

COMMISSION OF THE EUROPEAN COMMUNITIES

CGM (89) 532 final = SYN 146

Brussels, 13 November 1989

MODIFIED PROPOSAL FOR A COUNCIL DECISION

Adopting a specific research and technological development programme

in the field of health:

Human Genome Analysis: (1990-1991)

(Presented by the Commission in accordance with
Article 149, paragraph 3 of the EEC Treaty)

Explanatory Memorandum

- A. The first reading of the "Proposal for a Council Decision adopting a specific research programme in the field of health: Predictive Medicine: Human Genome Analysis (1989 - 1991)"(*) was carried out by the European Parliament during the part-session from 13 - 17 February 1989.

The essential message of the 38 amendments adopted by the Parliament is as follows: "The technical content of the research programme proposed by the Commission is justified, but care must be taken to see that individual rights are protected and respected while it is being carried out. Furthermore, it is essential to guarantee that throughout the programme the ethical, social and legal problems which may arise out of applications of ever more precise knowledge of the human genome are examined and debated. This debate should also identify the limits beyond which such applications would become unacceptable by society".

- B. The expression "Predictive Medicine" is no longer used in the title of the programme. It has reverted to "Human Genome Analysis", which corresponds to reality since the main aim is to increase our knowledge of human genetics. However, it is possible that this type of research, which will certainly lead to improvements in the treatment of patients suffering from certain diseases of genetic origin, will also lead subsequently to applications in predictive medicine. But the social acceptability of such applications must first be carefully evaluated.

The modified proposal is drafted in such a way as to guarantee the respect both of rules accepted by or acceptable to our democratic society and of the integrity and dignity of the person, not only while the programme is running but also in its medium- and long-term consequences.

The clear affirmation of the respect for the integrity and dignity of the person has consequences of which several aspects are defined in the modified proposal. The consequences both for the individual and for society of the application of the results obtained by research on the human genome must be analysed at the same time as the research is being

(*) COM(88) 424 final, 20 July 1988

carried out. Possible abuses must be identified, as must, where appropriate, recommended national or Community legislative measures. This task will be carried out by the Commission assisted by a high-level committee which it will set up for this purpose, representing different areas of science, law, philosophy and ethics, together with representatives of patients' associations.

The term "eugenics" which is contained in amendment no. 10 lacks precision. For this reason it is not used directly in the proposal. The approach described above guarantees the exclusion from the programme of any tendency towards a type of eugenics which would involve the "selection" of the human species by genetic means. This guarantee is further strengthened by the explicit exclusion of all research seeking to modify human genetic heritage by the alteration of germ cells, in accordance with Parliament's request (amendments nos. 21 and 33). But the modified proposal goes further: it excludes all intervention at any stage in the development of the embryo which might lead to hereditary changes. This technical possibility is indeed conceivable, and it must be rejected.

Protection is guaranteed of the confidentiality of information gained during the research and of the anonymity of those concerned.

The prenormative nature of the scientific data acquired, to be available to legislative authorities in particular, is highlighted.

Lastly, progress reports on the research and on studies of ethical, social and legal problems will be submitted annually to the Council and the European Parliament, and measures will be taken to keep the public fully informed of the Community action.

C. As far as the European Parliament's amendments are concerned:

- amendments Nos. 1, 3, 4, 7, 11, 12, 16, 17, 21, 22, 23, 28, 32, 33, 35 and 36 have been incorporated in the modified proposal. Amendments 21 and 33 have been supplemented to clarify the exclusion of all work seeking to "select" the human species.

- the intentions expressed in amendments nos. 5, 6, 8, 9, 10, 13, 20, 25, 26 and 41 are incorporated in the modified proposal in different terms, sometimes regrouped or at places in the text other than those foreseen in the amendments.

- amendments nos. 14, 15, 18, 19, 24, 27, 29, 30, 31, 34, 39 and 44 (budgetary amendment) are not incorporated in the proposal. However, the modified proposal expresses the ideas contained in some of these amendments, especially nos. 14, 15, 18, 19, 27, 29, 30 and 39.

