



EUROPEAN PARLIAMENT

2009 - 2014

Committee on Legal Affairs

2011/0401(COD)

18.9.2012

OPINION

of the Committee on Legal Affairs

for the Committee on Industry, Research and Energy

on the proposal for a regulation of the European Parliament and of the Council
establishing Horizon 2020 - The Framework Programme for Research and
Innovation (2014-2020)
(COM(2011)0809 – C7-0466/2011 – 2011/0401(COD))

Rapporteur: Piotr Borys

PA_Legam

SHORT JUSTIFICATION

This regulation is part of the Horizon 2020 package presented by the Commission in November 2011. The aim of the package is to establish the Framework Programme for Research and Innovation for the 2014-2020 period.

The European Union's research and innovation policy is of particular importance for the Union's competitiveness. The aim is for the EU to adapt to the changing world by pursuing a research policy which puts it at the forefront of technology, thus creating jobs and boosting the economy.

This regulation is the main instrument in the Horizon 2020 package. It establishes the Framework Programme for Research and Innovation itself. As the main regulation, this instrument is subject to the codecision procedure.

The Committee on Legal Affairs' interest in this decision is largely restricted to ethical issues, as its responsibility includes ethical questions related to new technologies. The committee has therefore restricted its amendments to the ethical issues raised by the draft regulation.

The main ethical issue at stake is that of research using human embryonic stem cells. The Seventh Framework Programme (2007-2013) was approved after a delicate compromise was reached on that ethical issue. This draft opinion aims to address that problem whilst aiming for greater legal certainty.

The committee therefore proposes that research which either involves the destruction of human embryos or which uses human embryonic stem cells should be completely excluded from EU funding. It would thus be up to individual Member States to decide, in line with their ethical rules, whether to fund such research from their own budgets.

AMENDMENTS

The Committee on Legal Affairs calls on the Committee on Industry, Research and Energy, as the committee responsible, to incorporate the following amendments into its report:

Amendment 1

Proposal for a regulation **Recital 23 a (new)**

Text proposed by the Commission

Amendment

***(23a) Research and innovation often
builds on the capacity of scientists,
research institutions, businesses and***

citizens to access, share and use scientific information. To increase the circulation and exploitation of knowledge, sustainable access to scientific publications, already embraced in the Seventh Framework Programme, should be a general principle for scientific publications which receive public funding from Horizon 2020. Furthermore, Horizon 2020 should experiment with online open access to scientific data produced or collected by publicly funded research aiming at open access to such data becoming the general rule by 2020. Where appropriate, the costs of publishing may be covered by the Horizon 2020 budget.

Amendment 2

Proposal for a regulation

Recital 24

Text proposed by the Commission

(24) Research and innovation activities supported by Horizon 2020 should respect fundamental ethical principles. The opinions of the European Group on Ethics in Science and New Technologies should be taken into account. Research activities should also take into account Article 13 TFEU and reduce the use of animals in research and testing, with a view ultimately to replacing animal use. All activities should be carried out ensuring a high level of human health protection in accordance with Article 168 TFEU.

Amendment

(24) Research and innovation activities supported by Horizon 2020 should respect fundamental ethical principles. The opinions of the European Group on Ethics in Science and New Technologies should be taken into account. Research activities should also take into account Article 13 TFEU and reduce the use of animals in research and testing, with a view ultimately to replacing animal use. ***Research activities should also respect the legal or administrative provisions and customs of Member States.*** All activities should be carried out ensuring a high level of human health protection in accordance with Article 168 TFEU ***and with Article 35 of the EU Charter of Fundamental Rights in order to facilitate the realisation of the right of everyone to access preventive health care and the right to benefit from medical treatment under the conditions established by national laws and***

practices.

Justification

This amendment seeks to stress that research remains subject to national law.

Amendment 3

Proposal for a regulation

Recital 25

Text proposed by the Commission

(25) 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 and is subject to stringent Ethics Review. No project involving the use of human embryonic stem cells should be funded that does not obtain the necessary approvals from the Member States. No activity should be funded that is forbidden in all Member States. No activity should be funded in a Member State where such activity is forbidden.

Amendment

(25) There are considerable differences between national laws on research using human embryos and human embryonic stem cells. Union policy should not seek to harmonise national legislation. In connection with the Seventh Framework Programme, the Commission declared that it would 'continue with the current practice and [would] not submit to the Regulatory Committee proposals for projects which include research activities which destroy human embryos, including for the procurement of stem cells'¹. This commitment should be inserted into this Regulation in order to ensure legal certainty. The Commission should actively support research aimed at developing alternatives to embryonic stem cells.

¹ ***Point 12 of the Commission statement re Article 6, annexed to Decision No 1982/2006/EC of the European Parliament and of the Council of 18 December 2006 concerning the Seventh Framework Programme of the European Community for research, technological development and demonstration activities (2007-2013) (OJ L 412, 30.12.2006, p. 1).***

Justification

The purpose of this amendment is to give legal force to the Commission's commitment on stem cell research.

