COMMISSION OF THE EUROPEAN COMMUNITIES

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Brussels, 28 February 1992

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Re-examined proposal for a

COUNCIL DECISION

adopting a specific research and technological development programme in the field of Biotechnology

(1990-1994)

(presented by the Commission pursuant to Article 149.2 (d) of the EEC treaty)

EXPLANATORY MEMORANDUM

The Commission presented to Council on 28 May 1990 the "Proposal for a Council Decision adopting a specific research and technological development programme in the field of Biotechnology (1990-1994)".

The European Parliament having given its opinion at first reading on 9 October 1991, the Commission presented an amended proposal which incorporated the 31 amendments which it had retained. This proposal was transmitted to Council on 18 October 1991.

On the basis of this amended proposal, the Council adopted on 28 November 1991 its Common Position, which incorporates, sometimes with modifications, 30 of the 31 amendments taken up by the Commission, as well as all the elements deriving from the inter-institutional agreement of 17 April 1991. The Commission was able to agree to this Common Position. In the course of the plenary session of February 1992, the Parliament adopted 4 amendments to the Common Position, bearing on the statement of scientific and technical objectives in Annex I.

Amendments nos. 1 and 4 have been accepted by the Commission, the latter subject to reformulation. Amendment no. 1 introduces drafting modifications [1] which emphasise the fundamental importance of a better understanding of biological and genetic mechanisms. Amendment no. 4 specifies the themes on which the assessments of social, legal and ethical aspects of biotechnology should focus.

Without prejudice to the orientation of the Common Position, these amendments refine certain objectives which the Parliament wished particularly to highlight.

To take account of the position of the European Parliament, the Commission presents to Council, on the basis of Article 149, paragraph 2 sub-section d of the EEC Treaty, a re-examined proposal which is based on the text of the Common Position with the exception of two modifications.

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[1] Does not apply to the Greek and French versions.

Re-examined proposal for a

COUNCIL DECISION

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

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 co-operation with the European Parliament [2],

Having regard to the opinion of the Economic and Social Committee [3],

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[1] OJ N° c 174, 16.7.1990, p. 53.

[2] Opinion delivered on (not yet published in the Official Journal) and Decision of (not yet published in the Official Journal).

[3] OJ N° c 31, 6.2.1991, p. 14.

Whereas, by its Decision 90/221/Euratom, EEC [1] the Council adopted a third framework programme for community activities in the field of research and technological development (1990-1994), specifying, inter alia, the activities to be pursued for contributing to the development of Europe's potential for understanding and using 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 Decision 90/221/Euratom/EEC;

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

Whereas research and technological development in this field should be linked to various relevant community policies and objectives;

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 Ecu 57 million for the centralized action of dissemination and exploitation of results, to be divided up in proportion to the amount envisaged for each of the actions;

Whereas, in the context of this programme, an assessment should be made of the economic and social impact as well as of any technological risks;

Whereas basic research in the field of biotechnology must be encouraged throughout the community;

[1] OJ N° L 117, 8.5.1990, p. 28.

Whereas, in addition to the specific programme concerning human resources and mobility, it is necessary to encourage the training of research workers in the context of this programme;

Whereas biological research, in particular that which uses the methods of recombinant DNA, is often subject to national laws with which the contractors must comply;

Whereas on 23 April 1990 the Council adopted Directive 90/219/EEC on the contained use of genetically modified micro-organisms [1] and Directive 90/220/EEC on the deliberate release into the environment of genetically modified organisms [2];

Whereas the positive development of biotechnology could be enhanced by concerted actions;

Whereas actions should be undertaken to ensure that the necessary consideration is given to the ethical and social effects of these projects, and their applications in agriculture, industry, health care and the environment; whereas such actions will ensure that information is made available to the public concerning the content of the programme;

Whereas the results which may be achieved by genetic research make it necessary to adopt an integrated approach which takes account of the scientific, safety, ethical and legal aspects of possible applications and of the need to ensure that the results are not used in an improper manner or subject to misrepresentation;

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[1] OJ N° L 117, 8.5.1990, p. 1.

