

COMMISSION OF THE EUROPEAN COMMUNITIES

COM(88) 806 final - SYN 182

Brussels, 3 January 1989

4412-221
05 070-1989

Proposal for a
COUNCIL DECISION

adopting a specific research and technological development
programme in the field of biotechnology (1990-94)

B R I D G E

Biotechnology Research for Innovation, Development and Growth in Europe
(1990-94)

(presented by the Commission)

S U M M A R Y

SUMMARY

Over the past ten years, the basic scientific successes of biotechnology have been brought closer to applications for a wide range of social and economic purposes, principally in health care and in agriculture. Throughout the world, new biotechnology products are now being brought to market, their benefits reaching patients, farmers and consumers. In the United States, public expenditure on biotechnology research amounts to \$ 2.7 bn per year (1) motivated by a clear perception in scientific, economic and political circles of its importance to the future competitiveness of US exports.

Within the EEC, action in biotechnology is one of the lines of the framework programme for Community activities in the field of research and technological development (2); the stated purpose being :

"To master the properties of living cells and to secure their exploitation, in the interests of consumers, by both industry and agriculture".

Past and current Community actions have aimed at strengthening the scientific base of Europe's biotechnology, and hence *inter alia* improving its international competitiveness. Through the Biomolecular Engineering Programme (1982-86) and the ongoing Biotechnology Action Programme (1985-89), the Community is stimulating a network for training and for transnational collaborative research in European Laboratories Without Walls (ELWW). Through collaboration with Member States, through other Community programmes and through a range of concertation activities including impact assessments, the Commission seeks to encourage the effective application of the fruits of biotechnology to the social and economic objectives of the Community and its Member States. These objectives include not only competitiveness, but the improvement of health and environment, and the promotion of scientific and industrial collaboration with developing countries.

Objectives of the proposed programme

The present proposal for a successor programme to BAP is in line with the above developments. Entitled BRIDGE (Biotechnology Research for Innovation, Development and Growth in Europe), it is planned for 1990-94, with a total budget of 100 Mio ECU.

The objectives of BRIDGE have been defined on the basis of past achievements in BEP and BAP and through recommendations received from a panel of Independent Experts, the European Parliament, industrial organisations and the CGC Biotechnology.

BRIDGE is subdivided, as was BAP, into two actions :

Action I for Research and Training, and Action II for accompanying actions grouped under the term "Concertation". Ninety per cent of the total budget will be devoted to Action I and 10% to Action II.

The main tasks of Action I will be to develop cooperative basic research and training through research adapted to the long term needs of the Community. This implies, for the removal of bottlenecks resulting from gaps in basic knowledge, the reinforcement of existing networks of ELWWs and their extension to new areas considered of high significance for the Community. Alternatively, larger targeted projects will be implemented, when necessary, for removing bottlenecks originating from scale or structural constraints. A very substantial effort is foreseen in the area of pre-normative research and, in particular, with regard to the assessment of risks possibly associated to the release of genetically engineered microorganisms. The research and training programme is subdivided into four sectors:

- information infrastructures
- enabling technologies
- cellular biology
- pre-normative research

Action II "Concertation" will cover a range of monitoring, information and collaborative activities to provide and facilitate the effective application of biotechnology to the social and economic objectives of the Community and of the Member States.

-
- (1) U.S. Congressional Office of Technology Assessment, "U.S. Investment in Biotechnology", April 1988.
 - (2) Council Decision of 28 September 1987, 87/516 : OJ L 302/1-23, 24.10.1987.

TABLE OF CONTENT

SUMMARY	1
TABLE OF CONTENT	iv
EXPLANATORY MEMORANDUM	1
Action I : RESEARCH AND TRAINING	3
1. Basis of the present proposal	3
2. Objectives and orientations of BRIDGE	8
3. Implementation schemes	10
4. Management principles	10
Action II : CONCERTATION	13
1. Origin and aims	13
2. Current activities and achievements	14
3. Opinions, evaluation and recommendations	15
4. Objectives and priorities for concertation	16
5. Implementation	16
PROPOSAL FOR A COUNCIL DECISION	1
Annexes : TECHNICAL ANNEX	7
EVALUATION CRITERIA	18
COMPETITIVENESS AND EMPLOYMENT IMPACT STATEMENT	22
FINANCIAL STATEMENT	25

EXPLANATORY MEMORANDUM

ACTION I : RESEARCH AND TRAINING

1. BASIS OF THE PRESENT PROPOSAL

The argumentation for a continuation of Community R&D efforts in biotechnology and the choice of the main orientations in the proposed programme are based upon :

- the assessment, by the Commission services and by independent experts, of past and ongoing R&D Community programmes in biomolecular engineering and biotechnology

- recommendations for future activities, as expressed by Commission and national experts, the European Parliament, a panel of independent experts, industrial bodies and the national delegations of the CGC "Biotechnology".

