Amended proposal for a

COUNCIL DECISION

amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: “Integrating and strengthening the European research area” (2002-2006)

(presented by the Commission pursuant to Article 250 (2) of the EC Treaty)
EXPLANATORY MEMORANDUM

1. BACKGROUND

– 30 September 2002: adoption of the Decision concerning the specific programme "Integrating and strengthening the European Research Area" under the 6th RTD Framework Programme.

– 23 April 2003: Inter-institutional Seminar on research into human embryonic stem cells.

– 9 July 2003: Commission proposal amending the Decision concerning the specific programme.

– 29 October 2003: Endorsed by the European Economic and Social Committee.

– 19 November 2003: Adoption of Parliament’s opinion with 18 amendments to the Commission’s proposal.

2. AIM OF THE COMMISSION’S PROPOSAL

The Commission’s proposal follows on from the Council meeting of 30 September 2002 which adopted the specific programme "Integrating and strengthening the European Research Area” under the 6th Framework Programme. The Commission proposal, based on Article 166(4), sets out a coherent set of guidelines concerning the principles which should govern decisions concerning Community financing of research projects involving the procurement of stem cells from supernumerary human embryos.

In order to allay fears that Community funding might indirectly encourage the production of embryos by in vitro fertilisation (IVF) over and above the number required, and to send out a political signal, the Commission is proposing that only supernumerary embryos created before 27 June 2002 (date of adoption of the 6th Framework Programme) can be used.

3. COMMISSION OPINION ON THE AMENDMENTS ADOPTED BY PARLIAMENT

3.1 General assessment.

In general, the amendments adopted by Parliament tally with the approach proposed by the Commission by allowing the Community funding of research projects involving the procurement of human embryonic stem cells from supernumerary embryos and hence the creation of new lines. However, certain amendments, and in particular those aimed at removing the cut-off date for the creation of supernumerary embryos call into question the approach adopted by the Commission on 9 July 2003.

3.2 Amendments accepted by the Commission in whole or in part or subject to reformulations

Amendments 4, 7, 12 and 13 can be accepted as adopted by Parliament since they clarify the text of the proposal and specify its content.
Amendments 8, 14 et 17 can be accepted as a whole but subject to reformulation for clarification.

Amendments 1, 6, 9, 15, and 18 are also acceptable but only in part and subject to reformulations.

3.3 Amendments not accepted by the Commission

A number of amendments cannot be accepted (amendments 2, 3, 5, 10, 16 and 19) which amend the substance of the proposal. This applies in particular to amendments 5 and 10 which do not contain a cut-off date for embryos used for the procurement of stem cells, as proposed by the Commission to take account of ethical sensitivities.

3.4 Conclusion

Pursuant to Article 250(2) of the EC Treaty, the Commission hereby amends its proposal accordingly.
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amending decision 2002/834/EC on the specific programme for research, technological development and demonstration: “Integrating and strengthening the European research area” (2002-2006)

(Text with EEA relevance)

THE COUNCIL OF THE EUROPEAN UNION,

Having regard to the Treaty establishing the European Community, and in particular Article 166(4) thereof,

Having regard to the proposal by the Commission¹,

Having regard to the Opinion of the European Parliament²,

Having regard to the Opinion of the European Economic and Social Committee³,

Whereas:

(1) At the Council meeting of 30 September 2002, the Commission stated that, until implementing provisions are established by 31 December 2003, it will not propose to fund any research involving the use of human embryos and human embryonic stem cells, with the exception of the study of banked or isolated human embryonic stem cells in culture.

(2) An inter-institutional seminar on bio-ethics took place on 24 April 2003 on human embryonic stem cells research under the sixth framework programme for research. There was an open debate among experts and representatives of the Council, the European Parliament and the Commission, on the basis of a Commission staff working paper⁴ on human embryonic stem cell research.

