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General Secretariat

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Contact: ivana.dutkova@consilium.europa.eu
codecision.adoption@consilium.europa.eu

Tel./Fax: +32.2.281.71.25

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 [2018/0224 (COD)]

- Adoption of the Council's position at first reading and of the statement of the Council's reasons
- Outcome of the written procedure initiated by CM 2164/21

Delegations are informed that the written procedure, opened by CM 2164/21 of 10 March 2021 was completed on 16 March 2021 and that all delegations voted in favour:

1. the adoption of the Council's position at first reading on the 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, as set out in document 7064/20 + REV 1 (It) and the statement of the Council's reasons as set out in the ADD 1 + COR 1 to that document;
2. the approval of the accompanying Council Statements, as set out in document 6692/21 ADD 1;
3. the approval of the Joint Political Statement, as set out in document 6692/21 ADD 2 and its publication in the *Official Journal of the European Union* together with the Commission statements, as set out in document 6692/21 ADD 3.

The required qualified majority has been reached. Therefore, the above position of the Council at first reading and the statement of the Council's reasons are adopted and the accompanying Council Statements and the Joint Political Statement are approved.

The Joint Political Statement by the Council, the European Parliament and the Commission and the statements by the Commission on Recital 47, Art. 6 and Art. 19 are reproduced in the Annex to this CM and will be published in the *Official Journal*¹.

The statements by France, Poland, Sweden, the Council and the statements by the Commission on Art. 5, Art. 16.1.d and International Cooperation are reproduced in the Annex to this CM.

The above statements will be included in the summary of acts adopted by the written procedure as statements to be entered in the Council minutes, in accordance with the third subparagraph of Article 12(1) of the Council's Rules of Procedure.

¹ C series.

Statement by the Council

The Council calls on the Commission to ensure the greatest involvement of the Council, during the negotiations of agreements associating third countries to Union programmes, including the EU Framework Programme for Research and Innovation, Horizon Europe, in accordance with Article 218 TFEU. To this end, a special committee may be designated by the Council in consultation with which the negotiations, including with regard to the design and content of such agreements, are conducted, in accordance with Article 218(4) TFEU.

In this regard, the Council recalls the principle of sincere cooperation among the EU institutions, laid down in art. 13(2) TEU, second sentence, and the relevant case-law of the EU Court of Justice on Article 218(4) TFEU, according to which the Commission must provide the special committee with all the information and documents necessary to monitor the progress of the negotiations, such as, in particular, the general aims announced and the positions taken by the other parties throughout the negotiations, in due time before the negotiating meetings, in order to allow the formulation of opinions and advice relating to the negotiations².

Where agreements associating third countries to Union programmes already exist and include a standing authorisation for the Commission to determine the specific terms and conditions applicable to each country concerning its participation in any given programme, and where the Commission is assisted in this task by a special committee, the Council recalls that the Commission must act in consultation with that special committee in a systematic manner during the negotiating process, for example by sharing draft texts ahead of meetings with the relevant third countries and by providing regular briefings and debriefings.

Where agreements associating third countries to Union programmes already exist but where no special committee is foreseen, the Council considers that the Commission should similarly engage with the Council and its preparatory bodies in a systematic manner during the negotiating process when determining the specific terms and conditions for the association to Horizon Europe.

² See judgment of 16 July 2015 in *Commission v Council*, C-425/13, EU:C:2015:483, paragraph 66.

Statement by the Council on Art. 5

The Council recalls that it follows from Articles 179(3) and 182(1) TFEU, read in combination, that the Union can adopt only one multiannual Framework Programme setting out all the Union research and technological development activities. The Council is therefore of the view that the European Defence Fund mentioned in Art. 1(2)(c) of the Regulation establishing the Union Research Framework Programme - Horizon Europe, covering both the research and technological development activities of this Fund, is a specific programme implementing the Framework Programme within the meaning of Art. 182(3) TFEU and falls within the scope of the Regulation establishing that Framework Programme.

