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COMMUNICATION FROM THE COMMISSION TO THE COUNCIL

CONCERNING THE REVIEW OF THE MULTIANNUAL RESEARCH PROGRAMME FOR
THE EUROPEAN ECONOMIC COMMUNITY IN THE FIELD OF BIOTECHNOLOGY
(1985 - 1989)

COM(86) 272 final

COMMUNICATION BY THE COMMISSION TO THE COUNCIL

PREAMBLE

In presenting the Guidelines for the new Community Framework Programme of Research and Technological Development for 1987-1991 (COM (86) 129 final of 17 March 1986), the Commission has stressed the importance which it attaches to the themes of :

- industrial competitiveness and, through it, improvement in the employment situation;
- the quality of life;
- the realisation of a Researchers' Europe.

Numerous initiatives have already been taken by means of Community research and technological development programmes in order to strengthen industrial competitiveness. It seems essential to pursue these efforts without delay; this has resulted in the preparation of three of the following four communications enclosed, which indicate the initiatives that the Commission intends to take with regard to :

- the launching of the second phase of the ESPRIT programme
- the revision of the BRITE programme
- the revision of the Biotechnology programme.

The last one is equally relevant to efforts to improve the quality of life of citizens of the Community.

The fourth communication enclosed gives more details of how the Commission views the revision of the Stimulation programme on exchanges of researchers; in this case it demonstrates the intention to support wholeheartedly the efforts being made to achieve a true Researchers' Europe.

The presentation of these four communications aims at assuring to provide the necessary impetus for the actions already undertaken on these priority themes; these four future programmes provide a good example of the priorities set by the Commission.

It is further self-evident that, in the spirit of the "Single European Act", these four communications prejudice neither the result of the debate going on in the Council and the Parliament on the orientations of the Framework Programme nor the formal corresponding proposal which the Commission will present in July 1986.

Furthermore, these four documents do not prejudice the corresponding draft decisions which will be presented later on to the Council and to the Parliament.

REVIEW OF THE MULTIANNUAL RESEARCH PROGRAMME

OF THE EUROPEAN ECONOMIC COMMUNITY

IN THE FIELD OF BIOTECHNOLOGY (1985 - 1989)

COMMUNICATION TO COUNCIL

1. TERMS OF REFERENCE

On 12 March 1985 the Council adopted a multiannual research action programme (1985 to 1989) for the European Economic Community in the field of biotechnology. In its decision, the Council made provision for the programme to be reviewed and possibly revised during its second year.

2. VALUE OF COMMUNITY TRAINING, RESEARCH AND CONCERTATION ACTIVITIES IN MODERN BIOTECHNOLOGY

In recent years the Council has adopted two Community R&D programmes in the field of new biotechnology :

- a) The BEP, Biomolecular Engineering Programme (April 1982 - March 1986; budget of 15 million ECU), which led to the establishment of an initial nucleus of Community research and training activities for the applications of enzyme engineering and genetic engineering in agriculture and the food industry;
- b) The BAP, Biotechnology Research Action Programme (1985-1989; budget of 55 million ECU) to continue and supplement the activities carried out under the BEP.

These two programmes have clearly demonstrated the value of Community training, research and concertation activities in biotechnology, the former by its excellent results and the latter by the success achieved in its initial stages. Both show the benefits in the way of project implementation and design obtained through the Community effort. Both bear witness to the

interest and enthusiasm shown by national laboratories in cross-frontier activities that allow them to combine their expertise and pool the facilities, materials and methods essential for the development of biotechnology.

2.1. The example of the biomolecular engineering programme (April 1982 to March 1986)

Because of the meagre funds available, this programme was focussed on the objectives considered to be the most urgent and important. It therefore covered only those applications of biomolecular engineering which were likely, through the genetic modification of agricultural species and the improvement of processing methods, to contribute in the long term to the resolution of certain Community agricultural problems. This first brief Community experiment in the very complex area of molecular genetics and enzymology can claim to its credit :

- success in attracting a large number of proposals,
- the establishment of a transnational network of research activities based on European cooperation,
- the quality of its scientific results and a number of breakthroughs towards applications of significance for the Community.