(3) In accordance with the statements to the Council minutes of 30 September 2002 and following the inter-institutional seminar of 24 April 2003, further guidelines should be established on principles for deciding on the Community funding of research projects involving the use of human embryos and human embryonic stem cells.

¹ OJ C […], […], p. […].
² OJ C […], […], p. […].
³ OJ C […], […], p. […].
There is a great diversity among Member States concerning the ethical acceptability of various research fields and this is reflected in the national laws in accordance with the principle of subsidiarity. In particular, regulation and legislation regarding research using human embryos created for the purpose of in vitro fertilisation and not used for this purpose any more (i.e. supernumerary embryos) and human embryonic stem cells is handled very differently among the Member States. Therefore this decision in no way affects national laws concerning embryonic stem cells. The specific programme already provides that national provisions apply and no research forbidden in any given Member State will be supported by Community funding to a legal entity established in that State.

In light of the current state of knowledge on human embryonic stem cells, new human embryonic stem cell lines, derived from human supernumerary embryos, are required.

The aims of stem cell research, especially the alleviation and cure of diseases which are currently not or not sufficiently treatable, are to be supported.

This decision is intended to apply specifically to Community funding of research activities involving the procurement of stem cells from human embryos 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 (supernumerary embryos). This decision amends the specific programme by introducing several conditions for deciding on the Community funding of such research.

Transplantation of human embryonic stem cells to patients during the commitment phase of the 6th framework programme (until the end of 2006) is not foreseen because strong basic research is still necessary.

This decision concerns the use of human embryos for research only and not for therapeutic purposes. Research on human embryonic stem cells is desirable for the development of innovative treatments and, in particular, of treatments using adult stem cells.

The present conditions are based on the principles established by the European Group on Ethics, especially the fundamental ethical principles underlined in the opinion No. 15: the principle of respect for human dignity (which requires provisions of guarantees against risks of arbitrary experimentation); the principle of human autonomy which entails the giving of informed consent and the protection of personal data; the principle of justice and of beneficence (namely with regard the improvement and protection of health); the principle of freedom of research (which should be balanced against other principles) and; the principle of proportionality (non-availability of adequate alternative methods in view of the scientific objectives to be reached).

These conditions should be assessed during the course of a scientific evaluation and an ethical review.

The experience from scientific communities from other regions of the world should also be used.

In order for this research to benefit the scientific community at large, 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 for research purposes.
In order to ensure transparency a list of research projects involving the use of human embryonic stem cells funded under the sixth framework programme should be published annually by the Commission.

The existence of supernumerary embryos after in vitro fertilisation constitutes an ethical dilemma and making them available for research purposes requires strong ethical safeguards.

The Decision 2002/834/EC\(^5\) should be amended accordingly.

HAS ADOPTED THIS DECISION:

Article 1

Annex I to Decision 2002/834/EC is amended in accordance with the Annex to this Decision.

Article 2

This Decision is addressed to the Member States.

Done at Brussels,

For the Council
The President
Annex

In part 1.1 of annex I to Decision 2002/834/EC, the following text shall be inserted after the 17th paragraph.

"Research on the use of human stem cells may be financed depending on the contents of the proposal and the legal framework of the Member State(s) involved.

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:

(a) 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;

(b) 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;

(c) 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;

(d) 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;

(e) the free, express, written and informed consent of the donor(s) should have been provided in accordance with national legislation prior to the start of the research activities procurement of the cells;

(f) no monetary compensation, or other benefit in kind or other consideration may must be granted or promised for the donation of embryos used for the procurement of stem cells;

(g) the protection of personal data, including the genetic data, of the donor(s) must have been ensured during the procurement and for any use thereafter;

(h) 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 set out in point (c) and (d) shall be assessed during the scientific evaluation.

Projects with adult somatic stem cells and umbilical cord blood cells should be encouraged and particularly comparative studies between all types of human stem cells.

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.
In order to contribute to optimising the use of human embryonic stem cell lines, the Commission will support the initiative to set-up of a European registry.

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.”