II

(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 12 March 1985

adopting a multiannual research action programme for the European Economic Community in the field of biotechnology (1985 to 1989)

(85/195/EEC)

THE COUNCIL OF THE EUROPEAN COMMUNITIES,

Having regard to the Treaty establishing the European Economic Community, and in particular Article 235 thereof,

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

Having regard to the opinion of the European Parliament (2),

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

Whereas Article 2 of the Treaty assigns to the Community the task of *inter alia* promoting throughout the Community a harmonious development of economic activities, a continuous and balanced expansion and an accelerated raising of the standard of living;

Whereas in its resolution of 14 January 1974 on an initial outline programme of the European Communities in the field of science and technology (4) the Council stated that the whole range of available ways and means should be used as appropriate, including concerted action projects, and that whenever it proves desirable that third countries, particularly European ones, should be associated in these projects, steps should be taken to make this possible;

Whereas in its resolution of 25 July 1983 on the first framework programme for Community research, development and demonstration activities (5) the Council approved the development of biotechnology as part of the objective 'promoting industrial competitiveness';

Whereas the ongoing multiannual research and training programme for the European Economic Community in the field of biomolecular engineering (6) has clearly underlined the possibility and utility of a Community action for the exploitation of modern biology in agriculture and industry;

Whereas the Commission submitted to the Council on 13 June 1983 a communication on the role of the Community in biotechnology;

Whereas the Commission submitted to the Council on 29 September 1983 a communication on biotechnology in the Community;

Whereas a Community research action programme is necessary for the development of biotechnology in the Community and, particularly for:

— the establishment of new methods for the synthesis of compounds with high added value and for lowering production costs,

— more efficient land use through the design of new crops which can provide important feedstocks for European industries,

— application of biotechnology to environmental protection,

(1) OJ No C 23, 25. 1. 1985, p. 4.
(2) OJ No C 12, 14. 1. 1985, p. 139.
(3) OJ No C 25, 28. 1. 1985, p. 14.
(4) OJ No C 7, 29. 1. 1974, p. 6.
(5) OJ No C 208, 4. 8. 1983, p. 1.
(6) OJ No L 375, 20. 12. 1981, p. 1.

— acceptability of the products of modern biotechnology through the use of new testing methods which render possible a more efficient and less costly evaluation of toxicity and biological activity,

— replacement of animal experiments with tests on cell cultures,

— new approaches in the detection, prevention and treatment of diseases,

— protection of health and environment against risks which may be associated with new developments in and the application of biotechnology;

Whereas the achievement of the objectives mentioned above requires that actions be implemented at Communitiy level which lead to:

— the establishment of a supportive infrastructure for biotechnology research in the Community,

— the elimination, through research and through training, of bottlenecks which prevent the exloitation by industry and agriculture of the materials and methods originating from modern biology,

— the experimental assessment of biohazards possibly associated with applications in agriculture and industry of biomolecular engineering;

Whereas it is necessary to monitor developments in biotechnology, with a view to assessing their strategic significance for Europe, and to promote effective concertation between the Community and its Member States in matters affecting the development of biotechnology; such monitoring is also needed to ensure that problems of a social, ethical and ecological nature, inherent in the application of this technology, may be recognized in good time and their adverse consequences prevented;

Whereas the Treaty has not provided the specific powers necessary for the adoption of this Decision;

Whereas the Scientific and Technical Research Committee (CREST) has expressed its opinion,

HAS DECIDED AS FOLLOWS:

Article 1

A research action programme for the European Community in the field of biotechnology is hereby adopted in the form set out in the Annex for a five-year period starting on 1 January 1985.

The programme includes work carried out as contract research, training and concerted action.

The work will be carried out by means of shared cost contracts to be placed with appropriate industrial organizations, research laboratories or university institutes or combinations of them.

The concerted actions consist of the coordination at Community level of research activities which are part of existing research programmes in the Member States and, where applicable, of the Community.

Encouragement and priority shall be given to contracts bringing together the technological resources of firms and institutions from different Member States, where possible.

Article 2

The funds estimated as necessary for the execution of the programme amount to 55 million ECU, including expenditure on a staff of 15.

