II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 9 September 1991

adopting a specific research and technological development programme in the field of biomedicine and health (1990 to 1994)

(91/505/EEC)

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),

Whereas, by 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 to 1994), specifying, *inter alia*, the activities to be pursued for contributing to the development of Europe's potential for understanding and using 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 basic research in the field of biomedicine and health must be encouraged throughout the Community;

Whereas, in addition to the specific programme concerning human resources and mobility, it might be necessary to encourage the training of research workers in the context of this programme;

Whereas matters relating to biomedical ethics should be studied, with particular reference to the 'recommendations guiding physicians in biomedical research involving human subjects' adopted by the 18th World Medical Assembly in Helsinki in June 1964 and subsequently amended in Tokyo in 1975, Venice in 1983 and Hong Kong in 1989;

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 ECU 57 million for the centralized dissemination and exploitation of results, to be divided up in proportion to the amount envisaged for each specific programme;

Whereas Decision 90/221/Euratom, EEC provides that a particular aim of Community research must be to strengthen the scientific and technological basis of European industry and to encourage it to become more competitive at international level; whereas it also provides that Community action is justified where research contributes, *inter alia*, to the strengthening of the economic and social cohesion of the Community and to the promotion of its overall harmonious development, while being consistent with the pursuit of scientific and technical excellence; whereas the programme in the field of biomedicine and health should contribute to the achievement of these objectives;

(1) OJ No C 174, 16. 7. 1990, p. 65.
(2) OJ No C 19, 28. 1. 1991, p. 110 and OJ No C 240, 16. 9. 1991.
(3) OJ No C 41, 18. 2. 1991, p. 1.
(4) OJ No L 117, 8. 5. 1990, p. 28.

Whereas small and medium-sized enterprises (SMEs) should be involved to the maximum extent possible in this programme; whereas account should be taken of their special requirements without prejudice to the scientific and technical quality of the 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, in the context of this programme, an assessment should be made of economic and social impact as well as of any technological risks;

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 Community in the field of biomedicine and health, hereinafter referred to as 'the programme', as defined in Annex I, is hereby adopted for the period 9 September 1991 to 31 December 1994.

Article 2

1. The funds estimated as necessary for the execution of the programme amount to ECU 131,67 million, including expenditure on staff and administration amounting to ECU 13 million.

2. An indicative breakdown of funds is set out in Annex II.

3. Should the Council take a decision in implementation of Article 1 (4) of Decision 90/221/Euratom, EEC, this Decision shall be adapted accordingly.

Article 3

Detailed rules for the implementation of the programme, including the amount of the Community's financial contribution, are set out in Annex III.

Article 4

1. In the second year of implementation of the programme, the Commission shall review it and send a report on the results of its review to the European Parliament and the Council; the report shall be accompanied, where necessary, by proposals for amendment of the programme.

2. At the end of the programme, an evaluation of the results achieved shall be conducted for the Commission by a group of independent experts. This group's report, together with any comments by the Commission, shall be submitted to the European Parliament and the Council.

3. The reports referred to in paragraphs 1 and 2 shall be established 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 5

1. The Commission shall be responsible for the implementation of the programme.

2. Contracts concluded by the Commission shall govern the rights and obligations of each party, in particular the arrangements for the dissemination, protection and exploitation of research results, in accordance with the provisions adopted pursuant to the second paragraph of Article 130k of the Treaty.

3. A work programme shall be drawn up in accordance with the objectives set out in Annex I 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 work programme.

Article 6

The Commission shall be assisted by a Committee of an advisory nature composed of representatives of the Member States and chaired by the representative of the Commission.

The representative of the Commission 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 lay down according to the urgency of the matter to be dealt with, taking a vote thereon should the need arise.

The opinion shall be entered in the minutes; moreover, each Member State shall have the right to request that its position be recorded in the said minutes.

The Commission shall take the greatest account of the opinion delivered by the Committee. It shall inform the Committee of the way in which it took the said opinion into account.

Article 7

1. The procedure laid down in Article 6 shall apply in particular to:

— the preparation and updating of the work programme referred to in Article 5 (3),

— the contents of the calls for proposals,

— the assessment of the research projects and concerted action provided for in Annex III and the estimated amount of the Community's contribution to them where this amount exceeds ECU 0,1 million per year,
— departures from the general rules set out in Annex III,
— the participation in any project by non-Community organizations, bodies and enterprises referred to in Article 8,
— any adaptation of the indicative breakdown of the amount set out in Annex II,
— the measures to be undertaken to evaluate the programme,
— arrangements for the dissemination, protection and exploitation of the results of research carried out under the programme.

