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

2002/0128(COD) - 11/08/2003 - Commission communication on Council's position

The Commission notes with satisfaction that the Council has endorsed the general approach taken in its amended proposal. The common position has followed the same direction on the Parliament's amendments as that of the Commission - accepting the majority of those related to technical aspects and, given the absence of a legal basis, rejecting those dealing with ethics. Although the common position differs on some particular issues from the Commission's amended proposal, it does cover 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 common position represents a carefully balanced compromise. In particular it maintains the Community's obligation to establish and regularly update specific technical requirements in all relevant fields. With regard to one of the key amendments rejected by both Commission and Council, the Commission stated that it aimed to prohibit the use of 'cells derived from cloned embryos' for 'transplant' - so-called 'therapeutic cloning' - using cells with genetic features identical to an existing cell or organism. Such applications are controversial ethical issues, with no consistent opinion in Member States and no likelihood of one being reached in the near future. In the opinion of the Commission, the Directive should not interfere with decisions to be made by each Member State concerning the use or non-use of any specific type of human cells or tissues, as was foreseen in the Commission's amended proposal. A solution that sets safety and quality requirements in cases where the use of such cells is permitted in a Member State is the preferred option. In conclusion, the Commission considers the common position to be a good compromise, which takes on board key European Parliament amendments, while still being in line with the Commission's amended proposal on all essential questions.