COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a

COUNCIL DECISION

adopting the second stage (January 1984-March 1986) of the multiannual research and training programme for the European Economic Community in the field of biomolecular engineering

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(submitted to the Council by the Commission)

REASONS FOR PROPOSAL

1. INTRODUCTION

1.1. Background information

Council adopted on 7 December 1981 (1) a multi-annual research and training programme for the European Economic Community in the field of biomolecular engineering (indirect action April 1982 to March 1986). In its decision, Council specified that the programme was to be revised before its third year of implementation and executed in two stages, the first stage running from 1 April 1982 until the revision and the second from this revision until 31 March 1986.

Council defined, in its decision, the scientific content of the programme and established the amount of the appropriations and the staff required for the execution of the programme already agreed. In the statements attached to the Council minutes, specifications were made which provided the list of priorities for research actions during the first stage : they focused on agriculture and on the area of agro-food production. As for the training actions, implemented by means of training contracts and grants for short training periods, they covered the entire content of the programme outlined in the decision of Council. When the programme was adopted, the financial means allocated amounted to 8 million ECU (including expenditure on a staff of three) but article 3 of the Council decision stated that the amount of the appropriations and the staff required to execute the programme were to be re-evaluated when the programme was revised.

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(1) OJ No L 375, 30.12.1980, p. 1-3.

1.2. Implementation of the first phase

Implementation started on 1 April 1982.

As far as research by means of cost-shared contracts is concerned a total number of 169 applications, representing a proposed research effort of 550 man/year and a total budget of 68 million ECU (with a request for Community funds of 31 million ECU), were received before the deadline of July 15, 1982. From these, after consultation with the ACPM for Biomolecular Engineering, 51 proposals were selected for the negotiation of contracts starting at the beginning of 1983 and involving, as support from the Commission, the totality (5,66 million ECU) of the funds foreseen for research actions in the budget of the programme. Among the 118 remaining proposals, many applications of excellent quality had to be rejected for lack of funding possibilities. The proposals accepted were selected on the basis of their scientific merits and in view of the necessity to constitute the initial nuclei of Community R&D for each of the priorities of the programme. The research sectors covered by these nuclei, which are often of sub-critical size and obviously need to be rapidly expanded, are the following :

- technology of second generation reactors for production of agro-food
- production of vaccines for farm animals
- degradation of ligno-cellulose
- identification and transfer of genes in plant cells
- nitrogen fixation
- regeneration of isolated cells of cereals and legumes.

With regard to training, 48 applications for training contracts were received at the closing date of June 15, 1982. Among these, 15 proposals were selected for an effective start on the 1st of January 1983. The areas covered by the training contracts is broad and concerns all sectors of biomolecular engineering. The laboratories participating as host-institutions in the training contracts have been chosen on the basis of their present leadership in European R&D. The deadline of July 15, 1983 has been established for the selection of training contracts foreseen to start in 1984.

5.3.1.1 Commitment in MioECU

Expenditures	1984	1985	1986	Total
Staff	0.12	0.14	0.04	0.30
Administ. and Technical Manag.	0.20	0.25	0.05	0.50
Contracts	6.20	----	----	6.20
TOTAL	6.52	0.39	0.09	7.00

5.3.1.2 Payment in MioECU

Expenditures	1984	1985	1986	Total
Staff	0.12	0.14	0.04	0.30
Administ. and Technical Manag.	0.20	0.25	0.05	0.50
Contracts	2.95	2.95	0.30	6.20
TOTAL	3.27	3.34	0.39	7.00

5.3.2 Methods of calculation

a) Personnel expenditures

Taking into account the appropriations already decided upon by Council (1 A post, 1 B post, and 1 C post), the minimal needs for the implementation of the 2nd phase of the programme are assessed to an additional staff of :

1 A post
1 C post.

These needs take into account the necessity to carry out the administrative and scientific management of approximately 50 new research contracts and 60 new training contracts.

