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'I' ITEM NOTE

From:	General Secretariat of the Council
To:	Permanent Representatives Committee
Subject:	Draft REGULATION OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL establishing Horizon Europe – the Framework Programme for Research and Innovation, laying down its rules for participation and dissemination, and repealing Regulations (EU) No 1290/2013 and (EU) No 1291/2013 **(first reading)** - Decision to use the written procedure for the adoption of the Council's position at first reading and of the statement of the Council's reasons = Statements

Statement by the Commission on Recital 47

The Commission intends to implement the EIC Accelerator budget in a way to ensure that the grant-only support to SMEs, including start-ups, corresponds to the support provided under the SME instrument budget of the Horizon 2020 Programme, in accordance with the terms established in Article 48, paragraph 1 and recital 47 of the Horizon Europe Regulation.

Statement by the Commission on Art. 6

Upon request, the Commission intends to exchange views with the responsible Committee in the European Parliament on:(i) the list of potential partnerships candidates based on the Articles 185 and 187 TFEU which will be covered by (inception) impact assessments; (ii) the list of tentative missions identified by the Mission boards; (iii) the results of the Strategic Plan before its formal adoption, and (iv) it will present and share documents related to work programmes.

Statement by the Commission on ethics/stem cell research- Art. 19

For the Horizon Europe 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 Horizon 2020 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 Europe Framework Programme explicitly excludes three fields of research from Union 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 Europe and the provisions for the ethics framework governing the Union 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 Union 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 Europe.

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 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 obtain the approval of the relevant national or local ethics committee prior to the start of the relevant activities. 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 Union 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 Union funding of subsequent steps involving human embryonic stem cells.