Amendment 4

Proposal for a regulation Article 13 – paragraph 1

Text proposed by the Commission

1. Linkages and interfaces shall be implemented across and within the priorities of Horizon 2020. Particular attention shall be paid in this respect to the development and application of key enabling and industrial technologies, to bridging from discovery to market application, to cross-disciplinary research and innovation, to social and economic sciences and humanities, to fostering the functioning and achievement of the ERA, to cooperation with third countries, to responsible research and innovation including gender, and to enhancing the attractiveness of the research profession and to facilitating cross-border and cross-sector mobility of researchers.

Amendment

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Justification

In view of the legal and ethical problems of certain kinds of research, legal research should also be funded by the proposal.

Amendment 5

Proposal for a regulation Article 15 – paragraph 1 a (new)

Text proposed by the Commission

Amendment

1a. In research projects where human beings are involved as subjects or end-users, Horizon 2020 shall ensure that all participants and societal groups are treated equally.

Amendment 6

Proposal for a regulation Article 15 a (new)

Text proposed by the Commission

Amendment

Article 15 a

Open Access

With a view to enhancing the exploitation and dissemination of results and thereby boosting European innovation, sustainable open access to publications resulting from research funded by Horizon 2020 shall be encouraged, whilst taking care to ensure that European scientists are able to publish in the most highly regarded journals and other fora. Open access to scientific data produced or collected in research funded by Horizon 2020 may be promoted.

Where publications resulting from Horizon 2020 are to be published in an open access, free-to-read format, the cost of publication shall be covered by the Horizon 2020 budget.

Amendment 7

Proposal for a regulation Article 16 – paragraph 1 – subparagraph 1

Text proposed by the Commission

Amendment

1. All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union **and** the European Convention on Human Rights and its Supplementary Protocols.

1 All the research and innovation activities carried out under Horizon 2020 shall comply with ethical principles and relevant national, Union and international legislation, including the Charter of Fundamental Rights of the European Union, the European Convention on Human Rights and its Supplementary Protocols, **the Declaration of Helsinki on Ethical Principles for Medical Research Involving Human Subjects of the World Medical Association, the Council of**

Europe Convention of 4 April 1997 for the Protection of Human Rights and Dignity of the Human Being with regard to the Application of Biology and Medicine, with its additional protocols, and Resolution No 59/280 of the General Assembly of the United Nations of 8 March 2005 on Human Cloning.

Amendment 8

Proposal for a regulation

Article 16 – paragraph 3 – point c

Text proposed by the Commission

(c) **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.

Amendment

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Amendment 9

Proposal for a regulation

Article 16 – paragraph 3 – point c a (new)

Text proposed by the Commission

Amendment

(ca) research which involves the destruction of human embryos;

Justification

This amendment precludes funding for research which involves the destruction of human embryos.

Amendment 10

Proposal for a regulation

Article 16 – paragraph 3 – point c b (new)

Text proposed by the Commission

Amendment

(cb) research using human embryonic

stem cells.

Justification

This amendment precludes the funding of research which uses human embryonic stem cells.

Amendment 11

Proposal for a regulation
Article 16 – paragraph 4

Text proposed by the Commission

4. Research on human stem cells, ***both adult and embryonic***, may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

Amendment

4. Research on ***other types of*** human stem cells may be financed, depending both on the contents of the scientific proposal and the legal framework of the Member States involved. No funding shall be granted for research activities that are prohibited in all the Member States. No activity shall be funded in a Member State where such activity is forbidden.

Justification

This is a consequential amendment following the ban on funding for research using human embryonic stem cells.

Amendment 12

Proposal for a regulation
Article 22 – paragraph 3 – point c

Text proposed by the Commission

(c) actions which bring together results from a range of projects, including those that may be funded from other sources, to provide user-friendly databases and reports that summarise key findings;

Amendment

(c) actions which bring together results from a range of projects, including those that may be funded from other sources, to provide user-friendly databases and reports that summarise key findings ***and, where relevant, their communication and dissemination to the scientific community and the general public;***

PROCEDURE

Title	Establishment of Horizon 2020 - The Framework Programme for Research and Innovation (2014-2020)	
References	COM(2011)0809 – C7-0466/2011 – 2011/0401(COD)	
Committee responsible Date announced in plenary	ITRE 13.12.2011	
Opinion by Date announced in plenary	JURI 13.12.2011	
Rapporteur Date appointed	Piotr Borys 19.12.2011	
Discussed in committee	26.4.2012	19.6.2012
Date adopted	18.9.2012	
Result of final vote	+: 18 -: 5 0: 2	
Members present for the final vote	Raffaele Baldassarre, Luigi Berlinguer, Sebastian Valentin Bodu, Françoise Castex, Christian Engström, Marielle Gallo, Giuseppe Gargani, Lidia Joanna Geringer de Oedenberg, Sajjad Karim, Klaus-Heiner Lehne, Antonio Masip Hidalgo, Jiří Maštálka, Alajos Mészáros, Bernhard Rapkay, Evelyn Regner, Francesco Enrico Speroni, Dimitar Stoyanov, Rebecca Taylor, Alexandra Thein, Rainer Wieland, Cecilia Wikström, Tadeusz Zwiefka	
Substitute(s) present for the final vote	Piotr Borys, Eva Lichtenberger, Angelika Niebler, Dagmar Roth-Behrendt, József Szájer	
Substitute(s) under Rule 187(2) present for the final vote	Jacek Włosowicz	