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COMMUNICATION FROM THE COMMISSION

on the European Citizens' Initiative "One of us"

1. INTRODUCTION

The European Citizens' Initiative, introduced by the Lisbon Treaty to encourage a greater democratic involvement of citizens in European affairs[1], allows one million citizens of the European Union (EU), coming from at least seven Member States, to call on the European Commission to propose legislation on matters of EU competence. Complete information on this new legal instrument and on all initiatives launched to date can be found in the Official Register on the European Citizens' Initiative[2].

"One of Us" is the second European Citizens' Initiative to have met the requirements set out in the Regulation of the European Parliament and the Council on the citizens' Initiative. It was officially submitted to the Commission by its organisers on 28 February 2014, having received the support of more than 1.7 million citizens with thresholds reached in 18 Member States.

In line with the provisions of the Regulation on the citizens' Initiative, the Commission has three months within which to present its response in a Communication setting out "its legal and political conclusions on the Initiative, the action it intends to take, if any, and its reasons for taking or not taking that action"[3].

The Commission received the organisers on 9 April 2014; on 10 April, the organisers were given the opportunity to present their Initiative at a public hearing organised by the Commission and European Parliament at the European Parliament. Annex I provides further information on the procedural aspects of the citizens' Initiative.

The subject matter of the "One of Us" Initiative concerns the "*juridical protection of the dignity, the right to life and of the integrity of every human being from conception in the areas of EU competence in which such protection is of particular importance*"[4].

Under the main objectives the organisers state that "*the human embryo deserves respect to its dignity and integrity. This is enounced by the European Court of Justice in the Brüstle case, which defines the human embryo as the beginning of the development of the human being. To ensure consistency in areas of its competence where the life of the human embryo is at stake, the EU should establish a ban and end the financing of activities which presuppose the destruction of human embryos, in particular in the areas of research, development aid and public health*".

The Annex requests three legislative amendments:

– The Financial Regulation[5]: Principle of consistency*: No budget allocation will be made for the funding of activities that destroys human embryos, or that presumes their destruction;*

[1] REGULATION (EU) No 211/2011 of the European Parliament and of the Council on the citizens' initiative,, OJ L 65, 11.3.2011, p. 1

[2] Official Register can be consulted online under: http://ec.europa.eu/citizens-initiative/public/welcome

[3] In line with the provisions of article 10 (1) of the Regulation on the citizens' initiative

[4] http://ec.europa.eu/citizens-initiative/public/initiatives/ongoing/details/2012/000005

[5] REGULATION (EU, Euratom) No 966/2012 of the European Parliament and of the Council of 25 October 2012 on the financial rules applicable to the general budget of the Union and repealing Council Regulation (EC, Euratom) No 1605/2002, OJ L 298, 26.10.2012, p. 1; COMMISSION DELEGATED REGULATION (EU) No 1268/2012 of 29 October 2012 on the rules of application of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union? OJ L 362, 31.12.2012, p. 1

– Research funding – The Horizon 2020 Regulation[6]: Ethical principles: The following fields of research shall not be financed: […] *Research activities that destroy human embryos, including those aimed at obtaining stem cells, and research involving the use of human embryonic stem cells in subsequent steps to obtain them;*

– Development cooperation - Development Cooperation Instrument (DCI) Regulation[7]: Scope: *The assistance of the Union, on the basis of this Regulation, shall not be used to fund abortion, directly or indirectly, through the funding of organizations that encourage or promote abortion. No reference is made in this Regulation to reproductive and sexual health, health care, rights, services, supplies, education and information at the International Conference on Population and on Development, its principles and Program of Action, the Cairo Agenda and the Millennium Development Goals, in particular MDG n. 5 about health and maternal mortality, can be interpreted as providing a legal basis for using EU funds to finance directly or indirectly abortion;*

The Initiative must be considered in accordance with EU Treaty rules, including notably the principles of conferral, proportionality and subsidiarity.

2. STATE OF PLAY

2.1. Human Dignity in EU Legislation

The Treaty on European Union (TEU) explicitly enshrines human dignity, the right to life, and the right to the integrity of the person. According to Article 2 TEU, "the Union is founded on the values of respect for human dignity, freedom, democracy, equality, the rule of law and respect for human rights, including the rights of persons belonging to minorities". According to Article 21 TEU, "the Union's action on the international scene shall be guided by the principles which have inspired its own creation, development and enlargement, and which it seeks to advance in the wider world: democracy, the rule of law, the universality and indivisibility of human rights and fundamental freedoms, respect for human dignity, the principles of equality and solidarity, and respect for the principles of the United Nations Charter and international law".

The Charter of Fundamental Rights of the European Union, which constitutes an integral part of the EU Treaties and which is binding upon the EU institutions, protects in its first three articles, respectively, human dignity, the right to life, and the right to the integrity of the person.

All EU legislation and all EU expenditure must comply with the Treaties and the Charter, and must therefore respect human dignity, the right to life, and the right to the integrity of the person. This therefore also applies to EU legislation and expenditure on human embryonic stem cell research and development cooperation.

It should be noted that the so-called Brüstle judgement of the European Court of Justice (Case C-34/10, Brüstle v Greenpeace), which was referred to by the organisers in their objectives, stated that "the purpose of the [Biotech] Directive is not to regulate the use of human embryos in the context of scientific research. It is limited to the patentability of biotechnological

[6] 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, OJ L 347, 20.12.2013, p. 104.

[7] REGULATION (EU) No 233/2014 of the European Parliament and of the Council of 11 March 2014 establishing a financing instrument for development cooperation for the period 2014-2020, OJ L 77, 13.03.2014, p. 44

inventions".[8] It did not deal with the question of whether such research can be carried out and whether it can be funded.