Article 3

During the second year the programme shall be reviewed. The result of this review shall be communicated to the Council and the European Parliament. This review may lead to the submission by the Commission of a proposal for a revision of the programme in accordance with the appropriate procedures.

Article 4

The Commission shall be responsible for the execution of the programme with regard to the contract research and shall be responsible for the coordination with regard to concerted actions.

The detailed implementation of the programme, particularly concerning the breakdown of the work between contract research and concerted actions is set out in the Annex.

Article 5

The Commission will be assisted in its function of programme management by the Management and Coordination Advisory Committee (CGC) (Biotechnology) created by Decision 84/338/Euratom, ECSC, EEC [1].

Article 6

With regard to the concerted actions in accordance with a procedure to be laid down by the Commission, after

[1] OJ No L 177, 4. 7. 1984, p. 25.

consulting the CGC, the participating Member States and the Community shall regularly exchange all useful information concerning the execution of the research covered by such activities.

The participating Member States shall provide the Commission with all information relevant for coordination purposes. They shall also endeavour to provide the Commission with information on similar research planned or carried out by bodies which are not under their authority.

Any information shall be treated as confidential if so requested by the Member State which provides it.

Article 7

1. In accordance with Article 228 of the Treaty the Community may conclude agreements with non-Member States participating in European cooperation in the field of scientific and technical research (COST) or international organizations with a view to ensuring cooperation between the Community concerted action projects referred to in the Annex and the relevant programmes of such States or international organizations.

2. The Commission is hereby authorized to negotiate the agreements referred to in paragraph 1.

Done at Brussels, 12 March 1985.

For the Council

The President

F. M. PANDOLFI

ANNEX

BIOTECHNOLOGY RESEARCH ACTION PROGRAMME (1985 to 1989)

The objectives of this programme are as follows:

ACTION I: RESEARCH AND TRAINING

SUBPROGRAMME 1:

Contextual measures for R&D in biotechnology

CONTENT

Measures to upgrade the quality and capabilities of facilities, resources and support services underpinning biotechnology research, particularly by the enhancement of existing activities in the Member States, but not excluding the development of new activities and collaboration in wider international activities where essential.

Measures to enhance access to these facilities, and encourage their use, in research, teaching, agriculture, industry and health care.

1. Bio-informatics

1.1. Data capture techniques (particularly advanced instrumentation and measurement, automated reading).

1.2. Data banks.

1.3. Computer modelling of biological structures, systems and processes.

1.4. Sophisticated computer software for the human interface with computerized facilities relating to the life sciences and biotechnology.

2. Collections of biotic materials

2.1. Organized collections of animal and plant cells, hybridomas, microorganisms, their viruses, and all other forms of biotic material of potential use and relevance to biotechnology.

2.2. Development of information and communication techniques for enhancing the quality and usefulness of such collections.

2.3. Development of techniques for the identification, characterization, conservation and resuscitation of the materials held in such collections.

IMPLEMENTATION

Through training actions and cost-shared contracts with appropriate institutions, with provision as necessary for workshops and meetings.

SUBPROGRAMME 2:

Basic biotechnology

(A) *Research and training*

CONTENT

Precompetitive research and research through training in areas of basic biotechnology where technical and scientific bottlenecks prevent the applications of modern genetic and biochemical methods to agriculture and industry.

1. Enzyme engineering

1.1. Development and evaluation of bioreactors (and particularly those which are multienzymatic, multiphasic or cofactor requiring) for industrial and medical applications, depollution and detoxification.

1.2. Modifications of enzyme properties, protein design, synthesis of artificial enzymes and development of new methods (including, for example, filtration, centrifugation and reverse osmosis) for large-scale and highly selective separation of proteins and other substances with industrial or agricultural value.

2. Genetic engineering

2.1. Improvement of soil-microorganisms (particularly Rhizobium, bacteria of the rhizosphere of graminaceae, mycorhiza) and of cultivated plants important for European agriculture.

2.2. Exploitation of plant products (particularly ligno-cellulose).

2.3. Applications to animal husbandry (particularly the production of vaccines and hormones and gene transfer in animals).