2. Where, pursuant to the third indent of paragraph 1, the amount of the Community contribution is less than, or equal to ECU 0,1 million per year, the Commission shall inform the Committee of the research projects and of the outcome of their assessment.

The Commission shall also inform the Committee of the implementation of the accompanying measures referred to in Annex III.

Article 8

1. The Commission is hereby authorized to negotiate, in accordance with Article 130n of the Treaty, international agreements with third countries which are members of COST, particularly the member countries of EFTA and the countries of Central and Eastern Europe, with a view to associating them with the whole programme or a part of it and, as regards Area 3, with other third countries and international organizations with a view to associating them with the whole programme.

2. Bodies and enterprises established in non-Community European States may, on the basis of the criterion of mutual benefit, be allowed to become partners in a project undertaken within the programme. For projects in Area 3 of Annex I, this option may be extended to bodies and enterprises from other non-Community countries engaged in research in the area.

No contracting partner based outside the Community and participating as a partner in a project undertaken under the programme may benefit from Community financing for this programme. Such partner shall contribute to the general administrative costs.

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 9 September 1991.

For the Council

The President

W. KOK

ANNEX I

SCIENTIFIC AND TECHNICAL OBJECTIVES AND CONTENT

The programme fully reflects the approach embodied in the third framework programme (1990 to 1994) in terms of the scientific and technical goals and the underlying aims which it pursues.

Paragraph 4c of Annex II to the framework programme forms an integral part of the programme.

Close coordination will be maintained with other relevant research programmes, including 'Biotechnology', 'Life sciences and technologies for developing countries', 'Telematics systems — health care' and 'medical research' under the Treaty establishing the European Coal and Steel Community, and also the 'Europe against cancer' programme.

The principle of subsidiarity will be applied to the maximum. Harmonization of the 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 main features of the projects will be quality and additionality, and their importance in terms of public health. 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.

Harmonized methods, specific to the relevant protocols (1), will ensure that data resulting from 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 recognized. Pre-normative research will be developed whenever needed for the completion of the internal market, with due regard for patients' needs.

Caution will be exercised and particular attention paid to the ethical, social and legal aspects of this work, especially those which may be linked to possible misuses of research findings.

Set out below is 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 harmonization of methodologies and protocols in epidemiological, biological, clinical and technological research.

The key targets will be :

Pre-competitive drug testing with a view to improved harmonization of norms and parameters 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.

Research into risk factors, especially in the context of occupational medicine, will be stepped up with a view to the identification of potential risk factors and the early detection of disease. There will be studies of the management of screening systems and its cost effectiveness. Research related to the genetic screening of workers for predispositions to occupational diseases and workplace hazards which implies those workers' participation will not be conducted without their consent.

Enhancement and application of biomedical technology in 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 gaining fundamental insights into failing human functions and 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.

(1) For the purposes of the Decision, 'protocol' in this context shall mean an experimental protocol, namely, a document which needs to be agreed before a particular collaborative experiment or research action, such as a clinical trial, is carried out. The protocol sets out, in order, the steps to be followed by all those taking part in the research, so that a harmonized method is used and results can be obtained in due course ready for dissemination, analysis and exploitation.

Support must be given to multi-centre studies between countries which might pave the way for the granting of patents and authorizations for the marketing of new medicinal products.

Emphasis will be placed on the harmonization of protocols and approaches in health services, 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 :

(a) *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 screening, assessment of preventive strategies, behavioural research and forecasting,

— basic research — concentrating on AIDS viruses, host response, pathogenesis and experimental models,

— clinical research — concentrating on clinical trials, clinical manifestations, support for clinical centres and national coordination,

— the development of a European vaccine against AIDS (EVA) will be actively pursued. A centralized facility will work in collaboration with industrial and academic laboratories to produce antigens, sera, cells and other materials,

— trials of antiviral drugs in AIDS management (ADAM), the latest research area, will be developed. Primary screening capacity will be increased by introducing new methods.

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

(b) *cancer :*

epidemiology and basic research on genomic and phenotypic changes in cancer cells (invasion and metastasis) and immune surveillance will be extended. Particular attention will be paid to the coordination of research work on oncogenes and antioncogenes. Priority support activities will include the improvement of European tumour cell and tissue bank resources, and the development of a scientific basis for 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.

Research will also be carried out on the links between risk factors and the incidence of cancer, in coordination with the relevant research programmes, 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 cancerology ;

(c) *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 ;

(d) *mental illness and neurological disease :*

multi-disciplinary 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 physiopathological conditions will be pursued to improve understanding of aetiopathogenic mechanisms.

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

Particular attention will also be paid to psychosocial phenomena during the development of diseases such as cancer, AIDS or cardiovascular disorders;

(e) *the ageing process, and age-related health problems and handicaps:*

comparative research will be carried out on perinatal illnesses (including study of the consequences of prenatal diagnosis) and paediatric illnesses and on the effectiveness of prophylactic and therapeutic measures.

