REPORT
drawn up on behalf of the Committee on Energy, Research
and Technology

on the proposal from the Commission of the European
Communities to the Council (COM(87) 481 final - Doc. C
2-255/87) on the revision of the multiannual research
programme for the European Community in the field of
biotechnology (1985 - 1989)

Rapporteur: Mr F. J. SANZ FERNANDEZ
By letter of 3 December 1987 the President of the Council of the European Communities consulted the European Parliament, pursuant to Article 130q(2) of the Treaty establishing the European Economic Community on a communication from the Commission to the Council on the revision of the multiannual research programme for the European Community in the field of biotechnology, together with a proposal for a Council decision.

On 18 January 1988 the President of the European Parliament referred this proposal to the Committee on Energy, Research and Technology as the committee responsible and to the Committee on Budgets for its opinion.

At its meeting of 23 September 1987 the Committee on Energy, Research and Technology appointed Mr SANZ FERNANDEZ rapporteur.

The committee considered the Commission proposal and the draft report at its meetings of 2 December 1987, 16 February and 25 February 1988.

At this last meeting the committee decided unanimously to recommend to Parliament that it approve the Commission proposal subject to the amendments set out below.

The Commission informed the committee that it was prepared to accept Amendments Nos. 1, 2, 3, 4 and 5.

The committee then unanimously adopted the draft legislative resolution as a whole.

The following took part in the vote: Mr Poniatowski, Chairman; Mr Adam and Mr Kolokotronis, Vice-Chairmen; Mr Sanz Fernandez, rapporteur; Mrs Faith, Mr Harlin, Mr Linkohr, Mrs Peus, Mr Pinto, Mr Robles Piquer, Mr Seligman, Mr Smith, Mr Turner, Mrs Viehoff and Mr Wedekind.

The opinion of the Committee on Budgets is attached to this report.

The report was tabled on 26 February 1988.

The deadline for tabling amendments to this report will appear on the draft agenda for the part-session at which it is to be considered.
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The Committee on Energy, Research and Technology hereby submits to the European Parliament, on the basis of the explanatory statement, the following amendments to the Commission proposal and the draft legislative resolution:

**COUNCIL DECISION**

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

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Preamble and first to sixth recitals unchanged

seventh recital

**Amendment No. 1**

Add the following to the seventh recital:

Whereas it is necessary to step up training activities and to evolve training schemes including, in particular, the organization of short intensive workshops, altogether allowing research scientists in the Member States to benefit from all the research facilities and scientific expertise in the Community, thus helping to reduce the disparities in development in the field of biotechnology between the various Member States of the European Community;

eighth to tenth recitals unchanged

eleventh recital

**Amendment No. 2**

This recital to read as follows:

Having regard to the necessity to ensure the participation of Spain and Portugal in the totality of activities envisaged by the programme;

twelfth recital unchanged
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.

Amendment No. 3

Add a second paragraph to read:

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.

The aims of this revision are to allow the balanced participation of Spain and Portugal in the current programme and the expansion of certain parts of the programme (bio-informatics; evaluation of the risks associated with modern biotechnology; training of researchers).

Article 2 unchanged

Amendment No. 4

At the end of Article 2, add the following:

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. The final amount of appropriations and the number of staff shall be determined on the basis of decisions taken annually by the budgetary authority in accordance with real needs.
ANNEX I

REVISION OF THE MULTIANNUAL RESEARCH ACTION
PROGRAMME FOR THE EUROPEAN ECONOMIC COMMUNITY

First to fourth indents unchanged

Fifth indent

Amendment No. 5

Fifth indent to read:

- Increase in training activities in all parts of the current programme.

- Increase in training and information activities in all parts of the current programme.

Sixth and seventh indents unchanged
embodifying the opinion of the European Parliament, at first reading, on the proposal from the Commission to the Council concerning a decision on the revision of the multiannual research programme for the European Community in the field of biotechnology (1985-1989)

The European Parliament,

- having regard to the proposal from the Commission to the Council(1),
- having been consulted by the Council pursuant to Article 130Q 2 of the EEC Treaty (Doc. C 2-255/87),
- considering the proposed legal basis to be appropriate,
- having regard to the report of the Committee on Energy, Research and Technology and the opinion of the Committee on Budgets (A 2-314/87),

1. Approves the Commission's 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 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;

4. Calls on the Council to notify Parliament should it intend to depart from the text approved by Parliament;

5. Instructs its President to forward this opinion to the Council and Commission.

(1) OJ No. C

EN(88) 0127E/0128E - 8 - PE 119.069/fi.
EXPLANATORY STATEMENT

I - PURPOSE OF THE COMMISSION PROPOSAL

1. The proposal for a Council decision submitted to us contains a re-examination of the multiannual research programme for the European Community in the field of biotechnology.

