COUNCIL DECISION

of 29 June 1990

adopting a specific research and technological development programme in the field of health: human genome analysis (1990 to 1991)

(90/395/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 provides that the framework programme is to be implemented through specific programmes developed within each activity;

Whereas, by its Decision 87/516/Euratom, EEC (4), as amended by Decision 88/193/EEC, Euratom (5), the Council adopted a framework programme for Community activities in the field of research and technological development (1987 to 1991), which defined activities to be undertaken in the field of health;

Whereas that Decision 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 two successive pluriannual programmes of research and training of the European Economic Community in the field of biotechnologies (6), the second of which is still in progress, have shown the possibility and usefulness of Community action promoting the utilization of modern biology for scientific, medical and industrial purposes;

Whereas the framework programme provides, under the heading 'Health' in the 'Quality of Life' section, for the initiation of new activities relating to the development of knowledge of the human genome;

Whereas, following the adoption of a third Community Framework Programme for activities in the field of research and technological development (1990 to 1994), it is necessary to continue the implementation of the second Framework Programme (1987 to 1991) by means of specific programmes for which the latter makes provision;

Whereas a specific programme to study the human genome is therefore necessary and, in particular, it is necessary to:

— develop and disseminate the basic technologies concerning the study of the human genome, with the intention of improving knowledge of matters of medical importance,

— increase the resolution of the human genetic map and improve the physical map by the creation of ordered clone libraries, as a basis for locating genes of medical importance on chromosomes and for a better general understanding of gene function, and

— organize networks and coordination, on a European and international scale, of researchers from all disciplines working in this field;

Whereas achievement of the abovementioned goals requires the undertaking at Community level of action aimed at:

— filling some existing gaps in scientific and technological knowledge, and

— encouraging cooperation between European research establishments with a view to furthering the development of existing technologies, while promoting all research sectors capable of generating new lines of research;

Whereas, simultaneously, measures must be taken to promote cooperation between the Community programme and similar ones developed in third countries or by international organizations;

Whereas the right to a genetic identity forms part of the integrity and the dignity of an individual and this principle is recognized in the constitutions and laws of Member States and in the Community legal system as forming part of the fundamental rights for which respect is ensured;

Whereas the results which can be achieved from human genome research require the development of an integrated

(1) OJ No C 27, 2. 2. 1989, p. 6 and OJ No C 303, 2. 12. 1989, p. 18.
(2) OJ No C 69, 20. 3. 1989, p. 85 and OJ No C 149, 18. 6. 1990.
(3) OJ No C 56, 6. 3. 1989, p. 7.
(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, 30. 12. 1981, p. 1 and OJ No L 83, 25. 3. 1985, p. 1.

approach, taking into account the medical, ethical, social and legal aspects of the possible applications of such results and the need to avoid any improper use thereof;

Whereas the development of an integrated approach was proposed by the European Parliament in its resolution of 16 March 1989 (1);

Whereas there are good grounds for guaranteeing the right of an individual to have an informed choice as to whether or not he should receive information concerning his genetic characteristics;

Whereas, in the absence of clear standards and provisions concerning possible developments in the field of genome analysis, there may be a risk, on the one hand, that attempts will be made to intervene in the human genome in order to make the modifications so obtained hereditary and, on the other, that genetic analyses will be carried out for monitoring purposes, which may have a profound effect on social life; whereas there are, accordingly, good grounds for taking the necessary steps to preclude unacceptable developments, particularly in terms of predictive medicine;

Whereas, furthermore, it is necessary to examine in detail, during the course of the programme, the prenormative aspects arising from human genome analysis by establishing a reliable scientific data set which could provide a basis for political authorities to establish sound, clear and responsible rules;

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 human genome analysis, as defined in Annex II, is hereby adopted for a period of two years commencing on 29 June 1990.

Article 2

1. The funds estimated as necessary for the execution of the programme amount to ECU 14 million, including expenditure on a staff of two.

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

(1) OJ No C 96, 17. 5. 1989, p. 165.

Article 3

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

Article 4

1. The Commission shall send the European Parliament and the Council an annual report on the progress of the programme.

2. In the second year of implementation of the programme, the Commission shall review it and send the results of its review to the European Parliament and the Council; the report shall be accompanied, where necessary, by proposals for amendment or extension of the programme.

3. An evaluation of the results achieved shall be carried out by independent experts and published in the form of a communication to the European Parliament and the Council.

4. The abovementioned reports shall be established having regard to the objectives and evaluation criteria set out in Annex II 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. It 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.

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 chairman may lay down according to the urgency of the matter, if necessary by taking a vote.

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

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

Article 7

The procedure 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 governing Community participation set out in Annex II,

— the participation in any project by third-country organizations and enterprises referred to in Article 8 (2),

— any adjustment to the indicative allocation of resources set out in Annex I,

— the measures to be undertaken to evaluate the programme,

— the arrangements for the dissemination, protection and exploitation of the results of research carried out under the programme.