1.1. Assessment of past and ongoing Community programmes

The first R&D Community activity in biotechnology was BEP (Biomolecular Engineering Programme) with a budget of 15 Mio ECU, which supported between April 1982 and March 1986 91 training contracts and 103 cost-shared research contracts with public and private laboratories in the Community. The second R&D programme in biotechnology is BAP (Biotechnology Action Programme) which covers the period 1985 - 1989 with a budget of 75 Mio ECU. The research activities of BAP are being executed, for the time being, in 90 transnational projects by groups of laboratories which agreed to join their efforts and to work together.

Detailed information on the implementation and achievements of these two programmes have been published by the Commission services (1, 2, 3).

BEP has been submitted to evaluation procedures carried out at three different levels : research contractors (1), CGC "Biotechnology" (4), Panel of Independent Experts nominated by the Commission.

- (1) Biomolecular Engineering in the European Community : achievements of the research programme (1982-1986), edited by E. Magnien, Martinus Nijhoff Publishers for the Commission of the European Communities, EUR 10658 EN, 1986.
- (2) European Laboratories Without Walls : focused pre-competitive research. R. van der Meer, E. Magnien - and D. de Nettancourt: Trends in biotechnology (1987) 4:277.
- (3) BIOTECHNOLOGY ACTION PROGRAMME. Progress report 1987 (2 volumes). Ed.: E. Magnien. Commission of the European Communities, EUR 11138 EN, Luxemburg, 1987. The 1988 issue will be published in January 1989.
- (4) COM(86) 272 final "Communication from the Commission to the Council concerning the review of the multiannual research programme for the EEC in the field of biotechnology", 21 May 1986.

BAP was assessed by the same Panel of Independent Experts who evaluated BEP (1).

Every one of these evaluations underlined the usefulness of Community R&D in biotechnology.

With regard to BEP, the CGC biotechnology considered that "its most convincing result is undoubtedly the creation of a climate favourable to transnational cooperation, the effects of which fall beyond the hopes expressed when the programme was launched".

Commenting on both BEP and BAP, the Evaluation Panel of Independent Experts stated that "... a major achievement of the research programmes, and one that is important for the future, has been to break down national frontiers between laboratories. We commend the Commission's initiative in linking groups into European Laboratories Without Walls, a useful concept that could be applied in other domains. We were impressed by the way some contractors, who had initially been sceptical about transnational cooperation, were now enthusiastic".

The Evaluation Panel concluded that the training activities in BEP and BAP had been successful and that the research programmes led to a number of substantial scientific achievements testifying for their high quality. The panel noted that "highly significant technical breakthroughs" (2) had been achieved by the programme particularly in sectors such as the genetics of plants and of industrial microorganisms. In sectors where such breakthroughs were not reached, the Panel considered that either the goals and bottlenecks had been insufficiently defined or that a critical mass of researchers had not been assembled.

1.2. Recommendations for future activities

1.2.1. Recommendations of the Evaluation Panel

The panel concluded its report (1) by a number of recommendations which, as far as the research activities of BRIDGE are concerned, call for "science-led" projects and "large scale" projects.

The panel considered that the following large scale projects are of particular importance :

- " - To sequence the yeast genome completely.
- To develop detailed molecular genetic maps for one plant and one animal species of economic importance to Europe.

(1) Evaluation of the Biomolecular Engineering Programme, BEP (1982-1986) and the Biotechnology Action Programme, BAP (1985-1989). Research Evaluation Report n° 32 - EUR 11833 EN/1.

