



European Communities

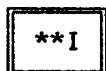
EUROPEAN PARLIAMENT

SESSION DOCUMENTS

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A3-0328/90/PART A



R E P O R T

of the Committee on Energy, Research and Technology

on the Commission proposal for a Council decision adopting a specific research and technological development programme in the field of biomedicine and health (1990-1994)
(COM(90) 0162 final - C3-0165/90 - SYN 267)

Rapporteur: Mr Alain POMPIDOU

Part A: Amendments
Draft legislative resolution

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PE 144.398/fin./Part A

A Series: Reports - B Series: Motions for Resolutions, Oral Questions - C Series: Documents received from other institutions (e.g. Consultations)



= Consultation procedure requiring a single reading



= Cooperation procedure (second reading) which requires the votes of a majority of the current Members of Parliament for rejection or amendment



= Cooperation procedure (first reading)



= Parliamentary assent which requires the votes of a majority of the current Members of Parliament

C O N T E N T S

	<u>Page</u>
Procedural page	3
A. Amendments to the Commission proposal	4
DRAFT LEGISLATIVE RESOLUTION	28

By letter of 11 June 1990 the Council consulted the European Parliament, pursuant to Article 130q (2) of the EEC Treaty on the Commission proposal for a Council decision adopting a specific research and technological development programme in the field of biomedicine and health (1990-1994).

At the sitting of 15 June 1990 the President of Parliament announced that he had referred this proposal to the Committee on Energy, Research and Technology as the committee responsible and to the Committee on Budgets and the Committee on the Environment, Public Health and Consumer Protection for their opinions.

At its meeting of 22 May 1990 the Committee on Energy, Research and Technology appointed Mr Pompidou rapporteur.

At its meetings of 28 June, 16 October, 7 November and 28 November 1990 it considered the Commission proposal and the draft report.

At the last meeting it adopted the draft legislative resolution by 14 votes, with 4 abstentions.

The following took part in the vote: Adam, chairman; Sälzer, vice-chairman; Pompidou, rapporteur; Anger, Bettini, Breyer, Ernst de la Graete (for Lannoye), Garcia Arias, Gasoliba i Böhm, Larive, Linkohr, Pierros, Quisthoudt-Rowohl, Regge, Robles Piquer, Rovsing, Sanz Fernandez and Verwaerde.

The opinion of the Committee on Budgets and the Committee on the Environment, Public Health and Consumer Protection are attached.

The report was tabled on 22 November 1990.

The deadline for tabling amendments will appear on the draft agenda for the part-session at which the report is to be considered.

A

Commission proposal for a Council decision adopting a specific research and technological development programme in the field of biomedicine and health (1990-1994)

Commission text¹

Amendments

(Amendment No. 1)

After the third recital, new recital a

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

(Amendment No. 2)

After the third recital, new recital b

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;

(Amendment No. 3)

After the third recital, new recital c

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

¹ For full text see COM(90) 0162 final - OJ No. C 174, 16.7.1990, p. 65

Commission text

Amendments

(Amendment No. 4)
Fourth recital

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 ECU 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 ECU, 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;

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 deemed necessary of 57 million ECU for the centralized dissemination and exploitation of results which is to be the subject of a decision of the Council in cooperation with Parliament; whereas, in view of the importance of this specific programme within the life sciences and technologies action a financial contribution to the centralized activities is required; whereas this contribution is proportional to the financial capacity of the programme and corresponds to the effective demand for the results of research from the socio-economic operators in all the Member States;

(Amendment No. 5)
Sixth recital

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 of the European Communities; 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 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 of the European Communities; 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;

Commission

(Amendment No. 6)
Article 1

Amendments

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.

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.

Amendment No. 7
Article 2(1)

1. The Community funds estimated as necessary for the execution of the programme under this Decision amount to 133 million ECU. Of this amount 1.33 million ECU is drawn for the centralized dissemination and exploitation of results. The amount thus reduced to 131.67 million ECU includes staff costs which may not exceed 4%. An indicative breakdown of expenditure is set out in Annex II.

