

# COMMISSION OF THE EUROPEAN COMMUNITIES

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## COMMUNICATION BY THE COMMISSION

REVISION OF THE MULTIANNUAL RESEARCH PROGRAMME FOR THE  
EUROPEAN COMMUNITY IN THE FIELD OF  
BIOTECHNOLOGY

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1988-1989)

COM(87) 481 final/2

REVISION OF THE MULTIANNUAL RESEARCH PROGRAMME  
FOR THE EUROPEAN COMMUNITY  
IN THE FIELD OF BIOTECHNOLOGY

1. INTRODUCTION

The essential objective of the biotechnology research action programme is to develop the Community's capacity to master and to exploit the applications of modern biology to agriculture and industry. The programme includes activities of research, training and concertation in the key areas of biotechnology, and is designed to enable each Member State to derive full benefit from the catalytic effect of work and activities jointly defined and executed<sup>1)</sup>.

This programme, adopted by Council on 12 March 1985<sup>2)</sup>, commenced on 1.1.1985 and will end on 31.12.1989. Its budget allocation is 55 Mio ECU.

2. RE-EXAMINATION OF THE PROGRAMME

The activities undertaken since 1985 are in line with the provisions foreseen by the first Framework Programme (1984-1987) of Community activities of research, development and demonstration, approved by the Council; and with the second Framework Programme for the period 1987-1991, which envisages an increase in the efforts devoted to research, training and concertation in biotechnology. They were the subject of a communication from the Commission to Council on 21 May 1986<sup>1)</sup>.

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- 1) COM (86) 272 final
  - 2) JO No. L 83/1 of 25.3.1985

### 3. PROGRAMME REVISION

#### 3.1 Conclusion of the re-examination.

In its communication to Council concerning the re-examination of the programme <sup>1)</sup>, the Commission emphasized the need to increase the resources devoted to the programme, and defined the various areas in which, without widening the range of activities in progress, an increase in the resources allocated since 1985 appears indispensable.

The objectives of the revision, taking into account the re-examination, are as follows:

- Intensification of efforts in the sector concerned with the evaluation of risks related to new biotechnologies, and particularly to the deliberate release of genetically engineered organisms.
- Strengthening of activities related to the biotechnology research infrastructure in the Community and, in particular, the use of information technology, data banks and electronic networks, in support of the harmonization of culture collections, and of genome sequencing and protein modelling projects.
- Initiation of studies and feasibility projects in preparation of future Community R & D activities during the period 1990-1994 (interest, need and cost of actions suggested as worthwhile and necessary components of an ulterior phase of the BAP programme): genome maps and sequences in yeast, bovines and crop species,...

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- Increase, in all parts of the current programme, of activities, mainly visits, publications, creation of an electronic network linking all laboratories participating in the programme, joint meetings, aiming at a timely dissemination of research results to the benefit of the scientific and industrial communities.
- Intensification of the training activities in progress, in all sectors of the programme.
- Participation of Spanish and Portuguese laboratories in the research and training activities in the revised programme.
- Intensification of the concertation activities and the extension of these activities to Spain and Portugal.

### 3.2 Budgetary requirements (indicative amounts).

The increase in expenditures on personnel (for 5 additional staff), on operational activities and on financing activities of research, training and concertation, which are needed for this revision of the programme are estimated at 20.0 Mio ECU, comprising:

- 4.30 Mio ECU\* for contracts in bio-informatics
- 4.40 Mio ECU\* for contracts in risk evaluation
- 4.00 Mio ECU\* for training contracts
- 4.00 Mio ECU\* for participation of Spain and Portugal in contract research
- 2.00 Mio ECU\* for studies and feasibility projects in support to the preparation of the next biotechnology R & D programme (1990-1994)
- 1.30 Mio ECU\* for staff expenditure (for concertation activities in particular) and operational costs in implementing new initiatives (including the dissemination of results to industry).

\*: indicative amounts

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- Bio-informatics:

The foreseen increase will be beneficial to the sector on bio-informatics where, as a result of having initiated in the current programme an activity on sequence data banks, on software development and on protein modelling, there is overwhelming evidence (also stressed from outside the Community Institutions: e.g. by CEFIC) for the pervading effect of information technologies and for their being instrumental in the analysis of any biological macromolecule. The amount of 4.30 Mio ECU foreseen in the present revision would approximately double the volume of activities in the programme which relates directly to the application of information to applied biological research. Such an amplification would provide the sector with the possibility to reach significance, while ensuring complementarity with A I M (Advanced Informatics for Medicine).

