

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(90)676 final-SYN 267

Brussels, 14 December 1990

Amended proposal for a

COUNCIL DECISION

adopting a specific research and technological development

programme in the field of Biomedicine and Health

(1990-1994)

(presented by the Commission pursuant to Article 149(3)
of the EEC-Treaty)

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EXPLANATORY MEMORANDUM

The modified proposal for a Council Decision for the research programme in biomedicine and health takes account of the amendments from the European Parliament which are either "horizontal", i.e. common to all programme proposals, or specific to this programme.

Horizontal amendments

The Commission's attitude with regard to these amendments is the same as for the other programmes. As far as comitology is concerned, the Commission still wishes for a Type III-a Committee, as it had proposed, while the Parliament wants this changed into a Type I Committee.

Specific amendments

The chief characteristics of the modifications arising from these amendments are as follows :

- Improvement of the presentation of the technical content (Annex I) substantially in accord with the guidance from CREST;
- addition of a fourth area of research in biomedical ethics, which goes along with the tendency to attach more importance to the ethical and social consequences of research;
- modification of the indicative distribution of the budget :

a reasonable reduction in the amount foreseen for human genome analysis (on account of the recent commencement of the programme which forms part of the second framework programme) and an increase of resources for the Area "Major health problems and diseases of great socio-economic impact", in particular for the AIDS sector.

Modified Proposal for a

COUNCIL DECISION

adopting a specific research and technological development programme in the field of Biomedicine and Health (1990-1994).

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 130q §2 thereof,

Having regard to the proposal from the Commission¹,

In cooperation with the European Parliament²,

Having regard to the opinion of the Economic and Social Committee³,

Whereas, by its Decision 90/221/Euratom, EEC⁴, the Council adopted a third framework programme for Community activities in the field of research and technological development (1990 to 1994), specifying inter alia the activities to be pursued for contributing to the development of the European potential for understanding and exploiting the properties and structures of living matter; whereas this Decision should be taken in the light of the grounds set out in the preamble to that Decision;

Whereas Article 130k of the Treaty stipulates that the framework programme shall be implemented through specific programmes developed within each activity;

Whereas an estimate should be made of the amount of Community financial resources needed to carry out this specific programme; whereas the definitive amounts will be fixed by the budgetary authority in line with the financial perspectives covering the period 1988-1992 included in the Interinstitutional Agreement of 29 June 1988⁵ and with any future financial perspectives covering the period 1993-1994;

1 OJ n° C

2 OJ n° C

3 OJ N° C

4 OJ N° L 117, 8.5.1990, p.28

5 OJ N° L 185, 15.7.1988, p.33

Whereas fundamental research must be specifically encouraged Community-wide in each of the strategic research sectors of the framework programme;

Whereas, in addition to the specific programme on human capital and mobility, training of researchers in each of the strategic research sectors of the framework programme must be ensured;

Whereas the social and human impact of the programme must be assessed by an independent panel and technology and risk assessment be undertaken, particularly in the field of bioethics;

Whereas, pursuant to Article 4 and Annex I of Decision 90/221/Euratom, EEC, the funds estimated as necessary for the whole of the framework programme include an amount of 57 million ecus for the centralised dissemination and exploitation of results, to be divided up in proportion to the amount envisaged for each activity; whereas in view of the importance of this specific programme within the "Life Sciences and Technologies" action the estimate of the financial resources needed by this programme is to be reduced by 1.33 million ecus, which amount is to be allocated to the said centralised activities, in order to comply with the second sentence of Article 130p §2 of the Treaty;

Whereas this programme must be implemented by the Commission; whereas to help accomplish this, the Member States are bound, pursuant to Article 5 of the Treaty, to facilitate the achievement of its tasks where necessary, notably within a committee;

Whereas this programme must be implemented essentially by the selection of research and development projects to enable them to benefit from Community participation; whereas the Commission should encourage the submission of such projects by the usual means of publishing calls for proposals in the Official Journal; whereas an exceptional procedure should also be devised so as to come into effect between calls for proposals to maintain a degree of flexibility enabling the Commission, in the face of the continuous evolution and gradual acceleration of technological progress, also to take into consideration spontaneous proposals consistent with the objectives of the programme;