2.2. Human Embryonic Stem Cell Research

2.2.1. Stem Cell Research

Human embryonic stem cell (hESC) research has the potential to contribute to the next generation of healthcare by offering treatments or possible cures for untreatable and/or life-threatening diseases, such as Parkinson's, diabetes, stroke, heart disease and blindness. For instance, 1.2 million European citizens are estimated to be suffering from Parkinson's disease today[9].

Embryonic stem cells are unique because they can form any of the cells of the body and scientists use this feature to make new cells that can be transplanted into patients to replace damaged or diseased tissue. In addition, studies of embryonic stem cells enable biologists[10] to understand how our tissues develop and maintain themselves, and stem cells are also used to screen new drugs to decrease their risk of toxicity and to advance pharmaceutical research. Embryonic stem cells are cell lines capable of producing an infinite number of identical cells which can be frozen, stored and shipped to other laboratories for further culture and experimentation. Researchers therefore almost always use cell lines that already exist rather than creating new ones using spare blastocysts[11] left over from fertility treatment which are donated for research following explicit, written, informed consent. Clinical trials of treatments based on human embryonic stem cells are ongoing, covering diseases such as spinal cord injury, heart failure and various forms of blindness, and are being carried out in US, France, South Korea and UK.[12]

Tissue-specific or adult stem cells have also been identified; they are found in certain tissues of the body and are valuable for therapy in some, but not all cases. Induced pluripotent stem cells (iPSC), are adult, specialised cells that have been genetically reprogrammed. The researcher who discovered this technique, building on prior knowledge obtained from research on embryonic stem cells, was awarded the 2012 Nobel Prize. Induced pluripotent stem cells have many similar properties to embryonic stem cells and research continues to make progress; however, these cells cannot yet be produced to clinical standard or be treated as natural cells. One clinical trial is beginning in Japan using induced pluripotent stem cells[13].

The discovery and ongoing development of iPSC has been reliant on hESC research, and embryonic stems cells remain important for the development of iPSC research – the knowledge derived from both is complimentary. Given the promise of stem cell therapies for many diseases and the fast pace of movement in research on them, many areas of research

[8] Paragraph 40 of the Judgment of the Court of Justice of the European Union (Grand Chamber), 18 October 2011, Reports of Cases 2011 I-09821

[9] http://www.epda.eu.com/en/#

[10] http://workshops.biologists.com/workshop_sept_2014.html

[11] A blastocyst is the structure consisting of about a hundred cells formed at about five or six days after fertilisation and not yet implanted in the uterus.

[12] www.clinicaltrials.gov; http://www.advancedcell.com

[13] http://apps.who.int/trialsearch/

may be pursued simultaneously to find the best cell source for a particular medical application.[14]

2.2.2. Competences and activities of Member States in this area

Human embryonic stem cell research in Europe is subject to national laws and regulations which vary from country to country. These range from countries which permit the establishment of human embryonic stem cell lines to those which do not permit this step but allow the importation of embryonic stem cell lines, those which prohibit any form of research on human embryonic stem cells, and those that have no specific legislation on the matter. Currently, human embryonic stem cell research is permitted, subject to controls and conditions in 18 Member States, whilst 3 prohibit it and the rest have no specific legislation.[15]

2.2.3. Competences and activities at Union level in this area

Treaty Provisions on Research

Article 182 of the Treaty on the Functioning of the European Union (TFEU) provides the legal basis for EU research programmes: "A multiannual framework programme, setting out all the activities of the Union, shall be adopted by the European Parliament and the Council, acting in accordance with the ordinary legislative procedure after consulting the Economic and Social Committee".

These EU research programmes are adopted without prejudice to Member State activities in the field of research. The reason is that according to primary EU law – the Lisbon Treaty, research is a parallel competence. According to Article 4(3) TFEU, "in the areas of research, technological development and space, the Union shall have competence to carry out activities, in particular to define and implement programmes; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs".

Horizon 2020 – The EU Research and Innovation Programme

Horizon 2020 is the EU Research and Innovation programme with nearly €80 billion of funding available over the next seven years (2014 - 2020). To develop this new programme, the Commission launched a wide-ranging consultation involving all key stakeholders, and took into account discussions with the European Parliament and Council, as well as lessons learnt from previous programmes. The Commission also took into account the recommendations of the European Group on Ethics[16] and the findings of a Eurobarometer survey, in which a randomised sample of citizens from across Europe were asked their views on a range of topics including embryonic stem cell research. The majority approved of

[14] With respect to this issue, 2012 Nobel Prize winner Yamanaka stated: "*Embryonic stem cells are still important for the development of iPS* cell research. Findings from research on embryonic stem cells, such as methods to create various types of cells, have been applied to iPS *cell research. That's why iPS cell research has evolved so rapidly. In addition, embryonic stem cells are used as control [comparison] materials when researchers conduct experiments on iPS cells and analyze their quality"* (http://articles.latimes.com/2010/nov/27/science/la-sci-yamanaka-20101127).

[15] ESF Science Policy Briefing 38, http://www.esf.org/publications/science-policy-briefings.html

[16] Recommendations on the ethical review of hESC FP7 research projects (Opinion 22) European Group on Ethics in Science and New Technologies (EGE) 20 June 2007. http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf
The EGE is an independent, pluralist and multidisciplinary body advising the European Commission on ethics in science and new technologies in connection with Community legislation or policies.

embryonic stem cell research.[17] The Commission, taking into account all aspects of support for research including the added value of support at EU level, ethical considerations and the potential health benefits of all types of stem cell research, presented its proposal in November 2011.

In the democratic process that led to agreement by Council and Parliament on Horizon 2020 in December 2013, the Commission, Council and Parliament also took into account all aspects of support for research. The outcome of Horizon 2020 discussions by elected representatives is that EU support for health research is foreseen and human embryonic stem cell research is possible, restricted to research subsequent to the establishment of stem cell lines.

