


# Procedure file

Basic information		
CNS - Consultation procedure Decision	2003/0151(CNS)	Procedure lapsed or withdrawn
Research RTD, 6th framework programme 2002-2006: funding for projects on stem cells		
Subject		
3.50.02.01 EC, EU framework programme		
4.20.02.04 Genetics and bioethics		

Key players			
European Parliament	Committee responsible	Rapporteur	Appointed
	<b>ITRE</b> Industry, External Trade, Research, Energy		10/07/2003
		PPE-DE <a href="#">LIESE Peter</a>	
	Committee for opinion	Rapporteur for opinion	Appointed
	<b>JURI</b> Legal Affairs and Internal Market		20/10/2003
		PPE-DE <a href="#">GARGANI Giuseppe</a>	
Council of the European Union	<b>ENVI</b> Environment, Public Health, Consumer Policy		09/09/2003
		EDD <a href="#">BLOKLAND Johannes</a>	
	Council configuration	Meeting	Date
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space) 2811</a>		25/06/2007
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space) 2550</a>		03/12/2003
	<a href="#">Competitiveness (Internal Market, Industry, Research and Space) 2547</a>		26/11/2003
European Commission	Commission DG <a href="#">Research and Innovation</a>	Commissioner	POTOČNIK Janez

Key events			
09/07/2003	Legislative proposal published	<a href="#">COM(2003)0390</a>	Summary
01/09/2003	Committee referral announced in Parliament		
04/11/2003	Vote in committee		Summary
04/11/2003	Committee report tabled for plenary, 1st reading/single reading	<a href="#">A5-0369/2003</a>	
17/11/2003	Debate in Parliament		

19/11/2003	Decision by Parliament	<a href="#">T5-0506/2003</a>	Summary
26/11/2003	Debate in Council	<a href="#">2547</a>	
26/11/2003	Modified legislative proposal published	<a href="#">COM(2003)0749</a>	Summary
03/12/2003	Debate in Council	<a href="#">2550</a>	Summary
25/06/2007	Resolution/conclusions adopted by Council		Summary
13/03/2008	Proposal withdrawn by Commission		
13/03/2008	Additional information		Summary

#### Technical information

Procedure reference	2003/0151(CNS)
Procedure type	CNS - Consultation procedure
Procedure subtype	Legislation
Legislative instrument	Decision
Legal basis	EC Treaty (after Amsterdam) EC 166-p4
Stage reached in procedure	Procedure lapsed or withdrawn
Committee dossier	ITRE/5/19939

#### Documentation gateway

Legislative proposal	<a href="#">COM(2003)0390</a>	09/07/2003	EC	Summary
Economic and Social Committee: opinion, report	<a href="#">CES1400/2003</a> <a href="#">OJ C 032 05.02.2004, p. 0081-0087</a>	29/10/2003	ESC	
Committee report tabled for plenary, 1st reading/single reading	<a href="#">A5-0369/2003</a>	04/11/2003	EP	
Text adopted by Parliament, 1st reading/single reading	<a href="#">T5-0506/2003</a> OJ C 087 07.04.2004, p. 0076-0390 E	19/11/2003	EP	Summary
Modified legislative proposal	<a href="#">COM(2003)0749</a>	26/11/2003	EC	Summary

#### Additional information

European Commission	<a href="#">EUR-Lex</a>
---------------------	-------------------------

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

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 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. ?

---

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

---

The committee adopted the report by Peter LIESE (EPP-ED, D) amending the proposal under the consultation procedure as follows: - whereas the Commission was proposing that human embryos used for the procurement of stem cells must have been created before 27 June 2002 (the date of adoption of the 6th framework programme), the committee said that the embryos must be 'supernumerary' early-stage (i.e. up to 14 days) but did not specify a cut-off date for their creation; - any decision on whether or not to allow funding of research on the use of human stem cells should depend both on the contents of the scientific proposal and the legal framework of the Member States involved; - support should also be given to research projects using adult somatic stem cells and umbilical cord blood cells; - research using adult stem cells and reprogrammed adult cells should get priority for financing; - research on embryo or foetal stem cells deriving from spontaneous or therapeutic abortion may be funded; - the prior agreement of the parents must be secured in cases where embryos are to be destroyed in order to produce human embryonic stem cell lines; - the Commission should set up a European register of embryonic stem cells, using the experience of the NIH (a leading US public medical research centre); - the list of research projects funded under the 6th framework programme involving the use of human embryonic stem cells, which is to be published yearly by the Commission, must include a justification stating why other procedures were not usable. ?

---

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

---

The European Parliament adopted a resolution based loosely on the draft by Peter LIESE (EPP-ED, Germany) making some amendments to the Commission's proposals. (Please see the summary of 04/11/03.) Parliament voted 300 votes in favour, 210 against and 19 abstentions. The amendments are as follows: - the proposed cut-off date (27 June 2002) for the procurement of human embryos used for the procurement of stem cells should be removed; - research using adult stem cells should be given priority for financing; - 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; - research funding should depend on the contents of the scientific proposal and the legal framework of the Member States involved; - no monetary compensation may be granted for the donation of embryos used for the recovery of stem cells; - research on embryo or foetal stem cells deriving from spontaneous or therapeutic abortion may be funded. It should be noted that the rapporteur Peter Liese, who had been advocating a compromise amendment, "disassociated" himself with the outcome of the vote.?

---

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

---

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.?

---

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

---

The Council examined a text put forward by the Presidency, following the Council's deliberations at its meeting on 26 November, on the establishment of implementing provisions for Community funding of research projects involving the use of human embryos and human embryonic stem cells. At the end of the discussion, the President concluded that no agreement could be reached either on the Commission's amended proposal or on the Presidency text. The Commission, for its part, could not support the Presidency text.?

---

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

---

The Council adopted conclusions on the coordination of Community funding programmes for research. It acknowledged the importance of improving synergies and complementarity between large Community funding programmes, including in the area of research and innovation policy as well as regional policy, in light of their respective goals.

It recognised the substantial work done by CREST in analysing the possibilities to better coordinate the use of the Research Framework

Programme and the Structural Funds to support R&D and welcomed the guidelines document and the 14 recommendations adopted at the 314th CREST meeting on 7 May 2007.

The Council recalled the six priority domains identified in the CREST guidelines:

- Develop RTDI strategies and strengthen the governance,
- Strengthen and develop the RTDI basis,
- Develop RTDI excellence,
- Develop R&D cooperation at European and international level,
- Strengthen exploitation and economic and social valorisation of R&D results,
- Improve communication and information.

The importance of improved communication between actors involved in FP and SF activities, was emphasised.

The Member States were called upon to implement the guidelines at national and regional level on a voluntary basis. It encouraged policy-makers to disseminate them widely in their area of responsibility.

The Council welcomed the Commission's intention to bring forward a Communication on Competitive European Regions Through Research and Innovation. It supported the idea that the impetus created by the adoption of FP 7 should be used and that the subject merits further discussion and follow-up activities at a European, national and regional scale, for example through qualified bodies such as CREST, COCOF, EURAB, involving the Committee of the Regions and regional policy and research and innovation experts.

Lastly, it underlined the particular importance of further discussion and follow-up activities on the development of RDTI strategies and the strengthening of governance and the development of RDTI excellence in this context.

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

---

As announced in Official Journal C 68 of 13 March 2008, the Commission decided to withdraw this proposal, which had become obsolete.