Department of Health

The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017

A consultation on draft regulations on coding and import of tissues and cells intended for human application

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Consultation on Regulations to Transpose EU/2015/565 and EU/2015/566

I am writing to invite your comments on draft Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017 on the coding and import of tissues and cells for human application.

In July 2007, the UK transposed three EU Directives 2004/23/EC, 2006/17/EC and 2006/86/EC[1]. These set safety and quality standards for tissues and cells intended for human application from donation, procurement, testing, storage, through to distribution and end use.

Two new Directives were published on 9 April 2015 amending or adding to the provisions identified in these earlier Directives.

Commission Directive EU/2015/565 (the Coding Directive) establishes a coding system that will facilitate the traceability of all human tissue and cells intended for human application. This Directive amends Directive 2006/86/EC as regards certain technical requirements for the coding of human tissues and cells

The coding Directive requires a Single European Code (SEC), in a specified format, to be allocated to tissue and cells distributed for human application, including those imported from third countries. There are certain exemptions from the application of the code, such as tissue and cells that will remain within the same centre from procurement to final use.

Commission Directive (EU) 2015/566 (the Import Directive) complies with articles within Directive 2004/23/EC as regards the procedure for verifying the equivalent standard of quality and safety of imported tissues and cells. The Directive sets out the procedures to verify that human tissue and cells imported from countries outside the EU and EEA meet the same high quality and safety standards applicable to tissue and cells procured within EU and EEA member states.

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[1] Directive 2004/23/EC setting standard of quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells,
http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2004:102:0048:0058:en:PDF

Commission Directive 2006/17/EC implementing Directive 2004/23/EC as regards certain technical requirements for the donation, procurement and testing of human tissues and cells,
http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:32006L0017&from=EN

Commission Directive 2006/86/EC implementing Directive 2004/23/EC 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,

http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2006:294:0032:0050:EN:PDF

Chapter 1: Overview

Introduction

This consultation document seeks views on a range of questions around the implementation of the two new Directives. Additionally, we need to test our assumptions of the likely cost of implementing both Directives.

Background

Directive 2004/23/EC (described here as the "Mother" Directive) was published in 2004 and set quality and safety standards for the donation, procurement, testing, processing, preservation, storage and distribution of human tissue and cells intended for human application. The purpose of the Directive is to ensure that wherever a patient is treated within the EU or in a member state of the European Economic Area (EEA)[2], they can be assured that the human derived tissue and cells used in their treatment meets the same quality and safety standards.

The Mother Directive included provision for a number of Commission Directives to be made to implement specific requirements. The first two Commission Directives were 2006/17/EC and 2006/86/EC. All three Directives were brought into force in 2007 by the Human Tissue (Quality and Safety for Human Application) Regulations 2007[3].

Provision was made within these Directives for additional Commission Directives, including provisions on coding for traceability and for import from countries outside the EU and EEA.

Commission Directive 2015/565, amends Directive 2006/86/EC, and establishes a Single European coding system to facilitate the traceability of all tissue and cells used within the EU/EEA from its initial procurement (or importation into the EU/EEA) through to final use.

Commission Directive 2015/566 builds on the requirements of the parent directive which requires Tissue Establishments that import tissues and cells from outside the EU/EEA, known as third countries, to ensure that they meet the equivalent standards of quality and safety required by these Directives.

Commission Directive 2015/565 and Commission Directive 2015/566 will be implemented by amendment Regulations made under section 2.2 of the European Communities Act 1972. This provides a mechanism for bringing European legislation into UK Law.
A copy of the draft Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017 is at Annex A.

[2] EEA member states include, in addition to the EU member states, Iceland, Lichtenstein and Norway. Although neither a member of the EU or the EEA, Switzerland is also part of the single market.

[3] 2007 No. 1523 The Human Tissue (Quality and Safety for Human Application) Regulations 2007 which came fully into force 5 July 2007

Copies of Commission Directive (EU) 2015/565 and Commission Directive (EU) 2015/566 are at Annex B and C respectively.

