

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

2002/0128(COD) - 05/02/2004 - Commission opinion on Parliament's position at 2nd reading

A compromise package concerning the proposed amendments of the European Parliament and which includes three draft declarations involving the Commission, was submitted to the European Parliament for the Plenary session on 15 December 2003 with the endorsement of the Council. The amendments approved by the Parliament reflect the compromise agreement reached between Parliament and Council, the compromise is acceptable to the Commission. These amendments are in line with the Common position of the Council, accepted by the Commission, and they respect all issues considered essential by the Commission to guarantee a high level of protection in the area of quality and safety of human tissues and cells. The amendments accepted concern the following issues: - promotion of worldwide standards; - clarification of the scope; - clarification on accreditation of establishments; - traceability; - labelling; - clarification on comitology; - clarification on the roles of third parties; - promotion of donation, - clarification on specific risks of cells, - equal access and transparency; - reconstruction of the donor's body; - voluntary and unpaid donations; - access to tissues and cells for establishments; - the mention of the chapter of human rights and the Convention; - anonymity; - comitology; - guidelines for inspection and training; - import; - non profit procurement; - editorial clarification; - provisions in case of termination of activities in the tissue establishments and - new annex on information to the donor. The Commission has included 3 declarations within the framework of the second reading on the proposal setting standards of quality and safety for the donation, procurement, testing, processing, storage, and distribution of human tissues and cells: - Declaration on Organ Transplantation : the important differences between organ transplantation and the use of other human substances such as blood, tissues and cells mean that a specific approach for organs in order to ensure safety and quality is necessary. Such an approach in the current situation characterised by shortage of organs has to balance two factors: the need for organs' transplantation which is usually a matter of life and death with the need to ensure high standards of quality and safety. The Commission believes that before considering any proposal it is necessary to conduct a thorough scientific evaluation of the situation regarding organ transplantation. The Commission will present a report on the conclusions of the analysis it undertakes as soon as possible. - Declaration on the future development of the relevant technical criteria : in the absence of specific Community legislation on the processing, preservation, storage and distribution of tissues and cells intended for industrially manufactured products the Council and the Commission agree that the concerns raised by the Parliament in respect of the requirements to be determined for establishments operating in this field, such as the requirement to operate on a 24-hour basis, will be addressed in the development of the relevant technical requirements referred to in article 28 of the Directive. - Declaration on the future development of the relevant technical criteria : the Council and the Commission agree that the concerns raised by the Parliament at first reading as regards the Annexes originally proposed by the Commission will be taken into account in the development of the relevant technical requirements referred to in article 28 of the Directive.