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"I/A" ITEM NOTE

From: General Secretariat of the Council

To: Permanent Representatives Committee/Council

Subject: Proposal for a Regulation of the European Parliament and of the Council laying down the rules for participation and dissemination in "Horizon 2020 -the Framework Programme for Research and Innovation (2014-2020)" and repealing Regulation (EC) No 1906/2006 (**first reading**)

- Adoption of the legislative act (**LA + S**)
- = Statements

Statement by Malta

Malta welcomes the Horizon 2020 Framework Programme as a key tool in realising the European Research Area, as well as in implementing the Europe 2020 Strategy Innovation Union flagship initiative and in delivering on the commitments made therein. In this context, Malta has been fully committed to and fully engaged in the negotiations aimed at shaping an inclusive Horizon 2020 Programme which rewards excellence and supports potential excellence.

In spite of this, Malta cannot agree with the eligibility for funding under the Horizon 2020 Framework Programme of activities that involve the destruction of human embryos.

It is also of the opinion that the approach envisaged by the Horizon 2020 Framework Programme does not take sufficiently into account the therapeutic potential of human adult stem cells.

Furthermore, Malta believes that the principle of subsidiarity should be fully abided by with the refrain of EU level financing of research activities involving matters of fundamental ethical principles, which differ among the Member States.

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 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.

Declaration of the Commission on Article 5(7) of the Specific Programme

"The Commission strongly regrets the inclusion of paragraph 7 in Article 5 introducing the examination procedure referred to in Article 5 of Regulation (EU) No 182/2011 for the granting of Union financial assistance to the projects or parts of projects selected following every call for proposals on the basis of the work programmes referred to in article 5 of the Specific Programme Implementing Horizon 2020. The Commission recalls that it did not propose this procedure in any of the sectoral MFF acts. This was intended to simplify the MFF programmes to the benefit of the recipients of EU funding. The approval of grant decisions without committee scrutiny would accelerate the procedure reducing the time-to-grant to the advantage of beneficiaries and avoiding unnecessary red tape and costs. Moreover, the Commission recalls that the taking of grant decisions is part of its institutional prerogative relating to the execution of the budget and therefore should not be adopted through comitology.

The Commission also considers that this inclusion cannot serve as a precedent for other funding instruments."

Declarations of the Commission

1) Declaration on the Fast track to Innovation

"The Commission intends to provide appropriate visibility among the research and innovation community for the FTI through awareness-raising and communication activities preceding the pilot call in 2015.

The Commission does not intend to limit the duration of FTI actions ex-ante. Factors such as time sensitivity and the international competitive situation shall be taken into sufficient account when evaluating the "impact" of a proposal, to allow for flexibility according to the various specificities within different fields of applied research.

In addition to the in-depth assessment carried out within the interim evaluation of Horizon 2020, the FTI pilot will be subject to a continuous monitoring of all practicalities related to the submission, evaluation, selection and budgeting of proposals under the FTI Call, starting from the first cut-off date in 2015.

To allow for the pilot to be effective and to make sure a proper evaluation can be conducted, this could necessitate supporting up to a hundred projects.”

2) Declaration on Energy (Framework Programme)

“The Commission acknowledges the essential future role of end-user energy efficiency and renewable energy, the importance of better grids and storage in maximising their potential, and the need for market uptake measures to build capacity, improve governance and overcome market barriers so that energy efficiency and renewable energy solutions can be rolled out.

The Commission will endeavor to ensure that at least 85%, of the energy challenge budget of Horizon 2020 is spent in non-fossil fuels areas, within which at least 15 % of the overall energy challenge budget is spent on market up-take activities of existing renewable and energy efficiency technologies in the Intelligent Energy Europe III Programme. This Programme will be implemented by a dedicated management structure and will also include support for sustainable energy policy implementation, capacity building and mobilisation of financing for investment, as been undertaken until today.

The remaining part will be devoted to fossil based technologies and development options, which are considered essential for reaching the 2050 vision and supporting the transformation to a sustainable energy system.