Implementation date

On the 23 June 2016, the EU referendum took place and the people of the United Kingdom voted to leave the European Union. Until exit negotiations are concluded, the UK remains a full member of the European Union (EU) and all the rights and obligations of EU membership remain in force. During this period the Government will continue to negotiate, implement and apply EU legislation. The outcome of these negotiations will determine what arrangements apply in relation to EU legislation in future once the UK has left the EU.

The requirements of these two new Directives required transposition by 29 October 2016 and to come fully into force on 29 April 2017. The Government is aiming to transpose these Regulations by summer 2017.

Transitional provisions within the Regulations for the import of tissues and cells will enable a licensee granted a licence under the existing provisions, to be treated as continuing to be licensed to import, provided the Human Tissue Authority is satisfied that the licensee has satisfied the necessary requirements in Regulation 11(4A) and the Human Tissue Authority has issued the licensee with the necessary certificate.

Transitional provisions for coding, enable tissues and cells in storage before 29 October 2016 and distributed before the end of the five years beginning with that date, to not have to apply the Single European Code required by these Regulations. We are also seeking your view that the small labels procedure to apply for tissues and cells in storage between 29 October and the coming into force date of the Regulations

Impact on establishments handling reproductive cells

There is a separate consultation document covering establishments handling reproductive cells.

Have your say

Although the requirements of the two Directives are fixed and amendments cannot be made, your views are invited on these draft transposing Regulations to implement the Directives and the associated HTA guidance(which can be found at https://www.hta.gov.uk/htas-draft-guidance); on the two Impact Assessments; and on any relevant issues that you feel the consultation document has not covered. Annex F includes the response form to the consultation questions.

What will implementation cost?

This consultation also seeks your views on our initial assessment of the costs of implementation of the coding Directive (attached at Annex D) and the import Directive (attached at Annex E). These give a broad estimate of the potential costs to the Human Tissue Authority as the Competent Authority in implementing the Regulations and the potential compliance costs for relevant establishments.

Chapter 2: Summary of The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017

These Regulations amend the Human Tissue (Quality and Safety for Human Application Regulations 2007 and the Human Tissue Act 2004, to implement Directive 2015/565 (the Coding Directive) which lays down technical requirements for the coding of tissues and cells as well as Directive 2015/566 (the fourth Directive) which sets out procedures for verifying standards of quality and safety of imported tissues and cells.

The details of each Commission Directive are summarised in Chapters 3 and 4.

The Key provisions of the Regulations are summarised below.

Regulation 1

Citation, commencement and interpretation

Specifies the title of the Regulations, the date they come into force and defines some terms used with the Regulations

Regulation 2

Amendments to the Regulations relating to the coding of human tissue and cells

Regulation 4 of the 2007 Regulations as it refers to 'the third Directive' is amended by Commission Directive (EU) 2015/565'

Regulation 20 is amended by inserting Regulation 20a and the Duties of Human Tissue Authority in relation to the application of the Single European Code

Regulation 3

Amendments to the Regulations relating to the import of human tissue and cells from third countries.

This makes amendments to the Regulations to designate the Import Directive as the 'fourth Directive' and sets out the duties of the Human Tissue Authority to ensure compliance with the Directive including:

i) new Regulation 20b and the inspection of third country premises;

ii) New Regulation 20c – importing license holders and third country suppliers and report of inspections etc.

iii) New Regulation 21a Inspection of documents held by an importing licence holder

iv) New Regulation 22a Importing licence holders: Requests for inspections

The new requirements only apply to imports of tissue and cells from third countries.

Regulation 4

Amendments to the Regulations relating to the implementation of the First Directive and tissues and cells distributed imported or exported for immediate transplantation or in an emergency.

Regulation 5

Amendments to the Act relating to the import of tissues and cells

Regulation 6

This clarifies the transitional arrangements for import of tissues and cells from non-EEA countries (designated as third countries)

Where immediately before the commencement date, if a licence holder is issued with a licence to import, it shall remain in force providing the Human Tissue Authority is satisfied that the licence holder continues to comply with the relevant provisions and has issued the licence holder with a certificate set out in Annex 11 of the fourth (Import) Directive

Regulation 7 and Regulation 8

These clarify arrangements for the application of the Single European Code. The provisions of the Coding Directive do not apply where tissues and cells are in storage before 29 October 2016 and are released for circulation within five years of that date.

