COUNCIL OF THE EUROPEAN UNION

Brussels, 3 June 2014

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INST 265
FIN 393
DEVGEN 152
COHOM 93
RECH 236
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COVER NOTE

from:	Secretary-General of the European Commission, signed by Mr Jordi AYET PUIGARNAU, Director
date of receipt:	2 June 2014
to:	Mr Uwe CORSEPIUS, Secretary-General of the Council of the European Union
No Cion doc.:	COM(2014) 355 final ANNEXES 1-5
Subject:	ANNEXES to the COMMUNICATION FROM THE COMMISSION on the European Citizens' Initiative "One of us"

Delegations will find attached the annexes to the Commission document COM(2014) 355 final ANNEXES 1-5.

Encl.: COM(2014) 355 final ANNEXES 1-5

EUROPEAN
COMMISSION

Brussels, 28.5.2014
COM(2014) 355 final

ANNEXES 1 to 5

ANNEXES

to the

COMMUNICATION FROM THE COMMISSION

on the European Citizens' Initiative "One of us"

ANNEX I: PROCEDURAL ASPECTS OF THE ONE OF US CITIZENS' INITIATIVE

In accordance with Article 4(2) of Regulation (EU) No 211/2011 the present Initiative was registered on 11/05/2012 and published in the Commission's online register.

The members of the Citizens' committee registered with the Commission are residents of the following Member States: France, Italy, the United Kingdom, Hungary, Poland, Spain, and Germany.

The Initiative was registered in Italian. Then the organisers provided translations of the title, subject-matter, and objectives of the Initiative in all official EU languages.

In accordance with the Regulation on the Citizens' Initiative, the forms used by citizens to give their support to the Initiative contained the title, subject-matter and objectives of the Initiative. The link to the Commission's online register was also available on the forms, allowing citizens who wished so to find more detailed information on the Initiative, as provided by the organisers in a draft legal act as part of their registration request. The organisers provided translations of this draft legal act in 19 official EU languages. This draft legal act may not have been consulted by all citizens who supported the Initiative.

The formal 12-month collection period for the Initiative ended on 11 May 2013. However, the Commission has accepted statements in support of the Initiative up until 1 November 2013, due to the difficulties that most organisers experienced as regards the setting-up of their online collection systems during the start-up phase of the European Citizens' Initiative[1]. After the verification of the collected statements of support by the relevant competent Member States' authorities, the organisers submitted their Initiative to the Commission on 28 February 2014, together with certificates issued by the 28 Member States' competent authorities and information on their sources of funding and support, in accordance with Article 9 of the Regulation.

The number of valid statements of support indicated in the certificates and information provided by the Member States' competent authorities are reflected in the table below. These figures take into account the additional collection period until 1 November 2013.

Member State	Number of signatories	Threshold to be counted among the minimum number of seven Member States
Belgium	5 478	16 500
Bulgaria	906	13 500
Czech Republic	11 468	16 500
Denmark	7 563	9 750
Germany	137 874	74 250
Estonia	2 417	4 500
Ireland	6 679	9 000

[1] press release 18/07/2012: http://ec.europa.eu/commission_2010-2014/sefcovic/headlines/press-releases/2012/07/2012_07_18_eci_en.htm

Greece	52 977	16 500
Spain	144 827	40 500
France	83 503	55 500
Croatia	12 778	9 000
Italy	623 947	54 750
Cyprus	6 407	4 500
Latvia	9 132	6 750
Lithuania	11 646	9 000
Luxembourg	5 469	4 500
Hungary	45 933	16 500
Malta	23 017	4 500
Netherlands	27 271	19 500
Austria	24 973	14 250
Poland	235 964	38 250
Portugal	65 564	16 500
Romania	110 405	24 750
Slovenia	3 481	6 000
Slovakia	31 951	9 750
Finland	1 230	9 750
Sweden	2 468	15 000
United Kingdom	26 298	54 750
Total	**1 721 626**	**Threshold reached in 18 Member States**

In accordance with Article 10 of the Regulation, the Commission:

- published on 28 February 2014 the relevant information in the register at:

http://ec.europa.eu/citizens-initiative/public/initiatives/finalised/details/2012/000005

- received the organisers on 9 April 2014.