The overall target for research in the field of ageing will be centred on preventing 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 live 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 social settings, and on specific pathologies relating to ageing such as senile dementia, osteoporosis, and disorders of the immune system.

Research will be carried out into the relationship between dysfunction, decrease in functional capacity and disabilities resulting therefrom.

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

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.

Area 3: Human genome analysis

This research will be aimed at 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 will the setting-up of a coordinating mechanism to sequence portions of the genome of major biological interest.

Emphasis will be placed on medical applications which contribute to the well-being of patients, in coordination with other elements of the specific programme, to ensure that advances in genetics are used to enhance human health. In particular, an attempt will be made to understand the genetic component of multifactorial conditions such as Alzheimer's disease, and to develop methods intended to improve treatment.

In addition, the results of this research could be applied to determine the genetic data of actual donors required for transplants.

Links will be maintained with appropriate international organizations or fora (e.g. HUGO, the human genome organization), as well as with research activities 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 the research programme in biomedicine and health should tie in closely with relevant activities elsewhere in the framework programme.

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.

Area 4: Research on biomedical ethics

This area will involve problems relating to the research carried out in Areas 1 to 3 of the programme. It may also be linked to the possible applications of the research results.

Work will deal with:

— evaluation of questions of biomedical ethics linked with the present research programme on biomedicine and health,

— evaluation of the social impact of the programme and the risks (including the technological risks) which might be associated with it.

This work will make use of data already available at national and/or European level, with particular reference to existing legislation or legislation under preparation in the area.

ANNEX II

INDICATIVE BREAKDOWN OF THE AMOUNT DEEMED NECESSARY

(in millions of ecus)

Area	Breakdown
1. Development of coordinated research on prevention, care and health systems	27,5
2. Major health problems and diseases of great socio-economic impact	72 (1)
3. Human genome analysis	27,5
4. Research on biomedical ethics	4,67
Total	131,67 (2) (3)

(1) Including ECU 25 million for AIDS research.

(2) Including expenditure on staff which comes to ECU 5 million and administrative expenditure totalling ECU 8 million. Five per cent of the total will be allocated to training research workers and specialists.

(3) A sum deemed necessary of ECU 1,33 million, not included in the ECU 131,67 million, will be earmarked as the contribution from the specific programme in the field of biomedicine and health to the centralized scheme for the dissemination and exploitation of results.

The breakdown between different headings does not exclude the possibility that projects could come under several headings.

ANNEX III

RULES FOR IMPLEMENTING THE PROGRAMME

1. The Commission will implement the programme on the basis of the objectives and of the scientific and technical content described in Annex I.

2. The rules for implementing the programme, referred to in Article 3, cover research and technological development projects, accompanying measures and concerted action. In selecting these, due weight must be given to the criteria listed in Annex III to Decision 90/221/Euratom, EEC and to the objectives set out in Annex I to this programme.

   — Research projects

   The projects will be the subject of shared-cost research and technological development contracts; Community financial participation will not normally be more than 50 %. Universities and other research centres participating in shared-cost projects will have the option of requesting, for each project, either 50 % funding of total expenditure or 100 % funding of the additional marginal costs.

   Shared-cost research projects must, as a general rule, be carried out by participants established within the Community. Projects in which, for example, universities, research organizations and industrial firms, including small and medium-sized enterprises, may participate must, as a general rule, provide for the participation of at least two partners, each independent of the other, established in different Member States. Contracts relating to shared-cost research projects must as a general rule be concluded following a selection procedure based on calls for proposals published in the *Official Journal of the European Communities.*

   Research contracts relating to human genome analysis (improvement of human gene mapping) must guarantee that members of the families involved are kept fully informed and consent to the use and study of their DNA. They must also guarantee full confidentiality and anonymity of personal data obtained under this programme.

   — Accompanying measures

   The accompanying measures referred to in Article 7 of the Decision will consist of:

   — the organization of seminars, workshops and scientific conferences,
   — internal coordination through the creation of integrating groups,
   — advanced technology training programmes, with emphasis being placed on multi-disciplinarity,
   — promotion of the exploitation of results,
   — independent scientific and strategic evaluation of the operation of the research projects and the programme.

   — Concerted action

   Concerted action consists of action by the Community to coordinate the individual research activities carried out in the Member States. Such action may receive funding of up to 100 % of coordinating expenditure.

3. The knowledge gained in the course of the projects will be disseminated both within the programme and by means of centralized action, pursuant to the Decision referred to in the tird subparagraph of Article 4 of Decision 90/221/Euratom, EEC.