It represents a limited revision with a view to:

- allowing a balanced participation by Spain and Portugal in the current programme,
- expanding certain aspects of this programme.

This revision will require increased expenditure amounting to an estimated 20 m ECU.

II - GENERAL OBSERVATIONS ON THE BIOTECHNOLOGY PROGRAMME

2. The biotechnology programme which was adopted by the Council on 12 March 1985, started on 1 January 1985 and will finish at the end of 1989.

Its initial budgetary allocation was 55 m ECU, with the result that when the 20 m ECU provided for the revision are added, the total amount available for the biotechnology programme will be 75 m ECU.

3. The framework programme for Community activities in the field of research and technological development provided a total of 280 m ECU for the exploitation and development of biological resources, 120 m ECU of which were intended for biotechnology, with a view to investigating the properties of living cells and ensuring their exploitation by both industry and agriculture in the interest of consumers.

4. Bearing in mind this last figure and the 20 m ECU allocated for the revision of the biotechnology programme for the period 1987-1989, a sum of about 100 m ECU is thus available for the subsequent period 1989-1991, the follow-up to the current biotechnology programme being constituted by a new four-year programme for the period 1990-1994, which should be on a far larger scale than the previous one.

5. Biotechnology will play a crucial role at the end of the century and Europe should therefore have an effective programme. Such a project is all the more necessary since there has been an intensification of research efforts in biotechnology at national level over the last two to three years and most Member State now have a separate programme which often receives considerable levels of public funding.

6. In two important reports for which Mrs Viehoff was rapporteur, the European Parliament and our Committee on Energy, Research and Technology specifically drew attention to this problem and expressed regret that the financial resources made available for biotechnology were considerably smaller than those for other areas, for example thermonuclear fusion.
7. Nevertheless, despite the relatively small sums devoted to biotechnology at Community level, the results obtained have been particularly encouraging and should themselves justify the Commission in adopting a bolder policy.

III - OBSERVATIONS ON THE COMMISSION'S REVISION OF THE BIOTECHNOLOGY PROGRAMME

8. In the own-initiative report drawn up some months ago, Mrs Viehoff drew attention to a number of fundamental shortcomings in the programme as it was originally conceived. She hoped that these could be remedied when the programme was revised.

9. It must be noted that, to a large extent, the content of the revision proposed by the Commission corresponds to some of the demands made by Parliament in its resolution of 16 February 1987.

10. First of all, the Commission proposes an increased budgetary allocation of about 4 m ECU to ensure the participation of Spain and Portugal in research contracts.

11. It is also necessary to consider the financing of certain activities which had not been taken into account in the past. Firstly, the Commission took the view that the bio-informatics sector was destined to expand considerably, hence the need for data banks concerning genetic sequencing, the development of specific software and anything which could relate to protein modelling.

It is of course also essential, as the Commission observes, to ensure that these activities complement the projects undertaken in the framework of information technologies. 4.3 m ECU would be devoted to expanding this activity.

12. In the eyes of most specialists, the major problems posed by biotechnology relate to the risks to which it could expose our society in a whole range of areas. For this reason it was essential that a European programme should pay attention to the evaluation of risks by studying all biological safety measures, in particular in relation to the agricultural applications of genetically manipulated organisms. A provision of 4.4 m ECU has been made to this end, which is a modest sum in relation to the disturbing effects which could be envisaged from the genetic diversity.

13. A sum of 4.4 m ECU has also been provided for training activities in response to the very heavy demand in this field. Such activities could be used in particular for Community countries where there are still far too few scientific staff in the field of biotechnology. Your rapporteur congratulates the Commission for incorporating such training projects directly into the programme.

The European Parliament has in any case always taken the view that a certain proportion of the total sum for research should be devoted to training projects in the field in question.
14. Lastly, the Commission proposes to undertake a certain number of studies and feasibility pilot projects, involving a sum of 2 m ECU, with a view to the preparation of the future research programme for 1990-1994. It is vital that a number of studies are made at this stage in order to establish the objectives for biotechnology for 1995. It would also be useful if these preparatory studies were undertaken in connection with the FAST programme, to ensure that all economic, social and human aspects are also covered.

15. As regards the management of the biotechnology programme, the proposed revision requires an increase in personnel assessed at five staff. The total costs involved and the operating costs are 3.1 m ECU.

IV - THE AMENDMENTS PROPOSED TO THE COMMISSION PROPOSAL

16. The Committee on Energy, Research and Technology's general assessment is positive. As already stated, all the elements proposed by the Commission are in line with the demands made by the European Parliament in its various resolutions.

It is quite clear, however, that the overall funding proposed, 20 m ECU, is insufficient. Whilst it will certainly be useful, it will not allow the significant progress which could be expected from this programme, to be made in a certain number of fields.

