

# EU Tissues And Cells Directive Newsletter

## EU Tissue Directive Derogation

**Introduction** We are pleased to be able to tell you that the Department of Health has decided to take up the option in the Directive that allows deferment (derogation) of its application for one year for those establishments already licensed by the HFEA at April 2004.

The Directive introduces new legal requirements for all units involved in the donation, procurement, preservation, testing, processing, storage and distribution of gametes and embryos. These requirements become mandatory in April 2006. **However, derogation will mean that centres licensed by the HFEA prior to April 2004 will not have to be inspected and licensed specifically under the Directive until April 2007.** Establishments not licensed by the HFEA before April 2004, and those that undertake IUI and GIFT that are not licensed by the HFEA, will need to be licensed under the Directive from April 2006.

This extra year gives more time for centres to develop total quality systems which are a central part of the requirements. It is important that centres start to focus on these now, in preparation for complying with the Directive. There has been much speculation concerning potential requirements for handling material in controlled laboratory conditions (the details of which are yet to be finalised by the European Commission). However, we urge centres to start thinking now about the implications of having total quality systems in place from April 2007.

### Incorporating the Directory into UK law

As far as reproductive cells are concerned, the Directive will be incorporated (transposed) into UK legislation by an amendment to the Human Fertilisation and Embryology Act 1990. The amendment will be achieved by way of regulations which the Department of Health intends to publish for consultation during 2005 before putting them to Parliament for consideration.

### The next step

In our role as competent authority for gametes and embryos we are working closely with the Department of Health on implementation plans. We are currently working up an inspection model that will take account of the Directive, and we will be responsible for ensuring compliance with all aspects of the Directive within the ART sector. The HFEA will issue further guidance to clinics as the detailed requirements become clearer.

**Organisations  
and groups  
involved in  
implementation**

A number of stakeholders and HFEA groups are now involved in implementing the Directive, as explained below:

<b>Department of Health Steering Group</b>	This group has over all responsibility for overseeing implementation of the Directive in the UK
<b>HFEA</b>	The HFEA will be the competent authority under the Directive for gametes and embryos, responsible for ensuring compliance with all aspects of the Directive
<b>HFEA Tissue Directive Implementation Steering Group</b>	This group which comprises of Authority Members and HFEA Executive is taking forward implementation work on behalf of the Authority, reporting to the Regulation Committee
<b>HFEA Tissue Directive Core Project Management Team</b>	This focussed team comprising of Policy and Regulation staff is working up detailed plans for an inspection and licensing model
<b>HFEA Stakeholders Consultation Forum</b>	Due to the fact that detailed requirements are being published by the European Commission piecemeal, we will not have time to carry out a full consultation on implementation plans. We are therefore discussing ongoing implementation work with a group of stakeholders representing all disciplines within the sector
<b>HFEA Advisory Group on Safety and New Technologies</b>	The work of this group includes exploring technologies that could potentially help centres meet requirements of the Directive on coding, labelling, and traceability
<b>EU Tissue Directive Consortium</b>	We are talking to ESHRE about the establishment of a Consortium to include a practitioner and a regulator from each Member State of the European Union. Its main aims will be to co-ordinate feedback to the Commission, improve consistency and share learning as the Directive is implemented across Europe
<b>Human Tissue Authority</b>	The HTA will be the competent authority under the Directive for non-reproductive tissues and cells. The HFEA and HTA will merge to form the Regulatory Authority for Fertility and Tissues following amendment to the HF&E Act 1990

**Progress on  
drafting the  
technical  
requirements**

The European Commission's consultation process for the first Commission Technical Directive concerning standards for donation, procurement and testing ended on 1<sup>st</sup> October. This is now back with the Commission to be finalised.

We hope that the second Commission Technical Directive on processing, preservation, storage and distribution will be published for consultation soon by the European Commission. We anticipate that this will include requirements for quality systems and coding. Centres will be alerted to the consultation and we encourage all stakeholders to respond to the Commission to help overcome the risk of standards being set inappropriately high for the ART sector.

We will continue to update centres on the drafting and finalisation of the technical requirements, which we are encouraging the European Commission to do as early as possible.

**Further  
information**

A copy of the Directive can be downloaded from our web site:

[www.hfea.gov.uk/AboutHFEA/HFEAPolicy/EUTissuesandCellsDirective](http://www.hfea.gov.uk/AboutHFEA/HFEAPolicy/EUTissuesandCellsDirective)

Further background information can also be found on the European Commission's web site:

[http://europa.eu.int/comm/health/ph\\_threats/human\\_substance/tissues\\_en.htm](http://europa.eu.int/comm/health/ph_threats/human_substance/tissues_en.htm)

If you have any queries about any aspect of the Directive and its implementation please contact: Charles Lister, Head of Policy, 0207 291 8230, [charles.lister@hfea.gov.uk](mailto:charles.lister@hfea.gov.uk) or Jenny Dimond, Policy Manager 0207 291 8238 [jenny.dimond@hfea.gov.uk](mailto:jenny.dimond@hfea.gov.uk).