



COMMISSION OF THE EUROPEAN COMMUNITIES

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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)

## EXPLANATORY MEMORANDUM

### **Introduction**

There is strong scientific interest world-wide in stem cell research. Although much basic and preliminary research is still needed, the investigation of stem cells has the potential to contribute greatly to a better understanding of the development of human life. Scientists are hopeful that stem cell research will provide essential progress in the development of therapies in several fields of medicine. This is particularly the case for the treatment of various degenerative diseases like Alzheimer's and Parkinson's but also for more common diseases like diabetes.

Stem cell research raises ethical questions, particularly when it involves the use of embryonic stem cells derived from human supernumerary embryos. At the same time, the suffering of so many patients who currently have no hope of an adequate cure, imposes an ethical duty to advance research.

Obviously, research involving the use of a human embryo can only take place within a framework of strict ethical conditions and safeguards.

Taking full account of the opinions of the European Group on Ethics in Science and New Technologies, the European Commission is now proposing a coherent set of strict ethical guidelines for deciding on and for monitoring the community funding of research involving the derivation of embryonic stem cells from human supernumerary embryos. Funding for this research is included in the scope of the sixth framework programme of the European Community for research, technological development and demonstration activities (2002 – 2006), as adopted by the European Parliament and the Council<sup>1</sup>.

With the present proposal, the Commission responds to a question that was left open in the decision-making process on the specific programme of the sixth framework programme for research, namely under what conditions community funding can be made available for projects involving such research.

The specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (2002-2006) (Decision 2002/834/EC)<sup>2</sup> (hereinafter referred to as "the specific programme"), adopted by Council on 30 September 2002, allows the funding of research activities involving the use of human embryos and human embryonic stem cells except in three areas:

- research activity aiming at human cloning for reproductive purposes (reproductive cloning),
- research activity intended to modify the genetic heritage of human beings which could make such changes heritable (germline gene therapy)<sup>3</sup>,
- research activities intended to create human embryos solely for the purpose of research or for the purpose of stem cell procurement, including by means of somatic cell nuclear transfer (commonly referred to as therapeutic cloning).

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<sup>1</sup> OJ C 232, 29.8.2002, p. 1.

<sup>2</sup> OJ L 294, 29.10.2002, p. 1.

<sup>3</sup> Research relating to cancer treatment of the gonads can be financed.

Community funding for stem cell research, involving human somatic stem cells as well as embryonic stem cells derived from human supernumerary embryos, is foreseen in the specific programme, in particular under the priority thematic area 1.1.1 « Life sciences, genomics and biotechnology for health », research priority (i) *"Advanced genomics and its applications for health"*, section "Applications of knowledge and technologies in the field of genomics and biotechnology for health". As an example, in this section *"Research will focus on...development and testing of new preventive and therapeutic tools, such as somatic gene and cell therapies (in particular stem cell therapies, for example those on neurological and neuromuscular disorders)"*<sup>4</sup>.

At the Council meeting of 30 September 2002, the Council and the Commission agreed that "detailed implementing provisions concerning research activities involving the use of human embryos and human embryonic stem cells shall be established by 31 December 2003."

Until that time, the Commission will not propose to fund such research, with the exception of proposals for projects that involve the use of banked or isolated human embryonic stem cells in culture. Such proposals shall be reviewed in light of the provisions already incorporated in the specific programme and according to procedural modalities agreed by the committee of Member States that assists the Commission in the implementation of the specific programme.

The Commission stated that it would submit, on the basis of article 166(4) of the Treaty, a proposal establishing further guidelines on principles for deciding on the Community funding of research projects involving the use of human embryos and human embryonic stem cells.

As also agreed at the Council meeting of 30 September 2002, the Commission published in April 2003 a staff report on the scientific advances and needs as well as the evolution of international and national legislation, regulations and ethical rules regarding the issue of research involving the use of human embryonic stem cells [SEC(2003)441]<sup>5</sup>. This report was transmitted to the European Parliament and the Council as a basis for discussion at an inter-institutional seminar, without prejudging the current proposal.

