

COMMISSION OF THE EUROPEAN COMMUNITIES

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Proposal for a
COUNCIL DECISION

adopting a specific research and technological development
programme in the field of Biotechnology
(1990-1994)

(presented by the Commission)

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Proposal for a
COUNCIL DECISION

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

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⁾

(1) OJ No C

(2) OJ No C

(3) OJ No C

Whereas by its Decision 90/221/Euratom, EEC⁽⁴⁾, the Council adopted a third framework programme for Community activities in the field of research and technological development (1990-94), specifying inter alia the activities to be pursued for contributing to the development of the European potential for understanding and exploiting the properties and structures of living matter; whereas this Decision should be taken in the light of the grounds set out in the preamble to that Decision;

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

Whereas an estimate should be made of the amount of Community financial resources needed to carry out this specific programme; whereas the definitive amounts will be fixed by the budgetary authority in line with the financial perspectives covering the period 1988-1992 included in the Interinstitutional Agreement of 29 June 1988⁽⁵⁾ and with any future financial perspectives covering the period 1993-1994;

Whereas, pursuant to Article 4 and Annex I of Decision 90/221/Euratom, EEC, the amount deemed necessary for the whole framework programme includes an amount of 57 million ecus for the centralized dissemination and exploitation of results, to be divided up in proportion to the amount envisaged for each activity; whereas in view of the importance of this specific programme within the "Life Sciences and Technologies" action the estimate of the financial resources needed by this programme is to be reduced by 1.64 million ecus, which amount is to be allocated to the centralized activities, in order to comply with the second sentence of Article 130p (2) of the Treaty;

(4) OJ No L 117, 8.5.1990, p.28.

(5) OJ No L 185, 15.7.1988, p.33.

Whereas this programme must be implemented by the Commission; whereas to help accomplish this, the Member States are bound, pursuant to Article 5 of the Treaty, to facilitate the achievement of its tasks where necessary, notably within a committee;

Whereas this programme must be implemented essentially by the selection of research and development projects to enable them to benefit from Community participation; whereas the Commission should encourage the submission of such projects by the usual means of publishing calls for proposals in the Official Journal; whereas a special procedure should also be devised so as to maintain a degree of flexibility enabling the Commission, in the face of the continuous evolution and gradual acceleration of technological progress, also to take into consideration spontaneous proposals consistent with the objectives of the programme;

Whereas the projects to be carried out under the programme must be selected with special attention to the principle of economic and social cohesion in the Community, the transnational nature of the projects and the support to be given to small and medium-sized enterprises;

Whereas it is only in the light of experience gathered in the course of this programme that the Commission will be able to propose and the Council to adopt supplementary programmes by having recourse to the means provided for in Articles 130l, 130m or 130o of the Treaty, if they contribute to the achievement of the programme's objectives, in accordance with the option made available by Article 2(2) of Decision 90/221/Euratom, EEC;

Whereas, in accordance with Article 130g of the Treaty, the Community's activities aimed at strengthening the scientific and technological basis of European industry and encouraging it to become more competitive include promoting cooperation on research and technological development with third countries and international organizations; whereas such cooperation may prove particularly beneficial for the development of this programme;

Whereas it is necessary, as Annex II to Decision 90/221/Euratom, EEC, provides, to reinforce biological knowledge as the common and integrated foundation needed for applications in agriculture, industry, nutrition and the environment.

Whereas the Scientific and Technical Research Committee (CREST) has been consulted,

HAS ADOPTED THIS DECISION:

Article 1

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

Article 2

1. The Community funds estimated as necessary for the execution of the programme under this Decision amount to 164 million ecus. Of this amount 1.64 million ecus is drawn for the centralized dissemination and exploitation of results. The amount thus reduced to 162.36 million ecus includes staff costs which may not exceed 2%. An indicative breakdown of expenditure is set out in Annex II.
2. Should the Council take a decision in implementation of Article 1(4) of Decision 90/221/Euratom, EEC, this Decision shall be adapted to take account of the abovementioned decision.
3. The budgetary authority shall decide on the appropriations available for each financial year.