(2) It is of course on the basis of such breakthroughs, ultimate consequence of the catalytic effects of transnational cooperation, that the programmes need to be judged. The complete list of scientific and technical achievements, which cannot be reproduced here, are to be found in the final report of BEP and in the last two annual reports of BAP (l.c.).

- To undertake a focused programme in protein engineering so as to understand and modify in a multi-disciplinary manner the structure and biological and/or physical properties of a few proteins.
- To elucidate the control of gene stability, transcription, post-transcriptional and post-translational processing, protein over-production, and secretion in one major industrial microorganism through genetic manipulation, biochemistry and cell physiology.
- To apply recent progress in molecular biology to the physiology and improvement of major European crops, including gene transfer to, and cell regeneration of, cereals.
- To establish a complete interconnection and cataloguing system for the major culture collections in all Member States with on-line access, for a fee, by all research workers. A pilot scheme, involving the current BAP contractors, should achieve these objectives by 1991.
- To continue to develop appropriate methodology for an assessment of the safety and ecological consequences of the release of genetically modified organisms, especially bacteria and viruses, in order to develop guidelines for best practice in the production and use of such organisms."

1.2.2. Resolution of the European Parliament on biotechnology in Europe
 and the need for an integrated policy (1)

In this resolution, which goes beyond the limits of R&D in biotechnology, and upon which the Commission reported on 30 October 1987 (2), the European Parliament acknowledged the "considerable success of BEP in stimulating transnational cooperation between European laboratories and the training of young scientists as well as coordinating research activities". The resolution noted, however, that BEP only had a limited budget and concentrated mainly on research connected with agriculture and the food processing industry, and specified the priorities and essential features for future Community programmes in biotechnology. Among many specifications which, in certain cases, concerned other programmes of the Community (medical research, cooperation with the third world countries, AIM ...), the European Parliament underlined the necessity to give priority in future to projects studying the problems posed by the intentional release of genetically engineered micro-organisms in the environment.

(1) O.J. of the European Communities, 16 February 1987, n° C 76/25.
 (2) Half-yearly report on actions taken on Parliament's own initiative resolutions (January to June 1987), SP(87) 2461/2, 30 October 1987, Commission of the European Communities.

1.2.3. The point of view of industrial organisations
.....

The organisations which expressed opinions are listed in Table 1, together with the titles of their reports.

IRDAC, the industrial research and development advisory committee of the CEC, delivered the most detailed opinion on the content of BRIDGE. Many of its recommendations are in line with the programme proposed by the Commission. In particular, it was through a request of IRDAC W.P.5 "Biotechnology" that the research activities implemented in the framework of BAP on "second generation bioreactors" are not suggested to continue within BRIDGE. On the other hand, their recommendations to rank as top priorities protein engineering, or plant and microbial biotechnology (with increased emphasis on physiology and metabolism), have been taken up entirely.

The first recommendations submitted by EBCG with regard to safety evaluation (detection methods, micro-ecosystems, biological containment, survival and speed of dispersal) have been integrated in the present proposal. Similarly, the various areas, including safety evaluation, which EBCG considered as priorities in its position paper "the approach of the biotechnology industry to BRIDGE" are parts of the present proposal. The CERIC report on bio-informatics in Europe goes beyond, in ambition and in scope, the activities restricted in BRIDGE to the information needs of three sectors: protein design, genome sequencing, data banks and information networks. Other programmes have been defined, such as AIM (Advanced Informatics for Medicine), which will also contribute to the main objectives outlined by CEFIC.

The "Green Industry Biotechnology Platform" and a group of 16 yeast related industries provided opinions which were restricted to the interest of defined industrial branches. The correspondence between their expectations and the provisions made by BRIDGE in the various sectors which they covered is extensive.

Table 1 : References to opinions expressed by industrial organisations

Industrial R&D Advisory Committee of the European Communities (IRDAC)

"Opinion on future R&D programmes in the field of biotechnology",
December 1987.

European Biotechnology Co-ordination Group * (EBCG)

"Safety Evaluation Through Risk Assessment in Biotechnology", March 1987.

"The Approach of the Biotechnology Industry to BRIDGE", November 1987.

European Council of Chemical Manufacturers Federation (CEFIC)

"Bio-informatics in Europe - An industry position paper", March 1987.

Green Industry Biotechnology Platform (GIB1P)

"Final opinion of GIB1P on the BRIDGE programme", April 1988.

