Human tissues and cells: quality and safety for the donation, procurement, testing, processing, preservation, storage and distribution

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The European Parliament adopted a resolution drafted by Peter LIESE (EPP-ED, Germany) and made several amendments to the Commission's proposal. (Please refer to the summary of 25/03/03.) The following amendments were also made: - "tissue" is redefined more precisely and explicitly excludes organs, blood and blood products; - the Directive expressly recognises the right of Member States to prohibit donation, procurement, testing, processing and distribution of tissues and cells of a particular origin, as well as imports of cells; - the Commission will assist Member States in cooperating in the preparation of guidance concerning the training and qualification of officials involved in inspection and control measures; - tissue banks have prescribed obligations in relation to human tissues and cells imported from third countries; - the data required to ensure full traceability must be kept for at least thirty years; - there must be no trading in unmodified tissues and cells. Where they are used as source material for manufacturing products for therapeutic use, such activities may be permitted for bodies and organisations operating on a profit basis; - in relation to commercial establishments, Member States must ensure tissues and cells are properly transferred in the event of termination of business or bankruptcy; - the procurement of tissues after an abortion requires special rules, and the directive introduces some details on this; - Parliament lays down detailed provisions for the protection of persons who are not in a position to give voluntary informed legal consent. Tissue and cell retrieval must be endorsed by an ethics committee. The interests of the donor who is unable to give consent must always take precedence over those of science and society; - Member States may exempt tissue banks which provide only tissues and cells for which there is no urgency from the requirement to operate on a 24-hour basis; - there are special requirements for umbilical cord and placenta, and the provision of information to parents; - there are special requirements for laboratory tests in relation to the collection of umbilical cord blood; - maximum storage time may be extended under certain conditions.