On 10 April 2014, in accordance with Article 11 of the Regulation, organisers were given the opportunity to present their Initiative in a public hearing organised at the European Parliament.

During the meeting at the Commission, the Commission was represented by Commissioner Geoghegan-Quinn and senior officials from DG DEVCO and other services concerned.

Both Commissioner Geoghegan-Quinn and Commissioner Piebalgs represented the Commission at the public hearing.

ANNEX II: Horizon 2020 Regulation – Article 19[2]

Article 19

Ethical principles

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.

Particular attention shall be paid to the principle of proportionality, the right to privacy, the right to the protection of personal data, the right to the physical and mental integrity of a person, the right to non-discrimination and the need to ensure high levels of human health protection.

2. Research and innovation activities carried out under Horizon 2020 shall have an exclusive focus on civil applications.

3. The following fields of research shall not be financed:

(a) research activity aiming at human cloning for reproductive purposes;

(b) research activity intended to modify the genetic heritage of human beings which could make such changes heritable (1);

(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.

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.

5. The fields of research set out in paragraph 3 of this Article may be reviewed within the context of the interim evaluation set out in Article 32(3) in the light of scientific advances.

[2] REGULATION (EU) No 1291/2013 of the European Parliament and of the Council of 11 December 2013 establishing Horizon 2020 - the Framework Programme for Research and Innovation (2014-2020) and repealing Decision No 1982/2006/EC.

ANNEX III: Horizon 2020 – Commission Statement[3]

Declarations of the Commission (Framework Programme)

2013/C 373/02

STATEMENT BY THE COMMISSION

For the Horizon 2020 Framework Programme, the European Commission proposes to continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 7th Framework Programme.

The European Commission proposes the continuation of this ethics 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 Horizon 2020 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 Horizon 2020 and the provisions for the ethics framework governing the Community funding of human embryonic stem cell research entail in no way a value judgment on the regulatory or ethics 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 judgment 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 Horizon 2020.

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 ethics review organised by the European Commission. In this ethics review, account is

[3] Official Journal of the European Union, C 373/1220.12.2013.

taken of principles reflected in the EU Charter of Fundamental Rights and 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 ethics 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 ethics check 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 ethics reviews and the European ethics review will be presented for approval, on a case by case basis, to the Member States, meeting as a committee acting in accordance with the examination procedure. 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 continue to 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 committee acting in accordance with the examination procedure 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.

ANNEX IV: FP7 Decision – Article 6[4]

Article 6

Ethical principles

1. All the research activities carried out under the Seventh Framework Programme shall be carried out in compliance with fundamental ethical principles.

2. The following fields of research shall not be financed under this Framework Programme:

— research activity aiming at human cloning for reproductive purposes,

— research activity intended to modify the genetic heritage of human beings which could make such changes heritable (2),

— 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.

3. 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 State(s) involved.

Any application for financing for research on human embryonic stem cells shall include, as appropriate, details of licensing and control measures that will be taken by the competent authorities of the Member States as well as details of the ethical approval(s) that will be provided.

As regards the derivation of human embryonic stem cells, institutions, organisations and researchers shall be subject to strict licensing and control in accordance with the legal framework of the Member State(s) involved.

4. The fields of research set out above shall be reviewed for the second phase of this programme (2010-2013) in the light of scientific advances.

[4] 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).

ANNEX V: FP7 – Commission Statement[5]

Re Article 6

For the 7th Framework Programme, the European Commission proposes to continue with the same ethical framework for deciding on the EU funding of human embryonic stem cell research as in the 6th 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 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

[5] Official Journal of the European Union, L 412/42, 30.12.2006.

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.