There can be no doubt that the programme was successful in attracting proposals since almost 300 proposals, in the main from the best laboratories in the Community, were received in response to the call published by the Commission. From this large number the Commission was able to select only those projects which met both the scientific quality criteria and the specific objectives of the programme. The selection was possibly too rigorous (slightly less than one-third of the proposals received were accepted) since lack of funds prevented many very valuable proposals from being included in the Community programme. Because of the lack of funds some research areas (physiology and stability of immobilized systems, early detection of genetic or pathological modifications, etc) had to be left out altogether.

A similar success was achieved in the case of training activities to complement the contract research programme. More than 200 young scientists applied to take part in these activities and 84 training contracts (for periods of from 6 to 24 months) were negotiated. With the best research centres in the Community serving as host laboratories, these made it

possible to lay the foundations for a vast European multidisciplinary training institutes without walls, something that is essential to the development of modern biotechnology. No single Member State can achieve this on a purely national basis. It is a typical example of the value and importance of the "European area".

The 63 cooperation agreements between the 103 laboratories taking part in the programme bear witness to the resolutely transnational nature of the BEP. These agreements cover both exchanges of research scientists and equipment and the pooling of certain infrastructure facilities or complete integration of activities.

They were brought about or encouraged by Commission staff when the programme was launched, during laboratory visits and at the 16 intrasectoral or multidisciplinary meetings organized while the contract work was in progress. A network of good laboratories, which is still not large enough but is extremely receptive to cooperation and the pooling of effort, has thus been set up for the first time in Europe in areas essential to the application of modern biology in agriculture and the food industry : development of bioreactors, identification, transfer and cloning of genes of significance for the processing of agricultural produce, improvement of cultivated species and soil micro-organisms through genetic engineering, application of biomolecular engineering to stock breeding and veterinary medicine.

The final point is the volume and quality of the scientific achievements obtained under the BEP. A few examples out of many are given below :

- The transfer by contractors in three different countries of genetic information into a few species belonging to a group of plants* that is not amenable to modern genetic engineering methods. This is a real world first as no other group had until then obtained such a decisive breakthrough in this area. This result, which opens the door to major long-term developments in the field of plant improvement, would probably have been obtained without the BEP but obviously the Community activity speeded it up.
- Sixteen laboratories have isolated and characterized at molecular level more than 20 different genes governing important properties in

* Monocotyledons, which include fodder grasses and cereals

crop plants such as the nutritional properties of the grain of cereals or legumes, resistance to insect pests and the production of secondary metabolites. This highly complex work is an absolutely essential preliminary to any further progress through genetic engineering, at the end of 1984, in the whole world, only 86 plant genes (compared to 1100 genes in mammals) had been partly described. The merit of the Community programme is to have organized the combining of effort and concentration of financing suited to the scale of the problems to be solved.

- The construction of plasmids and cloning of numerous genes likely to perform key functions in dairy fermentation, the production of new vaccines and the transformation of the constituents of wood.

- The development of bioreactors involving the co-immobilization of micro-organisms and enzymes and the use of multienzymatic systems necessary for the regeneration of expensive co-factors essential for the synthesis of chemicals of industrial interest (steroids for pharmaceutical uses, long-chain aldehydes as food additives, gluconic acid the pharmaceutical and food industries, etc.). Some of these developments are now in the pilot plant phase.

These successes should not, however, be allowed to conceal the weaknesses of the BEP which certainly suffered greatly from the inadequacy of its budget. Community support for work under contract barely exceeded an average of 50 000 ECU per year per laboratory, i.e. less than the cost of a research scientist per year and his operating expenses in most Community countries. University researchers, accustomed to the austerity of national budgets, content themselves with this low level of financing which in many cases nevertheless allows them to increase their work significantly. The situation is different in industrial laboratories where the BEP budget often appeared modest (see 2.2.1 below).

2.2 The launching of the Biotechnology Programme (1985-1989)

2.2.1 Research and training

The aim of this programme, launched by two calls for proposals in 1985 and 1986, is to continue, expand and supplement the Community activities under the BEP. Its budget (55 million ECU) is larger and, without losing sight of the need to concentrate efforts, the idea is

to expand the very narrow area covered by the BEP. In addition to the fields covered by the BEP, the programme makes provision for contextual measures for the pooling and improvement of existing R&D support facilities in the Member States (information storage and processing, collections of biotic materials) and specific projects for protein design, the applications of genetic engineering to industrial micro-organisms and the development of new in vitro systems for assessment of the pharmacological and toxicological properties of molecules. All these new activities have been defined in the light of Community requirements (need to focus research on objectives suited to industrial requirements, long-term contribution, by the application of research results to the evolution of Community agriculture, establishment of scientific data needed to prepare Community standards and regulations, assessment of potential risks). The aim, for each of the topics selected, is to enable the Community to benefit from the very high value added obtained by the pooling of research facilities and the combining of the research effort across frontiers.

