Import and Coding Directives

For tissues and cells in the human application sector
Import and Coding Directives

Introduction

EU Directives are being put in place for the coding and import of tissues and cells for human application (HA). These will be transposed into UK law during 2016 and the process of writing the UK Regulations is underway.

Copies of these Directives and an overview from the Department of Health (DH) are available:

- Donated Tissues and Cells for Human Application DH communication (PDF)

These Directives are due to come into force throughout the EU on or before 29 April 2017. When implemented, all HA licensed establishments will be required to meet the requirements laid out in these Directives. We were part of the European Working Groups for the drafting of both Directives. Through this, we have worked towards ensuring that they are robust while remaining proportionate.

Transposing the Directives

We are currently working closely with the Department of Health and stakeholders to transpose the Directives into UK legislation. This includes determining how the exemptions will apply in the UK.

DH will be consulting on the new legislation later on this year. We will also consult on our draft Directions and guidance. We will be holding workshops for stakeholders in the autumn. We will continue to share information with you as it becomes available through our newsletter and on our website.

Timeline

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Coding Directive

The Single European Code
From 29 April 2017, all tissue establishments in the EU will need to use the Single European Code (SEC). The SEC is a standardised coding system for facilitating the traceability of tissues and cells used for human application.

As a general rule, the SEC must be applied to all tissues and cells before they are distributed for human application. The following guidance explains:

- the different parts of the SEC,
- when each should be allocated and applied, and
- any exemptions which may mean you do not have to allocate or apply the SEC.

**Structure of the Single European Code**

The SEC is made up of two sections:

1. The Donation Identification Sequence (DIS); and
2. The Product Identification Sequence.

### Donation Identification Sequence

The ISO Country code for the England, Northern Ireland, Scotland and Wales is ‘GB’.

Your tissue establishment number is a 0, followed by your 5 digit licence number. For example, if your licence number is 99999, then your tissue establishment number will be 099999.

The Unique Donation Number is a unique number linked to a particular donation event.
If your organisation works with more than one tissue type under a single HTA licence, you will need to ensure the donation number is unique across all tissue types that you work with. If this is not possible please contact the HTA for further advice.

**Product Identification Sequence**

The Product Coding System Identifier shows the coding system you have used. These are:

- ‘E’ for the EUTC system
- ‘A’ for the ISBT128 system
- ‘B’ for the Eurocode system

The product number is the tissue or cell product number as specified by the coding system in use. If this is the EUTC, then this will be listed in the EU Tissue and Cell Product Compendium.

The split number distinguishes between tissues and cells which have the same unique donation number, product code and tissue establishment code. This should be used where one donor has donated more than one unit of tissues or cells at the same tissue establishment at one time.

Finally, the expiry date is the final date when the tissues and cells can be applied.

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**Allocating and Applying the Single European Code**

Allocation is when the DIS or SEC is formally assigned to a unit of tissues or cells using your internal traceability system.

Application is when the DIS or SEC has been included in the tissue or cells label. If the label is too small, the tissues or cells must be unambiguously linked to the SEC or DIS, as written in the accompanying documentation.

The DIS must be allocated either after procurement or after import from a third country supplier. The DIS should not be altered once it is allocated to tissues and cells released for circulation. The DIS can be altered to correct an encoding error. Such alterations require proper documentation.
Tissues and cells are released for circulation when they are transported to other premises for a purpose other than human application. For example, when sent to another licensed organisation or third party for testing or processing.

Before distributing tissues or cells for human application, you will need to:

- allocate the SEC;
- apply the SEC on the label of the tissues or cells in an indelible and permanent manner; and
- include the SEC in the accompanying documentation.

Distribution, in this sense, is the transfer of tissues and cells to another site for human application. Transferring for other purposes, such as processing, is considered releasing for circulation.

Importing tissue establishments should ensure that the SEC is applied to imported tissues and cells. This can be done by applying the SEC themselves. Alternatively, it can be delegated to third country suppliers as part of the terms of their written agreements.

**Exemptions**

For information on reproductive cells, please refer to the Human Embryology and Fertilisation Authority’s website.