Consultation of yeast industries

in "Sequencing the yeast genome, a detailed assessment", June 1988.

* The members of EBCG are CEFIC, CIAA (Confederation of Food and Drink Industries of EEC), EFPIA (European Federation of Pharmaceutical Industries' Associations), GIFAP (International Group of National Associations of Agrochemical Manufacturers) and AMFEP (Association of Microbial Food Enzyme Producers).

1.2.4. Opinion of the CGC "Biotechnology"
.....

The present proposal was prepared with the constant help and feed-back of the CGC "Biotechnology" and, in particular, through the guidance of 10 specific ad hoc groups, each created by the CGC, for reviewing a specific sector or subsector of BRIDGE and making recommendations. At its meeting of 17 November 1988, the CGC reviewed an earlier version of the document and examined, at the same time, draft suggestions for amendments prepared by subgroups of IRDAC W.P. for biotechnology. The CGC thereafter formulated final recommendations which are taken into account in the present proposal.

2. OBJECTIVES AND ORIENTATIONS OF BRIDGE

It is considered, on the basis of the assessments and recommendations outlined above, that the objectives of the programme should be :

- to foster transnational research and to promote its catalytic effects, for accelerating the production of biological data, materials and methods necessary for the safe and rational exploitation of useful organisms;

- to place such data, materials and methods at the disposal of industry, agriculture and research centres and to encourage their exploitation;

- to ensure that information generated under the programme is available for current discussions on the social acceptability of modern biotechnology;

- to establish, through normative research, the scientific basis necessary for the establishment of guidelines to regulate new and economically important production methods (including, in particular, those which are based upon the use of genetic engineering);

- to take advantage of the scientific competences dispersed throughout the Community for contributing, via training and scientific mobility, to the requirements of biotechnology operators in qualified scientific staff and in multidisciplinary combinations of expertise.

Two approaches will be followed for the development of the programme.

2.1. Removal of bottlenecks resulting from gaps in basic knowledge

In most areas of biotechnology, there is clearly a need for embarking on exploratory research ventures, particularly when insufficient basic knowledge of organismal biology has been reducing the scope for applying molecular methods. The primary requirement in this prevalent situation is to increase the multidisciplinaryity of research by fostering temporary combinations of skills. The uncertainty of the outcome recommends a reasonable dosage of efforts and of supporting funds but its importance justifies an active partnership with industries, either for an active collaboration of efforts or for the exploitation of data, methods and materials originating from the research. Finally, the difficulty and complexity of the work calls for the catalytic mobilisation of competences throughout the entire Community.

All these requirements can best be satisfied through the creation of European Laboratories Without Walls (ELWWs) similar to those which have been successfully promoted in the framework of BAP. The scientific content for cooperative projects foreseen for implementation by networks of ELWWs is outlined in annex to the proposal for a Council decision under the four headings : information infrastructure, enabling technologies, cellular biology and normative research.

2.2. Removal of bottlenecks resulting from structural or scale constraints

In several instances, the bottleneck to the exploitation of modern biology results from structural or scale constraints which could be overcome through a significant investment of skills and resources during a specific period. Community projects for the removal of such bottlenecks will, in many instances, represent the logical extension of activities initiated by European Laboratories Without Walls; they must, in all cases, clearly form part of the sectors outlined in annex to the proposal for a Council decision and are to be defined, at the time the call for proposals is prepared, in close cooperation with the relevant advisory committee. "Sequencing of the yeast genome", "High resolution automated microbial identification" and "Molecular identification of new plant genes" are examples, among several others, of subjects which could be addressed in this way.

2.3. Training

It is proposed, on the basis of recent analyses (1, 2, 3) and of several consultations of experts and expert committees, to continue in BRIDGE the activities which have been shown, through BEP and BAP, to answer an essential need of the Community for scientists trained in the complex areas of biotechnology.

Training in BRIDGE will therefore involve :

- the establishment of training contracts for junior and senior scientists with duration periods ranging from 6 to 24 months. The scientific scope for these "training through research" activities will cover each of the specific areas outlined in annex to the proposal for a Council decision.

- the organisation, as in BAP, of courses and summer schools in all areas of research where obvious training needs are identified during the implementation of the programme.

