II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 27 November 1989

on a specific research and technological development programme in the field of biotechnology (1990 to 1994) (Bridge)

(89/621/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

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

Having regard to the proposal from the Commission (1),

In cooperation with the European Parliament (2),

Having regard to the opinion of the Economic and Social Committee (3),

Whereas Article 130k of the Treaty stipulates that the framework programme shall be implemented through specific programmes developed within each activity;

Whereas, by Decision 87/516/Euratom, EEC (4), as amended by Decision 88/193/EEC, Euratom (5), the Council has adopted a framework programme for Community activities in the field of research and technological development (1987 to 1991), providing *inter alia* for activities ensuring the exploitation and optimum use of biological resources;

Whereas that Decision provides that a particular aim of Community research must be to strengthen the scientific and technological basis of European industry, particularly in strategic sectors of advanced technology, and to encourage it to become more competitive at the international level, and that Community action is justified where research contributes, *inter alia,* to the strengthening of the economic and social cohesion of the Community and to the promotion of its overall harmonious development, while being consistent with the pursuit of scientific and technical excellence; whereas the Biotechnology Research for Innovation, Development and Growth in Europe (Bridge) programme should contribute to the achievement of these objectives;

Whereas the activities provided for in the framework programme include, in particular:

— the establishment of Community research and development (R&D) for contributing a transnational dimension to national efforts and for facilitating technology transfer towards industry and agriculture in the areas of infrastructure, basic biotechnology and risk analysis,

— the continuous evaluation of the strategic significance of new developments in biotechnology and promotion of the essential coherence between the different areas of Community policy concerned with biotechnology;

Whereas Decision 81/1032/EEC (6) adopting the multiannual research and training programme for the European Economic Community in the field of biomolecular engineering and Decision 85/195/EEC (7) adopting, and Decision 88/420/EEC (8) revising, the

(1) OJ No C 70, 20. 3. 1989, p. 1 and OJ No C 198, 3. 8. 1989, p. 12.
(2) OJ No C 158, 26. 6. 1989, p. 81 and OJ No C 291, 20. 11. 1989.
(3) OJ No C 159, 26. 6. 1989, p. 26.
(4) OJ No L 302, 24. 10. 1987, p. 1.
(5) OJ No L 89, 6. 4. 1988, p. 35.
(6) OJ No L 375, 20. 12. 1981, p. 1.
(7) OJ No L 83, 23. 3. 1985, p. 1.
(8) OJ No L 206, 30. 7. 1988, p. 38.

multiannual research action programme for the European Economic Community in the field of biotechnology (1985 to 1989) have clearly demonstrated the utility of Community actions in biotechnology and the need for their expansion;

Whereas particular attention should be paid to ethical and social matters which may be associated with this programme;

Whereas the participation of European non-member States wholly or partially with projects in this programme is desirable;

Whereas it is desirable to involve small and medium-sized enterprises to the maximum extent possible in the biotechnology research and development programme;

Whereas the implementation of research and training actions in the COST framework is an essential element to complement R&D projects in the field of biotechnology;

Whereas the Scientific and Technical Research Committee (Crest) has given its opinion,

HAS ADOPTED THIS DECISION:

Article 1

A specific research and technological development programme (Bridge) for the European Economic Community in the field of biotechnology, as defined in Annex I, is hereby adopted for a period of four years from 1 January 1990.

Article 2

The funds estimated as necessary for the execution of the programme amount to ECU 100 million, including expenditure on a staff of 28.

An indicative allocation of funds is set out in Annex II.

Article 3

Detailed rules for the implementation of the programme and the rate of the Community's financial participation are set out in Annex I.

Article 4

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

2. At the end of the programme, an evaluation of the results achieved shall be conducted by the Commission, which shall report thereon to the European Parliament and the Council.

3. The abovementioned reports shall be established having regard to the objectives and criteria set out in Annex III to this Decision and in accordance with Article 2 (2) of Decision 87/516/Euratom, EEC.

Article 5

The Commission shall be responsible for the execution of the programme.

The Commission shall be assisted by a committee of an advisory nature, hereinafter referred to as 'the committee', composed of the representatives of the Member States and chaired by the representative of the Commission.