Chapter 3: Summary of the requirements of Commission Directive 2015/565 on the coding of tissues and cells for traceability purposes

A key principle enshrined in earlier European legislation (Directive 2004/23/EC (the Mother Directive) and Commission Directive 2006/86/EC) is that it must be possible to identify and trace all tissue and cells intended for human application at every stage of their journey from procurement to final use in treatment. This becomes particularly important where an adverse reaction or adverse event is linked to the tissue or cells. The primary mechanism for traceability is the application of an identifying code to all tissues and cells donated, procured, retrieved, processed, stored and distributed for human application.

Commission Directive 2015/565 (Annex B) augments these earlier Directives. The key requirements are summarised below:

- that Member States ensure the traceability of human tissues and cells from the donor to the recipient, and vice versa.
- to enable full traceability, a unique identifier must be used. The application of the Single European Code (SEC) will be applied to tissues and cells distributed in the EU and will provide uniform information on the main characteristics and properties of those tissues and cells.
- The 40-digit alpha-numeric SEC (see Annex VII of the coding Directive) should be allocated and applied to all tissues and cells (unless exemptions apply) at the latest before they are distributed for human application, including those imported from third countries.
- To aid implementation, the Commission will host and maintain an IT platform which contains the EU Tissue Establishment Compendium - a register of Tissue Establishments in the EU - and the EU Tissue and Cell Product Compendium, which is a register of tissue and cell products in use in the EU.
- The Competent Authority (Human Tissue Authority (HTA) is required to keep the register of tissue establishments in the UK updated to reflect any changes in tissue establishment authorisation, and to alert the Commission whenever there is a new tissue or cell product which will need to be included in the register of tissue and cell products.

The coding Directive makes provision for certain exceptions and exemptions.

Exemptions include:

- Where tissues and cells are procured/collected, stored and used within the ‘same centre’. Within the same centre means that all steps from procurement or import to human application are carried out under the same responsible person, quality management system and traceability system, within a healthcare centre comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location.
- The HTA proposes that this could include where the licensed Tissue Establishment and the organisation responsible for human application are part of the same Trust, but on

different hospital sites, providing there is suitable Designated Individual oversight and a single Quality Management System and traceability system are in place.

- Where the distribution and/or import of tissues and cells has been directly authorised by the HTA.
- Where tissues and cells already in storage on 29 October 2016 are exempt from the coding requirement, providing they are released for circulation within the European Union within 5 years of that date and that full traceability can be achieved by other means.
- Where tissues and cells already in storage, which remain in storage and are only released for circulation after the expiry of this five-year period and for which the application of the SEC is not possible (e.g. because the tissues and cells are stored under deep-freeze conditions) may use the procedure for small labels below.
- The Regulations allow an extension to this provision for tissues and cells stored between 29 October 2016 and the coming into force date and for which application of the SEC is not possible (e.g. because they are stored under deep-freeze conditions).
- Where the tissues and cells label size precludes the application of the SEC on the label - in such cases the code shall be unambiguously linked to the packaged tissues and cells through the accompanying documentation.

The HTA, as one of the UK's national competent authorities, is responsible for ensuring that the coding system is applied correctly by its licensed Tissue Establishments.

Article 1

Definitions

New definitions have been added to Article 2 of Commission Directive 2006/86/EC Directive. These include definitions of:

- Single European Code
- Donation identification sequence
- EU tissue establishment code (*For HTA licensed establishments, this will be your licensing number, preceded by a '0'. If your establishment uses multiple tissue types and you cannot ensure unique donation numbers across procurements please contact HTA for further advice)*
- Unique donation number (*The HTA will not be allocating unique donation numbers. Establishments should either allocate their own unique donation number or a globally unique number such as that used by ISBT128)*
- Product identification sequence
- Product code (*which allows for use of the new EUTC product coding system or continued use of existing product codes in the ISBT128 and Eurocode databases*)
- Split number