As far as implementation is concerned, the main procedures defined for the BEP will be used for the training and research activities under the BAP. In order to increase international cooperation as far as possible, a very high priority was given in the selection of research projects to combined proposals from laboratories situated in different Member States.

A high priority is also given to proposals from industrial laboratories or involving the direct or indirect participation of industry. The research contracts contain specific clauses for the protection of intellectual property.

After publication of the calls for proposals, the Commission received proposals for more than 1300 projects by 1 March 1986. The proportion of proposals selected will probably be less than one-seventh of those received and it is already clear from the first selection meetings that many many high-quality proposals will have to be rejected. This proposal for the review of the programme is designed to avoid that eventuality, which would have a deplorable effect on the enthusiasm and obvious desire of European Laboratories to associate themselves in transnational networks and work together in the Community context. It would also mean neglecting, for lack of

adequate funds, numerous areas of the programme in which only a few laboratories could enjoy Community support.

The review of the programme as proposed here would also put to good use the marked swing in European industry in favour of Community activities in biotechnology. This started in the last two years of the BEP when a relatively high number of industrial laboratories asked to be included in the networks of contractors set up for each part of the programme. It gathered momentum under the existing BAP, in particular through the declarations of interest by industry which accompanied most of the research proposals submitted by university or national laboratories. The time is ripe for the finalization of cooperation and/or joint financing agreements (see 4.2) between these laboratories and the industrial firms which have expressed interest in the research plans.

2.2.2. Concertation

Biotechnology research, whether included in Community, national or industrial programmes in Europe and elsewhere in the world, is the first stage in a process that must be completed by the dissemination of information and transfer to practical application. Its inclusion in the Community's socio-economic objectives will be really efficient only if the innovation can be put into application under favourable conditions (for example, in the perspective of solutions envisaged in the Green Paper (1) and in the document (2) that followed it : all within a clear and fair legal and regulatory framework based on recognized scientific data uniform throughout Europe).

This is the purpose of the Community's biotechnology activities and their effective implementation is the aim of the concertation activity as defined by the Council (decision of 12 March 1985, O.J. No.1 83/1).

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- (1) COM(85)333 Perspectives for the Common Agricultural Policy
 - (2) COM(85)750 A Future for Community Agriculture

The list of tasks includes :

monitoring and strategic evaluation of developments in biotechnology and selective dissemination of this information to the services concerned;

support or cooperation available to those responsible for policies implemented in sectors served by biotechnology or sensitive to the spin-off from biotechnology.

An initial review can already be made :

- within the Commission, dissemination of information and concertation to ensure a common approach in all domains (R&D and non R&D) touched by biotechnology;
- support for promotion of the efficiency of biotechnology in Europe in the service of socio-economic objectives through a range of different activities, generally carried out in the context of flexible networks (for example, organization of conferences and ad hoc meetings with all those concerned : research scientists, manufacturers, the agricultural world, international organizations such as the OECD, WIPO, EFB, CEFIC, GIFAP and COMASSO.

Those responsible for the concertation activity have helped to organize large international conferences such as that held by CEPS (Centre for European Policy Studies), Brussels, on "Industrial biotechnology in Europe : issues for public policy".

A conference organized by BIO-HELLAS on biotechnology and agriculture in the Mediterranean basin will be held in Athens in June 1986. The following year a seminar will be organized on biotechnology in Europe and Latin America : cooperation possibilities (in particular encouragement of dialogue between national biotechnology policy-makers and contractors to promote trade, investment, joint ventures and other channels for technology transfer and cooperation between Europe and Latin America).

The concertation activity also includes the promotion and exploration of new activities, the strategic aim of which is to help identify new programmes or ventures necessary for the progress of European

biotechnology and its application to the Community's socio-economic objectives.