Joint political statement on the re-use decommitted funds in Horizon Europe

In the Joint Declaration on the re-use of decommitted funds in relation to the research programme³ the European Parliament, the Council and the Commission agreed to make available again to the benefit of the research programme commitment appropriations, corresponding to the amount up to EUR 0,5 billion (in 2018 prices) in the period 2021-2027 of decommitments, which results from total or partial non-implementation of projects belonging to the 'Horizon Europe' Framework Programme or its predecessor 'Horizon 2020', as provided for in Article 15(3) of the Financial Regulation. Without prejudice to the powers of the budgetary authority and to the Commission's powers to implement the budget, the European Parliament, the Council and the Commission agree that the indicative distribution of that amount will be as follows up to:

- EUR 300 000 000 in constant 2018 prices for the cluster 'Digital, Industry and Space' in particular for quantum research;
- EUR 100 000 000 in constant 2018 prices for the cluster 'Climate, Energy and Mobility'; and
- EUR 100 000 000 in constant 2018 prices for the cluster 'Culture, Creativity and Inclusive Society'.

³ OJ C 444I, 22.12.2020, p. 3–3

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.

Statement by France

La France se félicite de l'ambition du nouveau programme de recherche et d'innovation de l'Union, "Horizon Europe", et apporte son soutien à l'adoption du règlement établissant ce programme.

Elle rappelle néanmoins sa réserve quant à la mention, au considérant 6, d'un "principe d'innovation".

Tout en reconnaissant l'utilité d'évaluer les conséquences de la réglementation européenne sur l'innovation, en cohérence avec la "boîte à outils pour une meilleure réglementation", elle souligne que le "principe d'innovation" ne fait l'objet d'aucune définition juridique, contrairement au "principe de précaution" qui est reconnu par les Traités (article 191, paragraphe 2, du Traité sur le fonctionnement de l'Union européenne) et par la jurisprudence relative à ce principe (voir, notamment, arrêt de la Cour de justice de l'Union européenne (Grande chambre) du 9 mars 2010 dans les affaires C-379/08 et C-380/08, *ERG*, et arrêt de la Cour (Grande chambre) du 1^{er} octobre 2019 dans l'affaire C-616/17, *Blaise e.a.*).

Statement by Poland

Equality between women and men is enshrined in the treaties of the European Union as a fundamental right. Poland ensures equality between women and men within the framework of the Polish national legal system in accordance with internationally binding human rights instruments and within the framework of fundamental values and principles of the European Union. Therefore, Poland understands wording "gender" as referring to "sex" in line with art. 8, 10, art. 19 para 1 and art. 157 para 2 and 4 of the Treaty on the Functioning of the European Union.

Statement by Sweden

The framework programme must be as open as possible. The best researchers shall be given the means to find answers to research questions and to solve societal challenges. Legal entities within the Union must be able to contribute to innovations to create welfare, jobs and security for the European citizens.

Exclusion from participation in the framework programme of European legal entities with ownership outside the Union must be strictly limited to exceptional cases and limited to particularly security sensitive areas. In these cases, clear conditions and criteria must apply. In this context, the competence of the Member States must be respected. Exclusion of European legal entities with ownership in strategic partner countries does not benefit European research and development, nor the Union's security and competitiveness.

Statement by the Commission on Art. 5

The Commission takes note of the compromise reached by the co-legislators on the wording of Article 5. In the Commission's understanding the specific programme on defence research mentioned in Article 1 paragraph 2 point c) is limited only to the research actions under the future European Defence Fund while the development actions are considered outside the scope of this Regulation.

Statement by the Commission on human rights on Art. 16.1.d

The Commission fully subscribes to the respect of human rights as laid down in Article 21 Treaty on the European Union and its 2nd sub-para "The Union shall seek to develop relations and build partnerships with third countries, and international, regional or global organisations which share the principles referred to in the first subparagraph." However, the Commission regrets the inclusion of the "respect of human rights" in the set of criteria for third countries to fulfil in order to be eligible for association to the Programme under Article 16 paragraph 1 point d)(1) d. No other EU programme for the future Multiannual Financial Framework saw the need to include such an explicit reference, while there is no question that the EU is seeking to pursue a consistent approach in its external relations with third countries as far as Human Rights protection is concerned across all its instruments and policy areas, and which should guide the Commission in the implementation of this provision.

Statement by the Commission on International Cooperation

The Commission takes note of the Council's unilateral declaration, which it will duly consider, consistently with the Treaty, the jurisprudence of the EU Court of Justice, and the principle of institutional balance, when it consults the special committee under article 218(4) TFEU.