- Expiry date (*For tissue and cells this will be the maximum storage time and will depend on storage conditions – for tissues and cells for which no expiry date is defined the expiry date shall be 00000000)*
- EU Coding Platform means the IT platform hosted by the EU Commission which contains the EU Tissue Establishment Compendium and the EU Tissue and Cell Product Compendium
- EU Tissue Establishment Compendium holds the register and information about all licensed tissue establishments
- EU Tissue and Cells Product Compendium holds a register of all tissues and cells within the EU and their respective EUTC, ISBT128 or Eurocode product codes
- EU Tissue Establishment Code (EU TE Code) – the unique identifier for accredited, designated and licensed tissue establishments. The EU TE Code consists of the ISO country code and the tissue establishment number set out in the EU Tissue Establishment Compendium
- Released for circulation means distribution for human application or transfer to another operator, for example for further processing with or without return
- Within the same centre means that all steps from procurement or import to human application are carried out under the same responsible person, quality management system and traceability system, within a healthcare centre comprising at least an accredited, designated, authorised, or licensed tissue establishment and an organisation responsible for human application at the same location
- Pooling means the physical contact or mixing in a single container, of tissues or cells from more than one procurement from the same donor or from two or more donors.

Traceability

Article 2 also makes amendments to existing provisions in Article 9 and Article 10 of the Commission Directive 2006/86/EC related to traceability of tissue and cells.
In particular, that traceability should be ensured through documentation and the application of the Single European Code (SEC) to all tissue and cells distributed for human application (except where exemptions apply).

The code must be eye readable. This can be in addition to another format, such as bar coding. The code is made up of two parts – a Donation Identification Sequence (DIS) and a Product Identification Sequence (PIS). The SEC can be printed with the DIS and the PIS separated by a single space or as two successive lines. The code, which is preceded by "SEC", consists of the following sequences:

Donation Identification Sequence (DIS):

> **EU tissue establishment code** - consisting of the 2 alphabetic character 'ISO country code', which for the United Kingdom of Great Britain and Northern Ireland is "GB" and the 6 alpha-numeric character 'Tissue establishment number'. In the UK the tissue establishment number will be the HTA licence number preceded by one zero. This element of the code will continue to be provided by the HTA and recorded centrally on the EU Tissue Establishment Compendium[4].

[4] The EU Tissue and Cells Establishment Compendium will be managed centrally by the European Commission.

Unique donation number – consisting of 13 alpha-numeric characters. *The HTA will not be allocating unique donation numbers. Establishments should either allocate their own unique donation number or a globally unique number such as that used by ISBT128. If your establishment uses multiple tissue types and you cannot ensure unique donation numbers across procurements from different clinical areas please contact the HTA for further advice.*

Product Identification Sequence (PIS):

Product code - consisting of the product coding system identifier, which is a 1 alphabetic character indicating the coding system to be used and 7 alpha-numeric characters which identify the product type. The product code will be determined from the EU Tissue and Cells Product Compendium[5], which lists the tissue and cell product codes for the three coding systems allowed:

- **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.

- **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/

- **Eurocod**e 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/

Establishments are not restricted to the use of only one coding system.

Importantly, where a code for a product is unavailable in one system (e.g. ISBT 128), establishments should use a general category from another system (e.g. 'OTHER' from EUTC) to code the product. At no point should products remain unlabelled due to product codes being unavailable. The HTA will issue further guidance on this.

Split number - 3 alpha-numeric characters, where this is applicable.

Expiry date - 8 alpha-numeric characters, i.e. YYYYMMDD. *(For tissues and cells for which no expiry date is defined, the expiry date shall be 000000000. The HTA proposes that this may be used where it is not possible to define an expiry date at the point of applying the SEC due to it being dependent on storage conditions)*

[5] The EU Tissue and Cells Product Compendium will be managed centrally by the European Commission.

Allocation of the Single European Code

Tissue establishments must allocate the Donation Identification Sequence after procuring the tissues and cells, or when receiving them from a procurement establishment, or when importing from a third country supplier. The only time that the DIS part of the code can be amended after allocation is if an error has occurred in compiling the DIS. Any change and the reasons for it must be fully documented by the establishment making the change.