The Directive allows us to exempt tissue establishments from the requirement to apply the SEC. The following guidance explains the relevant exemptions and how we expect these fit with the current regulatory framework in the UK.
**Transitional period**

Tissues and cells are already in storage on 29 October 2016 are exempt from the requirements to apply the SEC. This exemption applies if:

- the tissues and cells are released for circulation within 5 years – that is, by 29 October 2021; and
- full traceability is ensured using alternative means

For tissues and cells which are released after 29 October 2021, the SEC must be applied. If you cannot apply the SEC, you can unambiguously link the SEC to the tissues and cells, as set out in Article 10b paragraph 1(f). We expect this exemption will apply to tissues and cells stored under deep-freeze conditions.

**Same centre exemption**

This exemption can apply when tissues or cells remain within the same centre from either donation or import until application. This means all steps from procurement to human application are carried out at the same location:

- under the same responsible person (or DI);
- using the same quality management system and traceability system; and
- within a healthcare centre which includes:
  - at least a licensed tissue establishment, and
  - an organisation responsible for human application.

We are currently considering how this exemption may apply in the UK. If you think you may be affected by this exemption, please contact us.

**Direct Authorisation and Emergencies**

Tissue and cells which are distributed directly for immediate transplantation in the recipient may not need to have the SEC applied. The tissues and cells which may be exempt are referred to in Article 6(5) of the parent Directive 2004/23/EC.

We understand that in other EU countries this article has predominantly been used for imports of HSCT products. However in the UK, this exemption is not widely used. In addition in our current legislation, direct authorisation is only possible in an emergency.

We are currently reviewing arrangements in consultation with stakeholders and will provide a further update in due course.

If you work with HSCT and have any questions about how the Directives will affect you, please contact us.
External guidance

Guidance from the European Commission

The Commission have published guidance, alongside FAQs, which provide advice on applying the SEC. Please note, this guidance is based on the general requirements set out in the Directive and there may be differences in the way these requirements are implemented in the UK.

In particular, there are references to haematopoietic stem cells being exempt from application of the SEC. This exemption would apply when the direct distribution or import is authorised by the competent authority. We are currently working with DH and stakeholders to consider this issue. We recommend you read our guidance on exemptions.

Please feel free to contact us if you think that you will be affected.

Guidance for ISBT 128 users

ICCBBA have published guidance on how the SEC should be formulated and printed on tissue and cell products labelled with ISBT 128. Please read the guidance to help you prepare for the new coding Directives

Import Directive

Quality & safety of imported tissues & cells

The new Directive applies to import into the EU of:

- human tissues and cells intended for human application; and
- manufactured products derived from human tissues and cells intended for human applications, where not covered by other Union legislation

An importing tissue establishment is an organisation who is party to a contractual agreement with a third country supplier for the import of tissues and cells. Third countries are those outside of the EU.

Tissues and cells cannot be imported into the UK, other than by a licensed importing tissue establishment.

Importing tissue establishments are responsible for ensuring the quality and safety of imported tissues and cells. Tissues and cells must meet standards equivalent to the ones laid down in Directive 2004/23/EC. Equivalent standards means the tissues and cells are of the same safety and quality as tissues and cells procured within the EU. For example, they have been subject to the same mandatory serology testing, donor selection process and processing conditions.

An organisation offering brokerage services will normally be considered an importing tissue establishment if they are party to a contract with a third country supplier and have responsibility for verifying the quality and safety of the tissues and cells.
We expect that tissue establishments who currently hold a licence for import will need to renew their licence. This is because they will need to meet the requirements of the new Import Directive (see licensing section below).

We expect this will be in early 2017.

We also encourage you to audit your third country suppliers as part of this verification process.

**Exemptions**

**Direct authorisation**

The new Directive does not apply to the Import into the EU of human tissues and cells intended for human application that are authorised directly by the HTA. However, we do not directly authorise the import of tissues and cells on a regular basis.

We are currently reviewing arrangements in consultation with stakeholders and the Department of Health. We will provide a further update in due course.

**One-off imports**

One-off imports will be exempt from the requirements of documentation and written agreements set out in Annex I. They should, however, be carried out by licensed importing tissue establishments. In addition, one-off imports should not take place on a regular or repeated basis from the same third country supplier.

