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REVISED ADDENDUM TO "I/A" ITEM NOTE

from :	General Secretariat of the Council
to :	COREPER/COUNCIL
No. Cion prop. :	8087/05 RECH 80 ATO 45 COMPET 68 CODEC 266, 11142/06 RECH 181 ATO 74 COMPET 188 CODEC 703
Subject :	Proposal for a Decision of the European Parliament and of the Council concerning the 7th Framework Programme of the European Community for research, technological development and demonstration (2007-2013) [**first reading**] - Adoption (**cp + s)** (a) of the common position (b) of the statement of the Council's reasons - Statements

STATEMENT BY GERMANY

"Germany welcomes the 7th Research Framework Programme as an important instrument for strengthening the scientific and technological foundations of the Community and to foster its competitiveness in important thematic areas.

Protection of human dignity and the right to Life necessitate the comprehensive protection of human life from the moment of its creation. Therefore, European Union support to research should not provide any incentives for the killing of embryos.

Germany therefore welcomes the declaration of the European Commission to continue the practice of FP6, and not to propose to the competent Regulatory Committee under FP7 any projects for financing which foresee the destruction of human embryos.

Although it considers the provisions concerning research with human embryos and human embryonic stem cells to be still insufficient, Germany approves the seventh research framework programme because of its outstanding importance for European research and for social development in the European Union. In this, Germany assumes that, notwithstanding the planned review of this area in the mid-term of the seventh research framework programme, the presently reached agreement concerning the ban on financing the procurement of human embryonic stem cells out of human embryos will remain valid beyond this time span because of its fundamental importance".

STATEMENT BY AUSTRIA

"In principle Austria supports the 7th Research Framework Programme as an important instrument for strengthening the Community's scientific and technological bases and for improving Europe's competitiveness.

As far as bioethics issues in the 7th Framework Programme are concerned, Austria has always advocated funding ethically unobjectionable research on adult stem cells from Community funds.

Once again, Austria emphasizes her position, already expressed frequently, that activities which imply the use of human embryos must not be funded through the 7th Framework Programme for Research. Austria is strictly against this kind of Research for fundamental ethical reasons.

Austria regrets that Article 6 of the 7th Framework Programme Decision allows the financing of research on human embryonic stem cells. Therefore, Austria cannot agree to the overall 7th Framework Programme of the EC".

STATEMENT BY POLAND

"Poland fully recognises that the 7th Framework Programme is a key element of the renewed Lisbon Strategy involving partnership for growth and employment. The Programme represents an important step towards building the knowledge society, raising competitiveness and fostering social and economic progress throughout the EU.

In particular, Poland considers the creation of the European Research Council, the earmarking of significant funds for basic research and priority financing for the brightest young talents as highly valuable. Taking into account Europe's common interest, Poland has and will support increasing funds for research under the 7th Framework Programme.

Poland has steadfastly contributed to the realisation of the Lisbon Strategy and creation of the European Research Area. Our aim is to continue such activities and to support all steps taken in this regard by the Community. Furthermore, Poland holds in high regard the efforts made so far by the European Commission, the European Parliament and the Council, in preparing the proposal for the decision concerning the 7th Framework Programme. We would like to demonstrate forcefully this appreciation, by voting for the proposal.

However, during discussions on the details of the Programme implementation, Poland consistently signalled that research activities involving any use of human embryonic stem cells or human embryos constitute a departure from the basic moral standards. Furthermore, taking into account lack of sufficient knowledge concerning potential long-term consequences of such research, Poland indicated on numerous occasions that she could not agree to EU funding for it. Unfortunately, in its current form Article 6 of the decision concerning the 7th Framework Programme allows financing such research.

Therefore, considering fundamental ethical principles and other abovementioned arguments, Poland cannot agree to the EU funding for research activities involving any use of embryonic stem cells or human embryos. We are thus appealing to the Presidency and the European Commission to

take this aspect from the currently discussed text of the proposal for the decision on the 7th Framework Programme for a separate consideration. Such a move would allow Poland to support the suitably amended proposal".

STATEMENT BY PORTUGAL

"The compromise text which has been adopted is, naturally, progress towards the adoption of FP7. However, we must denounce the limitations that this debate has shown with regard to the development of bio-medical research in Europe. We welcome the acceptance of embryonic stem cell research in the 7th Framework Programme for Research and Technological Development (RTD), but we cannot refrain from deploring the inconsistency of trying to hide the necessity of obtaining these same embryonic cells.

To exclude from RTD projects the support to mechanisms for obtaining embryonic stem cells hides precisely the part of the RTD process that would most require stringent ethical scrutiny".

STATEMENT BY MALTA

In principle, Malta supports the Seventh Framework Programme for research, technological development and demonstration activities (2007-2013), as it constitutes an important instrument that reinforces in a tangible manner EU research, which is an effective driver for innovation and growth.

Malta, however, holds that the protection of human dignity and the right to life should be afforded the highest possible protection from its inception. In this respect, Malta stresses that activities which imply the use of human embryonic stem cells or embryos should not have been included in the scope of this EU publicly funded programme.

While Malta appreciates the statement by the Commission that it will continue with the current practice not to submit to the Regulatory Committee under FP7, proposals for projects which include

research activities which involve the destruction of human embryos, including for the procurement of stem cells, it considers that this does not go far enough, as it still allows the possibility of Community funding of subsequent stages involving human embryonic stem cells.

In this respect, Malta regrets that the Seventh Framework Programme does not adequately address the ethical concerns regarding research with human embryos and human embryonic stem cells. In view of this, Malta cannot agree to the overall Seventh Framework Programme, and is therefore voting against the Council's common position.

STATEMENT BY LITHUANIA

Lithuania recognises the significance and added value of the 7th Framework Programme for European competitiveness and R&D, and welcomes and supports the programme.

However, Lithuania cannot accept Article 6 which allows Community funding of human embryonic stem cell research, as Lithuania considers that this research violates fundamental ethical values.

Therefore, Lithuania is not in a position to vote in favour of the proposal for the 7th Framework Programme.

STATEMENT BY THE COMMISSION

"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 aimed 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 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".

STATEMENT BY THE COMMISSION RE ITEM 3(B)

"The Commission regards the close collaboration existing today between the European participants in fusion energy research as an added value for the EU. It will endeavour to ensure that the management structure of fusion energy research in FP7 should be devised in close consultation with the research community. Appropriate coordination will be ensured between the activities carried out by the European Joint Undertaking related, *inter alia* and as an initial priority, to the realisation of ITER and the other activities implemented under the thematic area "Fusion Energy Research" in FP7 through the research community aiming at improving scientific and technological knowledge in fusion energy."