- Risk assessment:

As foreseen, extensive use shall be made, in connexion with a call for expressions of interest from the Commission <sup>3)</sup>, of proposals on biosafety with respect to agricultural uses of genetically-manipulated organisms. It is considered that 20 additional contracts (that is to approximately one per member state in the case of air-borne microorganisms and one per member-state for soil microorganisms), bringing to 60 scientists/year the total amount of research staff involved in this part of the Community programme, should give significant dimensions to the sector. It will render possible the constitution of 2 working groups of 15 laboratories each, which is about the ideal number for cooperation (exchange of staff and material, pooling of experiments ...) to reach maximum intensity. This sector, presently very small in the programme, needs to be strengthened because it is through common research on the pathogenicity, toxicity,

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3) COM (86) 221

and the possible ecological disruptive effects of new genetic diversity that a scientific basis will be created for the establishment of efficient regulation.

- Training activities:

The addition during the period 1988-1989 of 4 Mio ECU to the budget foreseen for training activities would render possible, for both short term and long term training contracts, a sharp increase in the number of contracts awarded which would be adapted to the very heavy demands for access to training and for access to qualified trainees.

- Studies and feasibility projects:

They will be carried out with the view of assessing the technical requirements and the expected value for the Community of a fully integrated research on genome mapping and sequencing in species useful to man. The average cost of sequencing work is estimated for the time being at 1 ECU per base pair and a at 10.000 ECU/gene in the case of mapping. It should thus be possible, with the 2 Mio ECU requested in the present revision, to base the feasibility studies on the sequencing of approximately 100.000 base pairs and the mapping of 10 genes.

- Participation of Spain and Portugal:

In line with additional priorities stemming from the conclusions of the re-examination, such increase would enable at the same time the reinforcement of the concertation action and the enlargement to Spain and Portugal of all the activities (research, training and concertation) covered by the programme. The amount foreseen of 4.00 Mio ECU should render possible the negotiation of 30 to 40 contracts and therefore, a substantial involvement of both countries in all sectors of the programme.

- Staff expenditures and operational costs

The participation of Spain and Portugal to the programme together with the extension of contractual research (in bio-informatics and risk-assessment), of training and of the concertation action (which becomes more voluminous as the Community enlarges and biotechnology gains in complexity) will significantly increase the need for additional Commission staff.

Considering that 100 new research contracts and 150 new training contracts, together with a considerable increment in the administration of concertation activities, will result from the proposed revision of the programme, the requirements in additional staff are evaluated at 5 (2 A and 3 C).

In the same manner, and also in view of the fact that the Commission services are intending to expand their system of electronic mail between contractants, to develop special meetings between industry and university and to organize series of summer seminars for a better dissemination of specialized knowledge in biotechnology in all member states, specific budgetary provision are being made in the present revision for the coverage of additional operational costs.

The budget requested for staff expenditure (0.89 Mio ECU) and operational costs (0.41 Mio ECU) amounts to 1.30 Mio ECU.

3.3 Opinion of the CGC biotechnology.

Eleven delegations out of 12 expressed in principle their global support to the present proposal, which they considered to be well structured, established along clear lines and concentrated on a small number of priority objectives agreeable to all Member States. The delegation of the United Kingdom did not approve, however, the principle of the revision such as proposed by the services of the

Commission. The chairman underlined the necessity to maintain in the revision the transnational features and the consistency of research objectives which characterized the programme.

#### 3.4 Proposal for Council Decision (Annex 1).

Proposal for a  
COUNCIL DECISION

ANNEX 1

revising the multiannual research action programme  
for the European Economic Community in the field of  
biotechnology.  
(1985 - 1989)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic  
Community, and in particular Article 130 Q (2) thereof

Having regard to the proposal from the Commission <sup>1)</sup>,

In cooperation with the European Parliament <sup>2)</sup>,

Having regard to the opinion of the Economic and Social Committee <sup>3)</sup>,

Whereas Article 130 K of the Treaty provides that  
the Framework Programme is to be implemented through specific programmes  
developed within each activity; whereas the Council, when adopting  
the Framework Programme of Community activities in technological R & D  
(1987-1991), recognized the interest of exploitation and valorisation  
of biological resources, and particularly biotechnology <sup>4)</sup>;

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- 1) O.J. N°
- 2) Opinion of ...O.J. ....: approval (or amendment, or refusal) of  
O.J. ....
- 3) O.J. No
- 4) O.J. N°

Whereas the Council Decision 85/195/EEC<sup>5)</sup> introduced a multiannual research and training action programme for the European Economic Community in the field of biotechnology; whereas Article 3 of that Decision makes provision for the programme to be revised as from its second year of implementation.