[2] OJ N° L 117, 8.5.1990, p. 15.

Whereas the Commission has announced its intention to examine further the ethical implications of biotechnology using the appropriate advisory structure;

Whereas Decision 90/221/Euratom, EEC provides that a particular aim of Community research must be to strengthen the scientific and technological basis of European industry and to encourage it to become more competitive at international level; whereas it also provides 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 programme in the field of biotechnology is looked upon as contributing to the achievement of these objectives;

Whereas small and medium-sized enterprises (SME) should be involved to the maximum extent possible in this programme ; whereas account should be taken of their special requirements, without prejudice to the scientific and technical quality of the programme;

Whereas research in biotechnology may lead to improvements in agriculture and industrial efficiency and viability, in the preservation of the environment and health, and in quality products for the consumer;

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 co-operation on research and technological development with third countries and international organizations; whereas such co-operation 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 in the field of biotechnology, as defined in Annex I, is hereby adopted for a period commencing on ... [1] and ending on 31 December 1994.

[1] Date of adoption by Council.

Article 2

1. The funds estimated as necessary for the execution of the programme referred to in Article 1 amount to Ecu 162,36 million, including expenditure on staff and administration amounting to Ecu 7 million.

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

3. Should the Council take a decision pursuant to Article 1(4) of Decision 90/221/Euratom, EEC, this Decision shall be adapted accordingly.

Article 3

Detailed rules for the implementation of the programme and the amount of the community's financial contribution are set out in Annex III.

Article 4

1. In the second year of the implementation of the programme, the Commission shall review it and send a report on the results of its review to the European Parliament, the Council and the Economic and Social Committee; the report shall be accompanied, where necessary, by proposals for amendment of the programme.

2. At the end of the programme, an evaluation of the results achieved shall be conducted for the Commission by a group of independent experts. The group's report, together with the Commission's comments, shall be submitted to the European Parliament, the Council and the Economic and Social Committee.

3. The reports referred to in paragraphs 1 and 2 shall be established 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 5

1. The Commission shall be responsible for the implementation of the programme.

2. 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, in accordance with the provisions adopted pursuant to the second subparagraph of Article 130 k of the Treaty.

3. A work programme shall be drawn up in accordance with the aims set out in Annex I 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 work programme.

Article 6

The Commission shall be assisted by a Committee composed of representatives of the Member States and chaired by the representative of the Commission.

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 Chairman may lay down according to the urgency of the matter. The opinion shall be delivered by the majority provided for in Article 148(2) of the Treaty as regards adoption of decisions which the Council is required to adopt on a proposal from the Commission. The votes of the representatives of the Member States within the Committee shall be weighted in the manner set out in that Article. The chairman shall not vote.

The Commission shall adopt the measures envisaged when they are in accordance with the opinion of the Committee.

When the measures envisaged are not in accordance with the Committee's opinion, or if no opinion is delivered, the Commission shall without delay submit to the Council a proposal relating to the measures to be taken. The Council shall act by a qualified majority.

If, on the expiry of a period of three months from referral of the matter to the Council, the latter has not acted, the proposed measures shall be adopted by the Commission.

Article 7

1. The procedure laid down in Article 6 shall apply to:

- the preparation and updating of the work programme referred to in Article 5(3);
- the contents of the calls for proposals;
- the assessment of the projects and concerted actions provided for in Annex III and the estimated amount of the Community's contribution to them where this amount exceeds Ecu 0,3 million;
- departures from the general rules set out in Annex III;
- the participation in any project by non-Community organizations and enterprises referred to in Article 8;

- any adaptation of the indicative breakdown of the amount 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.

2. Where, pursuant to the third indent of paragraph 1, the amount of the Community contribution is less than, or equal to, Ecu 0,3 million, the Commission shall inform the Committee of the projects and concerted actions and of the outcome of their assessment.