Progress towards these targets will be monitored and the Commission shall regularly report on the progress achieved.

3) Declaration on the Article 6.5 (Framework Programme)

“Without prejudice to the annual budgetary procedure, it is the Commission’s intention to present in the context of the structured dialogue with the European Parliament an annual report on the implementation of the budget breakdown set out in Annex II of Horizon 2020 by priorities and specific objectives within these priorities, including any application of Article 6(5)”.

4) Declaration on Article 12 (Framework Programme)

"Upon request, the Commission will present the adopted work programmes to the responsible Committee in the European Parliament."

5) Declaration on Seal of Excellence (Framework Programme)

“Union level intervention enables EU-wide competition to select the best proposals, thereby raising levels of excellence and providing visibility for leading research and innovation.

The Commission considers that positively evaluated European Research Council, Marie Skłodowska-Curie, teaming actions, phase-2 SME instrument or collaborative project proposals that could not be funded for budgetary reasons, have still met the Horizon 2020 criterion of excellence.

Upon approval of the participants, this information can be shared with the responsible authorities.

The Commission therefore welcomes any initiatives to fund such projects by national, regional or private sources. In this context, cohesion policy also has a key role to play through building capacity."

6) Declaration on Spreading excellence and widening participation (Framework Programme)

“The Commission is committed to set up and implement the measures to close the research and innovation divide in Europe under the new heading ‘Spreading Excellence and widening participation’. The level of funding foreseen for these measures will not be lower than the amount spent in the Seventh Framework Programme on the actions addressing ‘widening participation’.

The new activities of COST undertaken in the context of ‘widening participation’ should be supported by the budget allocated to ‘Spreading excellence and widening participation’. The activities of COST which do not fall thereunder, and which should be of a equal order of magnitude in terms of budget, should be supported from the budget allocated to ‘6. Europe in a changing World - Inclusive, innovative and reflective societies’.

The major part of the activities related to the Policy Support Facility and to the transnational networks of National Contact points should also be supported by the budget allocated to ‘6. Europe in a changing World - Inclusive, innovative and reflective societies’.

7) Declaration on the guidelines on the criteria to implement the “bonus” (Rules for Participation)

“Regarding additional remuneration, it is the intention of the Commission to, without delay, issue guidelines on the criteria for its implementation after the adoption of the Horizon 2020 Rules for Participation and Dissemination.”

8) Declaration on Article 42 of the Rules for Participation

“It is the intention of the Commission to lay down time limits in the model grant agreement regarding the protection of results, taking into account the FP7 time limits.”

9) Declaration on direct costing for large research infrastructures (Rules for participation):

“In response to the demands from stakeholders, the Commission is committed to clarify the issue of direct costing of large research infrastructures along the lines described in this declaration.

The guidance on direct costing for large research infrastructures in Horizon 2020 will apply to the costs of large research infrastructures with a total value of at least EUR 20 million for a given beneficiary, calculated as the sum of the historical asset values of the individual research infrastructures as they appear in the last closed Balance Sheet of that beneficiary before the date of the signature of the grant agreement, or as determined on the basis of the rental and leasing costs of the research infrastructures.

Below this threshold, the guidance on direct costing for large research infrastructures in Horizon 2020 will not apply. Individual cost items may be declared as eligible direct costs in accordance with the applicable provisions of the grant agreement.

Generally, it will be possible to claim as direct costs all costs that both: fulfil the general eligibility criteria and are directly linked to the implementation of the action and can therefore be attributed directly to it.

For a large research infrastructure that is used for a project, this will typically be the case for the capitalised costs and for the operating costs.

‘Capitalised costs’ will be costs incurred to set up and/or renew the large research infrastructure, as well as some costs of specific repair and maintenance of the large research infrastructure together with parts or essential integral components.

‘Operating costs’ will be costs which the beneficiary incurs specifically for running the large research infrastructure.

By contrast, some costs could typically not be declared as direct costs, but would be deemed reimbursed through the flat-rate for indirect costs, e.g. rental, lease or depreciation costs of administrative buildings and headquarters.