Contracts concluded by the Commission shall govern the rights and obligations of each party, in particular the arrangements for the dissemination, protection and exploitation of research results.

Article 6

1. The representative of the Commission shall submit to the committee a draft of the measures to be taken. The committee shall deliver its opinion within a time limit which the chariman may lay down according to the urgency of the matter, if necessary by taking a vote.

2. The opinion shall be recorderd in the minutes of the committee; in addition, each Member State shall have the right to have its position recorded in the minutes.

3. The Commission shall take the utmost account of the opinion delivered by committee. It shall inform the committee of the manner in which its opinion has been taken into account.

Article 7

The procedures laid down in Article 6 shall apply in particular to:

— the contents of the calls for proposals,
— the assessment of the proposed projects and the estimated amount of the Community's contribution to them,
— departures from the general rules govering Community participation set out in Annex I,
— the participation in any project by non-Community organizations and enterprises referred to in Article 8 (2),
— any adaptation of the indicative allocation of funds set out in Annex II,
— the measures to be undertaken to evaluate the programme,
— arrangements for the dissemination, protection and exploitation of the results of research carried out under the programme.

Article 8

1. The Commission is authorized to negotiate, in accordance with Article 130n of the Treaty, agreements with international organizations, those non-member States participating in European Cooperation in the field of Scientific and Technological Research (COST) and those European countries having concluded framework agreements in scientific and technical cooperation with the Community, with a view to associating them wholly or partly with the programme.

2. Where framework agreements for scientific and technical cooperation between European non-member States and the European Communities have been concluded, organizations and enterprises established in those countries may, on the basis of the criterion of mutual benefit, become partners in a project undertaken within the programme.

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

Article 9

This Decision is addressed to the Member States.

Done at Brussels, 27 November 1989.

For the Council

The President

R. DUMAS

ANNEX I

PROGRAMME CONTENTS AND IMPLEMENTATION AND THE RATE OF THE COMMUNITY'S FINANCIAL PARTICIPATION

ACTION I: RESEARCH AND TRAINING

CONTENT

1. **Information infrastructure**

1.1. *Culture collections*

Development of a communication system for easy and rapid access to the most important service culture collections within the Community is to be achieved through support of:

— a promotion centre for culture collections, specifically designed for providing to European users (distribution of catalogues, patent regulations, printed and visual material) adequate information on expertise and services available in different European culture collections,

— a centralized European data bank, primarily on microorganisms and subsequently extended to other biotic materials (animal and plant cells, viruses, plasmids). The first phase towards this objective is to involve the harmonization of formats and data in the main service culture collections of the European Community.

1.2. *Processing and analyses of bio(techno)logical data*

— Applications of information technology (specialized software and equipment) such as required for the implementation of the activities in protein engineering and gene sequencing (see also 2.1 and 2.3).

— Updating and design of knowledge bases for storing and classifying bio(techno)logical data such as sequences, genetic maps, protein and biopolymer structures, risk assessment data.

— Exploitation of existing or newly developed information technology for rapid access to European knowledge bases and closed sequencing networks via an electronic network, including electronic input, on-line catalogues, electronic ordering, etc.

2. **Enabling technologies**

2.1. *Protein design/molecular modelling*

— Multidisciplinary approaches including genetic engineering and advanced structural methods aiming at improving the properties (such as stability, pH optimum, substrate specificity) of interesting proteins and their complexes (including glyocproteins).

— Development of methods to understand and predict structure/function relationships of proteins, such as those involved in folding, stability, crystallization, including theoretical methods for simulation of these properties, and their interactions with other related molecules.

2.2. *Biotransformation*

— Development of biological reactions using new strains of cells or novel enzymes for synthesis of key intermediates needed for the production of high added value substances (particular attention to be given to the bioconversion of agricultural surpluses) and for converting pollutants to innocuous compounds.

— Research addressing the problem of genetic and physiological stability of the free or immobilized genetically modified microbes or cells under biotransformation conditions.

— Research addressing the problem of enzymatic activity under extreme environments (organic solvents, pHs, temperatures, immobilization).

— Development of methods for the isolation and purification of biotransformation products (upstream and downstream processing).

— Development of specialized software and mathematical modelling for the control and analysis of biotechnological processes.