The Commission shall also inform the Committee of the implementation of the accompanying measures referred to in Annex III.

Article 8

1. The Commission is hereby authorized to negotiate, in accordance with Article 130n of the Treaty, international agreements with third countries which are members of COST, in particular the member countries of EFTA and the countries of central and Eastern Europe, with a view to associating them with all, or part, of the programme.

2. When framework agreements for scientific and technical co-operation have been concluded between the Community and European non-Member States, bodies and enterprises established in those countries may, in accordance with the procedures laid down in Article 6 and on the basis of the criterion of mutual benefit, be allowed to become partners in a project undertaken within the programme. For projects in Area 3 of Annex I, this option may be extended to bodies and enterprises established in other third countries as well as to international organisations engaged in research in this area.

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

Article 9

This Decision is addressed to the Member States.

Done at Brussels,

For the Council,
The president

ANNEX I

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. In particular, the objectives of the BRIDGE programme will be extended.

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. 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. The provisions of relevant Community directives must be applied as regards the ecological impact. These must also be applied to work carried out as a consequence of the provisions laid down in Article 8 of the Decision.

In monitoring, studying, and evaluating the ethical, social and economic implications and impacts of biotechnology, attention will be given to :

- diverse expert or public perceptions of its benefits and hazards, including the effects on such perceptions of diverse cultural and institutional perspectives;

- the factors which influence the credibility and acceptability of scientific evidence in policy areas concerned with biotechnology, including such areas as animal welfare, environmental protection, and consumer safety;

- the implications of biotechnology, in the light of ethical guidelines prepared by national or international bodies;

- the potential consequences for social progress and economic development of the applications and innovations in agriculture, medicine and industry which may result from biotechnology R&D; and the influence upon such progress and development of public policies for the promotion and regulation of biotechnology.

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 (for example, new drugs, industrial enzymes).

Target areas will include enzymes and proteins associated with biological membranes.

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

Structure of genes

The goal is a greater understanding of biological and genetic mechanisms. 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 contribute to 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 suitable microorganism, plant and animal species.

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, factors affecting transcription, RNA polymerases, their interactions with signals, ligands, DNA and posttranscriptional processes. 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. Research projects on human embryos are not included in this programme.

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 traits.

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.

The analysis of the biological material with a view to studying and protecting human health will utilize new animal models including, where necessary, transgenic animals. Any unnecessary suffering of such animals will be strictly avoided, and the Community provisions of Council Directive 86/609/EEC of 24 November 1986 [1] on the protection of animals used for experimental and other scientific purposes shall be applied.

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 micro-organisms, extremophile micro-organisms, 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). Pharmacological and toxicological test systems will be developed for prenormative purposes for the evaluation of biotechnology products, 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 neurons and their interactions. The biochemical, pharmacological and genetic characterisation of newly discovered neuroreceptors systems will constitute a specific objective of the programme.

[1] OJ N° L 358, 18.12.1986, p. 1.

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 risks will be carried out taking into consideration the need for a comprehensive understanding of the relevant characteristics of the ecosystems involved, such as the soil. Research will include the analysis of representative examples of interactions between microbial populations and other organisms in the ecosystems; the study of the impact of the introduction of genetically modified or genetically marked microorganisms on the rhizosphere or leaf surface; the determination of the behaviour and effects upon ecosystems of organisms including those 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 targetted support to decentralised collections of biotic materials; this support will be restricted to research and will exclude the maintenance or expansion of existinwcollections; a systematic assessment of the residual genetic variability of microbial, plant and animal species and varieties which have played a major role in regional and traditional European agriculture and food will be carried out.

Close co-ordination will be maintained with other relevant research programmes, including "Biomedicine and Health" and "Environment".

ANNEX II

INDICATIVE ALLOCATION OF FUNDS DEEMED NECESSARY

	Ecu millions
Area 1 - Molecular approaches	64
Area 2 - Cellular and organism approaches	81
Area 3 - Ecology and population biology	17.36
TOTAL	162.36 [1] [2] [3]

The breakdown between different areas does not exclude the possibility that projects could cover several areas.