Whereas support for the international competitiveness of European industry, through Community research and technological development programmes, is linked with the Community's external relations policy based on the principle of "the global equilibrium of opportunities", and that it is also in the light of this policy that participation of European companies owned by citizens of non-Community countries must be considered;

Whereas the projects to be carried out under the programme must be selected with special attention to the principle of economic and social cohesion in the Community, to the transnational nature of the projects and to the support to be given to small and medium-sized enterprises;

Whereas it is only in the light of experience gathered in the course of development of this programme that the Commission will be able to propose and the Council to adopt supplementary programmes by having recourse to the means provided for in Articles 130 l, 130 m or 130 o of the Treaty, if they contribute to the achievement of the programme's objectives, in accordance with the option made available by Article 2(2) of the Decision 90/221/Euratom, EEC;

Whereas, in accordance with Article 130g of the Treaty, the Community's activities aimed at strengthening the scientific and technological basis of European industry and encouraging it to become more competitive include promoting cooperation on research and technological development with third countries and international organisations; whereas such cooperation may prove particularly beneficial to the development of this programme;

Whereas it is necessary, as Annex II to Decision 90/221/Euratom, EEC, provides, to contribute to improving the efficacy of medical and health research and development in the Member States, in particular by better coordination of the Member States' research and development activities and application of the results through Community cooperation and a pooling of resources;

Whereas the Scientific and Technical Research Committee (CREST) has been consulted,

HAS ADOPTED THIS DECISION :

Article 1

1. A specific research and technological development programme for the European Economic Community in the field of biomedicine and health, as defined in Annex I, is hereby adopted for the period from the date of publication of this Decision in the Official Journal to 31 December 1994.

Article 2

1. The Community funds estimated as necessary for the execution of the programme under this Decision amount to 133 million ecus. From these funds, an amount of 1.33 million ecus is drawn for the centralised action of dissemination and exploitation of results. The amount thus reduced to 131.67 million ecus includes staff costs which may not exceed 4%. An indicative breakdown of expenditure is set out in Annex II.
2. Should the Council take a decision in implementation of Article 1(4) of Decision 90/221/Euratom, EEC, this Decision shall be adapted to take account of the above-mentioned decision.
3. The budgetary authority shall decide on the appropriations available for each financial year.

Article 3

Rules for the implementation of the programme are set out in Annex III.

Article 4

The rate of the Community financial contribution shall be laid down in accordance to Annex IV to Decision 90/221/Euratom, EEC

Article 5

1. During 1992 the Commission shall review the programme and address a report on the results of the review to the Council and the European Parliament, together with proposals for any necessary changes.
2. At the end of the programme, the Commission shall assess the results obtained. It shall address a report thereon to the Council and the European Parliament.
3. The reports shall be drawn up having regard to the objectives set out in Annex I to this Decision and in accordance with Article 2(4) of Decision 90/221/Euratom, EEC. These reports shall assess the coherence of the programme's measurable implementation with the six major concerns set out in Annex II of Council Decision 90/221/Euratom, EEC⁶.

Article 6

1. The Commission shall be responsible for the execution of the programme. It shall be assisted by a committee, hereinafter referred to as "the Committee", composed of representatives of the Member States and chaired by a representative of the Commission.
2. The contracts concluded by the Commission shall govern the rights and obligations of each party, including the procedures for disseminating, protecting and exploiting the research results, in accordance with the arrangements adopted pursuant to the second paragraph of Article 130k of the Treaty and, where appropriate, procedures for training and evaluation.
3. A work programme shall be drawn up at the start of the programme and shall be regularly revised. It shall set out the detailed objectives and types of projects to be undertaken, and the financial arrangements to be made for them. The Commission shall make calls for proposals for projects on the basis of the work programmes.