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THE COUNCIL OF THE EUROPEAN COMMUNITIES

Having regard to the Treaty establishing the European Economic Community, and
in particular to Article 130 Q (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 130 K of the Treaty stipulates that the framework programme
shall be implemented through specific programmes developed within each
activity;

Whereas by its Decision of 28 September 1987⁽⁴⁾ the Council has adopted a
framework programme of Community research and technological development
(1987-1991), in which it provided for activities to be undertaken in the
field of health;

1) OJ N°

2) OJ N°

3) OJ N° C 56/47, 6.3.1989

4) OJ N° L 302, 24.10.87, p. 1

Whereas, for the evaluation of each specific programme and the selection of Community actions, the framework programme sets out criteria among which is that of contributing to the strengthening of the economic and social cohesion of the Community, consistent with the pursuit of scientific and technical quality;

Whereas two successive pluriannual programmes of research and training of the European Economic Community in the field of biotechnologies⁽⁵⁾, of which the second is still in progress, have shown the possibility and usefulness of a Community action promoting the utilization of modern biology for scientific and industrial purposes;

Whereas the framework programme has foreseen in its activity "Quality of life" under the "Health" line 1.1, the initiation of new activities relating to the development of knowledge of the human genome;

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

- develop and spread the basic technologies concerning the study of the human genome, with the intention of improving knowledge of matters of medical importance,
- improve the resolution of the human genetic map and to refine the physical map by the creation of ordered clone libraries, as a basis for locating genes of medical importance and for a better general understanding of gene function, and
- organise networks and coordination, on a European and international scale, of researchers from all disciplines working in this field;

Whereas the carrying out of the above-mentioned goals requires the undertaking at Community level of actions aiming at:

- filling some existing gaps in scientific and technological knowledge, and
- encouraging cooperation between European research institutions with a view to furthering the development of existing technologies while

⁵⁾ OJ N° L 375, 20.12.1981, p. 1; OJ N° L 83, 25.3.1985, p. 1

promoting all research sectors capable of generating new lines of research;

Whereas, simultaneously, measures will be taken to promote cooperation between the Community programme and similar ones developed in non-Member States 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 approach taking into account ethical, social and legal aspects of their possible applications and the need to avoid any improper use of those results;

Whereas there are good grounds for guaranteeing the right of an individual in complete possession of the facts to choose whether or not to be informed of 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 are made to intervene in the human genome in order to make the modifications so obtained hereditary, and on the other hand that genetic analyses are 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 as regards predictive medicine;

Whereas, furthermore, it is necessary to develop 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 regulations;

Whereas the Scientific and Technical Research Committee (CREST) was consulted on the following measures,

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 the Annex, is hereby adopted for a period of two years commencing on 1 January 1990.

Article 2

The amount deemed necessary as the financial contribution from the Community for the execution of the programme is 15 million ECU, including costs of a staff of two persons.

Article 3

Detailed rules for the implementation of the programme are set out in the Annex.

Article 4

1. The Commission shall send to the Council and to the European Parliament an annual report on the progress of the programme.
2. In the second year of the programme implementation, the Commission shall undertake a review of the programme and it shall send the results of this review to the Council and to the European Parliament, together, if necessary, with any proposals for modification or prolongation 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 Council and to the European Parliament.
4. The above-mentioned reports shall be established taking account of the objectives and evaluation criteria set out in the Annex to this decision and in conformity with the provisions of Article 2, paragraph 2 of Decision 87/516/Euratom, EEC.

Article 5

The Commission shall be responsible for the implementation of the programme. It shall be assisted in its execution by an advisory committee, hereinafter called "the committee", composed of representatives of Member States and chaired by a representative of the Commission.

Article 6

1. The Commission shall submit to the committee a draft of the measures to be taken. The committee shall give its opinion within a period set by the chairman according to the urgency of the matter, decided by a vote if necessary.
2. The opinion shall be recorded in the report of the meeting; moreover, each Member State shall have the right to have its own opinion recorded in the report.
3. The Commission shall take due note of the opinion given by the committee. It shall inform the committee of the procedures through which that opinion was taken into consideration.

Article 7

The procedures 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 the Annex;
- the participation in any project by non-Community organizations and enterprises referred to in Article 8(2);
- 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.

Article 8

1. The Commission is authorized, in conformity with Article 130 N of the EEC Treaty, to negotiate agreements with non-member States and international organizations, particularly with non-member States taking part in

European cooperation in the field of scientific and technical research (COST) and with countries which have concluded scientific and technical framework cooperation agreements with the Community, with a view to associating them fully or partially with the programme.

2. Where framework agreements for scientific and technical co-operation between European non-Member States 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 the programme.

Article 9

This Decision is addressed to the Member States.

Done at,1989

For the Council,

The President

ANNEX

for a 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 function, 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 non-member States and international organizations.