On 24 April 2003, the inter-institutional seminar on bioethics took place, related to human embryonic stem cell research under the sixth framework programme for research. This seminar provided an opportunity for a discussion and sharing of views between experts (scientific, legal, and in ethics) and representatives of the European Parliament, the Council, the Commission, the Member states and the accession and candidate countries. The conference video can be visited in five languages on the internet<sup>6</sup>.

## **Commission proposal**

The Commission now submits, based on Article 166(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 addresses an important emerging field of research, which combines both high expectations for medical applications and profound ethical questions. It concerns especially the procurement of embryonic stem cells from human supernumerary embryos. This research will allow the derivation of new human embryonic stem cell lines, needed by the scientific

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<sup>4</sup> OJ L 294, 29.10.2002, p. 10.

<sup>5</sup> [http://europa.eu.int/comm/research/conferences/2003/bioethics/index\\_en.html](http://europa.eu.int/comm/research/conferences/2003/bioethics/index_en.html)

<sup>6</sup> [http://europa.eu.int/comm/research/conferences/2003/bioethics/index\\_en.html](http://europa.eu.int/comm/research/conferences/2003/bioethics/index_en.html)

community to advance knowledge and evaluate the real potential of this research for developing medical applications. In order to address both these scientific expectations and the ethical concerns, the Commission is proposing to fund such research only under strict conditions.

Within the specific programme, human somatic stem cell research (cells isolated from foetal or adult tissue) constitutes the main area of human stem cell research in terms of projects funded. Human somatic stem cell research started more than 20 years ago and has already demonstrated lifesaving therapeutic applications, while the culture of human embryonic stem cells was first made possible 5 years ago.

Research on human embryonic stem cells and research on human somatic stem cells are complementary since they have both advantages and limitations. A comparison between the two, appears today to be an essential element for advancing basic research and for assessing their potential use for medical applications.

Concerning the derivation of new human embryonic stem cell lines, community funding can only be made available for the derivation of these cells from human embryos created as a result of medically-assisted in vitro fertilisation designed to induce pregnancy and were no longer to be used for that purpose. Such human embryos, commonly referred to as supernumerary embryos, are kept frozen in dedicated facilities across Europe and are destined to be destroyed, according to national rules in place, if they are no longer the subject of a "parental project".

Excluding this research from community funding would have a negative impact. Collaborative research at community level avoids duplication of research and thus contributes to a reduction in the use of human supernumerary embryos for the derivation of human embryonic stem cell lines. In addition community funds stimulate exchanges of results and expertise among research teams from different Member States. This is expected to result in more rapid scientific progress for the benefit of patients across Europe even for those patients in countries where this research is not allowed.

By funding research projects involving the procurement of stem cells from human supernumerary embryos and setting strict ethical rules, the European community contributes in a responsible way to advancing this science for the benefit of patients across the world, while at the same time ensuring that it takes place within a clear ethical framework.

In parallel, the Commission is publishing in July 2003 a call for proposals on the set-up of a European registry of stem cells. It will fund, on the basis of a suitable proposal, such a registry and contribute to the establishment of public stem cell banks and their networking at European level. This should help scientists to access the different stem cell lines available in Europe in an easier and more affordable way. In doing so, the Commission will contribute to optimising the use of existing stem cell lines and help to ensure, in particular, that new human embryonic stem cell lines will be created only if necessary. This topic is part of the priorities set for the second call for proposals within the specific programme.

These guidelines will apply to the implementation of this specific programme. Scientific advances and national provisions will be regularly monitored by the Commission so as to take account of any relevant developments. In 2005, the Commission will produce a report providing an assessment of the stem cell research funded at community level and of the application of the guidelines established by this decision. The report will be taken into account in the preparation of successive research programmes.

## **The European context**

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.

No research involving the use of human embryos or human embryonic stem cells, of any type, will be supported by Community funding to a legal entity established in a country where such research is forbidden. Participants in research projects must conform to current legislation, regulations, and ethical rules in countries where the research will be carried out.