-
- (1) W. Dostal, Fast series n° 22 "New technology and development in employment", EUR 11386 EN, 1988.
 - (2) D.J. Bennett "Manpower, Education and Training in Biotechnology" A.A.B.B., London, 1988.
 - (3) A. Dollacker, M. Olast, E. Magnien "The advertised demand for qualified staff in biotechnology-related fields : a statistical approach", DG XII, 1986 (draft report).

3. IMPLEMENTATION SCHEMES

3.1. Cooperative networks projects ("N" projects)

These projects, such as defined above in 2.1., will be based on the BAP model with a contribution of the Community ranging from 200.000 - 400.000 ECU/year x project. Applications for support will be requested to provide a very clear matrix of the tasks suggested for each of the laboratories presenting the proposal. Only closely integrated projects, obviously leading to the formation of an active European Laboratory Without Walls, will be considered for funding.

When necessary, the Commission services will also organise transnational activities (visits, meetings, exchanges of information) between laboratories of high scientific level not involved in the implementation of science-led projects. It is expected that these laboratories, after a year or two of collaborations stimulated by small financial contributions will be ready, at the time BRIDGE is revised, to submit new transnational proposals for science-led projects.

3.2. Larger targeted projects ("T" projects)

Support of the Commission to "T" projects, such as defined above in 2.2., may vary from 1 to 3 Mio ECU per year and per project. The manner in which the work is distributed and research funds are allocated to each participating laboratory will be specific to each project. Sequencing of the yeast genome, one of the "T" projects proposed above by the Commission, represents a case where Community funds are going to be allocated to very many laboratories working in one single project.

3.3. Training

Training activities will be pursued on the BAP model. For training through research, it is planned to attribute a number of training contracts to junior and senior scientists corresponding to an average of 160 man/year. Benchfees will be attributed to the host-laboratories.

4. MANAGEMENT PRINCIPLES

4.1. Consultation of the advisory committee

Preparation of tender documents for research and training activities, assessment of proposals and selection of trainees, evaluation of results and diffusion of information on the programme will be made by the Commission in consultation with the relevant advisory committee.

4.2. Setting up of target-linked monitoring units

Owing to the complexity and the wide diversity of scientific subjects that are encompassed in the definition of modern biotechnology, much specialised expertise appears required for the

proper management of all programme areas. Target-linked monitoring units should be established in association with each "T" project and, if needed, with certain groups of "N" projects. Each monitoring unit could be constituted, with the scientific officer of the Commission, through a list of experts from the Commission and from advisory committees. Each monitoring unit should follow the progress of relevant projects towards specific goals of the corresponding part of the programme, and assist the Commission in various assessment and steering tasks. It should meet at least once a year, to analyse annual progress within the corresponding programme areas, and to report to the relevant advisory committee. These monitoring units could constitute one of the elements of a decentralised management system established progressively in the framework of the programme.

4.3. Criteria for selection of research projects

The selection of proposals will be carried out with the help of the advisory committee. The following criteria will be applied :

- the technical competence of the proposer
- the scientific interest of the proposal, its originality, its relevance to the scope of the programme and its feasibility (including ultimate economic feasibility)
- the likely contribution of the proposed research to safety, to the harmonisation of norms and to the economic strength and competitiveness of the European Communities
- the intensity of transnational collaboration (proposals not originating from at least two laboratories located in different Member States will not be considered for funding)
- the involvement of industry, through direct participation, co-financing, supply of materials, access to infrastructures, expression of interest for exploitation of research results ...
- when applicable, the assessment of risks possibly associated to the research proposed (each contractant will have to adhere most strictly to the rules and recommendations issued on the matter in the Member State where the laboratory is located).

4.4. Relationships and cooperation with other Community or international R&D programmes

"BRIDGE contributes to the implementation of the subdivision "4.1. Biotechnology" of the Community Framework Programme for research and technological development. It is complemented by current and future specific programmes foreseen under the subdivision "4.2. Agro-industrial technologies" and "4.3. Competitiveness of agriculture and management of agricultural resources". The ties between BRIDGE and these actions are very narrow, particularly with regard to ECLAIR and FLAIR which lie directly downstream of the programme.