1. The Community funds estimated as necessary for the execution of the programme under this Decision amount to 133 million ECU, including staff costs and a contribution to the centralized dissemination and exploitation of results. An indicative breakdown of expenditure for the implementation of this programme is set out in Annex II. The procedures for the dissemination and exploitation of results are set out in Annex III. An indicative breakdown of expenditure and the procedures concerning staff are set out in Annex II.

(Amendment No. 8)
Article 5(3)

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.

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, EEC¹.

¹ OJ No. L 117, 8.5.1990

Commission text

Amendments

(Amendment No. 9)
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.

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.

The European Parliament shall be informed of the deliberations of the committee in a comprehensive and timely manner.

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.

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 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.

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 annual work programmes.

Commission

Amendments

(Amendment No. 10)
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 the majority 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 the measures to be taken. The Council shall act by a qualified majority.

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 if necessary by taking a vote.

(Rest deleted.)

2. The opinion shall be recorded in the minutes; in addition, each Member State shall have the right to ask to have its position recorded in the minutes.

3. The Commission shall take the utmost account of the opinion delivered by the Committee. It shall inform the Committee of the manner in which its opinion has been taken into account.

Commission text

Amendments

(Amendment No. 11)
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 above-mentioned amount is more than 5 m ECU;
- 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 m ECU, 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.

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),
- the contents of calls for proposals, referred to in Annex III,
- the participation in any project by non-Community organizations and enterprises referred to in Article 10,
- any adaptation of the indicative breakdown of funds set out in Annex II,
- the measures to be undertaken to evaluate the programme and those projects submitted through the exceptional procedure,
- accompanying measures and arrangements for the dissemination, protection and exploitation of the results of the research, for encouraging fundamental research, training of researchers and technological assessment carried out under the programme.

The Commission shall notify the European Parliament of draft decisions which, in the exercise of the Commission's implementing powers, are forwarded to the Committee.

Commission text

Amendments

(Amendment No. 12)

Article 10

Where cooperation with third countries and international organizations 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.

Where cooperation with third countries and international organizations 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.

Priority will also be given to cooperation with regional groupings and European countries not members of the European Community in accordance with the guidelines agreed between the Council and the European Parliament¹.

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 as one of the objectives of 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.

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.

¹ Drawn up during the conciliation on the Framework Programme for Community activities in research and technological development 1990-1994.

Commission text

Amendments

(Amendment No. 13)
Annex I, third paragraph

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.

Close coordination will be maintained with other relevant research programmes, including 'Biotechnology', '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.

(Amendment No. 14)
Annex I, fourth paragraph

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.

The principle of subsidiarity will be applied to the maximum. Harmonization 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.

The existing research networks must be made more flexible to allow real interaction between laboratories and research centres and not just the exchange of information. Greater mobility of research workers should be encouraged, for example by facilitating short periods of work in the various laboratories. The research networks should also be strengthened by their developing specific very productive subject areas, in particular by developing open laboratories representing centres of excellence for basic and applied research.

Commission text

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.

Amendments

Harmonized 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.

(Amendment No. 15)
Annex I, fifth paragraph

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

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

(Amendment No. 16)
Annex I, Area 1

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.

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

This area covers the harmonization of methodologies and protocols in epidemiological, biological, clinical and technological research. The key targets will be:

Pre-competitive 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 co-ordinated networks, and with a view to an improved harmonization of norms, parameters and 'guidelines'.

Commission text

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.

Amendments

Risk factors relating to occupational health will be studied, with the aim of eliminating workplace hazards. Examples of risk factors at work include dangerous substances and biological agents, shiftwork, new technology in the office, and occupational health risks in health care workers. Related topics include audit in occupational health and effective means of informing workers about workplace safety issues. Research related to the genetic screening of workers for apparent predispositions to occupational diseases and workplace hazards will not be conducted.

