COMMISSION OF THE EUROPEAN COMMUNITIES



Brussels, 6.12.2006 COM(2006) 803 final

2005/0043 (COD)

OPINION OF THE COMMISSION

pursuant to Article 251 (2), third subparagraph, point (c) of the EC Treaty, on the European Parliament's amendments to the Council's common position regarding the proposal for a

DECISION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL

concerning the 7th Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013)

AMENDING THE PROPOSAL OF THE COMMISSION pursuant to Article 250 (2) of the EC Treaty

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1. Introduction

Article 251(2), third subparagraph, point (c) of the EC Treaty provides that the Commission is to deliver an opinion on the amendments proposed by the European Parliament at second reading. The Commission sets out its opinion below on the 40 amendments proposed by Parliament.

2. BACKGROUND

Date of the transmission of the proposal to the EP and Council (document COM(2005) 119 final - 2005/0043(COD)):

Date of the opinion of the Committee of Regions: 16 November 2005

Date of the opinion of the European Economic and Social Committee: 14 December 2005

Date of the opinion of the European Parliament in the first reading: 15 June 2006

Date of transmission of the amended proposal to the EP and Council: 28 June 2006

Date of adoption of the Common Position: 25 September 2006

Date of the opinion of the European Parliament at second reading: 30 November 2006

3. PURPOSE OF THE PROPOSAL

The proposal for the EC Framework programme, which covers the period 2007-2013, is based on Chapter XVIII of the Treaty, articles 163 to 171, which provides for an EU research policy and its financial instruments, in particular the multi-annual Research Framework Programme.

In order to strengthen excellence and raise the average level of research in Europe, the basic principle is to stimulate, organise and exploit all forms of cooperation in research, from collaboration in joint projects and networks to the coordination of national research

programmes, as well as the joint implementation of large technology initiatives and the common development of infrastructures of European dimension and interest.

The 7th Framework Programme is organised in four specific programmes, corresponding to four major objectives of European research policy:

- Cooperation. Support will be given to the whole range of research activities carried out in transnational cooperation, from collaborative projects and networks to the coordination of research programmes.
- *Ideas*. A European Research Council will be created to support investigator-driven "frontier–research" carried out by teams competing at the European level, in all scientific and technological fields, including engineering, socio-economic sciences and humanities.
- *People*. The activities supporting training and career development of researchers, referred to as "Marie Curie" actions, will be reinforced with a better focus on the key aspects of skills and career development and strengthened links with national systems.
- *Capacities*. Key aspects of European research and innovation capacities will be supported: research infrastructures; research for the benefit of SMEs; regional research driven clusters; unlocking the full research potential in the EU's convergence regions; science and society issues; horizontal activities of international co-operation.
- The Joint Research Centre's direct actions are also covered.

4. OPINION OF THE COMMISSION ON THE AMENDMENTS BY THE EUROPEAN PARLIAMENT

The amendments adopted by the European Parliament on 30 November 2006, relate mainly to the European Research Council, the renewable energy sources and energy efficiency, the budgetary distribution, the Risk Sharing Finance Facility. Some further modifications and the rearrangement of content, mostly in the themes of the Cooperation programme, have also been approved.

These amendments are the result of inter-institutional discussions that showed the complete agreement among the Commission, the European Parliament and the Council on all points included in them. Therefore, the Commission accepts all 40 amendments proposed by the Parliament.

The Commission also notes that the attached three statements on its side are elements of the overall final compromise that made possible the conclusion of the procedure at second reading.

5. CONCLUSION

Pursuant to Article 250(2) of the EC Treaty, the Commission amends its proposal as set out above.

Annex

Re: Article 6¹

"For the 7^{th} Framework Programme, the European <u>Commission</u> proposes to continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 6^{th} Framework Programme.

The European Commission proposes the continuation of this ethical framework because it has developed, based on experience, a responsible approach for an area of science which holds much promise and that has proven to work satisfactorily in the context of a research programme in which researchers participate from many countries with very diverse regulatory situations.