Application of the Single European Code

The tissue establishment (TE) must apply the SEC on the label of the product (unless an exemption applies), and mention that code in the accompanying documentation, at the latest before its distribution for human application. This application of the code may be carried out by a third party, provided the TE ensures compliance with the Directive.

Where tissues and cells are released by the TE other than for distribution to the end user (for example, for further processing), as a minimum the donation identification sequence must be applied at least in the accompanying documentation.

The SEC should be applied to the label on the primary container and linked with the accompanying documentation. However, where the containers are likely to be too small for the label to be applied, the code must appear on a separate sheet. This must be packaged with the primary container in a manner that ensures that they remain together.

For imported tissues and cells, the country of procurement and the exporting country (if different from the procurement country) must be provided either on the label or in accompanying documentation.

Accessibility and maintenance of the European coding system

The European Commission will host the EU coding platform and will be responsible for the EU Tissue Establishment Compendium and EU Tissue and Cell Products Compendium.

The EU Tissue Establishment Compendium will be a register of tissue establishments authorised or licensed under the tissue and cells Directives in the EU. It will contain information about each tissue establishment, including the tissue establishment number which forms part of the SEC. It will also provide details of the tissues and cells and activities that each tissue establishment is authorised or licensed for, the licence status (e.g. authorised, suspended, revoked etc.) and details of any conditions or exemptions on the licence.

Traceability Tissues and cells must be traceable through documentation and use of the SEC from procurement to human application or disposal and vice versa. Tissues and cells used for Advanced Therapy Medicinal Products (ATMPs) should also be traceable under this new directive at least until transferred to the ATMP manufacturer. Products supplied for ATMP manufacture need only have a DIS allocated, as a minimum appearing in the accompanying documentation.

Where tissues and cells are retrieved from the same deceased donor by two or more different tissue establishments, there needs to be an appropriate traceability system to ensure that there

are robust traceability links between the donation identification numbers allocated by each tissue establishment.

Transitional period

Application of the SEC will not be retrospective. Tissue and Cells in storage on 29 October 2016 are exempt from the coding requirement, providing they are distributed for use within the European Union within 5 years of that date and that full traceability can be achieved by other means. For tissues and cells which remain in storage and which are only released after the expiry of this five-year period and for which the application of the SEC is not possible, then the SEC should be unambiguously linked to the tissues and cells through the accompanying documentation.

Articles 2-4

Article 2 sets out the key implementation dates of 29 October 2016 and 29 April 2017, as indicated in Chapter 1. In the UK we are aiming to transpose the Directive by summer 2017.

Article 3 specifies the date the Directive came into force (29 April 2015).

Article 4 makes clear that it is addressed to all EU member states.

Consultation Questions relating to Coding

Activity

Question 1: **Based on your current activities, to how many tissue and cells products per year do you envisage applying the SEC?**

Question 2: Which coding system(s) are you planning to use at your establishment (ISBT 128, Eurocode or EUTC)?

Question 3: How will the application of the SEC be managed at your establishment when two or more retrieval teams from different tissues establishments procure from the same donor? How will traceability be managed and what communication arrangements are in place?

Question 4: We are aware of circumstances where it may be necessary to re-label already frozen products (e.g. to change an expiry date because storage conditions have been altered). How is this currently handled in your establishment and how often does this occur? Are there any other examples of when this might be necessary?

Question 5: For imported products, do you envisage applying the SEC on point of entry or delegating the responsibility to your third country supplier?

Question 6: Do you anticipate any issues or have any comments in relation to the interpretation of the same centre exemption, as outlined above?

Cost implications

Our impact assessment of the Coding Directive relied on a number of assumptions to estimate the costs that NHS and Private sector organisations will bear in complying with the Directive. These assumptions are described in paragraphs 23-44 of the impact assessment at Annex D.

We would welcome your feedback on the appropriateness of these assumptions, particularly those that support our estimates of the costs of installing new IT where required or upgrading existing IT (paragraphs 34-38).
In responding you may wish to consider the following:

- Much of the 40-digit alpha-numeric SEC can be generated using the information required to be kept by the tissue establishment.
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  What do you see as the extra costs to your centre of updating IT systems?