Where costs have been caused only in part by the activities of the project, only the part which is directly measured to the project can be declared.

For this purpose, the measurement system of the beneficiary must provide for an accurate quantification of the actual true value of the cost for the project (i.e. showing the real consumption and/or use for the project). This will be the case, if measurement is obtained from the invoice of the supplier.

The measurement of the cost is generally associated with the time used for the project, which must correspond to the actual hours / days / months of use of the research infrastructure for the project. The total number of productive hours / days / months must correspond to the full potential of use (full capacity) of the research infrastructure. The calculation of the full capacity will include any time during which the research infrastructure is usable but not used. However, the calculation of the full capacity will take due account of real constraints such as the opening hours of the entity, repair and maintenance time (including calibrating and testing).

If a cost can be directly measured to the research infrastructure but not directly to the project, because of technical constraints, an acceptable alternative will be measurement of these costs by means of units of actual usage relevant for the project, supported by accurate technical specifications and actual data, and determined on the basis of the beneficiary's analytical cost accounting system.

The costs and their direct measurement to the project must be supported by appropriate supporting documents allowing for a sufficient audit trail.

The beneficiary may prove the direct link through persuasive alternative evidence.

The Commission services will recommend best practices for direct measurement and supporting documents (e.g.: for capitalised costs: accounting statements accompanied by depreciation policy of the beneficiary as part of its usual accounting principles, showing calculation of the potential use and of the economic life of the asset, and evidence of its actual use for the project; for operating costs: specific explicitly labelled invoice related to the large research infrastructure, contract, project time, etc.).

Upon request of a beneficiary with large research infrastructures, and taking into account the resources available and the cost-effectiveness principle, the Commission is prepared to carry out an ex-ante assessment of the direct costing methodology of the beneficiary in a simple and transparent manner, to ensure legal certainty. These ex-ante assessments will be taken into full account during ex-post audits.

In addition, the Commission will establish a group consisting of representatives of relevant stakeholder organizations, to evaluate the use of the guidance.

The Commission confirms that it will promptly adopt guidance on direct costing for large research infrastructures, once Horizon 2020 regulations have been adopted. ”

10) Declaration on the SME instrument

“SME support in Horizon 2020 is of major importance and represents a prominent part to achieve its objective to foster innovation, economic growth and job creation. Therefore, the Commission will ensure high visibility of SME support in Horizon 2020, in particular through the SME instrument in the work programmes, guidelines and communication activities. All efforts will be undertaken that it is easy and straightforward for SMEs to identify and use the opportunities provided for them in the Societal Challenges and LEITs.

The SME instrument will be implemented through a single centralised management structure responsible for the evaluation and management of the projects, including the use of common IT systems and business processes.

The SME-instrument shall attract the most ambitious innovation projects of SMEs. It will be implemented primarily in a bottom up manner via a continuously open call tailored to the needs of SMEs as set in the specific objective “innovation in SMEs” while taking into account priorities and objectives of LEITs and societal challenges and allowing for cross-challenge/LEITs proposals, underpinning the bottom-up approach. This call may be reviewed/renewed every two years, to take into account the biannual strategic programmes. Where appropriate, calls on specific topics of strategic interest can be organised in addition to the call described above. These calls will use the concept and procedures of the SME instrument as well as its single entry point for applicants and the accompanying mentoring and coaching services.”

11) Declaration regarding articles 3 and 4 (Rules for participation)

“It is the intention of the Commission to include references to national law in the grant agreement regarding public access to documents and confidentiality, in view of finding an appropriate balance between the different interests.”

12) Declaration on Article 28 (Rules for Participation) (option of a 100% reimbursement rate for non-profit legal entities for innovation actions):

"The Commission notes that even non-profit entities may carry out economic activities which are close to market and whose subsidiation may create distortions in the internal market. Therefore, the Commission will assess ex-ante if eligible activities are of an economic nature, if cross-subsidiation of economic activities is effectively prevented, and if the funding rate for economic eligible activities has negative effects on competition in the internal market which are not outbalanced by its positive effects".