Whereas the re-examination which has been undertaken and whose conclusions were transmitted to the Council on 21 May 1986<sup>6)</sup>, has led the Commission to present a proposal for the revision of the programme motivated by the need to ensure its adequacy to the objective assigned to it;

Whereas the implementation of the research and training programme for the European Economic Community in the field of biotechnology has proved to be insufficient as yet for setting up, on a scale commensurate with the multiple implications of biotechnology in agriculture, industry and the environment, of transnational cooperation networks addressing the various levels of risk and their evaluation;

Whereas the area of bio-informatics requires both to ascertain the constitution of integrated networks for the storage, circulation and treatment of biological data, and to stimulate further computer-aided approaches in biotechnological research;

Whereas it is necessary to step up training activities and to evolve training schemes including, in particular, the organization of short intensive workshops, allowing research scientists in the Member States to benefit from all the research facilities and scientific expertise in the Community;

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5) JOJ No L 83, 25.3.1985, p.1

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Whereas it is essential to increase the involvement of Community industry in the activities and results originating from the research work under contract;

Whereas it is necessary to step up the concertation activities carried out, alongside the Community research and training effort, to improve national and Community activity in the field of biotechnology;

Whereas the recent emergence of certain critical areas of biological sciences (e.g. genome mapping and sequencing, and the exploitation thereof) means that Community biotechnology is relatively weak unless exploratory activity can be rapidly initiated before a new programme in biotechnology R & D 1990-1994 is prepared;

Whereas it is necessary to ensure participation by Spain and Portugal in the activities envisaged by the programme;

Whereas the Scientific and Technical Research Committee (CREST) has expressed its opinion,

HAS DECIDED AS FOLLOWS :

#### Article 1

The research action programme for the European Economic Community in the field of biotechnology (1985 to 1989) is hereby revised on the basis of the specifications in the Annex.

#### Article 2

The funds necessary to increase and expand the activities as planned in this revision, to which must be added the funds already allocated to the programme, are estimated at 20 Mio ECU, including expenditure on an additional staff of five.

Done at

for the Council

**REVISION OF THE MULTIANNUAL  
RESEARCH ACTION PROGRAMME FOR THE EUROPEAN ECONOMIC  
COMMUNITY IN THE FIELD OF BIOTECHNOLOGY  
(1985 to 1989)**

- Intensification of the current research effort in the sector of the programme that concerns the assessment of risks associated with modern biotechnology, and particularly with the deliberate release of genetically engineered organisms.
- Intensification of the current research effort in the area of information technology with emphasis upon processing data related to culture collections, genome sequences and protein modelling.
- Increase in the volume of current activities (visits, publications, electronic networks, meetings, summer workshops, ...) aiming at a timely dissemination of information on the programme and of research results; involvement of Community industry in the research activities and in the utilization of the data, materials and methods stemming from the research work under contract.
- Studies and feasibility pilot projects for the preparation of future Community R & D activities in biotechnology during the period 1990-1994.

- Increase in training activities in all parts of the current programme.
- Matching of resources (manpower) for the concertation activity to the requirements defined in the programme.
- Extension to Spain and Portugal of the totality of the activities envisaged by the programme.

FINANCIAL RECORD

1. RELEVANT BUDGET HEADING:

- Item : 7356
- Title : Research Action Programme - Biotechnology  
(1985 - 1989)

2. LEGAL BASIS

Article 130 Q § 2 of the EEC Treaty

Council decision

3. Non-compulsory expenditure.

4. DESCRIPTION AND JUSTIFICATION OF THE PROJECT.

4.1 Description

Revision of the multiannual research programme for the European Economic Community in the field of biotechnology.

The objectives of the revision are as follows:

- Intensification of the research effort in the sector of the current programme that concerns the assessment of risks associated with the deliberate release of engineered organisms.
- Organization (through network activities) and strengthening (through targeted contract research) of the area of bio-informatics, as a pervading component of the Community programme in biotechnology R & D.

- Increase, in all parts of the current programme, in activities concerning the dissemination and follow-through of the results of research under contract.
- Initiations of exploratory studies and pilot assays in the strategic field of genome mapping and sequencing.
- Increase in training activities in all parts of the current programme.
- Participation of Spanish and Portuguese laboratories in the research and training activities included in the revised programme.
- Reinforcement of the concertation activity and the extension of this activity to Spain and Portugal.

#### 4.2 Justification

The aim of the research action programme in biotechnology is to improve the capacity of the Member States to compete with the outside world in areas relevant to the preparation of improved agricultural and bio-industrial products. The programme is also intended to contribute to the establishment of new methods for the evaluation of biohazards and to the uniform and harmonious development of policies and regulations governing the promotion of modern biotechnology in the Community. These aims cannot be fully achieved without

stepping up the current effort in fields essential to the development of biotechnology, and without the participation of Spain and Portugal in the programme's activities.