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. Co-ordination 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 multi-centre studies between countries to facilitate the granting of patents, epidemiological studies and authorizations for the marketing of new medicinal products.

Commission text

Amendments

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

Harmonization of protocols and approaches in health services will be emphasized, 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.

(Amendment No. 17)

Annex I, Area 2, title and introduction

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

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

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

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

(Amendment No. 18)

Annex I, Area 2, 'AIDS'

AIDS

AIDS

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

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

- disease prevention - concentrating on specific epidemiological projects, studies of primary and secondary prevention, assessment of preventive strategies, behavioural research and forecasting.

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

- fundamental research - concentrating on AIDS Viruses, host response, pathogenesis and experimental models.

Commission text

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.

Amendments

- clinical research - concentrating on clinical trials, clinical manifestations, support of clinical centres and national co-ordination,
- 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, in particular the specific programme of research and technological development in the field of Life Sciences and technologies for developing countries will receive particular attention.

Commission text

Amendments

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.

(Amendment No. 19)
Annex I, Area 2, 'Cancer'

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-a-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.

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 anti-oncogenes. 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 harmonization with associated local and general approaches.

Commission text

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.

Amendments

Research will also be carried out regarding the environmental relationships which lead to increased incidence of cancer with the aim of developing approaches.

In conjunction with the 'Europe against Cancer' programme, a specific sector of the programme will be directed at research in the area of pediatric oncology.

(Amendment No. 20)

Annex I, Area 2, 'Cardiovascular disease'

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 lifestyle, 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.

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.

Commission text

Amendments

(Amendment No. 21)

Annex I, Area 2

'Mental illness and neurological disorders, and mental handicap'

Mental illness and neurological disorders, and mental handicap

A comparative analysis of aetiopathogenetic 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, multidisciplinary 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.

Mental illness and neurological disease

Multidisciplinary approaches to the study of aetiological factors and predisposing conditions will be developed in a range of psycho-social 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 pathologic and physiopathologic conditions will be pursued, to improve understanding of aetiopathogenetic mechanisms.

(Amendment No. 22)

Annex I, Area 2

'Ageing and age-related health problems and disabilities'

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.

Ageing, age-related health problems and handicaps

Research on perinatal (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.

Commission text

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 liaison with research on environmental protection.

Amendments

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 aging 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 related 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.

Organ transplants

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

(Amendment No. 23)
Annex I, Area 3

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).

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).

Commission text

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.

Amendments

Emphasis will be placed on medical applications which contribute to the well-being of patients, in coordination with other elements of BIOMED 1, 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 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. It is therefore important that BIOMED 1 should link closely with relevant activities elsewhere in the Framework Programme.

Particular attention 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.

Commission text

Amendments

(Amendment No. 24)
Annex I, Area 4 (new)

Area 4: Research on bioethical aspects

Studies will deal with:

- the compilation of current legislation on bioethics and current projects;

- the organization of meetings of experts in the field of bioethics with a view to drawing up Community positions;

- 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 organizations.

(Amendment No. 25)
Annex II

INDICATIVE BREAKDOWN OF EXPENDITURES

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%

INDICATIVE BREAKDOWN OF EXPENDITURES

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
with AIDS receiving 50% of the sum for Area 2
55-60%

Commission text

Area 3:

Human genome analysis
30-35%

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

Amendments

Area 3:

Human genome analysis
20-25%

Area 4

Research on bioethical aspects:

5% of the total for Areas 1, 2 and 3

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

The establishment plan deemed necessary for the duration of the programme consists of 18 statutory posts (A, B and/or C). The Commission shall indicate each year in the preliminary draft budget the number of staff deemed necessary and the corresponding expenditure.

The budgetary authority shall decide on appropriations.