It was agreed that EU level human embryonic stem cell research projects add value to Member State activities in this area in compliance with the principle of subsidiarity.[18] In the field of research, the EU adds value to Member States' activities by supporting cross-border collaborative research where a critical mass of complementary knowledge and financial resources is required for breakthroughs. This is particularly the case in human embryonic stem cell research, where bringing a new stem cell therapy to the clinic requires many scientific disciplines and many different skills and resources. Cross-border collaborative research projects also help increase coordination and reduce duplicative and therefore unnecessary production and use of stem cell lines.

It was also agreed that human embryonic stem cell research holds potential for valuable breakthroughs in health research and that the checks and balances proposed, identical to those agreed in FP7, provide appropriate safeguards to ensure compliance with the strict rules in place.

The Horizon 2020 Framework Governing Human Embryonic Stem Cell Research

Horizon 2020 support for human embryonic stem cell research is strictly governed by both general and specific provisions. As under the last framework programme for research (FP7), Horizon 2020 contains specific provisions governing direct financial support for human embryonic stem cell research. These are set out in Article 19 of the Horizon 2020 Regulation (ANNEX II) and the accompanying Commission Statement (ANNEX III), which was requested during the inter-institutional negotiations on the agreement between the Council of the European Union and the European Parliament, and which was presented by the Commission at the time of the adoption of the legislative act. The Statement is an integral part of the Horizon 2020 legislative package and serves to interpret the practical implementation of legislative provisions, given the diversity of views on this area of research and the different legal situation and practices in Member States. The Horizon 2020 package, including the provisions on human embryonic stem cell research were subject to the ordinary legislative process and adopted in a democratic manner, in full compliance with the Treaty provisions, through clear majorities by both co-legislators – the European Parliament adopted the

[17] http://ec.europa.eu/public_opinion/archives/ebs/ebs_341_en.pdf

[18] According to Article 5 TEU, "under the principle of subsidiarity, in areas which do not fall within its exclusive competence, the Union shall act only if and in so far as the objectives of the proposed action cannot be sufficiently achieved by the Member States, either at central level or at regional and local level, but can rather, by reason of the scale or effects of the proposed action, be better achieved at Union level".

Regulation at its plenary session on 21 November 2013[19] and the Council of the European Union at its meeting on 3 December 2013.[20]

The strict ethical framework within which Horizon 2020 operates mirrors exactly the provisions carefully agreed for FP7 (ANNEXES IV and V). As mentioned in the Horizon 2020 Commission Statement, the Commission proposed the continuation of the FP7 ethics framework because "*[the Commission] 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*". The framework is based on the recommendations of the European Group on Ethics in Science and New Technologies[21] and consists of the 'triple lock' system:

1. First and foremost, national legislation is respected – EU projects must follow the laws of the country in which research is carried out.

2. In addition, all projects must be scientifically validated by peer review and must undergo rigorous ethical review.

3. Finally, EU funds may not be used for derivation of new stem cell lines, or for research that destroys embryos - including for the procurement of stem cells.

The Horizon 2020 programme takes a societal challenge-based approach, addressing major concerns shared by citizens in Europe and elsewhere. In the field of health, this includes for example research on cancer, diabetes, Alzheimer's disease, and Parkinson's disease. In implementing its research programmes, the Commission does not publish calls for research proposals specifically on human embryonic stem cell research. Rather, it is for scientists to propose, in a bottom-up way, the best possible approaches for a particular study. EU research also allows for projects that may include a comparison of different cell types, including human embryonic stem cells and induced pluripotent stem cells, keeping all avenues of research open in the light of scientific advances. The European registry[22] of human embryonic stem cell lines, supported by the European Commission, facilitates the monitoring of existing human embryonic stem cells in Europe and beyond, improves their availability to scientists and helps avoiding the unnecessary establishment of new stem cell lines.

Article 19(3) of the Horizon 2020 Regulation states that "the following fields of research shall not be financed: 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; 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". The Article foresees that these fields of research may be reviewed within the context of the interim evaluation of Horizon 2020, in the light of scientific advances.

[19] 533 in favour, 29 against, 22 abstentions.
[20] 2 abstentions.
[21] http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf
[22] www.hescreg.eu hESCreg was created to offer the research community, legislators, regulators and the general public at large an in-depth overview on the current status of human pluripotent stem cell (hPSC) research in Europe.

Article 19(4) states that "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".

The evaluation, granting and funding of EU research project proposals involving human embryonic stem cells is strictly legislated. Compliance with the rules set out in Article 19 of the Regulation and in the Statement is assessed through a number of ex-ante and ex-post monitoring checks.

Horizon 2020 Ex-ante and Ex-post Checks on Human Embryonic Stem Cell Research

Each proposal involving human embryonic stem cells is scientifically evaluated by independent international peer review. This evaluation examines the necessity of using such stem cells to achieve the scientific objectives. Each proposal must also undergo a rigorous ethical review[23], which takes into account the principles reflected in the EU Charter of Fundamental Rights and relevant international conventions[24], and is undertaken by Commission appointed independent experts; any requirements specified by these reviewers become contractual obligations for the project participants.

Each proposal that has passed both the scientific evaluation and ethics review stages is then decided upon by the Commission and subjected to a specific Member State approval procedure at the level of the individual project to ensure it follows the laws of the country in which research is carried out. The Programme Committee, composed of representatives from all Member States and observers from countries associated to the Framework Programme, operates under the examination procedure for the approval of the funding of these projects. Only then are contracts, that include clear ethics provisions and reporting requirements, concluded.