2.3. *Gene mapping, genome sequencing, novel cloning methods*

— Sequencing the genome of yeast *(Saccharomyces cerevisiae)* or parts thereof and of *Bacillus subtilis.*

— Development of molecular genetic techniques to identify new meaningful plant genes, using the *Arabidopsis* genome as a resource; characterization of the identified genes.

— Development of advanced sequencing procedures and technology (see 1.2.) and integration of these procedures and technology in the sequencing projects.

3. **Cellular biology**

3.1. *Physiology and molecular genetics of industrial microorganisms*

Gene stability and expression, post-translational processes, genetic and metabolic regulation of overproduction, transport and secretion. These studies, adapted in each case to the current state of the art, will concentrate on some industrially interesting microorganisms, such as the genera lactic acid bacteria, *Streptomyces Pseudonomas, Bacillus, Clostridium, Corynebacterium,* and including the larger groups of lactic acid bacteria, extremophiles, yeasts and filamentous fungi.

3.2. *Basic biology of plants and associated organisms*

— Core processes for sexual breeding : mechanisms of flower initiation and evocation, differentiation of sex cells ; molecular bases of gamete recognition and selection systems.

— Fundamentals of plant cell regeneration : genetics and molecular biology of somatic and zygotic embryogenesis ; perception and transduction of growth-promoting signals.

— Molecular interfaces of plants and associated organisms : molecular bases of host-range and virulence ; characterization of plant defence reactions ; development of genetic techniques for pathogenic fungi or mycorrhizae ; regulation from plant/microbial signals of the expression of microbial/plant genes ; structural and functional identification of genes involved in N_2-fixing symbioses.

— Physiological attributes of crops : storage processes ; stress physiology ; nitrogen use efficiency.

3.3. *Biotechnology of animal cells*

— Animal cell engineering and culture technology leading to new or improved productions of important substances for industrial and zootechnical purposes.

— Animal genetics : mapping and sequencing of important genes ; methods of gene transfer ; and study of gene expression and regulation on cell cultures.

— Animal husbandry : improved immunity through genetically engineered vaccines of second generation.

4. **Prenormative research**

Prenormative research in biotechnology places itself at both ends of the research-development-exploitation chain.

4.1. *Safety assessments associated with the release of genetically engineered organisms*

— Monitoring and control techniques : sampling and probes for engineered organisms and introduced segments of DNA ; methods and instrumentation for high-resolution automated microbial identification and the establishment of adequate data bases ; creation of a bank of specific probes and chemical signatures for a large number of specific microorganisms ; eradication methods.

— Assessment techniques : biological containment ; gene stability and gene transfer ; development of microcosms and simulating methods for impact analysis.

— Acquisition of fundamental knowledge on gene behaviour (horizontal transfer between species, rearrangement of introduced genes in the host organism) and on the survival and adaptation of released organisms, in particular soil bacteria, and including modification of host range and tissue range for engineered viruses.

— Novel constructions : biologically contained organisms ; suicide vectors or constructions which cannot develop outside the host organism ; engineered organisms which can be destroyed in the environment by known and specific techniques.

4.2. In vitro *evaluation of the toxicity and pharmacological activity of molecules*

— Development of cellular and multicellular systems as surrogates for *in vivo* tissues and organs.

— Research addressing the problems of preparation, storage maintenance and growth of human cell cultures.

— Development of cell lines in which functional properties are better preserved.

IMPLEMENTATION

This part of the programme shall be implemented by means of training activities, research activities carried out on the basis of shared-cost research contracts, and participation in certain COST (Category A) activities.

Training actions shall be implemented through training contracts and courses for any of the themes defined above. The cost of these actions shall be borne by the Community.

Participants in a project conducted as a shared-cost action may be industrial enterprises, including small and medium-sized enterprises, research institutions, universities, or combinations of them, established in the Community or in those European third countries which have concluded framework agreements in scientific and technical cooperation with the Community. Pending the implementation of the provisions of a possible Council Directive on deliberate release into the environment of genetically modified organisms, proposals selected will have to conform, in the country where the release experiment is to take place, to relevant safety

regulations or guidelines; in those countries where no such regulations or guidelines have been developed, the project proposers planning to initiate release experiments will obtain the written consent from the competent authorities concerned.