The discussion paper COM(86)221, "Biotechnology in the Community : Stimulating Agro-Industrial Development" is the basis for a consultation between sciences, agriculture and industry. This activity should serve to deepen understanding on the evolution of industrial use of agricultural products on the one hand, and on the contribution biotechnology can make to non-food uses, to the production of non-traditional agricultural products, to production techniques, to quality diversification and to environmental protection on the other. This action should stimulate, in a second phase, the realisation of pilot projects.

In another field selected because of its importance for modern Biotechnology the exploratory venture "BICEPS" (Bio-Informatics : Collaborative European Programmes and Strategy) is designed to evaluate trends and requirements, and possibly planning needs in the field of bio-informatics (including medical informatics).

3. NEED TO REVIEW THE BIOTECHNOLOGY PROGRAMME

3.1 Research activities

It is essential to increase the volume of ongoing activities under the BAP in order to enable the transnational research networks that have just been set up in the Community to attain a critical scale without diluting the concentration of effort.

Without widening the research spectrum, it is necessary to increase to 25 - 30 the number of laboratories involved in each of the sub-sections of the programme which are regarded as particularly important for the development and use of biotechnology in the Community (enzyme engineering, applications of genetic engineering to agriculture, risk assessment, contextual measures to improve R&D support facilities). Now that an initial network of good university laboratories has been set up, it is necessary to involve European industry in the joint effort and to step up Community activities for the dissemination and follow-through of scientific results.

The response to the calls for research proposals made in 1985 and 1986 for the programme show that this increase in the volume of activities is absolutely in line with the requirements of research scientists who, for lack of funds, are unable to carry out projects that could make a highly significant contribution to the development of biotechnology in Europe. Excellent research proposals that meet the criteria of scientific quality and transnational involvement and are also in line with the specific objectives of the programme have been entered on reserve lists drawn up with a view to the possible revision of the Community programme.

3.2 Training activities

As in the case of research, it is necessary to step up the volume of these activities which provide opportunities for young scientists wishing to specialize in one of the many disciplines involved in modern biotechnology to receive training in the best Community centres.

The techniques are so complex and knowledge is increasing so fast that only if a great effort is made to combine training capacities in all the Member States will it be possible to provide industry with the research staff it needs to launch or expand its R & D activities.

With existing funds it is possible to allocate some 60 grants or training contracts each year (on average five per Member State). This is certainly not commensurate with Community requirements.

The scheme should also give some Member States less well equipped than others in the way of research laboratories an opportunity to participate fully in the Community programme and gradually to acquire expertise of a high scientific level.

3.3 Concertation activities

The concertation activity covers the nine tasks defined in the Council. Decision of March 1985. Briefly, they combine the monitoring of new developments throughout the world with the provision of information and assessments to the Commission and the Member States. These tasks, which provide the foundation for cooperation and greater coherence between

activities essential to the development of European biotechnology, call for the development and use of consultation and communications networks.

Their relevance is demonstrated by the increase in the number of requests received by those managing this activity as a result of the general expansion of biotechnology and the very great interest shown by several Community bodies (European Parliament : hearings, committee discussions, parliamentary questions; various Commissions departments : problems of interaction between biotechnology and various policy sectors concerning regulations, social impact, etc.). This growing interest is also found outside the Community institutions (for example, the meeting in December 1984 between the Commission and heads of European companies gave rise to the European Biotechnology Coordination Group - EBCG).

Activities to meet these demands are extremely labour intensive. Existing manpower resources fall so short of the requirements resulting from the programme that it is necessary to resort to expedients such as the taking on of temporary staff, who often do not match up so well to the requirements for correct execution of the tasks, and subcontracting.

4. REVIEW PROPOSALS

The aims and technical content of this review are as follows :

4.1 Increase in current training activities

Special attention should be given to the three areas (bio-informatics, protein design and plant biochemistry) which suffer most severely in the Community from the shortage of high-level research scientists. The particularly acute needs of some Member States for qualified staff for various sectors of the programme should be taken into account.