Article 3

Rules for the implementation of the programme are set out in Annex III.

Article 4

The rate of the Community financial contribution shall be laid down in accordance with Annex IV to Decision 90/221/Euratom, EEC.

Article 5

1. During 1992 the Commission shall review the programme and address a report on the results of the review to the Council and the European Parliament, together with proposals for any necessary changes.
2. At the end of the programme the Commission shall assess the results obtained. It shall address a report thereon to the Council and the European Parliament.
3. The reports shall be drawn up having regard to the objectives set out in Annex I to this Decision and in accordance with Article 2(4) of Decision 90/221/Euratom, EEC.

Article 6

1. The Commission shall be responsible for the execution of the programme. It shall be assisted by a committee, hereinafter referred to as "the Committee", composed of representatives of the Member States and chaired by a representative of the Commission.
2. The contracts concluded by the Commission shall govern the rights and obligations of each party, including the procedures for disseminating, protecting and exploiting the research results, in accordance with the arrangements adopted pursuant to the second paragraph of Article 130k of the Treaty.
3. A work programme for each year shall be drawn up and updated where necessary. It shall set out the detailed objectives and types of projects to be undertaken, and the financial arrangements to be made for them. The Commission shall make calls for proposals for projects on the basis of the annual work programmes.

Article 7

1. In the cases envisaged in Article 8(1), the Commission representative shall submit to the Committee a draft of the measures to be taken. The Committee shall deliver its opinion on the draft within a time limit which the chairman may set according to the urgency of the matter. The opinion shall be delivered by qualified majority as provided for in Article 148(2) of the Treaty in the case of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the Member States' representatives within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.
2. The Commission shall adopt the measures envisaged where they are in accordance with the Committee's opinion.
3. If the measures envisaged are not in accordance with the Committee's opinion, or if no opinion is delivered, the Commission shall forthwith submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.
4. If the Council has not acted within one month of submission of the proposal, the proposed measures shall be adopted by the Commission.

Article 8

1. The procedure laid down in Article 7 shall apply to:
 - the preparation and updating of the work programmes referred to in Article 6(3);
 - evaluation of the projects referred to in point 2 of Annex III, as well as the estimated amount of the Community's financial contribution when these projects are submitted through the ordinary procedure referred to in point 4 of Annex III and the abovementioned amount is more than 5 million ecus;

- evaluation of all projects submitted through the exceptional procedure referred to in point 4 of Annex III, as well as the estimated amount of the Community's financial contribution;
 - measures for evaluating the programme.
2. The Commission may consult the Committee on any matter falling within the scope of the programme.
3. The Commission shall inform the Committee with regard to;
- the progress of the programme;
 - planned calls for proposals, referred to in Article 6 (3);
 - projects, referred to in point 2 of Annex III, submitted through the ordinary procedure, for which the Community contribution is less than 5 million ecus, and the results of their evaluation;
 - accompanying measures, referred to in point 2 of Annex III;
 - concerted actions, referred to in point 2 of Annex III.

Article 9

In implementing this programme, supplementary programmes within the meaning of Article 130l, participation within the meaning of Article 130m and joint undertakings or any other structures within the meaning of Article 130o of the Treaty may also be decided on as the need arises.

Article 10

Where cooperation with third countries and international organisations aiming at achieving the objectives of this programme requires legal undertakings between the Community and the third parties concerned, the Commission shall be authorized to negotiate, in accordance with Article 130n of the Treaty, international agreements laying down the terms of such cooperation.

Decisions on the conclusion of such agreements shall be adopted in accordance with the procedure referred to in Article 130q (2) of the Treaty.

Article 11

This Decision is addressed to the Member States.

Done at,

For the Council,

The President

SCIENTIFIC AND TECHNICAL OBJECTIVES AND CONTENT

This specific programme fully reflects the approach embodied in the Third Framework Programme in terms of the scientific and technical goals and the underlying aims which it pursues.