Other relationships between BRIDGE and existing or future R&D Community activities are to be found in some of the areas covered by the programme "Environment", in the foreseen action for "Predictive Medicine", the "Science" plan, the programme "Science and Technique for Development", in ESPRIT (in particular area II.2 "knowledge engineering") and in the demonstration projects for the Energy Sector.

In all these cases, close coordination will be assured to exploit natural complementarities between programmes and to avoid any unnecessary duplication.

The generic and pre-competitive technological work envisaged for BRIDGE should, in the medium to long term range, create opportunities for Eureka projects with commercial aims.

The present links with the European Federation of Biotechnology (participation of Commission staff to meetings of the Science Advisory and Executive EFB Committees, attendance of EFB representatives to CEC workshops, support, as in June 1987, to the organisation of the European Congress on Biotechnology ...) will be maintained and intensified.

ACTION II : CONCERTATION

1. ORIGIN AND AIMS

Throughout the world, national administrations have recognised de facto that the interdisciplinary and multi-sectoral character of biotechnology demands inter-agency coordination for policy coherence. Recognising this, the Commission in 1984 established an inter-service Biotechnology Steering Committee, and supporting structures and activities; charged with implementing the range of priority actions for biotechnology defined in its previous communication to Council (1), leading to the preparation of Commission initiatives, such as the recent proposals for biotechnology regulation (2).

In March 1985, the Council Decision (3) establishing the Biotechnology Action Programme provided a mandate for a concertation action involving the Member States. The Council mandate defined the objectives :

"improving standards and capabilities in the life sciences, and enhancing the strategic effectiveness with which these are applied to the social and economic objectives of the Community and its Member States".

A list of supporting tasks was itemised, which can be summarised as:

- worldwide monitoring and information gathering; analysis and evaluation; storage; and selective diffusion;
- coordination and promotion of collaboration in policy areas affecting or affected by biotechnology,
 - (i) - across the services of the Commission
 - (ii) - between Commission and Member States,
- scope for more specific initiatives on key biotechnology-related topics such as agriculture and environment, Third World development, safety, public information, academic-industrial collaboration, and social dimensions.

Across all these areas, emphasis was placed on acting in conjunction with relevant services in the Community and the Member States, and through ad hoc, informal and flexible networks.

-
- (1) COM(83) 672 final/2, "Biotechnology in the Community", 4 October 1983.
 - (2) E.g. COM(86) 573 final, "A community Framework for the Regulation of Biotechnology", Communication from the Commission to the Council, 4 November 1986; COM(88) 160 final, "Proposal for a Council Directive on the contained use of genetically modified microorganisms" and "Proposal for a Council Directive on the deliberate release to the environment of genetically modified organisms", 4 May 1988; and COM(88) 165 final, "Proposal for a Council Directive on the Protection of Workers from the Risks related to Exposure to Biological Agents at Work", 5 April 1988.
 - (3) O.J. L 83 of 25 March 1985.

2. CURRENT ACTIVITIES AND ACHIEVEMENTS

Numerous activities have been initiated under these mandates, to provide a service of strategic awareness, analysis, recommendations for action, and supporting actions. Concertation is a service activity, to enable all Commission services, Member State agencies, or other actors involved in biotechnology to perform better or to coordinate better their actions. The following are examples of activities in which the concertation action has played a significant role :

- (i) - a documentation centre, now containing some 25.000 policy-relevant papers on biotechnology, is used increasingly by Commission and Member State colleagues, their advisers, consultants, researchers, and Parliamentary aids. Plans are in preparation to upgrade it, in particular to facilitate access and diffusion. Thousands of requests are met each year for information, advice and documentation; current activities are increasingly constrained by manpower and space limits.
- (ii) - ad hoc studies and workshops have led to actions on recommendations
 - the "BICEPS" planning exercise (Bio-Informatics : Collaborative European Programmes and Strategy (1)); provided foundations for reinforcing bio-informatics in BAP and BRIDGE, and for the AIM programme (Advanced Informatics in Medicine);
 - various studies, consultative meetings, a Commission discussion paper (2) and a call for expressions of interest prepared the proposal for the ECLAIR and FLAIR programmes (3, 4);
 - studies arising from the work of the Task Force for Biotechnology Information have led to concrete recommendations, well-supported by industry, for a European biotechnology information policy (5);