4.2 Increase in research activities

The sectors of the current programme which are of particular importance to the Community and for the development of its sectoral policies were identified after numerous talks with experts and discussions with national delegations to the Biotechnology CGC. At the same time the CGC chairman, accompanied by Commission representatives, visited the capitals of the Member States. During these visits in-depth talks with national representatives were held; the advisability of revising the programme and the form the the revision should take were examined in detail. This high-lighted the importance of expanding Community research in the following areas :

- Contextual measures (bioinformatics and collections of biotic materials) where Community support must lead to improved facilities open to research scientists in all Member States.
- Bioreactors : this area, essential to the future of biotechnology in Europe, is very poorly funded in the current programme. It is essential to master the complex, multienzyme, multiphase reactions involving the regeneration of co-factors in order to make sophisticated bioreactors for the synthesis of high value-added products available to European industry.
- Protein engineering : This very promising area of research is particularly poorly financed in the current programme. But the United States and Japon support major efforts in this area the latter country having adopted an ambitious programme in 1986. A concerted effort in Europe should open up new methods to understand and to prepare artificial proteins, for example new enzymes.
- Applications of genetic engineering : it was undoubtedly in the applications of genetic engineering to the dairy industries and to the improvement of cultivated species that the Community research set up by the biomolecular engineering programme reached the highest scientific quality.

The European laboratories are within reach of various spectacular achievements in the medium term for the dairy industry* and in the longer term for plant improvement. If the Community is to keep its lead, which is due in part to cooperation across frontiers, it is

essential to step up the current effort and to involve European industry right now in the research being done under the existing programme.

- Assessment of risks : this area, which is of great importance in view of the extremely rapid pace of the progress made by man in transforming, taming and harnessing the properties of living matter on a large scale, is confined in the existing programme to contract research by five laboratories. This embryonic transnational research network, which for the moment is concentrating mainly on the assessment of risks that may be associated with the release of modified micro-organisms, needs to be greatly reinforced and its objectives diversified. It should be able to provide scientific backing for the various regulations needed for the harmonious development of modern biotechnology.

In each of these areas the Commission departments plan to select some of the many proposals of an extremely high scientific level now on the reserve list and, together with the project leaders and manufacturers interested in the proposals, to lay the foundations wherever that appears desirable, for contractual agreements making Community support conditional upon the participation of industry in the research work or its financing.

The planned arrangements, based essentially on the selection of proposals already submitted to the Commission, should allow a rapid start to be made on new contractual activities in fields regarded as essential by European industry.

4.3 Stepping up of concertation activities

To expand the scope and increase the efficiency of the concertation activity to match the realistic and appropriate objectives of its brief as defined in section 3.3, an increase in staff will be required.

* Where genetic engineering can make a very significant contribution to improving the quality and yield of fermentation process.

4.4 Extension of the programme to Spain and Portugal

It is essential to extend the programme and its revised version to Spain and Portugal and to include these two Member States in the research, training and concertation networks set up for the development of biotechnology in the Community. It is clear from numerous talks with national officials and the scientific community in those two countries that Spain and Portugal can make a very useful contribution to the Community activities in progress and, like the other Member States, can benefit from the transnational dimension of the programme and its concentration on finding long-term solutions to major Community problems.

5. COMPATIBILITY WITH THE FRAMEWORK PROGRAMME

In its resolution of 25 July 1983 on a first framework programme (1984-1987) for Community research, development and demonstration activities, the Council approved the development of biotechnology under the goal of promoting industrial competitiveness.

The draft framework programme for 1987-1991 is now being prepared; it plans to increase the research, training and concertation activities in biotechnology.

6. CONSULTATION OF THE BIOTECHNOLOGY CGC

The results obtained under the biomolecular engineering programme have been evaluated by the Biotechnology CGC, which recognized the scientific quality of the programme.

It considers that "its most convincing result is undoubtedly the creation of a climate favourable to transnational cooperation, the effects of which go well beyond the hopes expressed when the programme was launched".

All the delegations to the CGC recognize that the principle of revising the biotechnology programme is both justified and useful. A very large majority would like to see a substantial increase in its funding.

Several delegations regard the revision as a transitional phase leading to a better understanding of the requirements for the transfer of technology and follow-through of results, which could be taken into account in 1989 by the second-generation programme (BAP II).

7. CONCLUSION

In the light of the Council's and the European Parliament's discussions on the general orientations for the Framework Programme for Community RD&T activities 1987-1991, and the terms of the formal Framework Programme proposal which it adopts, the Commission will prepare and submit a draft Council decision for the revision of the Research Action Programme "Biotechnology" 1985-1989.