6 O.J. n° L 117, 8.5.1990

Article 7

1. In the cases envisaged in Article 8(1), the Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time-limit which the chairman may set according to the urgency of the matter. The opinion shall be delivered by qualified majority as provided for in Article 148(2) of the Treaty for the adoption of decisions which the Council is called upon to make on a proposal from the Commission. When voting takes place in the Committee, the votes of the representatives of the Member States shall be weighted as specified in the above-mentioned Article. The chairman shall not take part in the voting.
2. The Commission shall adopt the measures envisaged where they are in accordance with the Committee's opinion.
3. If the measures envisaged are not in accordance with the Committee's opinion, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal relating to measures to be taken. The Council shall act by a qualified majority.
4. If the Council has not acted within one month of submission of the proposal, the proposed measures shall be adopted by the Commission.

Article 8

1. The procedure laid down in Article 7 shall apply to :
 - preparation and updating of the work programmes referred to in Article 6(3);
 - evaluation of the projects, referred to in point 2 of Annex III, as well as the estimated amount of the Community's financial contribution, when these projects are submitted through the ordinary procedure referred to in point 4 of Annex III and the above-mentioned amount is more than 5 million ecus;
 - evaluation of all projects submitted through the exceptional procedure referred to in point 4 of Annex III, as well as the estimated amount of the Community's financial contribution;
 - measures for evaluating the programme.

2. The Commission may consult the Committee on any matter falling within the scope of the programme.
3. The Commission shall inform the Committee with regard to :
 - the progress of the programme;
 - planned calls for proposals, referred to in Article 6(3);
 - projects, referred to in point 2 of Annex III, submitted through the ordinary procedure, for which the Community contribution is less than 5 million ecus, and the results of their evaluation;
 - accompanying measures, referred to in point 2 of Annex III;
 - concerted actions, referred to in point 2 of Annex III.

Article 9

In implementing this programme, supplementary programmes within the meaning of Article 130l, participation within the meaning of Article 130m and joint undertakings or any other structures within the meaning of Article 130o of the Treaty may also be decided on as the need arises.

Article 10

Where cooperation with third countries and international organisations aiming at achieving the objectives of this programme requires legal undertakings between the Community and the third parties concerned, the Commission shall be authorised to negotiate, in accordance with Article 130n of the Treaty, international agreements laying down the terms of such cooperation.

Priority will be given to cooperation with EFTA countries and European countries not members of the European Community. In accordance, where appropriate, with the guidelines drawn up between the Council and the European Parliament during the conciliation procedure on the third framework programme.

The negotiations for such international agreements may only be initiated with third countries who are already signatories of an agreement with the Community which explicitly cites research and technological development or scientific progress as one of the objectives of cooperation.

Decisions on the conclusion of such international agreements shall be adopted in accordance with the procedure referred to in Article 130q(2) of the Treaty.

Article 11

This Decision is addressed to the Member States.

Done at Brussels,

For the Council,
The President

SCIENTIFIC AND TECHNICAL OBJECTIVES AND CONTENT

This specific programme fully reflects the approach embodied in the Third Framework Programme in terms of the scientific and technical goals and the underlying aims which it pursues.

Paragraph 4C of Annex II of the Framework Programme forms an integral part of the present specific programme.

Close coordination will be maintained with other relevant research programmes, including "Biototechnology", "Life Sciences and Technologies for Developing Countries", "Telematics Systems - Health Care", "Medical Research" under the European Coal and Steel Community Treaty, and also the "Europe against Cancer" programme.

The principle of subsidiarity will be applied to the maximum. Harmonisation of approaches and methodologies used in different national programmes will be encouraged. The projects within the programme will have a European dimension based on research networks. Their main criteria will be quality and additionality. Strengthening of networks, particularly by the establishment of "European Laboratories Without Walls", will aim at the development of specific and competitive subject areas. Mobility of research workers between participating laboratories will be encouraged, including for short periods of time.

Harmonised methods, specific to the relevant protocols, will ensure that the data resulting from the projects carried out throughout the Community can be analysed and exploited anywhere in the Community. Coordination with national activities will ensure effective use of resources.

