with the EU TE) but the third country supplier might not know, at the time of freezing, which TE it will be sending to. How can this be managed?	Annex II part E point 1 (g) of Directive 2006/86/EC (as amended by 2015/565) requires that the SEC should appear on the primary container label but the subsequent paragraph clarifies that the information in points (d) (e) and (g) can be added on a separate sheet accompanying the primary container if it cannot be added to the primary container label.
4.23. If a TE receives finished tissues/cells from another EU Member State for distribution in its own Member State, is there a need to re-label with the SEC?	NO. As every Member State must implement the system, the tissues/cells distributed for clinical application should arrive already labelled in line with the requirements.
4.24. Is application of the SEC needed when exporting tissues/cells outside the EU?	YES. These products should be distributed with identical labels to those applied on products for EU distribution.
4.25. If tissues or cells are sent to another TE for processing and distribution, who should apply the	The TE responsible for allocating the donation identification number should apply at least the SEC-DI part of the SEC, which should appear unchanged on the final products; a SEC-PI may be applied, but it is not mandatory. The TE(s) receiving the tissues or cells for processing and distribution should allocate the appropriate SEC-PI, and apply the full SEC on the label of the final product distributed for human

SEC?	application.
4.26. If a TE sends tissues or cells for processing by a third party, which are afterwards returned to the TE for distribution, should the SEC by applied?	Directive 2006/86/EC as amended by Directive (EU) 2015/565 requires as a minimum that the tissues or cells that a TE sends to a third party be allocated the Donation Identification Sequence part of the SEC (as a minimum appearing in the accompanying documentation).
4.27. If a TE sends tissues or cells to an ATMP manufacturing facility for processing into an ATMP and subsequent distribution, should the SEC by applied?	Directive 2006/86/EC as amended by Directive (EU) 2015/565 requires as a minimum that the tissues or cells that a TE sends to a third party, including ATMP manufacturers, be allocated the Donation Identification Sequence part of the SEC (as a minimum appearing in the accompanying documentation).
4.28. What if there is not enough room to add the SEC on the tissue or cell product label?	In such circumstances, Directive 2006/86/EC as amended by Directive (EU) 2015/565 requires the application of the SEC only on associated documentation, unambiguously linked to the product.
4.29. What should a TE do if they are co-processing tissues or cells that already have their individual SECs (i.e. pooling)	In those rare circumstances where pooling is permitted, and the donations being pooled already have an allocated SEC-DI or full SEC, a new SEC-DI should be allocated to the pool. This situation may also arise where gametes from two donors, each with an allocated SEC-DI or full SEC, are being combined to make embryos. In these circumstances, full traceability of the original codes to the new SEC should be maintained in the TE records.
4.30. For stem cells derived from cord tissue, tooth, placental tissue, etc. How	Note that when a TE supplies tissues or cells for manufacture into medicinal products ('release for circulation'), only the SEC (DI) needs to be applied (see 4.24 above).

should the SEC (PI) be built?	
4.31. What is the correct understanding of "immediate" in the context of Direct Distribution (Article 6 paragraph 5 of Directive 2004/23/EC)? Does it mean within a certain timeframe or directly after reception, without storage or processing?	There is no definition of "immediate transplantation" in the legislation. Processing and storage activities following distribution (including direct distribution) and reception at the ORHA are not considered to fall under Directive 2004/23. Therefore, where directly authorised by the CA, the exemption for direct distribution applies if the intention was for immediate transplantation, even if the transplantation does not actually happen (e.g., HSC cells for patients who have temporarily fallen too ill for an immediate transplantation). Concretely, no SEC application is required if tissues or cells are stored at the ORHA after distribution. In the case of non-use and a decision to put the tissues or cells in an inventory of donations for future use by others, they must be transferred to an authorised TE, following usual procedures, including SEC application by the first TE to receive them.
4.32. Can the 'Direct Distribution' exemption be applied to haematopoietic stem cells where the CA controls the distribution via licensing of a TE in the ORHA rather than by individual direct distribution?	Authorisation of 'Direct distribution' does not need to be on a case-by-case basis and could be part of a more general authorisation, including of a TE in the ORHA. In this context, the MS could decide to apply the exemption.

5. **Examples of labels including SEC** (See also Q 4.17 regarding how the SEC should be displayed on a label)

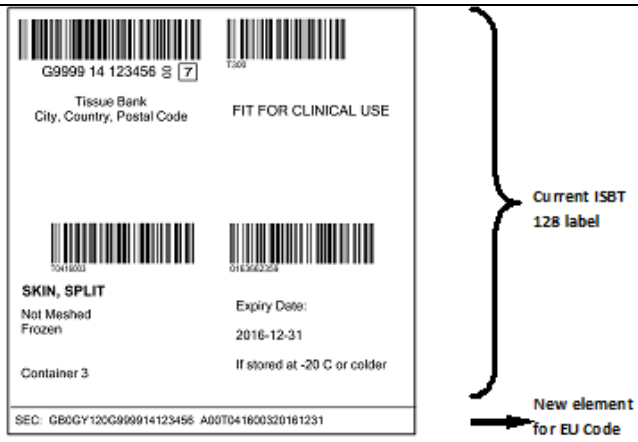

Figure 1: Addition of the EU code to an ISBT 128 label (invented data)

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

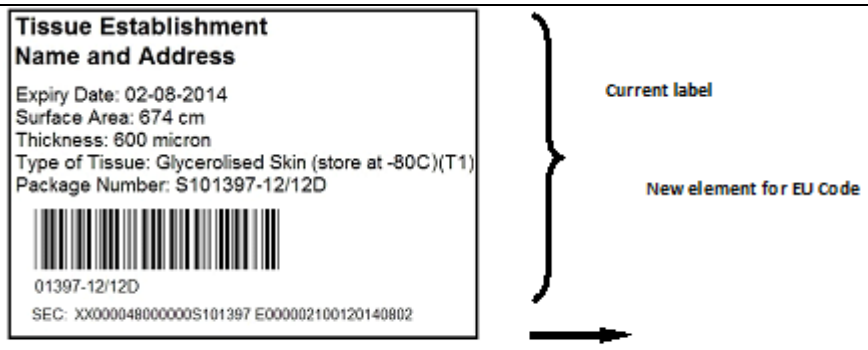

Figure 3: Addition of the EU code to a local label