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

2002/0128(COD) - 22/07/2003 - Council position

The common position has been adopted by unanimity. The Council states that it is to a great extent in line with the Commission's amended proposal. In particular, the Council shares the Commission's argument that amendments of an ethical nature are not acceptable, since they fall outside the scope of Article 152 of the Treaty. The Council, has, however, agreed to insert a general reference in the preamble to the need for altruism and non-profit procurement. The Council further notes that the Commission in its amended proposal introduced the clarification of provisions, as a result of their examination of the proposed Directive by the Council. The Council adopted - wholly, partly, or retaining only the substance - 15 of the 35 amendments adopted by the European Parliament, which were taken up, either wholly or in part, in the Commission proposal. These amendments are useful clarifications to the proposal that strengthens the quality and safety requirements. The scope of the directive is widened to include autologous cells to be used for medicinal products. Those amendments accepted by the Commission but not by the Council include: -one which aims to strengthen the provisions on traceability; -the requirement that the person responsible must have three years experience. These are therefore not part of the common position. Amongst the amendments accepted by the Council but not part of the amended proposal is the inclusion of a recital on the need to promote information and awareness campaigns with the specific theme "we are all potential donors." The following amendments were amongst those which were not integrated into the proposal by the Council or the Commission, and mainly deal with the following: -widen the scope of the Directive to include research with tissues/cells not intended to be applied in humans; -the use or non/use of certain types of tissues/ cells not intended to be applied in humans; -the use or non-use of certain types of tissues/ cells or some processes (i.e. embryos, cloning. See below on the declarations by the German and Italian delegations.) -ethical issues such as voluntary or unpaid donation, non-profit procurement, consent or ethics in general. Issues where the Council differs from the amended proposal deal mainly with the following: -the accreditation requirement not only for the establishments dealing with tissues and cells, but also for the procedures that they perform has been strengthened; -The Council has reaffirmed Member States' competence in matters of publicity in implementing the Directive; -the Council has also decided to refer the matters listed in the annex to the regulatory committee procedure. The following statement was made by the Italian delegation and entered in the minutes: "The Italian delegation considers that the principles set out in European Parliament amendment relating to the prohibition of the use of cloned embryos or human/animal hybrid embryos obtained through cloning as sources of material for transplants, should be retained. The risks inherent in the transplanting of cells or the use oftissues derived from cloned cells are considerable and evident, and are not in our view consistent with the provisions of a legislative proposal which has the ultimate aim of protecting human health by setting standards of quality and safety for cells and tissues used for human applications." The following statement was made by the German delegation and entered in the minutes: "The German delegation supports efforts to achieve a high level of health protection for EU citizens, in the framework of the above proposal for an EU Directive, in regard to the quality and safety of tissues and cells used in human beings. In this, the German delegation is guided by the strict requirements which already exist in Germany under current national legislation and by the legal framework set out in Article 152(4)(a) of the EC Treaty. The German delegation welcomes the intentions pursued by the European Parliament with its amendments to the proposed Directive, in particular the proposal contained in the amendment relating to the prohibition of the use of cloned embryos or human/animal hybrid embryos obtained through cloning as sources of material for transplants. Germany reserves the right to lay down more stringent protection measures when the Directive is transposed into national law, using the option provided for in the second clause of Article 152(4)(a) of the EC Treaty.