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(Acts whose publication is not obligatory)

COUNCIL

COUNCIL DECISION

of 7 December 1981

adopting a multi-annual research and training programme for the European Economic Community in the field of biomolecular engineering
(indirect action April 1982 to March 1986)

(81/1032/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,

Having regard to the opinion of the European Parliament ⁽¹⁾,

Having regard to the opinion of the Economic and Social Committee ⁽²⁾,

Whereas Article 2 of the Treaty assigns to the Community *inter alia* the task of 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 ⁽³⁾, the Council stated that the whole range of available ways and means should be used as appropriate, including indirect action;

Whereas a Community research and training programme in the field of biomolecular engineering is necessary for the achievement of the abovementioned objectives and, particularly, for the development of new technologies leading to:

- the development of improved agricultural and bio-industrial products,
- the determination of more efficient and safer production methods,
- reduced energy consumption and improvements in the balance of payments;

Whereas it is necessary to undertake experiments for assessing possible biohazards associated with applications in agriculture and industry of biomolecular engineering and to organize courses in good microbiological practice;

Whereas training incentives are essential for the exploitation of biotechnology by agriculture and industry;

Whereas it is advisable to promote the mobility of personnel between the organizations collaborating in the implementation of this programme;

Whereas the Treaty has not provided the necessary specific powers;

Whereas account should be taken of the opinion of the Scientific and Technical Research Committee (CREST) on the Commission proposal,

HAS DECIDED AS FOLLOWS:

Article 1

A biomolecular engineering research and training programme (hereinafter called 'the programme') for the

⁽¹⁾ OJ No C 327, 15. 12. 1980, p. 37.

⁽²⁾ OJ No C 230, 8. 9. 1980, p. 11.

⁽³⁾ OJ No C 7, 29. 1. 1974, p. 6.

European Economic Community is hereby adopted in the form set out in the Annex for a four-year period starting on 1 April 1982.

Article 2

The Commission shall be responsible for the implementation of this programme which shall be implemented in two stages. The first stage shall run from 1 April 1982 until the revision provided for in Article 5 and the second from this revision until 31 March 1986.

Article 3

The appropriations currently allocated for the execution of the already agreed programme, the amount of which is fixed at 8 million ECU, including expenditure on a staff of three, shall be entered in the budget of the European Communities.

The amount of the appropriations and the staff required to execute the programme shall be re-evaluated when the programme is revised as provided for in Article 5.

Article 4

In order to assist the Commission in implementing this programme, there is hereby established an Advisory Committee for the Management of the Research and Training Programme in the Field of Biomolecular Engineering, whose terms of reference conform to the Council resolution of 18 July 1977 ⁽¹⁾.

Article 5

The programme shall be subject to revision during the second year in accordance with appropriate procedures after consultation with the Committee referred to in Article 4. The decision to revise the programme shall be taken not later than 31 March 1984.

Article 6

Information resulting from the implementation of the programme shall be disseminated in accordance with Regulation (EEC) No 2380/74 ⁽²⁾.

Done at Brussels, 7 December 1981.

For the Council

The President

CARRINGTON

⁽¹⁾ OJ No C 192, 11. 8. 1977, p. 1.

⁽²⁾ OJ No L 255, 20. 9. 1974, p. 1.

ANNEX

BIOMOLECULAR ENGINEERING PROGRAMME

1. Development of new reactors using immobilized multienzyme systems including those requiring multiphase environment and cofactor regeneration

Special emphasis will be placed on the development of new procedures for the immobilization of:

- (a) single enzymes or combinations of enzymes able to synthesize fine chemicals of high added value with special reference to cofactor regeneration and stabilization of enzymes in non-aqueous or multiphase environment. Kinetic studies of the flow of matter in reactors using these new systems will also be promoted;
- (b) cells with particular reference to plant, yeast and mammalian cells;
- (c) subcellular organelles such as peroxisomes, chloroplasts, mitochondria, microsomes.

2. Development of bioreactors for human detoxification

Development of new procedures using immobilized enzymes for the removal of toxic substances from the human body with special reference to the development of biocompatible enzyme supports (e.g. non-toxic, immunocompatible, thrombocompatible, biodegradable) and of carriers provided with special sensors and tropisms for targeting exogenous enzymes.

3. The transfer of genes from diverse sources to the bacterium *Escherichia coli*, the yeast *Saccharomyces cerevisiae* and other suitable organisms

The orientation in this project will have special reference to:

- (a) the chemical construction of 'synthetic genes';
- (b) development of mutational tools (e.g. site specific mutagenesis);
- (c) overcoming the expression barriers for particular proteins;
- (d) modification to inhibit the degradation of enzymes in a foreign environment by such techniques as repression of proteolytic activity of the host cell or by tagging the desired protein to another which is excreted extracellularly;
- (e) post-translational modification, e.g. glycosylation;
- (f) the possibility of supporting the collection and storage (e.g. as mRNA or cloned in plasmids) for distribution to relevant laboratories in the Community of rare material such as tumours capable of synthesizing abnormally high quantities of specific hormones.

4. Development of cloning systems

Although cloning of foreign genes in the bacterium *Escherichia coli* is now routinely performed in many laboratories, little has been achieved on the cloning and expression in other organisms which are likely to be of great importance to European industry and agriculture. The first step is the development of practically applicable vectors in a wide range of different viruses, bacteria, fungi, algae, plants and animals. The stability, regulation and expression of transferred genes will be studied within the framework of this project and of projects 3 and 5.

5. Gene transfer in micro-organisms and in plants important to agriculture

- (a) The development and improvement of methods for introducing, when considered necessary for agricultural purposes, foreign genetic information in micro-organisms and in plants which play an important role in European agriculture. All methods likely to allow the transfer of genes between species which normally do not exchange genetic information in nature are to be considered in this

subproject. Particular attention is to be given, however, to modern techniques, including somatic cell hybridization, the transfer of individual chromosomes and the development of cloning systems and their exploitation.

- (b) Analysis and control of the stability, regulation and expression of transferred genes.
- (c) Analysis and control of plant regeneration *in vitro*, i.e. the production of differentiated organisms from isolated cells cultured *in vitro*, a step which constitutes one of the first conditions for the success of any project based upon recombinant DNA technology or somatic hybridization for the improvement of cultivated plants.

6. Improvement of methods for detecting contamination and for the assessment of possible risks associated with applications in agriculture and industry of biomolecular engineering

- (a) Improvement of methods for detecting contamination (including mutations and phage- or plasmid-modified variations of the process strain).
 - (b) Development of a procedure for assessing the risks which might result from the experimental or industrial use of micro-organisms and from large-scale applications of biomolecular engineering.
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