COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 28 May 1990

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)

CONTENTS

Proposal for a

COUNCIL DECISION

adopting a specific and technological development programme

in the field of Biomedicine and Health

(1990-94)

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 Commission,(1)

In cooperation with the European Parliament,(2)

Having regard to the opinion of the Economic and Social Committee,(3)

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(1) OJ No C

(2) OJ No C

(3) OJ No C

Whereas by its Decision 90/221/Euratom, EEC(4), the Council adopted a third framework programme for Community activities in the field of research and technological development (1990-94), specifying inter alia the activities to be pursued for contributing to the development of the European potential for understanding and expolting the properties and structures of living mattcr; 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 is to 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 1988(5) and with any future financial perspectives covering the period 1993 - 1994;

Whereas, pursuant to Article 4 and Annex I of Decision 90/221/Euratom, EEC, the amount deemed necessary for the whole framework programme includes an amount of 57 million ecus for the centralized 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 centralized activities, in order to comply with the second sentence of Article 130p (2) of the Treaty;

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(4) OJ No L 117, 8.5.1990, p.28.

(5) OJ No L 185, 15.7.1988, p.33.

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 a special procedure should also be devised so as 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 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, the transnational nature of the projects and 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 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 130I, 130m or 130o 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 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 organizations; whereas such cooperation may prove particularly beneficial for 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

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 a period of five years as from 1 January 1990.

Article 2

1. The Community funds estimated as necessary for the execution of the programme under this Decision amount to 133 million ecus. Of this amount 1.33 million ecus is drawn for the centralized 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 abovementioned 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 with 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.

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.

3. A work programme for each year shall be drawn up and updated where necessary. 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 annual work programmes.

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 in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the Member States' representatives within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

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 the 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:

   - the 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 abovementioned 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 130I, 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 authorized to negotiate, in accordance with Article 130n of the Treaty, international agreements laying down the terms of such cooperation.

Decisions on the conclusion of such 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 ....., ...

For the Council,

The President

Annex I

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 "Life Sciences and Technologies for Developing Countries", "Telematics Systems - Health Care", and "Medical Research" under the European Coal and Steel Community Treaty.

The principle of subsidiarity will be applied to the maximum, through encouraging the harmonization of approaches and methodologies used in different national programmes. The projects themselves will have a European dimension arising from their polycentric execution based on research networks. Harmonized methods, specified in the relevant protocols, will ensure that the data resulting from the projects carried out throughout the Community can be statistically analysed and coherently exploited anywhere in the Community.

Prenormative research will be developed whenever needed for serving patients' needs and for the completion of the Internal Market.

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

Area 1. Harmonization of methodologies and protocols in epidemiological, biological and clinical research

The essential features of this area are outlined below:Testing of drugs will be conducted through the development of networks, enabling both the collection of clinical and epidemiological data and the monitoring and surveillance of prescriptions and of adverse drug reactions.

Screening for risk factors will be covered, especially in the context of occupational health. Examples of risk factors at work include shiftwork, new technology in the office and occupational health risks in health care workers. Safety in laboratories is of particular importance. Related topics include audit in occupational health and ethical problems.

In biomedical technology, research will be directed towards the development of new coherent diagnostic procedures, such as medical imaging techniques. In the biomedical engineering area, the aim is to restore function as completely as possible to the handicapped, particularly by developing new biomaterials for use in prostheses, tissue replacements and artificial organs. Methods of monitoring the effects of treatment, and consequent restoration of function, will also be developed.

Harmonization of protocols and approaches as regards the management of health services will be emphasized.

Area 2. Applications to diseases of great socio-economic impact

Five economically and socially significant disease groupings will be considered, as described below:

AIDS

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

The disease prevention sector will concentrate on specific epidemiological projects, studies of primary and secondary prevention, assessment of preventive strategies, behavioural research and forecasting, using inter alia centres or facilities with unique characteristics.

The fundamental research sector will concentrate on AIDS viruses, host response, pathogenesis and animal studies.

The clinical research sector will concentrate on clinical trials, clinical manifestations, support of clinical centres and support of national coordination, e.g. by establishing a network of Clinical AIDS Reference Centres and other relevant groups. This immediately sensitive part of the programme will be given a special priority. Prenormative research will be included, with development of new drugs being emphasized.

The development of a European Vaccine against AIDS (EVA) will be actively pursued. Its objective is the promotion of collaborative research by the provision of high-quality reagents for investigations of the immune response to lentiviruses and the induction of protective immunity. A centralized laboratory facility will be provided, and arrangements will be made for industrial and academic laboratories to produce to agreed specifications required amounts of antigens, sera, cells and other materials; the centralized facility will be responsible for assaying the materials, together with their adequate storage and distribution.