Article 8

1. The Commission is authorized, in accordance with Article 130n of the Treaty, to negotiate agreements with third countries and international organizations, particularly with third countries participating in European Cooperation in the field of Scientific and Technical Research (COST) and with States which have concluded framework agreements for scientific and technical cooperation with the Community, with a view to associating them with the programme.

2. Where framework agreements for scientific and technical cooperation between third countries 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 this programme.

3. No contracting party 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 contracting party shall contribute to the general administrative costs.

Article 9

This Decision is addressed to the Member States.

Done at Luxembourg, 29 June 1990.

For the Council

The President

M. SMITH

ANNEX I

INDICATIVE INTERNAL ALLOCATION OF RESOURCES

	ECU million
Improvement of the human genetic map	3,3
Physical mapping (ordered clone libraries)	3,4
Data processing and databases	2,2
Improvement of the methods and basis for the study of the human genome	2,2
Training	1,9
Ethical, social and legal aspects	1,0
Management and staff	1,0
TOTAL	15,0

ANNEX II

SPECIFIC RESEARCH PROGRAMME IN THE FIELD OF HEALTH: HUMAN GENOME ANALYSIS

1. OBJECTIVES

Use and improvement of new biotechnologies in the study of the human genome for a better understanding of the mechanisms of genetic functions, as well as the prevention and treatment of human diseases. In the pursuit of these objectives, optimal cooperation will be sought with the programmes of third States and international organizations.

At the same time, measures will be taken to draw up an integrated approach to the medical, ethical, social and legal aspects of possible applications of results obtained through the programme to ensure that they are not misused and also, with prenormative aspects in mind, to establish a set of bioethical principles to be followed in the developments to come.

Alteration of germ cells or any stage of embryo development with the aim of modifying human genetic characteristics in a hereditary manner is excluded from the programme objectives.

2. TECHNICAL CONTENT

Precompetitive Community research, setting up and reinforcement of networks of European laboratories, and training, intended to allow the use of modern technologies for the study and setting up of the human genetic map as well as possible medical applications of the knowledge gained.

The research described below will require the use of data-processing facilities for the handling of data and the setting up of integrated databases to serve European networks, in close cooperation with other Community research programmes.

2.1. Improvement of the human genetic map

Setting up a European network, extending worldwide, for the collection and mapping of the DNA of large families, in order to provide research scientists with well-characterized genetic material and sets of probes to determine the location of the relative positions of genes on the chromosomes.

2.2. Setting up of ordered clone libraries of human DNA

Setting up of a European network of laboratories working on establishing overlapping clone libraries and support for limited sequencing of cDNA.

2.3. Improvement of the methods and basis for the study of the human genome

New biochemical reagents (restriction enzymes, etc.). Improvement of methods for the detection and localization of genetic markers (techniques for labelling DNA probes, amplification of genes, etc.). Development of new vectors for the cloning of large DNA fragments and of procedures for the transfection of chromosomes.

Development of model systems for the reproducible and stable expression of medically important genes both *in vivo* and *in vitro,* aimed at the wellbeing of patients. Development of new computer software for the storage and manipulation of data from genome sequencing and mapping.

2.4. Training

Setting up of a training programme to assist with the technology transfer of molecular genetics methods, in particular to Member States in which these techniques are currently underdeveloped.

3. IMPLEMENTATION

3.1. The programme shall be implemented through entering into cost-shared or marginal cost contracts, support to centralized facilities and new or existing networks, entering into training contracts, issue of training grants, organization of courses, consultations with national experts, organization of

study-group meetings, participation in seminars and symposia, publications, studies, dissemination of results to all interested groups and organization of public presentations.

For shared-cost contracts, the Community participation will be up to 50 % of the total expenditure. However, in the case of universities and research institutes carrying out projects under this programme, the Community may bear up to 100 % of the additional expenditure involved. In other cases, Community participation could reach 100 %.

Participants may be research establishments, universities, private enterprises or combinations thereof located in Member States or in the third countries referred to in Article 8, or competent organizations in a position to make a significant contribution.

Projects must be carried out by participants from more than one country, and include at least two independent partners from two Member States.

Fellows coming from third countries will be accepted in the training programme, provided that they meet the required conditions and that their costs are covered from other sources, such as other Community programmes or actions which support fellows coming from developing countries.

The contracts concluded by the Commission will govern the rights and the obligations of each party, in particular the means of distribution, protection and exploitation of the results of the research.

3.2. The drawing up of research contracts can only take place if the contracting parties undertake to abstain in this programme from all research modifying, or seeking to modify, the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary.

The contracts shall regulate the granting of licences arising out of research projects and, in particular, there shall be no right to exploit on an exclusive basis any property rights in respect of human DNA. In addition, the Commission shall reserve the right to publish the results of the research performed within the scope of the contracts.