- For some establishments adding the SEC to accompanying paperwork (rather than the storage container) will require licensed centres to update existing labels and forms to accommodate the SEC.

  Will this be a cost to your centre? What is your estimate of costs?

- There will be one-off transitional costs such as the training of staff to familiarise with the requirements, and amending Standard Operating Procedures.

  What is your estimate of costs?

Chapter 4: Summary of the requirements of Commission Directive (EU) 2015/566 on import of tissue and cells from non EU/EEA, "third", countries for human application

The primary purpose of the EU Tissue and Cells Directives is to give patients the assurance that all human tissue and cells used in their treatment in the UK meets the same high quality and safety standards regardless of the country in which the tissue or cells were retrieved. For that reason, all tissue and cells imported into EU/EEA countries for human application must meet the same quality and safety standards in line with EU legislation.

Exchanges of tissues and cells increasingly take place on a world-wide basis. Directive 2004/23/EC requires that imports of tissues and cells are undertaken by establishments accredited, designated, authorised or licensed by the Competent Authorities to verify the same level of safety and quality as those imported from the EU/EEA.

Many of the requirements in the import Directive are already established through the HTA's general regulatory processes, including the HTA's import licence and associated Guide to Quality and Safety, which is enforced via General Directions. These include carrying out inspections of importing tissue establishments every two years, and ensuring that the required standards are met. Therefore current import processes will be updated to take on board any additional requirements required by Directive 2015/566.

The key provisions in the Directive are outlined below:

Article 1: Scope

The provisions of the Directive apply to all centres importing tissues and cells for human application from establishments outside the EU/EEA area, except in the following circumstances:

- The import of tissues and cells referred to in Article 9(3)(a) of Directive 2004/23/EC directly authorised by the HTA,
- The import of tissues and cells referred to in Article 9(3) (b) of Directive 2004/23/EC which are directly authorised in cases of emergency treatment.

Where tissues and cells to be imported are intended to be used exclusively in manufactured products which are covered by other EU legislation (e.g. advanced therapy medicinal products), the import Directive will only apply to the donation, procurement and testing which takes place outside of the EU, as well as contributing to ensuring traceability from donor to recipient and vice versa.

Article 2: Definitions

The Directive adds new definitions of:

- Emergency – any unforeseen situation in which there is no practical alternative other than to import urgently tissues and cells from third countries for a known individual with a serious condition
- Importing tissue establishment – a tissue bank or other unit or body with a contractual agreement with a third country supplier for the import of tissues and cells for human application
- One-off imports – *see the section on one-off imports below*
- Third country supplier – *a tissue establishment or another body, established in a country outside of the EU, which is responsible for the export to the EU of tissues and cells it supplies to an importing tissue establishment*

Article 3: accreditation, designation, authorisation, or licensing of importing tissue establishments

Any establishment wishing to import tissue and cells from a third country supplier will need specific authorisation or a licence from the HTA.

The HTA already requires importing tissue establishments to be licensed but will require these tissue establishments to renew their licence under the new provisions of this Directive. It will no longer be possible for Import to be undertaken via a Third Party Agreement.

After verifying that the importing tissue establishment meets the requirements of the Directive, the HTA will issue the certificate provided in Annex II of the Directive. The certificate sets out the details of the importing tissue establishment and the scope of activities it is authorised to undertake. The HTA intends to amend the standard conditions of all import licences to restrict import activities to those stated on the licence. The draft HTA guidance sets out the proposed process and timescales for renewing import licences.

Once authorised, the importing tissue establishment or centre must not undertake any substantial changes to its import activities without the prior written approval of the HTA. In particular, this includes any changes to the types of tissues and cells imported, the activities undertaken in third countries which may have an influence on quality and safety, or the third country suppliers used.

Where an importing tissue establishment undertakes a ‘one-off’ import of a certain tissue or cell type which it is already authorised to import, but originating from a third country supplier not covered by its existing licence, then this is not considered to be a substantial change. However any import of a new tissue or cell type, even as a one-off, would be a substantial change.

See Article 5 for further information regarding ‘one-off’ imports.