In addition to the monitoring of the projects during implementation, the Commission will carry out ethics check on selected projects assisted by independent external experts to verify that the research is carried out according to the requirements put forward by the ethics review. In an ethics audit of 6 projects funded under FP7 that involved the use of human embryonic stem cells, the panel of independent external experts was satisfied that all ethics and regulatory requirements were fulfilled and that the projects were in compliance with the terms of their contract and the provisions of the FP7 legislative text. In a case where a project should be found to contravene the accepted ethical principles and the terms of conducting research using human embryonic stem cells, all provisions are in place to stop the project and impose appropriate penalties. No instances of non-compliance have been detected with respect to FP7 projects involving human embryonic stem cells.

The Commission strictly respected the commitment and monitoring of these principles in the previous framework programmes and regularly informed the Programme Committee of the overall progress of the implementation of the programme. It will follow the same monitoring and verification process for Horizon 2020. Under the FP7 Health programme (2007-2013),

[23]Based on opinion 22 of the European Group on Ethics in Science and New Technologies. http://ec.europa.eu/bepa/european-group-ethics/docs/publications/opinion_22_final_follow_up_en.pdf

[24] 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 EU funded 27 collaborative research projects involving the use of human embryonic stem cells; the more recent of these also include work on induced pluripotent stem cells. European Research Council grants (10) and Marie Skłodowska-Curie actions (24) have also involved human embryonic stem cell research[25]. No new human embryonic stem cell lines have been created with the support of funds from EU research projects.

The Commission is open and transparent about promoting responsible research and provides information about it to citizens and scientists. In addition to reporting the project details on the Commission's CORDIS site, projects are encouraged to set up their own websites, and the Commission supports the EuroStemCell website[26] which provides reliable, independent information and road-tested educational resources on stem cells and their impact on society.

2.3. Development cooperation

2.3.1 Maternal and Child Health in developing countries

287,000 women were still dying from pregnancy or childbirth-related complications around the world in 2010. Almost all of these deaths (99%) occur in developing countries and disproportionately affect those populations that are poor and most vulnerable.

Approaches to protect the health of the mother also protect the health of their babies. For example, the rate of pre-term births, which is the leading cause of newborn deaths, can be effectively addressed by improving access to family planning and good quality care for women, particularly adolescents. Therefore, skilled care before, during, and after childbirth is necessary to save the lives of both mothers and babies and requires access to comprehensive health services that integrate sexual, reproductive, maternal, newborn and child health services across the continuum of care.

One of the causes of maternal mortality is unsafe abortions, accounting for about 13% of all maternal mortality, resulting in 47,000 deaths each year, almost exclusively in developing countries. According to the World Health Organisation (WHO), the most effective intervention to reduce unintended pregnancies and induced abortion is improving access to family planning services and the effectiveness of contraceptive use[27]. The number of abortions could therefore be reduced. In almost all countries of the world[28], the law permits abortion to save the woman's life, and in the majority of countries, abortion is allowed to preserve the physical and/or mental health of the woman.

2.3.2 Competence and activities of the EU Member States

The development cooperation of the EU Member States in the area of maternal and child health is guided by the Millennium Development Goals (MDGs) and the 'International Conference on Population and Development' Programme of Action.

'International Conference on Population and Development' Programme of Action

At the International Conference on Population and Development (ICPD) held in Cairo in 1994, 179 countries - including all 28 EU Member States - adopted a programme of action

[25] Full project details may be found on CORDIS http://cordis.europa.eu/
[26] http://www.eurostemcell.org/
[27] WHO (2012): Safe abortion: technical and policy guidance for health systems; p.87, 90
[28] Only six countries prohibit abortions under all circumstances. Source: United Nations; World Abortion Policies 2013; www.unpopulation.org

defining equality and the empowerment of women as a global priority, from the perspective of universal human rights but also as an essential step towards poverty eradication[29].

A woman's ability to access reproductive health and to have her reproductive rights recognised is a cornerstone of her empowerment and contributes to sustainable development. The programme calls for actions to provide universal access to family planning and sexual and reproductive health services and reproductive rights. Amongst others, the programme identifies unsafe abortions as a major public health concern and asks for prevention of unwanted pregnancies to receive the highest priority. In no case should abortion be promoted as a method of family planning. Abortion care needs to take place in the legal context of each country. The ICPD underlines that where it is not against the law, abortion should be safe.

Every five years since 1994, countries have reconvened to reconfirm these commitments and review progress on the Programme of Action. The benchmarks added at the first such review conference of the ICPD in 1999 went on to inform the eight Millennium Development Goals.

Millennium Development Goals

In 2000, the Heads of State and Government of 189 countries - including all 28 EU Member States - adopted in the UN General Assembly, the Millennium Declaration with a set of eight Millennium Development Goals that included ambitious targets for the reduction of maternal and child mortality by 2015. MDG 4 aims to reduce the mortality rate among under-five children by two thirds. MDG 5 aims to reduce maternal mortality by three quarters between 1990 and 2015 and achieve universal access to reproductive health.

The Millennium Development Goals have since become the benchmark for global development policy. They have led to an unprecedented focus on human well-being, human development and human poverty in the international community. The UN is currently coordinating a structured process to define a development framework beyond 2015 when the current MDGs expire.

2.3.3 Competence and activities carried out at Union level

Treaty Provisions on Development Cooperation

The main objective of the EU development cooperation policy is to reduce and then eradicate poverty[30], in full respect of human dignity. This comes out strongly in the EU's commitment to the MDGs to reduce extreme poverty and hunger, improve wellbeing of people by reducing maternal and child mortality, combat HIV/AIDS, malaria and other diseases. The new EU development policy, the Agenda for Change,[31] reiterates the human-centred approach by setting human rights (democracy and rule of law) and inclusive, sustainable growth for human development as important goals of development aid.

EU development cooperation measures are adopted without prejudice to Member States' activities in the field of development cooperation. According to Article 4(4) TFEU, development cooperation is a parallel competence: "in the areas of development cooperation and humanitarian aid, the Union shall have competence to carry out activities and conduct a common policy; however, the exercise of that competence shall not result in Member States being prevented from exercising theirs".