The contracts will guarantee that the members of the families participating in the studies referred to in paragraph 2.1 will be fully informed of, and have consented to the use and study of, their DNA. The contracts will also guarantee complete protection of the confidentiality and anonymity of the personal data obtained in the programme.

3.3. The Commission will ensure that during the execution of the programme there will be wide-ranging and in-depth discussion of the ethical, social and legal aspects of human genome analysis and that possible misuses will be identified regarding applications of the results obtained or of future developments of that research. It will ensure that the far-reaching consequences of the research will be evaluated in a responsible manner and will submit to the European Parliament, the Council and the Economic and Social Committee an annual report, possibly with legislative recommendations arising as much from the research policy angle as from the legal one. To this end, the Commission will obtain advice from experts in different fields of science, law, philosophy and ethics, together with representatives of patient's associations.

4. EVALUATION CRITERIA

The communication from the Commission to the Council on a Community action plan relating to the evaluation of Community research and development programmes [1] states that the objectives and milestones for each research programme have to be set out in verifiable and, where possible, quantitative form. These reference marks are listed below:

4.1. The long-term objective of this programme is to contribute to a better understanding of the mechanisms of genetic function as well as to the fight against human diseases arising from genetic variation (including genetic diseases *sensu stricto* and many common diseases with a genetic component, such as heart disease and cancer), through early diagnosis, prevention, and improvement of prognosis and therapy. The Commission proposes to achieve this objective by:

— the organization of networks of laboratories around European facilities for (a) the improvement of the human genetic map, and (b) the setting up of ordered clone libraries of human DNA, either of the complete genome or of selected chromosomes, together with cDNA sequencing,

(1) OJ No C 14, 20. 1. 1987, p. 5.

— the launching of a programme of prenormative research aiming at improvement of the methods and basis of the study of the human genome,

— the setting up of a programme of training to increase the distribution of modern genetic technologies in Europe and to improve technological know-how in European laboratories,

— the promotion of cooperation with third countries and international organizations.

4.2. The primary short-term objective is that the programme should succeed in establishing the abovementioned European networks of laboratories in the fields of:

— the human genetic map,

— ordered clone libraries of human DNA and cDNA sequencing,

— improvement of the methods and basis for the study of the human genome,

by using data-processing facilities for data-handling and by setting up integrated databases.

These objectives should be verifiable in 1991.

4.3. Particular objectives to be attained within two years of the programme's implementation are as follows:

1. Concerning the human genetic map:
   — the present total of 40 well-studied large families which form the basis for the genetic map should be increased to 60 families,
   — genetic material from these families, and DNA probes, should be made available to the European laboratories concerned, while respecting the individual rights of those families,
   — a central facility should be identified to pool the results and establish an improved genetic map at the one to five centimorgan level, and an integrated databank should be set up.

2. The strategies for setting up ordered clone libraries of human DNA should be compared and a better approach defined; facilities for maintaining the stocks of cloned DNA fragments should be established and the available clones dispatched to interested European laboratories.

3. Substantial improvements should be obtained in the following research fields to improve the methods and the basis for the study of the human genome:
   — new reagents, such as restriction enzymes,
   — methodology for cloning large DNA fragments and for the transfection of chromosomes,
   — gene vectors adapted to human somatic celles *in vitro*,
   — methodology for the detection of a particular gene in a cell,
   — localization, cloning and sequencing of new genes, especially those which are disease-related,
   — new computer software for processing of DNA sequence data.

4.4. In addition, the programme should ensure that the following general criteria are met:

1. That throughout the execution of the programme, the ethical, social and legal aspects of human genome analysis should be the subject of wide-ranging and in-depth discussions, and possible abuses of the results or later developments of the work should be identified; principles for their utilization and control should be proposed.

2. That the drawing up of research contracts should presuppose that the contracting parties undertake to abstain in this programme from all research modifying or seeking to modify the genetic constitution of human beings by alteration of germ cells or of any stage of embryo development which may make these alterations hereditary.

3. That the members of the families taking part in the studies mentioned in point 2.1 must have been informed and must have given their consent, and the confidentiality and anonymity of personal data must be ensured.

4. That the development and the application of somatic gene therapy are not provided for within the framework of the present programme.

5. That only somatic actual or potential medical applications should be facilitated.

6. That potential opportunities for industrial development should be explored.

7. That the overall scientific standard of the participating European laboratories must have been improved.

8. That, taking account of the results of Community, national or commercial research activities in human genetics, the evaluation panel should consider whether the human genome analysis has contributed to the transfer of knowledge and the development of the results of the said activities in regions of the Community other than those in which the research was conducted. The evaluation panel should also ascertain whether cooperation with third countries and international organizations has indeed been achieved and whether this cooperation has had positive results.