

EU Tissues and Cells Directive Newsletter

November 2005

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Update on technical requirements

The first Commission Technical Directive, covering procurement, donation and testing, is expected to be finalised by the end of this year. We anticipate that the second Commission Technical Directive, covering processing, preservation, storage and distribution, will be finalised later in 2006.

Implementation dates

As the requirements of the second Commission Technical Directive are unlikely to be finalised until after the April 2006 implementation date for the 'parent' Directive, the Department of Health has announced a staggered approach to implementation. In September, the Department contacted all relevant establishments to explain the new time frame.

In summary, the framework of the Directive will be implemented by existing legislation from April 2006. The implementation dates for the two Commission Technical Directives are then expected to follow between autumn 2006 and autumn 2007.

This means that the previously unlicensed IUI/GIFT centres will have additional time to prepare for the Directive before they will be inspected by the HFEA. Although there are two separate implementation dates given for the two Commission Technical Directives, it is likely that establishments will be expected to be able to demonstrate compliance with both from April 2007.

As establishments have to be inspected once within a two year period, all the formal inspections will then be rolled out between April 2007 and April 2009. We anticipate that the regulations will allow for 'provisional' licenses to be issued bringing all relevant establishments into the licensing framework by April 2007, prior to their formal inspection.

It has already been established that previously licensed centres are eligible for derogation of one year—meaning they don't have to be inspected specifically against the Directive until April 2007. We will continue to update all centres as new information emerges and we expect the next significant development will be the finalisation of the first Commission Technical Directive. We will contact you when this happens.

For more information about what this means for the IUI and GIFT establishments, go to www.hfea.gov.uk

Transposition regulations

Due to the timescale around finalising and implementing the technical requirements as outlined left, we expect that the regulations that will transpose the Directive to UK law will be issued for consultation by the Department of Health in mid 2006. There will remain some uncertainties about practical aspects until the regulations are drafted. However, the HFEA will continue to clarify relevant issues with centres as soon as is practically possible.