-
- (1) BICEPS summary report available, and 15 supporting study or workshop reports.
 - (2) COM(86) 221/2, Discussion Paper, "Biotechnology in the Community : Stimulating Agro-Industrial Development", 15 April 1986.
 - (3) COM(87) 667, Proposal for a Council Decision to adopt a first multi-annual programme (1988-1993) for biotechnology-based agro-industrial research and technological development "ECLAIR" (European Collaborative Linkage of Agriculture and Industry through Research), 18 December 1987.
 - (4) COM(88) 351, Proposal for a Council Decision to adopt a multi-annual research and development programme in food science and technology (1989 to mid-1993) FLAIR (Food-Linked Agro-Industrial Research), 24 June 1988.
 - (5) "The Role of Information Technology and Services in the Future. Competitiveness of Europe's Bio-industries", report prepared for the Commission, January 1988, by ASFRA consultants.

- (iii) - secretariat of interservice groups such as the Biotechnology Steering Committee, BRIC, and Bio-RDD.

These and other activities are pursued in implementation of the multi-service strategy defined in 1983.

3. OPINIONS, EVALUATION AND RECOMMENDATIONS

The above initiatives, both in the general aim of strategic coherence and the specific examples cited, are in accordance with the recommendations of IRDAC (1). The EVALUATION PANEL (2) recommended that

"The concertation activity should also be expanded in line with the general growth of the biotechnology research programme, to about 10% of the total budget of BRIDGE"; and

"should concentrate on four major tasks, of which the last is new :

- (i) The coordination of the Commission's approach to biotechnology, including the dissemination of information internally, and the formulation of proposals for future initiatives.
- (ii) The concertation of biotechnology activities of Member States.
- (iii) The provision of information on the advantages, limitations and safety of biotechnology to politicians, scientists and the general public in the Community and in Associated States under the Lomé Convention.
- (iv) Activities designed to promote the formation and growth of small and medium-sized biotechnology firms."

These recommendations are generally acceptable to the Commission, and in the proposals for the future of the concertation action, the objectives, tasks and resource requirements have taken these recommendations into account. Current tasks have been reviewed and focussed more closely towards the above priorities; in line also with the recommendations of the CGC (Biotechnology).

-
- (1) IRDAC, Industrial R&D Advisory Committee of the Commission of the European Communities, "Opinion on future R&D programmes in the field of biotechnology", December 1987.
 - (2) "Evaluation of the Biomolecular Engineering Programme, BEP (1982-1986) and the Biotechnology Action Programme, BAP (1985-1989)", expert panel, Summer 1988.

4. OBJECTIVES AND PRIORITIES FOR CONCERTATION

The objectives for concertation originally defined by the March 1985 Council Decision (see §1 above) remain pertinent, but their effective pursuit through specific actions and tasks will be updated to take account of :

- (i) - worldwide developments in biotechnology over the last few years - for example, the increased importance of worldwide electronic networking, databanks, and related information infrastructure; the rapidly growing competitive challenge from newly industrialising countries;
- (ii) - the recent and likely future evolution of Community and Member State policies related to or influenced by biotechnology - for example, the launching of the agro-industrial programmes ECLAIR and FLAIR will diminish the need for the concertation action to promote new activities in this area.

The implementation of the supporting tasks (see §1) will thus be modified, taking into account the recommendations of the Evaluation Panel, IRDAC, the programme management committee, and other needs identified via the networks (industrial, scientific, public interest etc.). In particular, collaboration will be reinforced with those responsible for biotechnology-related matters in Member State administrations and agencies.

5. IMPLEMENTATION

Implementation of the concertation action will be through in-house work, in collaboration with Commission services, Member States and other interested bodies; based on the continued development and more effective exploitation of the monitoring, information base, information diffusion and analysis activities; the commissioning of study reports, the organisation of workshops and meetings, and support for "Task Force" activities around the aims outlined above.

Although some staff increase are seen as essential to cope with the growing volume of biotechnology activities, maximum use will be made of external services, and of collaborative activities with biotechnology-related units in Member State administrations and public agencies. The secondment of Member State staff over periods typically of 1 to 3 years will be particularly encouraged, in order to reinforce links with Member State actions in biotechnology.

*

* *

PROPOSAL FOR A COUNCIL DECISION