The calculations are based upon annual figures estimated for 1983 at 75.100 ECU for an A post and 29.800 ECU for a C post and upon a rate of salary increase amounting to 8% per year.

b) Expenditure for administrative and technical operations

They cover travel, mission and meeting expenses as well as the cost of scientific and technical assistance whenever it proves necessary for the implementation of the programme.

c) Expenditure in respect of contracts

Since the nature of the work and the qualifications of the contracting parties vary, it is impossible to introduce a standard method of calculation. The average cost of 90.000 ECU in 1982 per scientist/year with an annual increase of 8% of the cost of the research and a contribution from the Commission of 50% to the cost of this research were used as a basis for estimation. However, the Advisory Committee on Programme Management (ACPM) will always be consulted on the allocation of funds.

6. FINANCIAL INCIDENCE ON RUNNING SUPPLIES FOR PERSONNEL AND MANAGEMENT :

(see point 5 above)

7. FINANCING OF EXPENDITURES

Funds to be included in future budgets

8. FINANCIAL IMPLICATIONS IN RESPECT OF REVENUE :

- Community tax on income of officials

- Contribution of officials to pension scheme

9. TYPE OF CONTROL FORESEEN :

- Scientific controls : ACPM
  Officials appointed by DG XII

- Administrative controls :

  . Budget implementation : Directorate-General for Financial Control

  . Regularity of expenditure : Directorate-General for Financial Control and Contract Department of DG XII.

FINANCIAL RECORD

1. BUDGET CHAPTER :

   - Post : line 7370

   - Title : Biomolecular Engineering

2. JURIDICAL BASIS

   Article 235 of EEC Treaty
   Council Decision

3. DESCRIPTION OF ACTION AND OBJECTIVES

   Second stage (January 1984 - March 1986) of the multiannual research and training programme for the European Economic Community in the field of biomolecular engineering.

   Programme carried out, by means of cost-sharing contracts with research organizations in the Member States and by means of training contracts, along the following projects :

   1. Development of new reactors using immobilized multienzyme systems including those requiring multiphase environment and cofactor regeneration.

   2. Development of bioreactors for human detoxification.

   3. The transfer of genes from diverse sources to the bacterium Escherichia coli, the yeast Saccharomyces cerevisiae and other suitable organisms.

   4. Development of cloning systems.

   5. Gene transfer in micro-organisms and in plants important to agriculture.

   6. Improvement of methods for detecting contamination and for the assessment of possible risks associated with applications in agriculture and industry of biomolecular engineering.

   The objective of these actions are to accelerate the production of data, biological materials and methods in bio-engineering which are necessary for the domestication and the transformation of the basic properties of living organisms useful to man and to place such data, materials and methods at the disposal of industries and agricultural research centres.

4. JUSTIFICATION OF ACTION

There is a need to promote in the Community, through oriented research and through training, the exploitation of basic discoveries in modern biology and to increase in this manner, by an integrated effort, the capacity of the Member States to compete with the outside world in areas dealing with the elaboration of improved agricultural and bio-industrial products. The proposed activities are not only intended to contribute to the reduction of deficits in trade and in patents but should also lead to the establishment of new methods for the estimation of bio-hazards possibly associated to modern biotechnology and, in the long run, to the decrease of energy consumption and the diminuation of waste products. Finally, it should allow the uniform and harmonious development throughout the Community of the regulations and protection devices which should always be associated, from the start, with new and economically important exploitation methods. Considering the present gap which separates the Community of Member States from countries with advanced technology and the partition which too often isolate in Europe basic research from industrial research, these results can only be obtained through a global and continuously renewed analysis of the Community needs and through the stimulation of Community activities which allow the pooling together of competences and of research tools.

5. FINANCIAL INCIDENCE OF ACTION ON INTERVENING SUPPLIES

(including costs for staff and expenses for administrative and technical management).

5.1 Total cost during the entire term envisaged ..... 12.6 MioECU

5.2 Participation to funding

- on Community budget ..... 7.0 MioECU
- by national administrations) ..... 5.6 MioECU
- by other sectors at national level)

5.3 Multiannual schedule

1.5. Development of methods for detecting contamination and for the assessment of possible risks associated with applications of biomolecular engineering in agriculture and industry.