The use of such one-off exemptions will be limited to situations where tissues and cells are stored in a third country for future use. For example, autologous donations, or donations directed to close relatives. These may have been stored in a third country and the recipient subsequently wishes to have the tissues or cells imported into the EU. Such imports of specific tissues or cells should normally not occur more than once for any given recipient. They also should not include tissues or cells for third parties.

**Licensing**

We anticipate that all importing tissue establishments will need to renew their import licence to comply with the new Directive. Our aim is to ensure continuity of licensing, and to minimise the burden of renewing your licence. In order to renew your licence, we expect that you will have to provide the information set out in Annex I of the Directive. You will also need to provide the documentation in Annex I part F:

1. A copy of your written agreement(s) with your third country supplier(s)
2. A detailed description of the flow of imported tissues and cells from procurement until you receive them at your importing tissue establishment
3. A copy of the third country supplier’s export authorisation certificate. Where a specific export authorisation certificate is not issued, please provide certification from the relevant third country competent authority or authorities. Certification must authorise the third country supplier’s activities in the tissue and cells sector, including exports. This documentation must also include the contact details of the third country
competent authority or authorities. Where such documentation is not available, alternative forms of documentation must be provided. For example, reports of audits of the third country supplier.

The requirements for the contents of written agreements with suppliers are set out in Annex IV of the Directive.

Once licensed, importing tissue establishments cannot undertake any substantial changes to their import activities without our prior written approval.

Substantial changes include any changes to the:

- type of tissues and cells imported;
- activities undertaken in third countries which may have an impact on the quality and safety of imported tissues and cells;
- third country suppliers used.

You must also notify us before you stop carrying out any licensable activities. This includes stopping licensable activities all together, or no longer carrying a particular activity. For example, ceasing to process but continuing to procure and distribute tissues and cells.

You must notify us without delay, of:

- any revocation or suspension, in part or in full, of a third country supplier’s authorisation to export tissues and cells; and
- any other decision taken for reasons of non-compliance by the competent authority of the country in which the third country supplier is based, which may be relevant to the quality and safety of imported tissues and cells.

We may restrict activities by adding conditions, suspending or revoking activities on a licence of an importing tissue establishment. We may choose to do this if an establishment no longer meets the requirements of Directives 2004/23/EC and 2015/566. This may be identified through inspection or other control measures.

**News**

**February 2016: timing update**

In December 2015, we said that the Department of Health was aiming to consult on the draft Regulations from February 2016. Unfortunately this has been delayed, but we will keep you updated on timeframes and still expect to be able to consult early this year. We are working closely with the Department to ensure that we can provide draft guidance in sufficient time to allow you to prepare for implementation.

**December 2015: HTA Guidance on the Import and Coding Directives**

We are currently working with the Department of Health to transpose the coding and import Directives into UK legislation. We expect to have the draft Regulations available for consultation from February 2016.
September 2015: HTA Guidance on the Import and Coding Directives

In September the HTA wrote to all establishments in the human application sector with guidance on the Import and Coding Directives (pdf). The guidance aims to assist establishments in preparing for the implementation of these Directives. The new EU Directives for the coding and import of tissues and cells for human application (HA) are due to come into force throughout the EU on, or before, 29 April 2017.

If you have any questions about either Directive, please contact the HTA marking your enquiry 'EU Import/Coding Directive'.

June 2015: EU Coding and Import Directive workshop for the human application sector

To explore the impact of the new Directives, the HTA held a workshop on 9 June, to which a representative group of licensed establishments from across the HA sector were invited. The Department of Health (DH) also attended and gave an overview of the legal framework for the new Directives, including the process of transposition into UK law. You can read a summary of the workshop here

Further information

EU Compendia

The EU Tissue Establishment and Tissue and Product Compendia will be available online from 31 May 2016.

We are currently reviewing and updating the information we provide for publication in the Tissue Establishment Compendia. This information relates to licensed establishments and will match the information on our website. To review the information that will be included, please check our establishment register.

Contact

If you have any questions about either Directive, please contact us either by email or on 020 7269 1900.