

# EU Tissues And Cells Directive Newsletter

**Introduction** The Tissue Directive introduces new legal requirements for all establishments involved in the donation, procurement, preservation, testing, processing, storage and distribution of gametes and embryos. The requirements become mandatory in April 2006, but centres licensed by the HFEA prior to April 2004 do not have to meet the specific requirements of the Directive until April 2007.

We had hoped that all the detailed requirements of the Directive would be finalised by April 2005. However, the European Commission's process for doing this has taken longer than anticipated, and at the time of writing neither of the two Commission Technical Directives has been completed. We recognise that this makes it difficult for clinics to plan ahead, and it also makes it difficult for the HFEA to produce guidance well ahead of the implementation deadline. However, we have a good idea of what the final requirements will include from the 'parent' Directive itself, and the latest publicly available information on the technical requirements which can be downloaded from the Commission's website (details below).

As things stand we expect that the first Commission Technical Directive (covering donation, procurement and testing) will be finalised very soon. We anticipate that the second (covering processing, preservation, storage and distribution) will also be published for consultation during the next few weeks and be finalised by the autumn.

Despite the slow progress of the technical requirements there are other aspects that we wish to provide an update on, and which we hope will eventually help with clinics implementation of the requirements:

**Collaboration with professional bodies** For clinics covered by both the HF&E Act and the Directive there will be a single inspection assessing compliance with both pieces of legislation. This will have major implications for the HFEA Code of Practice, which we will be updating and revising over the next year. During 2003/04 the professional bodies worked on developing a set of standards for assisted conception clinics and this provides the basis for a compliance manual for clinics to use in meeting the requirements of the Directive. We are currently bringing a group of representatives of the professional bodies back together to further work up and eventually agree the standards.

We are also exploring the option of re-casting the Code of Practice as a standards document so that the single HFEA inspection is backed up by a single Code.

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While it could be some time before the technical requirements are finalised, we encourage centres to start looking at introducing total quality management systems now. This will include producing a quality manual containing standard operating procedures (SOPs) for all systems and processes, including quality control and validation. We are in discussion with the professional bodies about producing guidance on what work centres should start putting in place.

### Transposition of the Directive to UK law on

The Directive will be brought into UK law by way of regulations that will amend the HF&E Act. The Department of Health (DH) is overseeing this process, and aims to publish the draft regulations for consultation in the summer. We are working closely with DH in preparing explanatory notes that will provide further details on how each aspect of the Directive will impact on clinics.

### European Assisted Conception Consortium (EACC)

The HFEA has facilitated the setting up of the EACC. This consortium will be supported by ESHRE who will provide the secretariat function. The inaugural meeting is being planned to take place during the coming weeks and it is likely that there will be a meeting at the ESHRE conference in June.

The aim of the Consortium is to bring together national ART regulators and practitioners within the European Union for professional cooperation and joint action. Among other things the Consortium will present joint positions to the European Commission on matters concerning the regulation of assisted conception services in the EU, and share learning during implementation of the Tissue Directive.

### Bar coding and radio frequency identification (RFID)

The potential use of these technologies in helping centres with witnessing and auditing procedures was discussed at our recent annual conference. There has also been press coverage concerning some of the trials that are being carried out, and the products that are on the market.

The HFEA's Advisory Group on Safety and New Technologies (SANT) is currently considering bar coding and RFID. The group is exploring the types of product available and evidence relating to safety and efficacy. This work will lead to the production of a specification which centres can use when considering purchasing bar coding or RFID products, so that they can be sure that the products will meet both HFEA and Tissue Directive requirements. We hope to complete this work in the autumn and in the meantime we urge centres to take into account the current uncertainties over the technical requirements of the Directive before committing to any particular system.

### New Tissue Establishments

The Directive will expand the HFEA's regulatory remit to include previously unlicensed IUI and GIFT establishments. Laboratories performing sperm testing and preparation may also be affected if they are not part of a currently licensed centre.

Over the last year the HFEA and DH have endeavoured to ensure that information on the Directive reaches all relevant services that may be affected. However, there is no central list of IUI or GIFT services and we are concerned that there may be practitioners who are not aware that they need to contact the HFEA to be included in the licensing framework under the Directive. If you are aware of colleagues, service providers, or anyone else who may be affected we encourage you to suggest they contact the HFEA using the contact details below. This will help ensure that all those affected receive up to date information and have as much time as possible to prepare for implementation.

### Further information

A copy of the Directive can be downloaded from our website:

[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:

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