The fundamental role of basic research in underpinning the work of the programme is recognised. Prenormative research will be developed whenever needed for the completion of the Internal Market, in respect of serving patients' needs.

The following presents an analytical description of the content of the programme, based on and taking account of the above elements.

Area 1 Development of coordinated research on prevention, care and health systems

This area covers the harmonisation of methodologies and protocols in epidemiological, biological, clinical and technological research.

The key targets will be :

Precompetitive drug testing and research into the monitoring and surveillance of drug prescribing practices, patient compliance and the incidence of adverse drug reactions will be carried out, based on clinical and epidemiological data collected through coordinated networks, and with a view to an improved harmonisation of norms, parameters and guidelines.

Risk factors relating to occupational health, including dangerous substances and biological agents, will be studied with the aim of their identification, and of risk prevention and of early detection of disease. Among the subject fields will be information methods for workers about safety and cost-effective management of screening systems. Research related to the genetic screening of workers for apparent predispositions to occupational diseases and workplace hazards, and which implies those workers' participation, will not be conducted without their consent.

Enhancement and application of biomedical technology to medical and health care will be directed towards the development of coherent systems and procedures for diagnosis, therapy, prevention, care and rehabilitation. Coordination of basic research (modelling) in biomedical technology will be aimed at fundamental insight into failing human functions and on the characteristics of biomaterials. Applied technological research will be aimed at artificial systems to restore failing human functions and alleviate handicaps as completely as possible.

Lastly, support must be given in these different fields to multicentre studies between countries to facilitate the granting of patents, epidemiological studies and authorisations for the marketing of new medicinal products.

Harmonisation of protocols and approaches in health services will be emphasised, particularly with Europe 1992 in view. Research will be carried out into the financing of health care, the management of the health care workforce, and health care systems. The methodology of research into prevention, therapy and rehabilitation will also be studied.

Area 2 Major health problems and diseases of great socio-economic impact

Major health problems and economically and socially significant disease groupings will be considered, in particular the following :

AIDS

The research will take into account the activities already developed by the Community and will be spread over five main sectors :

- disease prevention - concentrating on specific epidemiological projects, studies of primary and secondary prevention, assessment of preventive strategies, behavioural research and forecasting,
- fundamental research - concentrating on AIDS viruses, host response, pathogenesis and experimental models;
- clinical research - concentrating on clinical trials, clinical manifestations, support of clinical centres and national coordination,
- the development of a European Vaccine against AIDS (EVA) will be actively pursued. A centralised facility will work in collaboration with industrial and academic laboratories to produce antigens, sera, cells and other materials,
- testing methods of Antiviral Drugs in AIDS Management (ADAM) will be developed. Primary screening capacity will be increased by introducing additional primary screening methods.

In this specific area collaboration with other European Community actions, including the specific programme on "Life Sciences and Technologies for Developing Countries", will receive particular attention.

CANCER

Epidemiology and fundamental research on genomic and phenotypic changes in cancer cells (invasion and metastasis) and immune surveillance will be extended. Particular attention will be paid to research into oncogenes and antioncogenes. Priority support activities will include the improvement of European tumour cell and tissue bank resources, and the development of the scientific basis for common guidelines for anti-cancer drug screening.

Research will concentrate on improved methodologies involving differing combinations of surgery, radiotherapy, chemotherapy and immunotherapy, and their subsequent harmonisation with associated local and general approaches.

Research will also be carried out on the links between environmental factors and the incidence of cancer, with the aim of developing preventive approaches, in coordination with the research programme on the environment.

In conjunction with the "Europe against Cancer" programme, particular attention will be paid to research in the area of paediatric oncology.

CARDIOVASCULAR DISEASE

The various forms of heart and circulatory disease will be studied, focusing on research where coherent broadly-based clinical and epidemiological surveys are most useful; this will include correlation between genetic factors, lifestyle, nutrition, and the incidence and development of cardiovascular disturbances, the effects of prophylactic and therapeutic measures, the development of new regimens for treatment including non-invasive methods of diagnosis, and the testing of drugs.