- (1) The decision on the 7th Framework Programme explicitly excludes three fields of research from Community funding:
 - Research activities aiming at human cloning for reproductive purposes;
 - Research activities intended to modify the genetic heritage of human beings which could make such changes heritable;
 - 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.
- (2) No activity will be funded that is forbidden in all Member States. No activity will be funded in a Member State where such activity is forbidden.
- (3) The decision on FP7 and the provisions for the ethical framework governing the Community funding of human embryonic stem cell research entail in no way a value judgement on the regulatory or ethical framework governing such research in Member States
- (4) In calling for proposals, the European Commission does not explicitly solicit the use of human embryonic stem cells. The use of human stem cells, be they adult or embryonic, if any, depends on the judgement of the scientists in view of the objectives they want to achieve. In practice, by far the largest part of Community funds for stem cell research is devoted to the use of adult stem cells. There is no reason why this would substantially change in FP7.
- (5) Each project proposing to use human embryonic stem cells must successfully pass a scientific evaluation during which the necessity of using such stem cells to achieve the scientific objectives is assessed by independent scientific experts.
- (6) Proposals which successfully pass the scientific evaluation are then subject to a stringent ethical review organised by the European Commission. In this ethical review, account is taken of principles reflected in the EU Charter of Fundamental Rights and

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relevant international conventions such as the Convention of the Council of Europe on Human Rights and Biomedicine signed in Oviedo on 4 April 1997 and its additional protocols and the Universal Declaration on the Human Genome and the Human Rights adopted by UNESCO. The ethical review also serves to check that the proposals respect the rules of the countries where the research will be carried out.

- (7) In particular cases, an ethical review may be carried out during the lifetime of the project.
- (8) Each project proposing to use human embryonic stem cells must seek the approval of the relevant national or local ethics committee prior to the start of the project. All national rules and procedures must be respected, including on such issues as parental consent, absence of financial inducement, etc. Checks will be made on whether the project includes references to licensing and control measures to be taken by the competent authorities of the Member State where the research will be carried out.
- (9) A proposal that successfully passes the scientific evaluation, the national or local ethical reviews and the European ethical review will be presented for approval, on a case by case basis, to the Member States, meeting as a Regulatory Committee. No project involving the use of human embryonic stem cells will be funded that does not obtain approval from the Member States.
- (10) The European Commission will continue to work to make the results from Community funded stem cell research widely accessible to all researchers, for the ultimate benefit of patients in all countries.
- (11) The European Commission will support actions and initiatives that contribute to a coordination and rationalisation of HESC research within a responsible ethical approach. In particular, the Commission will support a European registry of human embryonic stem cell lines. Support for such a registry will allow a monitoring of existing human embryonic stem cells in Europe, will contribute to maximise their use by scientists and may help to avoid unnecessary derivations of new stem cell lines.
- (12) The European Commission will continue with the current practice and will not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells. The exclusion of funding of this step of research will not prevent Community funding of subsequent steps involving human embryonic stem cells."

Re: "Energy" theme

"The ten themes of the Cooperation Programme include research needed to underpin the formulation, implementation and assessment of Community policies to which the Commission attaches a central role. It appreciates the importance that the European Parliament attaches to energy policy in general and to the promotion of energy efficiency and renewable energy sources in particular. In order to allow the Parliament to follow the implementation of the Programme, the Commission intends to continue the policy of transparency and provision of information. Appropriate information on projects funded by the FP will be fully available to the public through the internet. Particular attention will be given to ensuring, at least every two years, a comprehensive presentation of projects related to rational and efficient use of energy and the role of renewable energy sources."

Re: "Ideas"

"In the context of the progress report referred to in Article 7.2 and preceding the interim evaluation, the <u>Commission</u> will present to the European Parliament and the Council by mid-2008 a Communication on the methodology and terms of reference to be used for the review to be carried out by independent experts concerning the ERC's structures and mechanisms. If necessary the Commission will present a proposal for the adaptation of the Framework Programme."