[29] UNFPA (1995): International Conference on Population and Development - ICPD - Programme of Action A/CONF.171/13/Rev.1

[30] Art. 208, TFEU

[31] Council Conclusions, 14 May 2012: Increasing the Impact of EU Development Policy: an Agenda for Change

Articles 208-211 TFEU provide the legal basis for EU development cooperation measures. Article 208(2) TFEU determines that both "[T]he Union and the Member States shall comply with the commitments and objectives they have approved in the context of the United Nations and other competent international organisations".

The added value of action at Union level is based on the EU's global field presence, its wide-ranging expertise, its supranational nature, its role as facilitator of coordination, and the potential to realise economies of scale. The "European Consensus"[32] adopted by the Member States, the European Commission, the Parliament and the Council in 2005 identifies shared values, goals, principles and commitments for the implementation of development programmes at Member State and Union level: reducing poverty, respect for human rights, democracy, fundamental freedoms and the rule of law, good governance, gender equality, solidarity, social justice and effective multilateral action.

Main EU financing instruments for development cooperation

The main EU financing instruments for development cooperation are the European Development Fund (EDF)[33] and the Development Cooperation Instrument (DCI)[34]. The EDF supports co-operation with countries in Africa, the Caribbean and the Pacific and focuses on economic, social and human development, and regional cooperation and integration. It is managed by the Commission with EU Member States contributing to it directly.

The DCI on the other hand, provides bilateral support to developing countries which are not covered by the EDF and thematic support to all partner countries on priority themes such as human rights, democracy and good governance, inclusive and sustainable growth.

The 11th EDF for 2014-2020 will have a budget of EUR 30.5 billion. The DCI will receive an allocation of EUR 19.7 billion from the EU budget for the period 2014-2020.

Before proposing these new financing instruments for 2014-2020 and in addition to the impact assessment and the internal review of different evaluations, audit and mid-term review reports, the Commission held between 26 November 2010 and 31 January 2011 a public consultation on future funding for EU external action. This process was based on a public online questionnaire accompanied by a background paper 'What funding for EU external action after 2013?'[35] The Commission presented a legisltative proposal in December 2011, taking into account all aspects of development policy including the added value of support at EU level to developing countries in accordance with the principles of the European Consensus on Development (2005) and the "Agenda for Change".

The DCI Regulation was adopted on 11 March 2014 in accordance with article 209 TFEU: "The European Parliament and the Council, acting in accordance with the ordinary legislative procedure, shall adopt the measures necessary for the implementation of development cooperation policy, which may relate to multiannual cooperation programmes with developing countries or programmes with a thematic approach." The democratic process showed that clear majorities in both the European Parliament and the Council (the European Parliament adopted the Regulation at its plenary session on 6 December 2013 and the Council

[32] Joint statement by the Council and the representatives of the governments of the Member States meeting within the Council, the European Parliament and the Commission on European Union Development Policy: 'The European Consensus' (OJ 2006/C 46/01), OJ C 46, 24.02.2006, p. 1

[33] COUNCIL REGULATION (EC) No 617/2007 of 14 May 2007 on the implementation of the 10th European Development Fund under the ACP-EC Partnership Agreement, OJ L 152, 13.06.2007, p. 1

[34] REGULATION (EU) No 233/2014

[35] http://ec.europa.eu/europeaid/how/public-consultations/5240_en.htm

of the European Union at its meeting on 11 March 2014) supported the policy priorities and objectives for development policy including cooperation on the priority themes as proposed by the Commission.

Priorities for EU development funding in the health sector, including sexual and reproductive health and rights

The DCI Regulation recalls in its article 2 that the fight against poverty in line with the MDGs remains the primary objective of development cooperation. This includes the promotion of the full and effective implementation of the ICPD Programme of Action, as indicated in Annexes I and II of the Regulation.[36]

Under the DCI Regulation, priorities for EU funding are reflected in geographic and thematic Multiannual Indicative Programmes (MIP) which are subject to a strategic dialogue with the European Parliament. During the strategic dialogue held in the first quarter of 2014, the Parliament requested better attention to be given to women's rights and gender equality in the MIPs. These changes are being integrated into the MIPs as a result of the strategic dialogue.

Priorities of EU funding are also determined jointly with the governments of the partner countries. In the area of health, EU funding is therefore focused on strengthening partner countries' health systems so that they can provide universal access to a comprehensive package of quality health services. EU action is based on national healthcare plans defined by public authorities of recipient countries. So long as these health systems comply with human rights and international requirements, it is the sovereign right of each of our partner countries to decide on the range of services and how they are offered to their citizens. The EU's role is to support these countries' efforts to develop effective systems for health service provision throughout the continuum of care.

EU funding may support building and rehabilitating health care facilities, training of health personnel, providing equipment, essential medicines and supplies as well as providing technical assistance and policy advice to governments in support of national health strategies. The preferred mode for such funding is through the regular budget of partner countries to improve country ownership and sustainability of programmes. This aid modality, called "budget support", focuses on supporting sector policies and reforms to improve governance and service delivery to populations, leading to concrete and measurable results through the conduct of a policy dialogue with the government and the definition of indicators to be reached. During the period 2002-2010 the EU has committed EUR 5 billion to support the public budgets of partner countries, and an additional EUR 1.3 billion specifically to the health budgets or government programmes of partner countries. [37] An important other channel of EU funding is through UN agencies active in the health sector and Global Health Initiatives such as the Global Fund to fight AIDS, Tuberculosis and Malaria, and the GAVI Alliance. During the period 2002-2010 the EU has committed EUR 1 billion to these beneficiaries.

