ANNEX F

CONSULTATION QUESTIONS: REPRODUCTIVE CELLS

Name of Respondent/Organisation	
Address	
Date of response	

Consultation Questions relating to the draft regulations
Question 1: Do you have any comments on the draft regulations?

Consultation Questions relating to Coding
Question 1: Based on your current activities, how many times per year do you envisage applying the SEC to sperm, eggs or embryos at your centre?

Question 2: Can you identify any disadvantages that the coding Directive will bring to your centre?
Question 3: Is it practical to require that accompanying documentation should be sealed within secondary/tertiary packaging. Are there any circumstances where this would not be practical?
Question 4: 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 licensed centres already submit to the HFEA. Therefore, what is the extra cost to your centre of updating the IT system?

- 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?

- One-off transitional costs will include items such as dedicated staff time to familiarise themselves with the coding requirements and amending standard operating procedures. What is your estimate of these costs for your centre?

Consultation Questions relating to import from Third Countries
Question 1: Substantial changes to import activities, such as a change in third country supplier's premises, will require prior written approval from the HFEA before imports can continue. What type of change do you think is "substantial" and, therefore, would need approval?
Question 2: It is the duty of the Person Responsible to assure the HFEA that the third country supplier operates to quality and safety standards equivalent to those of EU/EEA approved establishments. What steps do you think your centre will need to take to be able to provide the HFEA with this assurance?

Question 3:

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 Directive. These assumptions are described in paragraphs 18-36 of the impact assessment at Annex E. We would welcome your feedback on these assumptions, particularly our estimates of the costs of updating written agreements with third party suppliers (Paragraphs 25 – 30).

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 themselves with the requirements, amending standard operating procedures and updating third party agreements. What do you think will be the cost to your centre?

- Are there any other one-off or recurring costs that could affect your centre when integrating the import Directive into current practice, such as applying to the HFEA for authorisation? If so, please provide an estimate of these costs for your centre?

- The import Directive requires licensed import centres to have a written agreement with any third country supplier and to notify the HFEA when there is a change to the relationship. How many hours do you anticipate it will take your centre to comply with these requirements?

Any other comments?

Please send this response form by email to:

EUTissue&CellsConsultation@dh.gsi.gov.uk

Alternatively by post to:
EU Tissue & Cells Consultation
Department of Health
Room 101/102
Richmond House
79 Whitehall
London SW1A 2NS

Closing date for consultation responses is Friday 7 April 2017