Article 4: Inspection and other control measures

Examination of importing arrangements will remain part of the competent authority’s inspection of establishments holding an import licence, and will continue on the current two-year cycle. If requested, the HTA will also provide information on the findings of inspections and other control

measures to the competent authorities of other Member States. If tissues and cells are subsequently distributed to another Member State, the HTA may be requested to carry out inspections or other control measures of the importing tissue establishment by that Member State.

The HTA will be empowered to inspect the activities of third country suppliers by way of the written agreement which the importing tissue establishment has in place with the third country supplier. This is only likely to be exercised in exceptional circumstances.

Article 5: Applications for accreditation, designation, authorisation, or licensing as an importing tissue establishment

It will be for the Designated Individual at the importing establishment to satisfy his or herself that tissue and cells imported from a third country supplier meet the necessary quality and safety standards. They will be required to evidence this assurance to the HTA when applying for an import licence.

Applications to import must be supported by the documentation listed in Annex I of the Directive. The HTA will publish information on the format of new applications and renewals of existing licences, together with any additional information that needs to be provided.

The Directive allows for exemption from some of the documentation and written agreement requirements for one-off imports. These one-off imports must be carried out by a licensed or authorised importing tissue establishment and be for the personal use of an intended recipient. They should not take place on a regular or repeated basis from the same third country supplier.

The use of this exemption is limited to situations where a person has/have had tissues and cells stored in a third country for their future use. For example, autologous donations or donations directed to close relatives where the person then wishes to have such tissues and cells imported into the EU on their behalf. Normally this should not occur more than once for any given recipient and should not include tissues or cells for third parties.

In certain circumstances, the import of PBSC and bone marrow for a known recipient may be considered to be a one-off import. Importers of these products should refer to the draft HTA guidance.

One-off imports can be exempt from the documentation requirements of Annex I, part F and Annex III, providing there are suitable measures in place to regulate such imports to ensure traceability and that the imported tissues and cells are not applied to anyone other than their intended recipients. The HTA will determine what notification and/or information will need to be provided for one-off imports.

Article 6: Updated information

Any changes to importing activities will require authorisation or licensing by the HTA. Tissue establishments should also inform the HTA if they cease any, or all, import arrangements.

The same arrangement for reporting serious adverse reactions and events will apply to incidents involving imported tissue and cells. A serious adverse event could relate to an incident at the exporting third country establishment that could affect the quality and safety of the imported tissue and cells.

Tissue establishments must also report, without delay, any suspension or revocation of a third country supplier's authorisation, or any other decision relating to non-compliance taken by the third country's national authority, which may be relevant to the quality and safety of the imported tissue and cells.

Article 7: Written agreements

Importing tissue establishments must have written agreements in place with third country suppliers where any of the activities of donation, procurement, testing, processing, preservation, storage or export to the EU are carried out outside of the EU.

The written agreement must specify the quality and safety requirements to be met to ensure the equivalency with the standards applicable in EU/EEA countries as laid down in Directive 2004/23/EC.

The agreement shall include, as a minimum, the information listed at Annex IV of the Directive.

The agreement must also set out the right of the HTA to inspect the activities, including the facilities of the third country supplier, for the duration of the written agreement and for a period of 2 years following its termination, should it need to do so. A copy of the agreement must be provided to the HTA as part of the application of authorisation or licensing.

Article 8: Register of importing tissue establishments

Licensed centres must keep a record of all imports that includes: the type of tissue and cells imported and their origin and destination. This information must also be collected for all one-off imports.

Article 9: Transposition

Article 9 sets out the key implementation dates of 29 October 2016 and 29 April 2017, as indicated in Chapter 1. The UK will seek to transpose by summer 2017.

Articles 10 and 11

Article 10 (entry into force) specifies the date the Directive came into force (29 April 2015) and Article 11 (Addresses) that it is addressed to all EU member states.

Consultation Questions relating to Import

Q1: Substantial changes to import activities that could influence the quality and safety of tissue and cells, require prior written approval from the Competent Authority.

What type of changes would you consider as substantial, requiring prior approval from the HTA, and how often would you make such a change at your establishment?