Paragraph 4A of Annex II of the Framework Programme forms an integral part of the present specific programme.

Pre-normative research will be carried out in each of the areas described below, with emphasis on the safety assessment of new techniques and novel products.

The ethical and social implications of biotechnology will be monitored and studied. A multidisciplinary approach involving representatives from the various sciences, professions and activities concerned will be pursued. Special attention will obviously be given to the areas of biotechnology covered by Community research. For all projects conducted in this framework, contractors will be requested to provide, when applicable, information necessary for the detailed evaluation of the social, ethical and ecological impact of their studies, and, where necessary, approval from the responsible authorities.

Information technology will be used throughout the programme for collecting, pooling, analyzing, distributing or simulating data.

Research will be carried out at the level of molecules, cells, organisms and populations. Integration between levels will be assured.

The following presents an analytical description of the content of the programme, based on and taking account of the above elements.

Area 1. Molecular approaches

Protein structure and function

Research under this theme is aimed at two goals. First, to understand and control biological functions carried out by proteins (enzymes, hormones, antibodies, receptors, body structures, etc.). Second, to produce tailor-made proteins adapted to the specific requirements of man (new drugs, industrial enzymes, artificial organs, etc.).

Target areas will include enzymes and proteins associated with biological membranes participating in energy transduction (chemi-osmotic enzymes); immunoglobulins and their interactions with antigens, protein messengers and receptors. The latter work is connected with research described below on biological communication systems.

A specific objective of the programme will be the analysis of structure-function relationships for a number of membrane proteins.

Structure and function of genes

The ultimate goal is to provide the knowledge necessary for a rational use of biological species important in agriculture, industry and the diagnosis of genetic disorders. The study of the genetic message in representative species will be pursued at two levels: precise ordering of the genes within chromosomes (gene mapping) and detailed determination of the chemical composition of genes (gene sequencing).

Efforts will be undertaken to complete the sequencing work of the entire genome of yeast, which displays a genetic structure and organisation (genome) comparable to that of plants and animals, and to initiate a Community effort for sequencing genes in a model plant species (Arabidopsis) and physical mapping in Drosophila. This work will complete research under the BRIDGE programme on mapping the genes in Arabidopsis and on sequencing certain chromosomes in yeast.

A specific objective will be the sequencing of more than 10 million nucleotides in the organisms studied.

Close liaison will be maintained with research under the Human Genome Analysis programme to ensure that developments in methodology, mapping and sequencing techniques are shared with mutual benefit.

Expression of genes

In order to make full use of the above information on gene structure, the processes through which the information stored as DNA in the genes is expressed in the form of active proteins will be studied in some models of practical importance. Transcription factors, RNA polymerases, their interactions with signals, ligands and DNA will be examined. A specific objective is the analysis of a number of DNA polymerases and transcription factors in yeast, plants and mammalian cells.

Area 2. Cellular and organism approaches

Cellular regeneration, reproduction and development of living organisms

In order to provide basic knowledge required by biotechnology, comparative studies of reproductive events (meiotic pairing, gamete packaging, gamete recognition and fertilization), cell-cell interaction and cell replication in animals and plants will be undertaken. Research will be centred on the control of development, cell commitment and cell totipotency in higher organisms starting with the simplest levels of organisation, namely gametes, eggs, proliferating lines and their reorganisation into organs and embryos.

At the same time, with regard to pre-normative research, in vitro test systems will be elaborated which take into account the high specificity of modern drugs and their potential toxic effects during cell differentiation and organogenesis.

Metabolism of animals, plants and microbes; essential physiological tracts

The objective is to provide industrial and agricultural operators with the basic knowledge required for a more rational exploitation of resources in production, processing and animal husbandry. New animal models, more representative of human material, will be developed for biological analysis, including the use, where necessary, of transgenic animals relevant to the study of human health and its protection.

