Research RTD, 6th framework programme 2002-2006: funding for projects on stem cells

2003/0151(CNS) - 09/07/2003 - Legislative proposal

PURPOSE : to amend decision 2002/834/EC on the specific programme for research, technological development and demonstration : "Integrating and Strengthening the European Research Area" (2002-2006). CONTENT : to recall, the 6th Research Framework Programme (FP6 2003-2006), as adopted by the Council of Ministers and the European Parliament in 2002, allows for the funding of human embryonic stem cell research in relation to the fight against major diseases. Such research, in particular when it involves the derivation of stem cells from human supernumerary embryos, can only take place within a framework of clear and strict ethical guidelines. The EU research programme includes ethical provisions related to sensitive areas of research. In light of the sensitive nature of human embryonic stem cell research, the Council and the Commission agreed at the time of the decision-making process on FP6 that further ethical guidelines would be adopted before the end of 2003 for deciding on and for monitoring the EU funding of human embryonic stem cell research. The Commission now submits, based on Article 166, paragraph 4, of the Treaty, a proposal to the Council for the modification of the specific programme, on which the European Parliament will express its opinion. This proposal presents a coherent set of strict ethical guidelines that will apply to the EU funding of research projects involving the derivation of stem cells from human supernumerary embryos. In order to be funded by the Community, research projects involving the procurement of stem cells from human embryos must also meet the following conditions: - prior to the start of research activities, participants must obtain ethical advice at local or national level in the countries where the research will be carried out; - the human embryos used for the procurement of stem cells must have been created before 27 June 2002 as a result of medically-assisted in vitro fertilisation designed to induce pregnancy, and were no longer to be used for that purpose; - the project must serve particularly important research aims to advance scientific knowledge in basic research or to increase medical knowledge for the development of diagnostic, preventive or therapeutic methods to be applied to humans; - all other alternative methods (including existing or adult stem cell lines) must have been examined and demonstrated not to be sufficient for the purposes of the research in question; - the free, express, written and informed consent of the donor(s) should be provided in accordance with national legislation prior to the start of the research activities; - no monetary compensation or other benefit in kind must be granted or promised for the donation; - the protection of personal data, including the genetic data, of the donor(s) must be ensured; - where appropriate, the participants in research projects must follow quality and safety standards on donation, procurement and storage in accordance to the state of the art, in order to ensure in particular the traceability of these stem cells. The scientific evaluation and the ethical review organised by the Commission of the research proposals shall include verification of these conditions. The conditions shall be assessed during thescientific evaluation. The opinions of the European Group on Ethics in Science and New Technologies, and in particular those relating to research involving the use of human embryonic stem cells will be taken into account. The participants in research projects should use their best efforts to make the newly derived human embryonic stem cell lines available to the scientific community on a non-profit making basis for research purposes. A list of research projects involving the use of all types of human embryonic stem cells funded under the sixth framework programme will be published yearly by the Commission.