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[1] Including expenditure on staff amounting to Ecu 3,5 million and administration expenditure totalling Ecu 3,5 million.

[2] An amount deemed necessary of Ecu 1,64 million, not included in the Ecu 162,36 million, will be earmarked as the contribution from the specific programme in the field of biotechnology to the centralized scheme for the dissemination and exploitation of results.

[3] At least 10% of the funds will be allocated to basic research. Between 5 and 7% of the funds will be allocated to training of researchers. Up to 3% of the funds will be allocated to the assessment of ethical and socio-economic effects and technological risks.

ANNEX III

RULES FOR IMPLEMENTING THE PROGRAMME

1. The Commission will 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, concerted actions and accompanying measures. Selection of projects must take account of the criteria listed in Annex III to Decision 90/221/Euratom, EEC and of the objectives set out in Annex I to this programme.

- Research projects

  The projects will be the subject of shared-cost research and technological development contracts and Community financial participation which will not normally be more than 50%. Universities and other research centres participating in shared-cost projects will have the option of requesting, for each project, either 50% funding of total expenditure or 100% funding of the additional marginal costs.

  Shared-cost research projects must, as a general rule, be carried out by participants established within the Community. Projects in which, for example, universities, research organizations and industrial firms, including small and medium-sized enterprises, may take part must provide, as a general rule, for the participation of at least two partners, independent of each other and established in different Member States. Contracts relating to shared-cost research projects must, as a general rule, be concluded following a selection procedure based on calls for proposals published in the Official Journal of the European Communities.

- Co-operative research projects

Co-operative research is intended for a group of undertakings, in particular SMEs, which do not have their own research facilities, in order to resolve common technical problems. One or more outside organizations (research associations, universities or undertakings) will be appointed to carry out the research.

50% of the research costs of these projects will be covered for a period normally not exceeding two years. These projects must be submitted by undertakings which are to take part in planning and piloting the research and implementing the results.

- Concerted actions

Concerted actions consist of action by the Community to co-ordinate the individual research activities carried out in the Member States. They may benefit from funding of up to 100% of co-ordinating expenditure.

- Accompanying measures

The accompanying measures referred to in Article 7 and described in Annex I will in particular be implemented through:

- the organization of seminars, workshops and scientific conferences;

- internal co-ordination through the creation of integrating groups;

- advanced technology training programmes, with the emphasis being placed on multidisciplinarity;

- promotion of the exploitation of results;

- independent scientific and strategic evaluation of the operation of the projects and the programme.

3. The knowledge acquired in the course of the projects will be disseminated both within the specific programme and by means of a centralized activity, pursuant to the Decision referred to in the third subparagraph of Article 4 of Decision 90/221/Euratom, EEC.

4. Each proposal should include an environmental impact statement. The statement should also include an undertaking to comply with the relevant safety rules.

Rejected amendments

Amendment n° 2 sought to modify the first sub-title of the area "Ecology and population biology". The wording proposed by the Parliament extends however beyond the framework of this specific programme and the limits of biotechnology in order to include complete parts of ecology.

Amendment n° 3 sought to open activities on genetic resource conservation to cooperation with non-participating organisations, possibly established outside the Community. Article 8 paragraph 2 of the Common Position meets however to a sufficient extent the expectation of the European Parliament in specifying, for projects falling under the area "Ecology and Population Biology", that the possibility of cooperation is in principle open to bodies and enterprises in any third country as well as to international organisations active in this research area.

(Amendment No. 2)
Annex I, area 3, first subtitle

Ecological implications of biotechnology	Ecology and environmental impact assessment of biotechnology

(Amendment No. 3)
Annex I, area 3, fourth paragraph a (new)

These activities will be carried out in cooperation with relevant international organizations active in this field within the European Community, national and regional agricultural research organizations and countries outside the European Community, with particular reference to Third World countries.

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