Research will concern the regulatory mechanisms governing some of the biological functions or metabolic activities in species which are important to man (e.g., as specific objectives, production and secretion in microorganisms, metabolic pathways under extreme environments, nitrate assimilation in plants, food utilisation and metabolic control in animals, etc.).

Communication systems within living matter

The goal is to provide industrial biotechnologists, agricultural and medical operators with a new approach to dealing with the complexity of living systems. This emerging subject will be studied at the cellular and systemic level.

Research will be focused on the immune and the nervous systems. Immunological studies will concern the complex interaction between the three main types of cells (antigen presenting cells, T-lymphocytes and B-lymphocytes) responsible for the reaction of the animal body to foreign substances (antigens). Concerning pre-normative objectives, pharmacological and toxicological test systems will be developed, with special attention to immune reactions in "drug targeting" and immunotoxicology as such. Synergism with protein engineering will be assured.

In neurobiology, attention will be given to the basic unit of the brain, the neuron. The production, release and specific reception of chemical messengers used by neurons to communicate among themselves and to transmit messages to target cells such as muscles and glands will be a priority. The biochemical, pharmacological and genetic characterisation of newly discovered neuroreceptors systems will constitute a specific objective of the programme in view of possible applications to the diagnosis and treatment of pathological behaviour. The interaction between neurons and the development of neural networks will also be studied. This research will complement projects undertaken in the ESPRIT and SCIENCE programmes, dealing with the informatic, behavioural, cognitive and physiological aspects of neurobiology.

Area 3. Ecology and population biology

Ecological implications of Biotechnology

The goal is to study the environmental implications of biotechnology and, in particular of the release by man of living organisms in the environment in connection with the industrial, agricultural and environmental policies of the Community.

Particularly in the case of microorganisms, the systematic analysis of possible adverse effects will be carried out taking into consideration the need for a comprehensive understanding of the ecosystems involved. Research will include the analysis of representative examples of interactions between microbial populations and with their hosts; the study of the impact of the introduction of genetically modified microorganisms on natural microbial populations in different habitats; the determination of the behaviour and effects upon ecosystems of organisms modified by genetic engineering (including as a complement to ongoing research in BRIDGE, fishes and insects).

Conservation of genetic resources

The aim is to ascertain the real dimension of the problem of loss of genetic diversity. Knowledge of genetic erosion in plants, animals and microorganisms will be pursued, collected and circulated.

Taxonomy will be revitalised with inputs from molecular biology, providing specific and target support to decentralised collections of biotic materials; a systematic assessment of the residual genetic variability of agricultural and industrial species of regional and traditional importance will be initiated.

These activities will be carried out in cooperation with relevant international organisations and countries outside the European Community.

Work in this area will link into Community research programmes dealing with environmental issues.

INDICATIVE BREAKDOWN OF EXPENDITURES

in %, for the period 1990-1994.

<u>Area 1.</u> Molecular approaches	35 - 40
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<u>Area 2.</u> Cellular and organism approaches	45 - 55
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<u>Area 3.</u> Ecology and population biology	10 - 15
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The breakdown between different areas does not exclude the possibility that projects could cover several areas.

Annex III

Rules for Implementing the Programme
and Activities for Dissemination and Exploitation of the Results

1. The Commission shall implement the programme on the basis of the scientific and technical content described in Annex I.
2. The rules for implementing the programme, referred to in Article 3, comprise research and technological development projects, accompanying measures and concerted actions.

The projects shall be the subject of shared-cost research and technological development contracts.

The accompanying measures consist of applying the means to ensure proper technical execution, management and evaluation of the programme, as well as adequate dissemination and accessibility of the results, and coordination, training and consciousness-raising of the participants in the programme.

The concerted actions are those defined in the Financial Regulation.

3. The participants in the projects must be natural or legal persons established in the Community, such as universities, research organizations and industrial firms, including small and medium-sized enterprises, or associations thereof, in particular European Economic Interest Groupings (EEIGs).

Natural or legal persons established in countries which have concluded agreements with the Community foreseeing scientific and technical research, may, based on the criterion of mutual advantage, take part in the projects undertaken in the context of this programme. The contracting parties under such arrangements shall not benefit from Community funding. They shall contribute to the general administrative costs.