Shared-cost research projects involving research centres (and/or universities) and industry are strongly encouraged. Industrial participation should constitute an important criterion of selection in the progrmame.

For shared-cost contracts, the Community participation will be up to 50 % of the total expenditure. Alternatively, in respect of universities and research institutes carrying out projects under this programme, the Community may bear up to 100 % of the additional expenditure involved.

Two types of transnational research projects, which will normally be carried out by participants from more than one Member State (irrespective of participants from third countries), are foreseen:

— N projects, for the integration in adapted Community structures (European Laboratories Without Walls: ELWW) of research efforts in areas where the main bottlenecks result from gaps in basic knowledge. The contribution of the Community in such projects shall not exceed ECU 400 000 per year per project.

— T projects, for the removal, through a significant investment of skills and resources, of important bottlenecks resulting from structural and scale constraints; the contribution of the Community in such projects may vary from ECU 1 to 3 million per year per project.

Shared-cost research contracts shall be awarded following a selection procedure based on calls for proposals published in the *Official Journal of the European Communities.*

Special attention will be paid to the dissemination of the programme results in accordance with Community rules and taking into account contractual arrangements in order to maximize the effects of this work and to allow all enterprises, particularly small and medium-sized enterprises, in all regions of the Community, including the less-favoured ones to benefit.

COST activities (Category A) associated with Action I

CONTENT

— Marine primary biomass.
— *In vitro cultures* for the purification and propogation of plants.
— Methods for early detection and identification of plant diseases.
— Vesicular-arbuscular (VA) mycorrhizae.
— Development of vaccines against coccidiosis.

IMPLEMENTATION

Implementation shall take place through the organization of meetings, consultation of experts, publications, exchange of research workers between laboratories, coordination contracts.

ACTION II: CONCERTATION

CONTENT

In conjunction with the relevant Commission services and the Member States, the following tasks will be executed:

(i) monitoring developments in biotechnology, particularly in the field of R&D, assessing their implications, and hence informing services of the Commission and interested public authorities having related responsibilities;

(ii) identifying possible ways in which the contextual conditions for the beneficial development of biotechnology in Europe may be improved, and the effectiveness and coherence of Member State and Community biotechnology programmes and related policies enhanced, including those involving international collaboration;

(iii) disseminating knowledge and helping to increase public awareness and understanding of the nature, potential, and possible risks associated with biotechnology;

(iv) identifying the need for and helping to promote greater activity in the biotechnology small-firm sector in the Community.

IMPLEMENTATION

The action wil continue to develop the work (begun under BAP) of *ad hoc* collaboration between groups and individuals with interests and capabilities in the life sciences and biotechnology, so creating networks, as informal and flexible as possible, adapted to the needs of encouraging coordination through the exchange of information between the participants, and assisting the broader diffusion of information required by the above tasks.

Specifically, the work will involve inhouse analysis, the setting-up and the exploitation of an organized information base, and missions. It will also include as necessary the commissioning of study reports, the organization of workshops and meetings, and support for the production of reports and dissemination of information.

An appropriate part of the resources of Action II, Concertation, will be devoted to actions concerning the wider implications of research and development in the areas of biotechnology — e.g. for consumers, society, environment and development — featuring in Action I.

ANNEX II

INDICATIVE ALLOCATION OF FUNDS

		(millions of ecus)
Action I: Research and training		
— Contract research		76,5
(To be divided equally between N projects (ECU 38,25 million) and T projects (ECU 38,25 million))		
— pre-normative research	15,5	
— cell biology	27,0	
— enabling technologies	27,0	
— information infrastructure	7,0	
— Training activities		12,0
— COST activities		2,0
Action II: Concertation		9,5
		100,0 (1)

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(1) Of which approximately 9 % staff costs.

ANNEX III

PROGRAMME OBJECTIVES AND EVALUATION CRITERIA

The Commission's communication to the Council concerning a Community plan of action relating to the evaluation of Community research and development activities for the years 1987 to 1991 (COM (86) 660 final) state that the objectives and milestones of each research programme have to be set out in a testable form. The objectives and milestones of the programme are set out below.

