

MIDDAY EXPRESS

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Human cells and tissues: Commission adopts safety rules for processing, preservation, storage and distribution

The European Commission has today adopted a second set of technical rules to help implement the EU legislation on quality and safety standards for human tissues and cells. A first set of implementing rules was adopted in February, providing safety rules for the first phases of the process: donation, procurement and testing (see MEX/06/0208). This second set of rules covers the subsequent phases: processing, preservation, storage and distribution. It also incorporates tissue coding requirements, measures to ensure traceability between donor and recipient and vice versa, and rules for reporting serious adverse reactions and events.

Among the measures laid down in today's Directive are requirements for the accreditation of tissue establishments and tissues and cell preparation processes. The Directive also details the procedures that tissue establishments have to follow for notifying serious adverse reactions and events to the national competent authorities, as well as the procedures for the annual reporting on these notifications to the European Commission. With a view of ensuring that all human tissues and cells are traceable from the donor to the end user and vice versa, the Directive also defines the basis for a single European identifying code for all donated material. These rules will help to ensure a high level of public health protection in all Member States, and prevent the transmission of diseases via donated tissues and cells.

For further information, see:

http://ec.europa.eu/health/ph_threats/human_substance/tissues_en.htm