The financial means for the execution of research actions shall not be lower than 80% of the total budget allocated to the 2nd stage of the programme.

2. Training

2.1. Development of new reactors using immobilized multi-enzyme systems, including those requiring multi-phase environment and co-factor regeneration;

2.2. Development of bio-reactors for human detoxification;

2.3. The transfer of genes from diverse sources to the bacterium Escherichia coli, the yeast Saccharomyces cerevisiae and other suitable organisms;

2.4. Development of cloning systems;

2.5. Gene transfer in micro-organisms and in plants important to agriculture;

2.6. Improvement of methods for detecting contamination and for the assessment of possible risks associated with applications in agriculture and industry of biomolecular engineering.

The financial means for the execution of this training action shall not exceed 20% of the total budget allocated to the second stage of the programme.

Annex 2

OPINION OF THE ACPM "BIOMOLECULAR ENGINEERING"

During its meeting of October 28-29 in Brussels the ACPM "Biomolecular Engineering", in accordance with article 5 of the decision of Council adopting a two stages multi-annual research and training programme for the European Economic Community in the field of biomolecular engineering (OJ No L375, 30.12.1981), examined in detail the scientific programme to be executed during its second stage.

The ACPM is unanimously of opinion that it is the interest of the Community to supplement and broaden knowledge and expertise in biomolecular engineering with the view of rendering possible new developments in biotechnology.

The ACPM stated unanimously that the programme for the 2nd stage is based on a valid assessment of Community needs in the area of bio-engineering, that the research and training actions foreseen will allow a stimulation of efforts which are essential for European industry and European agriculture, and that the revised programme is sufficiently flexible to permit its continuous adaptation to the progress of science and technology.

The ACPM stated unanimously that adequate budgetary means and staff expenditures must be foreseen in order to create a proper basis for a meaningful Community Biomolecular Engineering programme.

The ACPM emphasized unanimously that the decision adopting the second stage of the Biomolecular Engineering programme should be taken as early as possible in 1983 in order to allow for the publication of a call for tenders and a proper timing for the selection and negotiation of contracts.

Prof. H.C. VAN DER PLAS
(Chairman of the
Biomolecular Engineering ACPM)

Brussels, November 1982

Whereas account should be taken of the opinion of the Scientific and Technical Research Committee (CREST) on the Commission proposal;

Whereas account should be taken of the opinion of the Advisory Committee (ACPM) for the Management of the Biomolecular Engineering Programme,

HAS DECIDED AS FOLLOWS:

Article 1

The second stage of the multi-annual research and training programme, hereinafter called "the programme", for the European Economic Community is hereby adopted, in the form set out in the Annex for the period starting on 1 January 1984 and ending on 31 March 1986.

Article 2

The appropriations necessary for the execution of the second stage of the programme, which are to be added to those already allocated for the first stage, are estimated at 7 million ECU, including expenditure related to an additional staff of two. These appropriations shall be entered in the general budget of the European Communities.

ANNEX

1. Research actions

1.1. Development of second generation bioreactors (multienzymatic, multiphasic or co-factor requiring) for detoxification and for industrial applications including agro-food applications. Are also included in this sector research activities focusing upon:

- the study of the physiology and the stability of cell populations, including genetically manipulated cells, in relation with whole cell immobilization.

- the analysis and prevention of enzyme inactivation in immobilized systems (particularly under non physiological conditions specific of high salinity, non-aqueous, high temperature and extreme pH environments).

1.2. Improved production, by means of biomolecular engineering methods, of substances for:

- animal husbandry (particularly vaccines, hormones, ...),

- agro-food industries.