5. TYPE OF EXPENDITURE AND METHOD OF CALCULATION

5.1 Method of calculation

Revision of the Biotechnology Research Action Programme will involve staff and operating costs and expenditure on the financing of Community research by shared-cost contracts and of Community training by contracts of secondment.

The calculation of staff costs is based on the following annual figures:

	<u>1988 *</u>	<u>1989</u>
A.	88.500	91.155
C.	35.100	36.153

(\* ) 50 % for 1988

The operating costs cover the expenses of meetings of contractors, participation in symposia, tutorial time and attendance of junior researchers at short summer workshops, travel and subsistence costs for experts and Commission staff, regular visits to participant institutions, publication of the results of Community research, connection of contracting laboratories through electronic networks and the purchase of capital goods necessary for proper management of the programme (word processing machines,

photocopier, etc.). The annual cost is estimated at about 4.300 ECU per research contract in each sector of activities and shall include as well the expenses of organizing short training workshops and of intensifying the information flow from and to European industry. Expenditure for contracts has been calculated on the basis of an overall annual contribution of:

- 90.000 ECU for shared-cost research contracts,
- 35.000 ECU for the training contracts involving payment of a lump sum to the host laboratory,
- 25.000 ECU for training contracts for inexperienced research scientists.

5.2 Calculation (indicative amounts)

Staff expenditure :	Mio ECU
- Research and Training in Biotechnology)	
(2 A) )	0.89
- Concertation (3 C) )	
Operating costs:	
- Risk assessment sector	0.09 )
- Bio-informatic sector	0.09 )
- Integration of Spain and Portugal in	0.08 )
the pre-established research network	) 0.41
- Summer workshops	0.08 )
- Communication channels with European	0.07 )
Industry	

Contract expenditure:

- Risk assessment sector	4.40 )
- Bio-informatic sector	4.30 )
- Exploratory activity for the preparation of a future programme (1990-1994)	2.00 ) 18.70
- Extension to Spain and Portugal of activities covered by all other sectors of the programme	4.00 ) )
- Training contracts	4.00 )

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**Total 20.00**

6. FINANCIAL IMPLICATIONS IN RESPECT OF EXPENDITURE

6.1 Schedule of commitment and payment appropriations

Commitment appropriations/in million ECU

Approved programme	Outturn 1985	Outturn 1986	Budget 1987 + subsist	1988	1989	TOTAL
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Subtotal	3.62	29.95	12.41	5.47	3.55	55.00
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Proposed revision						
Staff				0.29	0.60	0.89
Operating				0.18	0.23	0.41
Contracts				16.53	2.17	18.70
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Subtotal				17.00	3.00	20.00
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<b>TOTAL</b>	<b>3.62</b>	<b>29.95</b>	<b>12.41</b>	<b>22.47</b>	<b>6.55</b>	<b>75.00</b>
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Payment appropriations/in million ECU

Approved programme	Outturn 1985	Outturn 1986	Budget 1987 + reports	1988	1989	1990+	TOTAL
Subtotal	0.96	7.72	11.60	14.10	16.84	3.78	55.00
Proposed revision							
Staff				0.29	0.60		0.89
Operating				0.18	0.23		0.41
Contracts				2.93	8.97	6.80	18.70
Subtotal				3.40	9.80	6.80	20.00
<b>TOTAL</b>	<b>0.96</b>	<b>7.72</b>	<b>11.60</b>	<b>17.50</b>	<b>26.64</b>	<b>10.58</b>	<b>75.00</b>

6.2 Share of Community financing in the total cost of the programme revision (million ECU)

Total cost throughout the planned duration : **35.50**

Share in the financing:

- from the Community budget	<b>20.00</b>
- from national budgets )	
- other sectors at national level )	<b>15.50</b>

Share of Community financing as % : **56 %**

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IMPACT ON COMPETITIVENESS AND EMPLOYMENT

Proposal for a Council Decision adopting a revised multiannual research and training programme for the European Community in the field of biotechnology (1985-1989).

1. The aims of this revision are to allow balanced participation of Spain and Portugal in the current programme and expansion of certain parts thereof (bio-informatics; evaluation of the risks associated with modern biotechnology; and the training of researchers).
2. The revised programme will be implemented through shared-cost contracts concluded with national institutes, university research departments and industrial laboratories.
3. Some of the research activities could therefore have direct repercussions on competitiveness and employment; it is in the much longer term, however, through training activities and industrial and agricultural innovations arising from research work, that the programme could exert a considerable impact on competitiveness and employment.