EU funding can also be used to finance civil society organisations, particularly where access to basic health services needs to be improved for marginalised and hard-to-reach populations, especially in contexts of emergency or conflict, i.e. in situations where governments are unable or unwilling to take effective action on their own. Most of the funding to civil society organisations is however targeted at developing their advocacy capacity and strengthening their role to contribute to policy-making, monitor reforms and hold governments to account.

[36] REGULATION (EU) No 233/2014

[37] http://ec.europa.eu/europeaid/how/evaluation/evaluation_reports/2012/1308_docs_en.htm, Annex II

During the period 2002-2010 the EU has committed EUR 1.3 billion to civil society organisations working in the health sector.

Of the EUR 3.2 billion of development funds that the EU spent in the 5-year period 2008-2012 on the health sector in partner countries, EUR 1.5 billion were spent on maternal, new-born, and child-health calculated by a methodology agreed by the G8. Specifically, EUR 87 million went to reproductive health care, EUR 17 million to family planning, and EUR 95 million to controlling sexually transmitted diseases. Contributions to the Global Fund to fight AIDS, Tuberculosis and Malaria account for another EUR 503 million.

Alignment on the ICPD programme of action and the MDGs

EU development funding is closely aligned with the objectives and international commitments agreed in the ICPD programme of action and the MDGs. Even though the Union was not a signatory of these landmark international agreements when they were adopted, their objectives and commitments were subsequently integrated in the EU law setting out the Union's policy on development cooperation, with clear references included in the European Consensus on Development, the Council Conclusions on the EU role in Global Health[38], the Council Conclusions on the Overarching Post 2015 Agenda[39], as well as the 2007-2013 and 2014-2020 DCI Regulations.

The European Parliament adopted several resolutions[40] in support of the MDGs and the ICPD in which it asked "for the EU to strongly defend the right to the highest attainable standard of health, including sexual and reproductive health and rights and the integration of HIV/AIDS, inter alia in the provision of voluntary family planning, safe abortion and contraceptives"[41].

In full alignment with ICPD principles, EU development assistance does not promote abortion as a method of family planning. Rather it aims to reduce recourse to abortion through expanded and improved family-planning services; give priority to the prevention of unwanted pregnancies and eliminate the need for abortion. EU funding focuses on meeting the needs of vulnerable and disadvantaged women, adolescents, single women, refugees and displaced women, women living with HIV, and rape victims.

Controls on the use of EU development funds

The EU contractual terms[42] are strict to ensure that all interventions funded by EU development assistance respect the legislation of the countries where they take place. All EU grant recipients and their staff must comply with human rights. The use of EU funds for their intended purposes is ensured through various control activities, and checks and balances along the project cycle management.

The Commission monitors the performance of projects and programmes through independent assessments carried out by external experts using internationally accepted criteria. In 2013 this system of Results Oriented Monitoring reviewed more than 1,600 ongoing and closed projects and programmes (including budget support operations) across all sectors of EU

[38] Council Conclusions on the EU role in global health, 10 May 2010
[39] Council conclusions on the Overarching Post 2015 Agenda, 25 June 2013
[40] European Parliament Resolutions of 23.10.2012 (2012/2002(INI)); of 12.03.2013 (2012/2222(INI); of 11.12.2013 (2013/2057(INL))
[41] European Parliament Resolution of 13.06.2013 on the Millennium Development Goals – defining the post-2015 framework (2012/2289(INI)
[42] PRAG 2014: Procurement and Grants for European Union external actions. see chapters 2.3.3; 2.3.4; 2.4.14; and annex e3h2; http://ec.europa.eu/europeaid/prag

support.[43] 64 of these projects and programmes concerned the health sector, and 22 concerned the sector of population policies/programmes and reproductive health. 81% of the projects monitored in these two sectors were rated 'very good' or 'good' (compared to 75% on average for projects across all sectors of EU cooperation). For those projects were major difficulties are identified, a specific follow-up is ensured by the Commission. This 'on-the-spot' independent monitoring is complementary to the own internal monitoring carried out by Commission staff.

In addition to evaluations at project or programme level, strategic evaluations made by independent external experts provide important feedback on impact and results achieved. This was the case in 2012 with the evaluation of the European Commission support to the health sector, which found that it was coherent with the EU development policy and well-focused on poverty reduction[44]. EU support was found to have made significant contributions to health service quality improvements and strengthened institutional and procedural systems related to transparency and accountability in the countries in which it has implemented programmes.

The European Court of Auditors annually reviews the management of the EU's development aid. In its recent report on the EDF, the Court states that EU Delegations had a good overview of the operational implementation of projects, chiefly through monitoring visits.[45]

Results from all evaluations and audits were taken into account in the definition of the new financial instruments for the 2014-2020 financial framework, including the DCI.

In complement to monitoring and evaluations, financial audits and verifications provide assurance on the legality and regularity of external aid operations. Recipients of EU aid that have made false declarations, committed substantial errors, irregularities or fraud will have their grants suspended and may be excluded from further EU financing and be subject to financial penalties.

[43] European Commission: Annual Report 2014 on the European Union's development and external assistance policies and their implementation in 2013 (to be published on: http://ec.europa.eu/europeaid/multimedia/publications/index_en.htm)

[44] http://ec.europa.eu/europeaid/how/evaluation/evaluation_reports/2012/1308_docs_en.htm

[45] European Court of Auditors (2013): Annual Report on the activities funded by the 8th, 9th and 10th European Development Funds; (2013/C 331/02)

3. ASSESSMENT OF THE EUROPEAN CITIZENS' INITIATIVE REQUESTS

3.1. General observations

As referred to in the introduction of this Communication, the objective of the European Citizens' Initiative "One of Us" is that the EU establish a ban and end the financing of activities that presuppose the destruction of human embryos, in particular in the areas of research, development aid and public health to respect human dignity and integrity. To this end, the financial regulation, the regulation for the research framework programme Horizon 2020 and the regulation establishing a financing instrument for development cooperation should be modified as appropriate.