MENTAL ILLNESS AND NEUROLOGICAL DISEASE

Multidisciplinary approaches to the study of aetiological factors and predisposing conditions will be developed in a range of psychosocial environments. The aim of such studies will be to improve understanding of the causes of mental illness and also the evolution from pathology to disability and social disadvantage, and to develop new methods of prevention and care.

A global approach to the study of central nervous system malfunctioning common to pathological and physio-pathological conditions will be pursued, to improve understanding of aetio-pathogenic mechanisms.

Specific studies will be carried out in the areas of enzymology, neuroendocrinology and genetics.

Particular attention will also be paid to the part played by mental processes in the development of diseases such as cancer, AIDS or cardiovascular disorders.

AGEING, AND AGE-RELATED HEALTH PROBLEMS AND HANDICAPS

Research on perinatal illnesses (including the study of the social and economic impact of prenatal diagnosis) and paediatric illnesses and on the effectiveness of prophylactic and therapeutic measures will be carried out.

The overall target for research in the field of ageing will be directed towards prevention of and coping with dependency. A concerted approach to the study of ageing will be pursued in order to identify essential elements in the maintenance of the quality of life in the aged, in preventing or delaying the functional decline of the individual, and in reducing costs to society. Emphasis will be placed on longitudinal studies on ageing in different cultural settings, and on specific pathologies relating to ageing such as senile dementia, osteoporosis, and disorders of the immune system. Special attention will be given to the effects of the environment on health, especially on people in the more vulnerable age groups; this will be pursued in close liaison with research on environmental protection.

Studies will be carried out on methods of improving organ transplants.

Area 3 Human Genome Analysis

This research will be developed towards the completion and the integration of the genetic and physical maps. In addition, the study of the genetic basis for biological functions will be pursued, as well as the setting-up of a coordinating mechanism to sequence a portion of the genome of major biological interest (e.g. the portion coding for the Human Lymphocyte Antigen system).

Emphasis will be placed on medical applications which contribute to the well-being of patients : In coordination with other elements of the research programme in biomedicine and health, to ensure that the advances in the understanding of genetics are used to enhance human health : In particular, on understanding the genetic component of multifactorial conditions such as Alzheimer's disease, and on developing methods intended to improve therapies.

Links will be maintained with appropriate International organisations or forums (e.g. HUGO, the Human Genome Organisation), as well as with research actions in non-member states using similar or complementary approaches. The Community programme is characterised by its emphasis on gene mapping and on the use of information resulting from the analysis of other species' genomes. It is therefore important that the research programme in biomedicine and health should link closely with relevant activities elsewhere in the framework programme.

Particular attention and caution will be given to the ethical, social and legal aspects of this work, especially to those which may be linked to possible misuses of research findings. No research modifying, or seeking to modify, the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary will be carried out under this programme.

However, the results of this research must enable the genetic data of the donors required for transplants to be established at any time.

Area 4 Research on Biomedical ethics

Studies will deal with :

- the compilation of current legislation on bioethics and current projects;
- the organisation of meetings of experts in the field of bioethics with a view to drawing up Community positions;
- the evaluation of the social impact of the programme, as well as any technological risks which may be associated with it;
- the assessment of the bioethical aspects of the various research programmes in the framework programme of Community activities and research.

Preparatory studies will be undertaken with a view to the setting up of a European ethical observatory in conjunction with the European Institutions and organisations.

Annex II

INDICATIVE BREAKDOWN OF EXPENDITURES

In %, for the period 1990-1994

Area 1 Development of coordinated research on prevention, care and health systems	20 - 25
Area 2 Major health problems and diseases of great socio-economic impact, <u>with AIDS receiving 50% of the sum for Area 2</u>	55 - 60
Area 3 Human Genome Analysis	20 - 25
Area 4 <u>Research on Biomedical ethics :</u> <u>5% of the total for Areas 1, 2 and 3.</u>	

The breakdown between different areas does not exclude the possibility that projects could cover several areas.