4. The choice of projects shall be carried out according to the following order of priority, the first method being the rule, the second the exception:

The participants in the projects shall be selected on the basis of the ordinary procedure of calls for proposals referred to in Article 6 (3) and published in the Official Journal of the European Communities.

The Commission may also accept proposals according to an exceptional procedure and under the conditions mentioned below, when they make a particularly promising and significant contribution as regards the originality of the theme proposed, the novelty of the scientific and technical approach and the methodology of execution, also taking into account the particular nature of the proposers.

A favourable technical evaluation of such proposals shall not by itself be a sufficient justification for accepting a project; this exceptional procedure may only apply after verification that the nature of the project, as defined above, does not justify the use of the normal procedure for calls for proposals.

The exceptional procedure must be completed before the ordinary procedure in such a way that the available amount for the Community's financial participation in projects retained by the ordinary procedure can be determined precisely. The closing date for the exceptional procedure shall be published each year in the Official Journal.

The amount of the financial participation of the Community for all the projects retained by the exceptional procedure will be decided each year, in relation to the projects selected according to particularly strict criteria of excellence. In any case, this amount may not exceed 15%; it may be revised each year in the light of experience.

The Commission shall draw up a vade mecum setting out all the rules applicable to this exceptional procedure in order to guarantee full transparency.

5. The projects must involve at least two mutually independent partners established in different Member States.
6. The Commission may encourage the participants to form a European Economic Interest Grouping (EEIG) or make other arrangements for carrying out projects, such as those on a large scale, permitting decentralized management adapted to the specific requirements of the project.
7. The knowledge acquired during the course of the projects shall be disseminated on the one hand within the specific programme and on the other hand by means of a centralized activity, pursuant to the decision referred to in the third paragraph of Article 4 in Decision 90/221/Euratom, EEC.

FINANCIAL STATEMENT

1. BUDGET HEADING AND TITLE

Part B of the general budget

Subsection 6, Item 6221

Specific programme of Community RTD activities in the field of
Biotechnology (1990-1994).

2. LEGAL BASE

Article 130 Q(2) of the Treaty.

3. OBJECTIVES AND DESCRIPTION

See Annex I of the proposal.

4. FINANCIAL IMPLICATIONS

Amounts deemed necessary in MIOECU :

Programme implementation	162.36
Centralized action for dissemination and exploitation	1.64
 TOTAL	 164.00

The indicative operational breakdown of the 162.36 MIOECU for the programme implementation is given in Annex II of the proposal.

Indicative multiannual schedule (in MIOECU) :

	1990	1991	1992	1993	1994 ¹⁾	TOTAL
Commitments	--	30	39.30	59	34.06	162.36
Payments	--	8	22.10	38	94.26	162.36

The definitive yearly amounts will be determined by the budgetary authority in accordance with the financial perspectives for the period 1990 -1992 (annexed to the Interinstitutional Agreement of 29 June 1984) and with subsequent financial perspectives which may be adopted for 1993 and 1994.

5. STAFF AND ADMINISTRATIVE EXPENDITURE

In addition to the principal means of action which are contracts (annex III), the above amounts include programme-related staff and administrative expenditure estimated at no more than 7 MIOECU.

The expenditure on staff will not exceed 2% of the amount deemed necessary for the programme implementation. This implies a maximum of 30 statutory posts (A, B and/or C) at any given time during the life of the programme. The infrastructure costs related to statutory staff will be borne by Part A of the budget.

¹⁾ for the payment appropriations: 1994 and beyond

6. IMPLICATIONS FOR REVENUE

The contributions by third country contractors towards the cost of administration of the programme will be reused pursuant to articles 27.2 and 96 of the Financial Regulation³⁾.

7. TYPES OF CONTROL

Control will be exercised by:

- the Programme Management Committee (scientific control)
- the services of the DG responsible for the execution of the programme, possibly assisted by independent experts
- the Commission's Financial Controller.