The Commission has carefully examined this request.

As regards the request to stop EU financing of these activities and modify the Financial Regulation, it should be noted that according to Article 87 of the Financial Regulation, all EU expenditure must be in compliance with the EU Treaties and the Charter of Fundamental Rights. The EU Financial Regulation therefore already ensures that all EU expenditure, including in the areas of research, development cooperation and public health, must respect human dignity, the right to life, and the right to the integrity of the person. Moreover, the purpose of the Financial Regulation is to provide financial rules in general terms and not for a specific field of EU policy, in particular for establishing and implementing the EU budget.

3.2. Human embryonic stem cell research

The European Commission has carefully analysed the request of the European citizen's Initiative to introduce legislation that would ban any EU financing of "*research activities that destroy human embryos, including those aimed at obtaining stem cells, and research involving the use of human embryonic stem cells in subsequent steps to obtain them"*.

As described above, the legislation on the current EU research programme contains detailed provisions governing EU support for human embryonic stem cell research. These provisions were only recently (December 2013) agreed by the EU co-legislator, i.e. the European Parliament and the Council, through the ordinary legislative procedure, in full accordance with Article 182 TFEU. The provisions for funding under Horizon 2020 were agreed taking into account all aspects, including ethical considerations, EU added value and potential health benefits of all types of stem cell research.

The Horizon 2020 provisions on human embryonic stem cell research are carefully calibrated and together constitute a "triple lock" system involving:

1. First and foremost, national legislation is respected – EU projects must follow the laws of the country in which research is carried out.

2. In addition, all projects must be scientifically validated by peer review and must undergo rigorous ethical review.

3. Finally, EU funds may not be used for derivation of new stem cell lines, or for research that destroys embryos - including for the procurement of stem cells.

They include a set of explicit exclusions and conditionalities, a number of rigorous ex-ante checks (scientific review, ethics review), additional layers of decision-making at the level of the individual project involving the Member States, contractual obligations, detailed reporting

requirements, and ex-post audits (Please refer to ANNEXES II and III for full texts of Article 19 and the Commission Statement). System-level audits have demonstrated that the system put in place is well-designed and complied with in accordance with the highest ethical standards. In addition, the Commission does not solicit explicitly research proposals involving human embryonic stem cells.

The Commission considers that the Horizon 2020 provisions on human embryonic stem cell research are in full accordance with the EU Treaties and the Charter of Fundamental Rights of the European Union.[46] It also considers that these provisions already address a number of important requests of the organisers notably that the EU does not fund the destruction of human embryos and that appropriate controls are put in place. The Commission considers, however, that it cannot meet the request of the organisers that the EU does not fund research subsequent to the establishment of human embryonic stem cell lines. The reason is that the Commission formulated its proposal taking into account ethical considerations, potential health benefits, and the added value of support at EU level, for all types of stem cell research. This proposal was adopted by the co-legislator, i.e. the European Parliament and the Council, based on an agreement democratically reached during the inter-institutional negotiations.

3.3. Development cooperation

The European Commission has carefully analysed the request of the Citizens' Initiative to introduce legislation that would ban any potential EU funding of activities that destroy human embryos or presume their destruction, i.e. specifically any direct or indirect financing of abortion through development aid.

The underlying objective of the Citizens' initiative is a reduction in the number of abortions undertaken in developing countries.

In developing partner countries where the EU supports the health sector, it provides assistance to the health-care systems, either supporting integrated service provision that includes sexual, reproductive, maternal, newborn and child health services across the continuum of care, or providing budget support to assist countries to improve national health service delivery. By definition, that assistance will contribute directly or indirectly to the entire spectrum of health services offered by partner countries, which may or may not include abortion-related services to save the mother's life. This comprehensive EU support contributes substantively to a reduction in the number of abortions because it increases access to safe and quality services, including good-quality family planning, a broad range of contraceptive methods, emergency contraception and comprehensive sexual education.

While the objective of EU development cooperation is universal and equitable access to good quality care for all citizens, the EU fully respects the sovereign decisions of partner countries as to which health services will be provided and how they are packaged as long as they are in line with agreed human rights principles. Therefore the Commission does not favour earmarking aid for certain services only, because it would make the comprehensive and effective support of a country's health strategy more difficult.

[46] Horizon 2020 Regulation, Article 19, paragraph 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".

The Commission considers that the EU must live up to its international commitment to the achievement of MDG 5. Despite impressive gains in contraceptive use, a substantial number of mothers still die every year as a result of abortions that are performed without the necessary skills or in an environment lacking minimal medical standards. According to the WHO, maternal deaths and illness can be dramatically reduced by improving the safety of such health services.

The Commission applies stringent rules and any funding is and shall always be in full respect of the EU regulatory framework and the relevant national legislation. Once funding is granted, comprehensive and transparent oversight mechanisms are put in place. The oversight is effective, and the Commission is committed to the continued application of contractual and monitoring safeguards and to do so in a fully transparent manner.

Finally, while the UN has started the process of defining a new development agenda beyond 2015, the EU is currently working to ensure that the main principles and commitments of ICPD Programme of Action and the MDGs are incorporated in the post-2015 framework. The robust international consensus on the scope and definition of sexual and reproductive health and rights codified in the ICPD Programme of Action in 1994 has just been reconfirmed in its April 2014 review[47] that will serve as the basis for the September 2014 United Nations General Assembly Special Session on ICPD. The principles agreed at the ICPD continue to shape global development cooperation and are strongly supported by the EU and its Member States.

4. CONCLUSIONS

In reply to the European Citizens' Initiative "One of Us", the Commission concludes as follows:

4.1 General

EU primary legislation explicitly enshrines human dignity, the right to life, and the right to the integrity of the person. The EU Financial Regulation states that all EU expenditure should comply with EU primary legislation. Therefore the Commission does not see a need to propose changes to the Financial Regulation.