1.3. Upgrading of plant products, particularly ligno-cellulose, by means of biomolecular engineering methods.

1.4. Improvement, by means of genetic engineering, of plants and microorganisms which play on important role in agriculture. Research activities in this sector are to include:

- the characterization of the structure and the expression of microbial and plant genomes, including their organelles and plasmid DNA,

- the study of the molecular mechanisms of interactions between plants and symbiotic microorganisms and the improvement by genetic engineering of these symbiotic relations,

- the development of methods for the identification, transfer and expression of new genetic information in cultivated plant species,

- the control of regeneration and differentiation of plant cells and plant protoplasts into mature organisms,

- the use of biomolecular engineering for the early detection of genetic or pathogenic changes in plants.

Financial means: the appropriations estimated as necessary for the execution of the second stage of the programme should be 7 million ECU, including expenditure for an additional staff of two (1 A post and 1 C post).

The financial means for the execution of the training action shall not exceed 20% of the total budget to be allocated to the second stage of the programme. The financial means for the contribution of the Commission to research actions by means of cost-shared contracts with laboratories in the Member States shall not be lower than 80% of the total budget to be allocated to the second stage of the programme.

Taking into account the appropriations already decided upon by Council for the first stage of the programme, these estimations bring to a total of 15 million ECU, including expenditure on a staff of five, the total appropriations allocated to the programme.

This proposal is in line with the following statements entered in the minutes of the Council of 7.12.1981, which mentioned that :

"The Commission considered that a staff complement of five (2 A's, 1 B, 2 C's) was needed to carry out this programme. If the Council agrees to this complement, the Commission undertakes to reduce the staff complement of the programme "Biology - Health Protection" by two persons compared with the ceiling decided by the Council. The Commission further considered that three officials (1 A, 1 B, 1 C) would suffice to carry out the first phase of the programme".

"The Council specified that when taking the revision decision which will re-evaluate the amount and the staff allocated to the programme, due account must be taken of the draft compromise worked out at CREST providing for an overall amount of 15 million ECU for a four-year programme running from 1981 to 1984".

Annex 1

Proposal for a
COUNCIL DECISION

adopting the second stage (January 1984-March 1986) of the multi-annual research and training programme for the European Economic Community in the field of biomolecular engineering

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

Having regard to the proposal from the Commission,

Having regard to the opinion of the European Parliament (1),

Having regard to the opinion of the Economic and Social Committee (2),

Whereas Article 2 of the Treaty assigns to the Community, inter alia, the task of promoting throughout the Community a harmonious development of economic activities, a continuous and balanced expansion and an accelerated raising of the standard of living;

Whereas by Decision 81/1032/EEC the Council adopted a research and training programme in the field of biomolecular engineering (3); whereas the programme is to be implemented in two stages, the first stage running from 1 April 1982 until the revision of the programme in 1983 and the second stage from this revision until 31 March 1986;

Whereas the Council decided that the amount of the appropriations and the staff required to execute the programme is to be re-evaluated when the programme is revised;

Whereas the implementation of the first stage of the programme through research and training contracts has clearly confirmed the need for the strengthening of the programme during the second stage;

Whereas the importance of research and training at Community level in the area of biomolecular engineering is fully recognized in the framework programme (1984-1987) prepared by the Commission (4);

Whereas the Treaty has not provided the necessary specific powers;

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(1)
(2)
(3) OJ No L 375, 30.12.1981, p. 1.
(4) COM(82) 865, 21.12.1982.

The research programme for the second stage, described in annex 1, focuses, with only few modifications, on those very same objectives which were considered as priorities for Community R&D during the first stage of implementation. This choice, which takes into account the necessity, underlined by the European Parliament, for clearly specified objectives, was made after detailed discussions with scientists and national representatives of R&D in the Member States (see in annex 2 the opinion of the ACPM Biomolecular Engineering). It is based upon an assessment of Community needs and of the achievements which are likely to be fulfilled through a programme with limited budgetary resources. The conclusion that the actions presently in progress in the first phase should be reinforced stem from :

- the massive response of laboratories in the Member States to the call for tenders issued for implementing the first phase of the programme. This response demonstrated the interest and need of European laboratories for support in the R&D areas covered by the programme; the quality of the numerous proposals which had to be rejected clearly showed, moreover, that it is possible, in order to give full significance to the programme, to increase the size, often sub-critical, of the nuclei of Community R&D constituted for each sector of the first phase.