Testing methods for Antiviral Drugs in AIDS Management (ADAM), the most recent domain of research, will be developed. Primary screening capacity will be increased by introducing additional primary screening methods; further research will be undertaken on the mode of action of promising compounds, and consideration may be given to ways of scaling up their production.

Cancer

Research will concentrate on improved methodologies involving differing combinations of surgery, radiotherapy, chemotherapy and immunotherapy, and their subsequent harmonization. Local approaches involving surgery and radiotherapy will be studied vis-à-vis improved methods of removing all visible tumour tissue, aiming to leave a minimal tumour burden with resulting maximization of the effects of new systemic treatments as they become available. More effective methods of local control, as well as of systemic treatments, will be developed in order to achieve rapid improvement in overall survival. Selectivity of radiotherapy will be further improved, e.g. using light ion therapy and Boron neutron capture therapy (BNCT), aiming at an improved survival rate.

Epidemiology and fundamental research on genomic and phenotypic changes in cancer cells (invasion and metastasis) and immune surveillance will be extended. 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.

Cardiovascular Disease

The various forms of heart and circulatory disease will be studied, focusing on research where coherent broadly-based clinical surveys are most useful; this includes correlation between life style, nutrition, and the incidence and development of cardiovascular disturbances, the effects of prophylactic and therapeutic measures, the development of new regimens for the treatment and the testing of drugs.

Mental Illness and Neurological Disorders, and Mental Handicap

A comparative analysis of aetio-pathogenetic factors and conditions relative to the incidence of mental illness in widely different psycho-social environments will be carried out in order to obtain an insight into the responsible mechanisms. Systems for the handling and treatment of patients will be compared in order to identify the most effective. A coherent, multidisplinary approach to the study of central nervous system malfunctioning common to mental illness and neurological disorders will be pursued. Multiple sclerosis and Parkinson's disease are examples.

A comparative study of the handling of the mentally handicapped and of their rehabilitation will be carried out. The approach will be broad and comprehensive, ranging from the molecular to the socio-economic aspects.

Ageing, and Age-Related Health Problems and Disabilities

Comparative research on perinatal and paediatric illnesses and on the effectiveness of prophylactic and therapeutic measures will be carried out.

A concerted approach to the study of ageing, with emphasis on the clinical aspects, will be pursued in order to identify, on a large-scale factual basis, 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. Special attention will be given to the effects of the environment on health, especially on people in the more vulnerable ages; this will be pursued in close liason with research on environmental protection.

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 consortium 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 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 organizations or forums (e.g. HUGO, the Human Genome Organization), as well as with research actions in non-member states using similar or complementary approaches. The Community programme is characterized by its emphasis on gene mapping and on the use of information resulting from the analysis of other species' genomes.

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.

Annex II

INDICATIVE BREAKDOWN OF EXPENDITURES

in %, for the period 1990-1994

Area 1.	Harmonization of methodologies and protocols in epidemiological, biological and clinical research	20 - 25
Area 2.	Applications to diseases of great socio-economic impact	45 - 50
Area 3.	Human Genome Analysis	30 - 35

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

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 the Financial Regulation.

3. The participants in the projects must be natural or legal persons established in the Community, such as universities, research organizations 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 agreements with the Community foreseeing scientific and technical research, may, based on the criterion of mutual advantage, take part in the projects undertaken in the context of this programme. The contracting parties under such arrangements shall not benefit from Community funding. They shall 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 (3) and published in the Official Journal of the European Communities.

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 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.

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 15%; 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 decentralized 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 centralized activity, pursuant to the decision referred to in the third paragraph of Article 4 in Decision 90/221/Euratom, EEC.

FINANCIAL STATEMENT

1. BUDGET HEADING AND TITLE

Part B of the general budget

Subsection 6, Item 6223

Specific programme of Community RTD activities in the field of Biomedical and Health Research (1990-1994)

2. LEGAL BASE

Article 130 Q(2) of the Treaty.

3. OBJECTIVES AND DESCRIPTION

See Annex I of the proposal.

4. FINANCIAL IMPLICATIONS

Amounts deemed necessary in MIO ECU:	
Programme implementation	131.67
Centralized action for dissemination and exploitation	1.33
TOTAL	133.00

The indicative operational breakdown of the 131.67 MIO ECU for the programme implementation is given in Annex II of the proposal.