4.2 Human embryonic stem cell research

The Horizon 2020 provisions on human embryonic stem cell research have only recently been decided by the EU co-legislator (in December 2013). They involve a carefully calibrated set of exclusions and conditionalities, rigorous ex-ante checks, case-by-case decision-making involving the Member States, contractual obligations, reporting requirements, and ex-post audits. These provisions explicitly exclude from EU funding the destruction of blastocysts for research purposes and fully respect national legislation on human embryonic stem cell research. System-level audits have demonstrated that the system in place is well-designed and complied with in accordance with the highest ethical standards. The Commission underlines that research proposals involving human embryonic stem cells are not explicitly solicited.

[47] http://www.un.org/en/development/desa/population/commission/sessions/2014/index.shtml

The Commission considers that the Horizon 2020 provisions on human embryonic stem cell research are in full accordance with the EU Treaties and the Charter of Fundamental Rights of the European Union.[48] It also considers that these provisions already address a number of important requests of the organisers notably that the EU does not fund the destruction of human embryos and that appropriate controls are put in place. The Commission considers, however, that the request of the organisers that the EU does not fund research subsequent to the establishment of human embryonic stem cell lines cannot be met. The reason is that the Commission formulated its proposal taking into account ethical considerations, potential health benefits, and the added value of support at EU level, for all types of stem cell research. This proposal was adopted by the co-legislator, i.e. the European Parliament and the Council, based on an agreement democratically reached during the inter-institutional negotiations.

The Commission will continue to strictly apply the 'triple lock' system and respect the monitoring and verification rules already observed in FP7 and as outlined in Article 19 of the Horizon 2020 Regulation and associated Commission Statement (Please refer to ANNEXES II and III for full texts of Article 19 and the Commission Statement). This will be done in a fully transparent manner.

Article 19 of the Horizon 2020 Regulation states in its fifth paragraph that the list of fields of research that shall not be financed included in its third paragraph may be reviewed within the context of the Horizon 2020 interim evaluation to be carried out by 31 December 2017. The decision to undertake this specific review will depend on the development of the scientific areas and technologies concerned.

With respect to future EU support for health research, the Commission will carefully follow scientific advances in research, notably in the field of induced pluripotent stem cell research, which have many similar properties to embryonic stem cells but cannot yet be produced to full clinical standard or be treated as natural cells, and provide support as appropriate.

The Commission agrees with Opinion 22 of the European Group on Ethics and New Technologies that "should alternatives to hESCs with the same potential as embryo-derived stem cells be found in the future, the implications of such developments for both scientific and ethical aspects of the hESC-based research projects ought to be taken into account as soon as possible"[49]. This means that once fully equivalent alternatives to hESCs are available, the Commission will explore their full deployment and potential and will revert to the European Group on Ethics and New Technologies for an Opinion in the light of results of hESC research and of scientific advances in alternatives to hESC.

In the meantime, the Commission will continue to provide support for the European Registry for human embryonic stem cell lines to facilitate the monitoring of existing hESCs in Europe and to help optimise their use by avoiding unnecessary derivations of new hESC lines.

[48] Horizon 2020 Regulation, Article 19, paragraph 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".

[49] Recommendations on the ethical review of hESC FP7 research projects - Opinion No 22 - 20 June 2007, p. 41.

4.3 Development cooperation

The Commission concludes that the EU currently has the necessary legal framework to effectively manage EU development funding in a way that helps minimise the number of abortions performed in developing countries. While the Citizens' Initiative does not directly challenge the core objectives and commitments of the MDGs and the ICPD programme of action, the Commission considers that a funding ban would constrain the Union's ability to deliver on the objectives set out in the MDGs, particularly on maternal health, and the ICPD, which were recently reconfirmed at both international and EU levels.

The UN has started the process of defining a new development agenda beyond 2015, and the EU is currently working to ensure that the main principles and commitments of ICPD Programme of Action and the MDGs are incorporated in the post-2015 framework. The robust international consensus on the scope and definition of sexual and reproductive health and rights codified in the ICPD Programme of Action in 1994 has just been reconfirmed in its April 2014 review[50] that will inform the September 2014 United Nations General Assembly Special Session on ICPD. The principles agreed at the ICPD continue to shape global development cooperation and are strongly supported by the EU and its Member States. The Commission will strive to inform stakeholders and civil society through an international conference in 2015 promoting a better understanding of the new international instruments with a view to improving the effectiveness of development and humanitarian aid policy and cooperation.

The Commission will continue to improve its monitoring and oversight systems, and regularly report on progress to the European Court of Auditors. For example, the Commission is developing tools and guidance to strengthen monitoring systems and assess the quality of audit reports. The Commission is also delivering on better reporting of operational results of EU funded development programmes. Such reporting systems will inform management practices, lead to more accountability, transparency and visibility of EU aid, and ultimately enhance the impact of EU Development objectives as set out in the Agenda for Change.[51]

A mid-term review of the DCI is due to take place no later than end 2017. The mid-term review will analyse the evidence from evaluations, both thematic and programmatic, and feed the strategic dialogue with the co-legislators. Thus, the Commission's approach is based on a full democratic and transparent review that is ongoing and permanent.

In accordance with article 10(2) of the ECI regulation, the present Communication will be notified to the organisers of the Initiative as well as to the European Parliament and the Council and it will be made public.

[50] http://www.un.org/en/development/desa/population/commission/sessions/2014/index.shtml

[51] Commission Staff Working Document "Paving the way for an EU Development and Cooperation Results Framework", 10.12.2013, SWD(2013) 530

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[52]. 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

[52] 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[53]

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.

[53] 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[54]

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

[54] 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[55]

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.

[55] 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[56]

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

[56] 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.