- the confirmation that plant cells, a basic material in the first phase of the programme, are indeed amenable to modifications through genetic engineering and to exploitation by fermentation (see, for instance, the recent involvement of organizations such as IPRI, Monsanto, Nestlé, Unilever or the Wolfson Institute of Biotechnology in plant cell research).

Only one change is introduced to the scientific programme, namely the extension to pharmaceutical and fine chemicals industries of the second generation bioreactor technology which, in the first phase, was restricted to the production of agro-food. This change results from the fact that recent and expected technical developments make it possible to catalyse reactions of increased complexity which lead to products of higher added value in many biotechnology-based industries.

The research proposed is fully compatible with some of the main orientations defined for biotechnology R&D in the Framework Programme of the Commission, and with specific recommendations presented in the report "Forecasting and assessment in the field of science and technology" of the Commission services. While it is not possible to outline here in details all the relations between the present proposal and the scientific orientations and recommendations mentioned above, it can nevertheless be stated that the objectives retained for the second phase (production of substances with high added value for the industries, preparation of animal vaccines, transformation of ligno-cellulose, creation of plant cell-lines meeting the requirements of European agriculture and agro-industry, improvement of symbiotic relations between plants and microorganisms) are among those which are considered as essential priorities for Community R&D.

2.2 Training actions

The Commission, in full agreement with the ACPM Biomolecular Engineering, is of the opinion that the training actions serve an essential purpose for the proper retraining of scientists, their mobility, the acquisition of skills necessary for multidisciplinary research and the transfer of information between public and private enterprises. It is therefore considered that the effort accomplished during the first phase must be continued and the advertisement of funding possibilities intensified. The scientific field to be covered by the training actions is not to be modified and should consist of the six areas defined in the Council decision of 7 December 1981.

1.3. Relations with the R&D Framework Programme and the "Biotechnology R&D Action Programme"

1.3.1. As regards the Framework Programme, the present Biomolecular Engineering Programme is directly related to the following goals and objectives :

- Promotion of agricultural competitivity
- Promotion of industrial competitivity (new technologies)

as well as to

- Improvement of raw materials management
- Development of renewable energies
- Improvement of safety and protection of health.

1.3.2. The Commission has announced its intention to present in the near future to Council a plan for "Action Programmes" related to the various objectives of the Framework Programme (2).

In this respect a "R&D Action Programme for Biotechnology" is envisaged by the Commission. Its aim would be to pool and strengthen Community R&D in areas of key importance for agriculture and industries. The programme proposal would consist of horizontal actions from which all sectors of biotechnology should benefit, and vertical actions focused upon the solution of certain specific problems.

This programme, if implemented, will include the present Biomolecular Engineering Programme and will foresee its extension beyond April 1986.

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(2) COM(82) 865 of 21 December 1982.

2. PROGRAMME PROPOSAL FOR THE SECOND STAGE

In order to allow for the revision of the programme and the implementation of its second stage, the Commission asks that the project of Council decision (annex 1) be adopted.

The Commission considers, in this respect, that several reasons militate in favour of a rapid adoption and implementation of the revised programme. Most of these reasons have been outlined in the initial proposal (3) of the Commission and concern the need, now widely recognized, to promote in the Community, through oriented research and training actions, the exploitation of basic discoveries in modern biology which are likely to increase the capacity of the Member States to compete with the outside world in key areas dealing with the elaboration of improved agricultural and bio-industrial products.

As in the first phase, the programme is to consist of research actions by means of cost-shared contracts and of training actions.

2.1. Research actions

The constitution and consolidation at Community level, of action groups composed of some of the best laboratories in Europe and involved in a joint research effort for the elimination of specific bottlenecks to biotechnological developments, is one of the means through which the Community may hope to bridge part of the present gap with countries, like Japan and the United States, of advanced technology.

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(3) COM(79) 793 final