This amendment represents the transfer of 15 m ECU from Area 3: human genome analysis, to Area 2: applications to diseases of great socio-economic impact. This transfer has no budgetary effect for human genome analysis as this field already has funding of 15 m ECU for 1991-1992.

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 fields covered by this specific programme.

Commission text

Amendments

3. The projects mentioned in paragraphs 1 and 2 shall be the subject of agreements concluded with the universities and research institutes organized in research networks.

4. The results of the technological and risk assessment for bioethical aspects, as provided for in Area 4 above, shall be communicated to Parliament with the evaluation reports.

(Amendment No. 26)

Annex III, Paragraph 2, fourth subparagraph

The concerted actions are those defined in the Financial Regulation.

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

Rates of Community participation will be in accordance with Annex IV of Council Decision 90/221/Euratom, EEC.

(Amendment No. 27)

Annex III, Paragraph 3

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).

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).

The participants in the projects must make 50% of their research and development expenditure in the European Community.

Commission text

Amendments

Natural or legal persons established in countries which have concluded co-operation 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. They will contribute to the general administrative costs.

The Commission reserves the right to check a posteriori whether the applicant has made at least 50% of research and development expenditure in the Community. If this were not the case, the Commission would be entitled to cancel funding of the programme.

Natural or legal persons established in countries which have concluded co-operation 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.

(Amendment No. 28)
Annex III, Paragraph 4

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.

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 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:

Commission text

Amendments

(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 No. 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 organizations or institutions outside the Commission, and it shall delegate the work accordingly.

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 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.

Commission text

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 of the European Communities.

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 project 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.

Amendments

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 project selected according to particularly strict criteria of excellence. In any case this amount may not exceed 10% of the annual budget appropriations; 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.

It shall forward this vade mecum to Parliament at the latest before this Decision is adopted.

Commission text

Amendments

(Amendment No. 29)

Annex III, after paragraph 4, new paragraph 4a

4a. No Member State may attribute to a national, regional, local, departmental or other governmental budget any Community funds allocated to organizations of that Member State in implementation of projects accepted under the terms of the project selection procedure described in paragraph 4 above.

(Amendment No. 30)

Annex III, paragraph 7

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.

7. The knowledge acquired during the course of the projects shall be disseminated with the specific programme and by means of, and in compliance with, the provisions governing the centralized action to be the subject of a decision taken by the Council in cooperation with Parliament pursuant to the third paragraph of Article 4 in Decision 90/221/EURATOM, EEC. The financial contribution of this programme amounts to ECU, in accordance with the financial provisions of Council Decision concerning centralized activities.

DRAFT LEGISLATIVE RESOLUTION

(Cooperation procedure: first reading)

embodying the opinion of the European Parliament on the Commission proposal for a Council decision adopting a specific programme of research and technological development in the field of biomedicine and health (1990-1994)

The European Parliament,

- having regard to the Commission proposal to the Council (COM(90) 0162 final - SYN 267)²,
 - having been consulted by the Council pursuant to Article 130q(2) of the EEC Treaty (C3-0165/90),
 - having regard to the report of the Committee on Energy, Research and Technology and the opinions of the Committee on Budgets and the Committee on the Environment, Public Health and Consumer Protection (A3-0328/90),
 - having regard to the Commission position on the amendments adopted by Parliament,
1. Approves the Commission proposal subject to Parliament's amendments and in accordance with the vote thereon;
 2. Calls on the Commission to amend its proposal accordingly, pursuant to Article 149(3) of the EEC Treaty;
 3. Calls for the conciliation procedure to be opened if the Council should intend to depart from the text approved by Parliament;
 4. Asks to be consulted again should the Council intend to make substantial modifications to the Commission proposal;
 5. Calls on the Council to incorporate Parliament's amendments in the common position that it adopts in accordance with Article 149(2)(a) of the EEC Treaty;
 6. Instructs its President to forward this opinion to the Council and Commission.

² OJ No. C 174, 16.7.1990, p. 65