In accordance with Article 2 of the Financial Regulation 2), the use of appropriations will be subject to analyses of cost-effectiveness and the realization of quantified objectives will be monitored.

External audit may be carried out by the Court of Auditors in accordance with the Treaty.

³⁾ Financial Regulation of 21 December 1977, as last amended by Regulation 610/90 of March 1990.

FICHE D'IMPACT SUR LA COMPETITIVITE ET L'EMPLOI

1. Justification en faveur de la proposition

Le programme de recherche et de développement technologique proposé a pour objectif primordial de contribuer, à moyen et à long terme, à la promotion de la compétitivité industrielle, des innovations agricoles et de la croissance économique dans la Communauté.

En l'absence d'un tel programme, le champ des nouvelles technologies auxquelles donne régulièrement naissance la biologie moderne, sera moins vite exploité par l'industrie et l'agriculture européennes.

2. Caractéristiques des entreprises concernées

A long terme, les agriculteurs, les fournisseurs de l'agriculture, les industries de transformation des produits agricoles, les industries de la santé, les secteurs chimique et pharmaceutique sont directement concernés par la proposition.

A court et moyen terme, cependant, les secteurs immédiatement concernés par les résultats du programme sont ceux du diagnostic et du traitement des troubles immunologiques et neurobiologiques et, dans une moindre mesure, de la microbiologie industrielle. L'accroissement des efforts communautaires en faveur du génie des protéines et du séquençage des génomes devrait promouvoir encore davantage les innovations dans le domaine de la bio-informatique et de l'instrumentation.

3. Obligations que le programme impose aux entreprises

Il s'agit des mêmes obligations qui sont imposées à tous les laboratoires participant au programme, à savoir:

- conformité de la recherche proposée à l'annexe technique du programme
- partage des frais (en règle générale à 50%)
- coopération transnationale
- libre accès des sites aux agents de la Commission
- participation à des séminaires et à des réunions de contractants organisés par la Commission
- rapports annuels d'activités et de résultats.

4. Obligations indirectes susceptibles d'être imposées aux entreprises par les autorités nationales, régionales ou locales

Obligation de suivre les normes et règlements nationaux qui concernent certaines recherches en génie génétique et l'exploitation des résultats de cette recherche.

5. Dispositions relatives aux PME

L'action de recherche du présent programme ne prend aucune disposition spécifique à l'égard des PME qui devraient pourtant en être largement bénéficiaires. Souvent incapables d'effectuer à elles seules de longues et difficiles recherches, ces entreprises dépendent des résultats de la recherche-développement financée par des fonds publics. Leur participation aux projets sera examinée d'un oeil favorable lors de la sélection des propositions.

La dissémination de l'information relative aux résultats de la recherche, et tout particulièrement à l'intention des PME, sera mise au premier rang des priorités.

Les conditions de participation privilégient les PME en ce sens que tous les participants à un projet BIOTECH seront traités sur un pied d'égalité.

6. Incidence probable :

a) sur la compétitivité des entreprises

BIOTECH ne devrait avoir aucun effet immédiat sur la compétitivité des entreprises. Toutefois, il pourrait avoir divers effets à court et moyen termes et de nombreux effets à long terme - voir point 1.

b) sur l'emploi

Les effets du programme sur l'emploi sont difficiles à évaluer. Toutefois, une meilleure compétitivité internationale de la biotechnologie européenne pourrait contribuer à réduire le déclin à long terme de l'agriculture et devrait avoir des conséquences favorables sur l'emploi dans divers secteurs industriels, en particulier dans les firmes à fort potentiel de croissance dans des créneaux spécialisés du marché à haute valeur ajoutée.

7. Consultations des organisations représentatives

La liste des organisations industrielles consultées durant la phase préparatoire du programme inclut, notamment, le groupe de travail "biotechnologie" du comité consultatif de la recherche et du développement industriel de la Commission des Communautés européennes (IRDAC).

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