## **Regulatory procedure**

According to the article 6(3) of the decision 2002/834/EC on the specific programme for research, technological development and demonstration: "Integrating and strengthening the European Research Area" (2002-2006), any research project involving the use of human embryos and human embryonic stem cells will be submitted to a regulatory committee. This committee is, in this instance, the programme committee for this specific programme and the appropriate configuration is the one on: "Life sciences, genomics and biotechnology for health".

## **Implementation details**

### **Scope**

The proposed guidelines are 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 no longer to be used for that purpose (supernumerary embryos).

### **Reference**

The proposed guidelines are based on the principles established by the European Group on Ethics, especially the fundamental ethical principles underlined in the opinion No 15 "Ethical aspects of human stem cell research and use"<sup>7</sup>.

### **Guidelines**

This proposal amends the specific programme by introducing specific conditions for deciding on the Community funding of research activities involving the procurement of stem cells from human supernumerary embryos. These conditions will be assessed during the course of a scientific evaluation and an ethical review, both of which will be systematically performed for such research.

In the course of the scientific evaluation, the experts will assess whether the proposed research project serves particularly important research aims, whether there is an adequate alternative method to the use of these human embryonic stem cells and whether there are high quality and safety standards on donation, procurement and storage.

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<sup>7</sup> [http://europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://europa.eu.int/comm/european_group_ethics/index_en.htm)

In the course of the ethical review, the experts will assess whether ethical advice at local or national level in the countries where the research will be carried out is provided, whether a free, express and informed consent of the donors is obtained, whether the measures taken to protect the personal data including genetic data are adequate, and the absence of any monetary compensation for the donation.

Whenever the procurement of human embryonic stem cells from supernumerary embryos (as defined above) is not foreseen at the start of the project but is envisaged at a later stage during its implementation, a scientific evaluation and an ethical review will be implemented before these research activities may be undertaken.

This community funded research may only use existing human supernumerary embryos that were created before 27 June 2002, the date of adoption by Parliament and Council of the sixth framework programme.

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 this respect, the Opinion N° 16 "Ethical aspects of patenting inventions involving human stem cells" of the European Group on Ethics in Sciences and New Technologies is providing guidance.

In order to ensure transparency in Community funding of research activities involving human embryonic stem cells, the Commission will publish yearly a list of research projects involving the use of human embryonic stem cells funded under the sixth framework programme.

This proposal amends the Decision 2002/834/EC on the specific programme for research, "Integrating and strengthening the European Research Area" (2002-2006). The text of the proposed guidelines (see Annex) is to be introduced after the 17th paragraph of Annex I, Part 1.1 "Priority Thematic Areas of Research"<sup>8</sup>.

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<sup>8</sup> OJ L 294, 29.10.2002, p. 8.

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**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)**

**(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 Commission<sup>9</sup>,

Having regard to the Opinion of the European Parliament<sup>10</sup>,

Having regard to the Opinion of the European Economic and Social Committee<sup>11</sup>,

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 an open debate was held among experts and representatives of the Council, the European Parliament and the Commission, on the basis of a Commission staff working paper<sup>12</sup> 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.

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<sup>9</sup> OJ C [...], [...], p. [...].

<sup>10</sup> OJ C [...], [...], p. [...].

<sup>11</sup> OJ C [...], [...], p. [...].

<sup>12</sup> SEC (2003) 441 of 3.4.2003.

- (4) 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 of research using human embryos and human embryonic stem cells is handled very differently among Member States. 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.
- (5) 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.
- (6) 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.
- (7) 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).
- (8) These conditions should be assessed during the course of a scientific evaluation and an ethical review.
- (9) 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.
- (10) 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.
- (11) The Decision 2002/834/EC<sup>13</sup> should be amended accordingly.

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<sup>13</sup> OJ L 294, 29.10.2002, p.1.



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 17<sup>th</sup> paragraph.

“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 be provided in accordance with national legislation prior to the start of the research activities;
- (f) no monetary compensation or other benefit in kind must be granted or promised for the donation;
- (g) the protection of personal data, including the genetic data, of the donor(s) must be ensured;
- (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.

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”.