Q2: Do you anticipate any issues with providing the information and documentation required in Annex I and Annex III of the Import Directive?

Q3: Costs of Implementation of the Import Directive
Our impact assessment of the Import Directive relied on a number of assumptions to estimate the costs the NHS and private sector organisations will bear in complying with the import Directive. **These assumptions are described in paragraphs 18-36 of the impact assessment at Annex F. We would welcome your feedback on these assumptions**.

In responding you might wish to consider the following:

- One-off transitional costs to licensed centres in order to implement the import Directive. These include: dedicated staff time to familiarise with the requirements, amending Standard Operating Procedures and updating written agreements. What do you think will be the cost to your establishment?

- The import Directive requires licensed import establishments to gain approval from the Competent Authority when there is a substantial change. How many hours do you anticipate it will take your licensed centre to comply with these requirements?

- Are there any other one-off or recurring costs that could affect your licensed centre when integrating the import Directive into current practice? If so, please provide an estimate for how much these will cost your licensed centre.

- the costs of updating written agreements with third party suppliers (Paragraphs 25 – 30 of the impact assessment).

Chapter 5: Responding to the consultation

The consultation process

This document seeks views on the draft regulations to implement new EU Commission Directives on the coding and import of tissues and cells intended for human application.

The consultation is being run in accordance with the Cabinet Office guidance on Consultations, which is available at:

https://www.gov.uk/government/publications/consultation-principles-guidance

The closing date for the consultation is **Friday 7 April 2017**. Responses received after this date may not be taken into account.

There is a response form with a full list of the questions we are asking in this consultation in Annex F. When returning the response form, please state whether you are responding as an individual or representing the views of an organisation. If you are responding on behalf of an organisation, please make it clear who the organisation represents,

Please send your responses by email to: EUTissue&CellsConsultation@dh.gsi.gov.uk

Responses may also be submitted via web form at:
https://www.gov.uk/government/consultations/coding-and-import-regulations-for-human-tissues-and-cells

Alternatively by post to:
EU Tissue & Cells Consultation
Department of Health
Room 101
Richmond House
79 Whitehall
London SW1A 2NS

Comments on the consultation process itself

If you have concerns or comments which you would like to make relating specifically to the consultation process itself please contact:

Consultations Coordinator
Department of Health
2E08, Quarry House
Leeds
LS2 7UE

Email: Consultations.co-ordinator@dh.gsi.gov.uk
`

Please do not send consultation comments to this address

Confidentiality of information

We manage the information you provide in response to this consultation in accordance with the DH Personal Information Charter, which can be found at:

https://www.gov.uk/government/organisations/department-of-health/about/personal-information-charter

Information we receive, including personal information, may be published or disclosed in accordance with the access to information regimes, primarily the Freedom of Information Act 2000, the Freedom of Information (Scotland) Act 2002, the Data Protection Act 1998 and the Environmental Information Regulations 2004.

If you want the information that you provide to be treated as confidential, please be aware that, under the Freedom of Information Act, there is a statutory Code of Practice with which public authorities must comply and which deals, among other things, with obligations of confidence. In view of this, it would be helpful if you could explain to us why you regard the information you have provided as confidential. If we receive a request for disclosure of the information we will take full account of your explanation, but we cannot give an assurance that confidentiality can be maintained in all circumstances. An automatic confidentiality disclaimer generated by your IT system will not, of itself, be regarded as binding on the DH.

The DH will process your personal data in accordance with the Data Protection Act and, in most circumstances, this will mean that your personal data will not be disclosed to third parties.

Summary of the consultation

A summary of the response to this consultation will be made available before or alongside any further action, such as laying legislation before Parliament, and will be placed on the Consultations website.

ANNEXES

This consultation document has the following annexes, which are published separately:

- Annex A: The Human Tissue (Quality and Safety for Human Application) (Amendment) Regulations 2017
- Annex B: Commission Directive (EU) 2015/565 on coding
- Annex C: Commission Directive (EU) 2015/566 on imports
- Annex D: Coding Impact Assessment
- Annex E: Import Impact Assessment
- Annex F: Consultation Questions