It is to be hoped that, for the period 1990-1994, the Commission will submit a proposal which corresponds to the strategic importance of biotechnology.

17. Your rapporteur felt that various amendments would make it possible to clarify certain aspects in order to remove all ambiguity with regard to the intention and scope of this revision.

18. The purpose of these amendments is:

(i) to specify the objectives of this revision in the articles of the proposal for a decision instead of only considering this aspect in an annex (Amendment No. 3).

(ii) to introduce the idea of a balanced participation by all the Community countries in the biotechnology programme. This request only appears in paragraph 20 of the resolution of 16 February 1987 (Amendment No. 1).

(iii) to ensure that the participation of Spain and Portugal would relate both to activities in progress and activities provided for in the present revision (Amendments Nos. 2, 5, 6).

(iv) to take into account the opinion of the Committee on Budgets, by incorporating the amendment it adopted (Amendment No. 4).

(v) to stress the need to provide the general public with information with regard to biotechnology research (Amendment No. 5).
At its meeting of 23 September 1987 the Committee on Budgets appointed Mr PAPOUTSIS as draftsman of the opinion on all the proposals relating to the framework programme on research and technological development in the Community.

At its meeting of 25 February 1988 the committee considered the draft opinion. It adopted the conclusions unanimously:

Present: Mr Cot, Chairman; Mr Papoutsis, draftsman; Mr Abens (deputizing for Mr Rigo), Mr Arias Canete, Mr Barbarella, Mr Bardong, Mr Cammanno Bernal, Mr Colom i Naval, Mr Dankert, Mr Elles, Mr Früh (deputizing for Mr Mizzau), Mrs Fuillet, Mr Hackel, Mrs Hoff, Mr Langes, Mr Louwes, Mr Lucas Pires, Mr Normanton, Mr O'Malley, Mr Poetschki (deputizing for Mr Chiusano), Mr Tomlinson, Mr Visser (deputizing for Mr D. Martin) and Mr von der Vring.
INTRODUCTION

1. The Commission's proposal relates to the revision of the multiannual research programme in the field of biotechnology, pursuant to Article 3 of the Council's decision on this subject of 12 March 1985.

2. The aims of this revision are to intensify efforts to increase the effectiveness of the programme and to extend its activities to Spain and Portugal with the participation of laboratories in those countries.

3. More specifically, the Commission takes the view, in the light of the conclusions derived from the re-examination of the programme, that the revision should cover the following areas:

- **bio-informatics**: the use of information technologies in applied biological research;

- **risk assessment**: extensive recourse to proposals on biosafety with respect to the use of genetically manipulated organisms in agriculture;

- **training**: intensification of training activities in all sectors of the programme in view of the heavy demand for specialist staff;

- **studies and feasibility projects**: completion of a detailed study in the field of genome mapping and sequencing in species useful to man;

- **extension to Spain and Portugal** of all activities (research, training and concertation) covered by the programme;

- **administrative requirements** in terms of staff and operating costs associated with the achievement of the objectives set out above.

GENERAL REMARKS

4. According to the communication from the Commission, the revision of the biotechnology programme will result in additional expenditure of 20 m ECU, broken down as follows:

- **bio-informatics**: 4.3 m ECU
- **risk assessment**: 4.4 m ECU
- **training**: 4.0 m ECU
- **feasibility studies**: 2.0 m ECU
- **extension (Spain and Portugal)**: 4.0 m ECU
- **operating costs**: 1.3 m ECU

Total: 20.0 m ECU

The total budgetary cost of the programme is therefore estimated at 75 m ECU as 55 m ECU have already been allocated.
5. In view of the above, it should be noted that the additional cost of the programme, minus the sum allocated for extending it to Spain and Portugal, represents an increase of roughly 30\% in relation to the amount originally allocated - two years after its implementation. This clearly demonstrates that the original estimates of expenditure were merely indicative and gives weight to the view that the budget allocation procedure guarantees closer alignment with actual financial requirements to ensure the implementation of the programme.

6. In the period between the adoption of the original programme and its revision, the Community was enlarged to include Spain and Portugal and the Single Act came into force. Consequently, the implementation of the programme in general and the aims of research activities in preparation for a future programme (1990-1994) in particular must help achieve the objectives set out in the Single Act. This being the case, it is perhaps appropriate to stress that the exploitation of the Community's scientific potential must be the first step towards implementing the programme. As a result, the Commission must endeavour to ensure that the funds allocated when agreements are concluded will help further the aims of economic and social cohesion, bearing in mind the scope for economic exploitation and use of biological resources and of biotechnology in particular.

CONCLUSIONS

In view of the above, the Committee on Budgets proposes the following amendment:

Article 2

To read:

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 m ECU, including expenditure on an additional staff of five.

The final amount of appropriations and the number of staff shall be determined on the basis of decisions taken annually by the budgetary authority in accordance with real needs.