1. An amount equivalent to 10% of the total shall be used for projects encouraging fundamental research, which should be clearly identified.
2. An amount equivalent to 5% of the total shall be devoted to projects encouraging the training of researchers in the field covered by this specific programme.

Annex III

RULES FOR IMPLEMENTING THE PROGRAMME AND ACTIVITIES
FOR DISSEMINATION AND EXPLOITATION OF THE RESULTS

1. The Commission shall implement the programme on the basis of the scientific and technical content described in Annex I.
2. The rules for implementing the programme, referred to in Article 3, comprise research and technological development projects, accompanying measures and concerted actions.

The projects shall be the subject of shared-cost research and technological development contracts.

The accompanying measures consist of applying the means to ensure proper technical execution, management and evaluation of the programme, as well as adequate dissemination and accessibility of the results, and coordination, training and consciousness-raising of the participants in the programme;

The concerted actions are those defined in Article 92 of the Financial Regulation.

3. The participants in the projects must be natural or legal persons established in the Community, such as universities, research organisations and industrial firms, including small and medium-sized enterprises, or associations thereof, in particular European Economic Interest Groupings (EEIGs).

Natural or legal persons established in countries which have concluded cooperation agreements on scientific and technical research with the Community may, on the principle of mutual benefit, participate in the projects undertaken in the framework of this programme. Such contracting parties will not benefit from Community financing under the framework programme. They will contribute to the general administrative costs.

4. The choice of projects shall be carried out according to the following order of priority, the first method being the rule, the second the exception.

The participants in the projects shall be selected on the basis of the ordinary procedure of calls for proposals referred to in Article 6(4) and published in the Official Journal of the European Communities.

Where other criteria of scientific excellence are satisfied, and in accordance with the guidelines agreed between Council and the European Parliament, in the case of a number of project proposals of equal scientific value, preference shall be given :

- (i) to project proposals whose implementation involves project participants in less-developed regions and/or regions in industrial decline as defined by Articles 8 and 9 of Council Regulation EEC N° 2052/88.
- (ii) to project proposals involving small and medium-sized enterprises or an association of such enterprises.

The Commission shall determine in each case whether the management of the programme, or parts thereof, can be undertaken by organisations or institutions outside the Commission, without delegation of its decision-taking powers.

The Commission may also accept proposals, according to an exceptional procedure and under the conditions mentioned below, when they make a particularly promising and significant contribution as regards the originality of the theme proposed, the novelty of the scientific and technical approach and the methodology of execution, also taking into account the particular nature of the proposers.

A favourable technical evaluation of such proposals shall not by itself be a sufficient justification for accepting a project; this exceptional procedure may only apply after verification that the nature of the project, as defined above, does not justify the use of the normal procedure for calls for proposals.

The exceptional procedure shall come into effect after the first call for proposals and must be completed before the ordinary procedure in such a way that the available amount for the Community's financial participation in projects retained by the

ordinary procedure can be determined precisely. The closing date for the exceptional procedure shall be published each year in the Official Journal of the European Communities.

When it submits the preliminary draft budget the Commission shall inform the budgetary authority whether the appropriations approved in the budget of the previous year have also financed projects retained by the exceptional procedure and the amounts allocated. Should these projects cover several programmes, it shall state the type of committee which assisted it.

The amount of the financial participation of the Community for all the projects retained by the exceptional procedure will be decided each year, in relation to the projects selected according to particularly strict criteria of excellence. In any case this amount may not exceed 10%; it may be revised each year in the light of experience.

The Commission shall draw up a vade-mecum setting out all the rules applicable to this exceptional procedure in order to guarantee full transparency.

5. The projects must involve at least two mutually independent partners established in different Member States.
6. The Commission may encourage the participants to form a European Economic Interest Grouping (EEIG) or make other arrangements for carrying out projects, such as those on a large scale, permitting decentralised management adapted to the specific requirements of the project.
7. The knowledge acquired during the course of the projects shall be disseminated on the one hand within the specific programme and on the other hand by means of a centralised activity, pursuant to the decision referred to in the third paragraph of Article 4 in Decision 90/221/Euratom, EEC.

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