At the same time measures will be taken to develop an integrated approach to the 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 development of integrated databases to serve European networks.

2.1 IMPROVEMENT OF THE HUMAN GENETIC MAP

Establishment of a Europe-based 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 well-being 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 cost-shared or marginal cost contracts, support to centralized facilities and networks, training contracts, training grants, 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.

Community participation will be up to a maximum of 50% in the case of cost-shared contracts and could reach 100% in other cases.

Participants may be research institutions, universities, private enterprises, or combinations of them, located in Member States or in the non-member States referred to in Article 7, 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 one participant from one Member State.

Fellows coming from non-member States 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 from all research 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 above will be fully informed about 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 discussions 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 Council and to the European Parliament 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 patients' associations.

4. EVALUATION CRITERIA

The Communication from the Commission to the Council relating to the evaluation of Community research and development programmes⁽⁶⁾ 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 management of networks of laboratories set up 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;

⁶⁾ OJ N° C 14, 20.1.87, p. 5

- the launching of a programme of precompetitive research aiming at improvement of the methods and basis for 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 non-member States and international organizations.

4.2 The primary short-term objective is that the programme should succeed in establishing the above-mentioned 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,

all using data-processing facilities for data-handling and developing integrated data bases.

These objectives should be verifiable in 1991.

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

4.3.1 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 1 to 5 centimorgan level, and an integrated databank should be set up.

4.3.2 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.

4.3.3 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 cells 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 the storage, collation and analysis of DNA sequence data.

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

4.4.1 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.

4.4.2 That the drawing up of research contracts shall presuppose that the contracting parties undertake to abstain from all research 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.

- 4.4.3 The members of the families taking part in the studies mentioned in paragraph 2.1 must have been informed and given their consent, and the confidentiality and anonymity of personal data must be ensured.
- 4.4.4 That the development and the application of somatic gene therapy are not provided for within the framework of the present programme.
- 4.4.5 That actual or potential medical applications should be facilitated.
- 4.4.6 That potential opportunities for commercial developments should be obtained.
- 4.4.7 That the overall technological standard of the participating European laboratories must have been improved.
- 4.4.8 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 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 non-member States and international organizations has indeed been achieved and whether this cooperation has had positive results.

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FICHE FINANCIERE

PROGRAMME ANALYSE DU GENOME HUMAIN

Les points 1 à 4 de la fiche financière originale de la proposition COM(88)424 restent inchangés.

5. INCIDENCE FINANCIERE DE L'ACTION SUR LES CREDITS D'INTERVENTION

(Y compris les dépenses de personnel (1 agent de catégorie A, 1 agent de catégorie C) et les dépenses de fonctionnement administratif et technique).

5.1. Coût total pendant toute la durée envisagée 30 Mio Ecus

5.2. Part dans le financement

- du budget communautaire..... 15 Mio Ecus
- des budgets nationaux et)
- d'autres secteurs au)..... 15 Mio Ecus
niveau national)

5.3. Echéancier pluriannuel du budget communautaire

5.3.1. Crédits d'engagement en Millions d'Ecus

	<u>1990*</u>	<u>1991</u>	<u>TOTAL</u>
Personnel	0,21	0,21	0,42
Fonctionnement	0,20	0,25	0,45
Contrats et bourses	12,09	2,04	14,13
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Total	12,5	2,5	15,00

5.3.2. Crédits de paiement en Millions d'Ecus

	<u>1990*</u>	<u>1991</u>	<u>1992</u>	<u>1993</u>	<u>TOTAL</u>
Personnel	0,21	0,21	-	-	0,42
Fonctionnement	0,20	0,25	-	-	0,45
Contrats et bourses	3,79	5,54	3,10	1,70	14,13
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Total	4,2	6,0	3,10	1,70	15,00

* Ces montants figurent à l'APB 90 - ils sont sujets à modification au cours de la procédure budgétaire en cours.

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DOCUMENTS

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i det levende fæstags som
et bilag.

ANNEXE I

REPARTITION INTERNE DES RESSOURCES
A TITRE INDICATIF

	<u>Mécu</u>
Amélioration de la carte génétique de l'homme	3,3
Cartographie physique (Bibliothèques coordonnées de clones)	3,4
Traitement des données et bases de données	2,2
Amélioration des méthodes et des bases de l'étude du génome humain	2,2
Formation	1,9
Aspects éthiques, sociaux et légaux	1,0
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Gestion et effectifs	<u>1,0</u>
TOTAL	15,0