2.4. Production of vaccines, proteins and hormones for human medicine.

3. Physiology and genetics of species important to industry and to agriculture

3.1. Study of poorly understood basic functions in microorganisms (particularly chemo-autotrophs, methanotrophs, mycorhiza) which appear to be promising for future industrial use.

3.2. Analysis of factors governing the yield and stability of microorganisms during industrial exploitation or in relation to symbiotic relationships with higher plants.

3.3. Identification of factors and mechanisms governing important properties in cultivated plants (particularly in Triticum, Vicia, Brassica).

4. Technology of cells and tissues cultured *in vitro*

4.1. Analysis of factors governing yield and stability during continuous cultivation or in mixed populations.

4.2. Control of the differentiation of plant cells and of their regeneration in entire plants.

4.3. Methodology of animal cell cultures (in particular for the production of monoclonal antibodies).

4.4. Development of microanalytical methods for the identification and quantification of biologically important molecules.

4.5. Study of cell biology applied to the prevention, detection and treatment of a few selected diseases which are particularly important from a socioeconomic point of view.

5. Screening methods for the evaluation of the toxicological effects and of the biological activity of molecules:

the tests (essentially *in vitro* and non-invasive *in vivo)* to be developed should contribute to a better understanding of structure-function relationships and to the uniformization of screening procedures throughout the Community.

6. Assessment of risks:

development of new methods for detecting contamination and for the assessment of possible risks associated with applications in industry (particularly during downstream processing) and agriculture of biomolecular engineering.

IMPLEMENTATION

— Training actions to be implemented, through training contracts, short-term training grants and courses for each of the themes defined above.

— Cost-shared research actions: they will concentrate on the themes which are implemented in the ongoing biomolecular engineering programme and on certain actions foreseen in the following sectors:
  — technology of cells and tissues cultured *in vitro*,
  — screening methods for the evaluation of the toxicological effects and of the biological activity of molecules.

(B) *COST activities associated to the programme as category II*

CONTENT

— Aquatic primary biomass (marine macroalgae)

— Plant *in vitro* culture

IMPLEMENTATION

Through the organization of meetings, consultation of experts, publications, exchange of research workers between laboratories, coordination contracts.

(C) *Involvement in the activities of the 'Technology, growth and employment' working group created at the Versailles summit of 1982*

CONTENT

— Coordination and concertation in 'basic biology' (area 1: data banks; area 2: collections of biotic materials)

— Representation of the Community to the 'International network of biotechnology'

IMPLEMENTATION

Through the organization of meetings, consultations of experts, and publications in the two areas covered by the activities foreseen in 'basic biology'.

ACTION II: CONCERTATION

CONTENT

Concertation activity will be implemented with the objectives of 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.

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

— monitoring the strategic implications of developments elsewhere in the world for biotechnology-based industry in Europe,

— working with the services of the Community, Member States and other interested parties to identify ways in which the contextual conditions of operation for biotechnology in the Community may be further improved, to promote its development in all useful applications, and the supporting scientific capabilities,

— responding to the needs for research and information in support of the specific actions of other services of the Commission,

— identifying opportunities for enhancing through concertation and cooperation the effectiveness of biotechnology-related programmes in the Member States, and promoting collaborative initiatives in biotechnology with and between industry and universities,

— consideration of how the safe and sustainable exploitation of the renewable natural resource systems in Europe may be enhanced by the application of biotechnology,

— promoting in cooperation with developing countries and relevant institutions the pursuit of the same task (see preceding paragraph) within their respective regions,

— monitoring and assessing developments in biotechnology bearing on safety and other aspects of the 'social dimension',

— disseminating knowledge and increasing public awareness of the nature and potential and risks of biotechnology and the life sciences,

— establishing an *ad hoc* system of 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 particular problems under study: the networks to have the triple function of providing an active input into the programme, encouraging coordination through the exchange of information between the participants, and assisting the broader diffusion of information envisaged in the preceding task.

IMPLEMENTATION

Essentially through in-house work, the setting-up and the exploitation of an organized information base and through missions, but will include as necessary the commissioning of study reports, the organization of workshops and meetings, support for the production of reports and diffusion of information.