Action I: Research and training

1. The long-term objective is to contribute to the exploitation and the optimum use of biological resources in the Community, thus improving the research capabilities and infrastructures necessary for the competitiveness of the European agriculture and biotechnology industry, and for the protection of the environment. This aim is to be pursued through the removal of scientific and technical bottlenecks resulting either from gaps in knowledge or from scale and structural constraints. Research projects will be executed in the interactive way, making full use of integration between disciplines, bringing needs and opportunities in different Member States together, combining different expertises from basic and applied fields.

2. The primary short-term objectives are, therefore, to elicit proposals for research and for training activities on a scale commensurate with the Community resources proposed and, thereafter, to implement these activities ('N' projects, 'T' projects, training, and cooperation with third countries) in such a way that multidisciplinary transnational cooperation and scientific mobility are vigorously promoted. These objectives are to be testable in 1992 to 1993.

3. Particular objectives, testable in 1995, to be attained through 'N' projects including the following:

3.1. constitution of networks for transnational cooperation in each of the four areas (information infrastructure; enabling technologies; cellular biology; prenormative research) of the programme;

3.2. transnational cooperation as demonstrated through the analysis of scientific publications (each specific network or ELWW to produce at least one paper, either with transnational authorship or with acknowledgement of materials/methods supplied by other contract partners);

3.3. high quality of scientific achievements, as demonstrated through consultations of scientific experts and through analysis of citation records of scientific articles summarizing the results of the research;

3.4. expression of industrial interest as underlined, at least in 20 % of the projects, by industrial involvment during the implementation phase or, outside the Bridge legal framework, at the time of exploiting the results of the research.

4. Particular objectives, to be attained through the constitution and implementation of 'T' projects, include the following:

4.1. setting out a description, in terms of research efforts and expected benefits, of specific targets, such as the sequencing of the yeast genome, high-resolution automated microbical identification or molecular identification of new plant genes;

4.2. accomplishment, two years after initiation of a 'T' organization project, of progress towards the specified targets (namely through having made the right provisions and commitments securing that scientific goals are attainable by the time the programme is completed);

4.3. significant contributions indicating that the specified targets have been reached and that the specific interest of industry, agriculture or environmental control has been met.

5. For the training programme, the aim is to provide fellowships in research laboraties of a high scientific level for approximately two years for junior scientists, and one to two years for senior scientists. Particular objectives are the following:

5.1. accomplishment of a marketing effort in all Community Member States;

5.2. return of most fellows, after their training period, to any other Community Member States, if not their own country of origin, to work in biotechnology;

5.3. organization of training courses, summer schools and workshops, with support from the programme, and including participants from industry whenever possible. Where appropriate, representatives of other disciplines may also be invited to participate in these activities.

The above criteria can be partially tested in 1993, but a further examination should be made in 1998.

Action II : Concertation

The evaluation of the concertation action will consider whether the programme has in fact implemented the tasks specified in the Decision, and whether their implementation has effectively contributed to the stated objectives. More specific evaluation criteria are as follows :

1. Concertation with Member States : the concertation action should have assisted those responsible for biotechnology in Member States' administrations :

1.1. to be aware of current and planned Commission initiatives in areas relevant to biotechnology ;

1.2. to be aware of biotechnology activities and plans in other Member States ;

1.3. consequently, to have taken into account, in their national plans or initiatives for biotechnology, activities at Community level or in other Member States.

2. Impact on the conditions for biotechnology in Europe : the concertation action should be examined to establish whether and to what extent it has contributed to improving the contextual conditions in Europe for the safe development and beneficial application of biotechnology ; with particular reference to international competitiveness ; to the formation and growth of small companies and to the climate of public opinion about biotechnology.

3. Impact on the development of international collaboration in biotechnology, particularly in the field of R&D & D, and including developing countries.

4. Taking account of the results of Community, national or private sector research activities in biotechnology, it shall be considered whether the Bridge programme has :

4.1. contributed to the application of the results of the said research activities in the regions of the Community other than those in which the research was conducted ;

4.2. given adequate consideration to all the selection criteria set out in Annex III to Decision 87/516/ Euratom, EEC which includes that of contributing to the strengthening of the economic and social cohesion of the Community, while being consistent with the pursuit of scientific and technical excellence.