Indicative multiannual schedule (in MIO ECU)

	1990	1991	1992	1993	1994(1)	TOTAL
Commitments	-	25	24.50	59	23.17	131.67
Payments	-	7	17.92	29	77.75	131.67

The definitive yearly amounts will be determined by the budgetary authority in accordance with the financial perspectives for the period 1990-1992 (annexed to the Interinstitutional Agreement of 29 June 1984) and with subsequent financial perspectives which may be adopted for 1993 and 1994.

5. STAFF AND ADMINISTRATIVE EXPENDITURE

In addition to the principal means of action which are contracts (Annex III), the above amounts include programme-related staff and administrative expenditure estimated at no more than 13 MIO ECU.

The expenditure on staff will not exceed 4% of the amount deemed necessary for the programme implementation. This implies a maximum of 18 statutory posts (A, B and/or C) at any given time during the life of the programme. The infrastructure costs related to statutory staff will be borne by Part A of the budget.

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(1) for the payment appropriations: 1994 and beyond

6. IMPLICATIONS FOR REVENUE

The contributions by third country contractors towards the cost of administration of the programme will be reused pursuant to articles 27.2 and 96 of the Financial Regulation(2).

7. TYPES OF CONTROL

Control will be exercised by :

- the Programme Management Committee (scientific control)

- the services of the DG responsible for the execution of the programme, possibly assisted by independent experts

- the Commission's Financial Controller

In accordance with Article 2 of the Financial Regulation(2), the use of appropriations will be subject to analyses of cost-effectiveness and the realization of quantified objectives will be monitored.

External audit may be carried out by the Court of Auditors in accordance with the Treaty.

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(2) Financial Regulation of 21 December 1977, as last amended by Regulation 610/90 of March 1990

STATEMENT OF IMPACT ON COMPETITIVENESS AND EMPLOYMENT

1. The main reason for introducing the measure

The programme aims to contribute to improving the effectiveness of research and development in medicine and health in the Member States, in particular through better co-ordination of their research and development activities, to applying their findings through Community co-operation and to using available resources in common.

This pre-competitive and mainly concerted action programme seeks to add to the sum of basic and clinical knowledge, and then to make publicly available all new information as early, as often and as extensively as possible. Businesses of any size will thus have the opportunity to benefit from their developing any matters of their own choice arising from such Community research activities.

2. Features of the businesses in question

The businesses can be of any nature or size, including small and medium-sized ones, and their interests may range from items of medical equipment and supplies through to pharmaceutical agents such as new or improved vaccines or drugs.

3. Obligations imposed directly on businesses

The same obligations are imposed on all institutions participating in the programme including: conformity of the proposed research with the technical annex of the project, transnational cooperation, free site-access to Commission agents, participation in seminars and meetings of contractors organized by the Commission, and annual reports of activities and results.

4. Indirect obligations likely to be imposed on businesses by national, regional or local authorities

No such obligations are foreseen following the implementation of this Council decision.

5. Special provisions in respect of small and medium-sized enterprises

None, as mentioned earlier.

6. Likely effects on:

a. The competitiveness of business

As the programme is aimed at pre-competitive research, not leading directly to new commercial products or processes, there will be no immediate effect on the competitiveness of business. It will nevertheless contribute to the improvement of the scientific basis needed by companies to improve or develop their mid- and long-term competitive capabilities.

As the technical work develops, dissemination of information about the research results will commence - so providing new subject-matter which may in turn interest European businesses.

b. Employment

The effects on employment of the programme (inasmuch as these can be measured) are and will continue to be of an indirect nature.

7. Consultation of representative organizations

The Industrial Research and Development Advisory Committee has been consulted during the preparation of the programme.

Specific research and technological development programme
in the field of Biomedicine and Health

SUMMARY OF 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 "Life sciences and technologies for developing countries", "Telematics Systems - Health Care", and "Medical Research" under the European Coal and Steel Community Treaty.

The principle of subsidiarity will be applied to the maximum, through encouraging the harmonization of approaches and methodologies used in different national programmes. The projects themselves will have a European dimension arising from their polycentric execution based on research networks. Harmonized methods, specified in the relevant protocols, will ensure that the data resulting from the projects carried out throughout the Community, can be statistically analysed and coherently exploited anywhere in the Community.

Prenormative research will be developed whenever needed for serving patients' needs and for the completion of the Internal Market.

The content of the programme, based on and taking account of the above elements, covers the following areas:

Area 1. Harmonization of methodologies and protocols in epidemiological, biological and clinical research

Area 2. Applications to diseases of great socio-economic impact

Area 3. Human genome analysis

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