

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

2002/0128(COD) - 16/12/2003 - Text adopted by Parliament, 2nd reading

The European Parliament adopted a resolution drafted by Peter LIESE (EPP-ED, Germany) and reached agreement on a package of compromise amendments regarding the donation, procurement, testing, processing, preservation, storage and distribution of human tissues and cells. With the support of other political groups, the rapporteur reached an agreement in negotiations with the Council that tissues and cells should be donated on a voluntary basis without direct payment. Detailed rules will be left to the Member States. The Council agreed to accept Parliament's opinion on this key issue. It was also agreed that Member States should endeavour to ensure voluntary and unpaid donations of tissues and cells. Donors may receive compensation, which is strictly limited to making good the expenses and inconveniences related to the donation. Member States will define the conditions under which compensation may be paid. The procurement of tissues and cells as such is carried out on a non-profit basis. On the question of traceability of human tissues and cells, it was agreed that tissue establishments should keep the data necessary to ensure traceability at all stages. Data required for full traceability shall be kept for a minimum of 30 years after clinical use. Data storage may also be in electronic form. Regarding cloned human embryos, it was agreed that existing legislation in the Member States should remain into force. This directive does not interfere with Member States' decisions concerning the use or non-use of any specific type of human cells, including germ cells and embryonic stem cells. However, for any particular use of such cells in a Member State, this directive will require the application of all provisions necessary to protect public health, given the specific risks of these cells based on the scientific knowledge and their particular nature, and guarantee respect for fundamental rights. This compromise amendment replaces the original amendment, in which Parliament had demanded that cloned human embryos, and human-animal hybrid embryos produced by cloning, aggregation or any other procedure, and tissues and cells derived from that, should be excluded as sources of material for transplantation. Since the Council could not accept this amendment, the rapporteur recommended that the House accept the less far-reaching compromise amendment, indicating that in doing so a conciliation procedure could be avoided. Parliament adopted this amendment with 503 votes in favour, 42 against and 12 abstentions.