Annex F

CONSULTATION QUESTIONS: HUMAN TISSUE

Name of Respondent/Organisation	
Address	
Date of response	

Consultation Questions relating to Coding
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 (ISBT128, 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 tissue establishments procure from the same deceased

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 previously 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 E.

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.

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 time to familiarise with the requirements, and amending Standard Operating Procedures.

What is your estimate of costs?

Consultation Questions relating to Import from Third Countries

Question 1

What type of changes, would you consider as substantial requiring prior approval from the HTA? How often do you envisage making this change at your establishment?

Question 2

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

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.

What is your estimate of the costs of updating written agreements with third party suppliers (Paragraphs 25 – 30 of the impact assessment)

Any other comments, including comments on the draft HTA Guidance which can be

found at https://www.hta.gov.uk/htas-draft-guidance

Please send this response form by email to: **EUTissue&CellsConsultation@dh.gsi.gov.uk**

Alternatively by post to:

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Closing date for consultation responses is Friday 7 April 2017