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BIOTECHNOLOGY IN THE COMMUNITY

(Communication from the Commission to the Council)

COM(83) 672 final/2

1. INTRODUCTION

In its communication to the European Council of Stuttgart in June 1983 ("Biotechnology : The Community's role", (COM (83)-328 final), the Commission emphasised the importance of modern biotechnology for the future of industrial, agricultural developments and health in the Community; and defined the factors which account, in spite of Europe's outstanding capacities in the study and application of the life sciences, for the current relative weaknesses in the Member States in biotechnology. These weaknesses were ascribed to :

- fragmentation of research efforts in basic biotechnology and in certain specific areas of the agro-food and chemical sectors and of the health industries.
- a shortage of technicians and scientists with advanced training in the multidisciplinary fields of modern biotechnology,
- the absence in the Community of a context supportive and encouraging for biotechnology in such aspects as :
 - . access at competitive prices to raw materials of agricultural origin
 - . a large internal market with common rules, regulatory regimes and laws on intellectual property
 - . logistic support for scientific and industrial infrastructure requiring European scale : data banks, culture collections, centres of specialist expertise.

Scientific and technical objectives in biotechnology were outlined in the Framework Programme for Community S/T Activities 1984-87 (COM(83) 260 final) adopted by the Council in its Resolution of 25 July 1983 (O.J. C 208/1).

In the Stuttgart communication cited, the Commission defined several priority objectives for overcoming present weaknesses and declared that precise and detailed proposals for Community action would be put forward in the course of 1983. These proposals are contained in the present communication, embracing both the scientific and technical objectives and the other necessary actions.

2. INSUFFICIENCIES IN THE COMPETITIVENESS OF EUROPEAN R&D IN MODERN BIOTECHNOLOGY

The fundamental importance of biotechnology in economic and social development is recognised throughout the world.

The Member States of the Community, strong in all traditional sectors of applied biology and in the research base, have recently committed major investments for the development and exploitation of modern biology. In spite of these efforts, the Community is being outspent by the U.S. by a factor of 2:1 in public sector research, and more in industry; and "outplanned" by the Japanese, who have for over 10 years been elaborating a coherently planned approach to developments in the life sciences and their industrial and medical applications, in carefully selected sectors. Not unrelated to these trends is the evidence of a substantial current European deficit in trade and in patents, and of continuing emigration of European scientists to the United States, attracted particularly by the high quality infrastructure and scientific environment.

In May 1983 a U.S. report, prepared for the Office of Science and Technology Policy of the White House by a working group drawn from several federal agencies, assessed the competitive situation in biotechnology as follows :

"Japan will be the stiffest competitor to the U.S.", and regarding the countries of Western Europe :

"In general, the lack of qualified scientists and engineers (particularly in process and purification technologies), inadequate industry/university cooperation, and belated and insufficient R&D funding by industry and government, are probably the biggest barriers to commercial competitiveness in these countries. In addition, the West German and British Governments are concerned over the emigration of scientists from their countries, many of whom are working in the U.S..."

A report (Oct. 1983) from the Office of Technology Assessment of the U.S. Congress similarly sees only Japan as a serious competitor to the U.S. in biotechnology.

3. REASONS FOR THE WEAKNESSES OF EUROPEAN BIOTECHNOLOGY

Ultimately, the European weaknesses can be ascribed to a fragmentation of effort into groups and programmes too small for the dimensions of the problems, to a relative scarcity of qualified staff and to the absence, at Community level, of adequate contextual support for research, development and exploitation.

The fragmentation, isolation and even dispersion of national efforts were acceptable as long as the traditional applications of biology to industry and agriculture could develop separately, slowly and within isolated disciplines. This situation non longer holds because modern biotechnology is in essence multidisciplinary in its approach, complex in its solutions, and is being advanced with great rapidity. Any attempt at improvement within the Community has to take into account the four following requirements :

- critical mass
- supportive context for research
- supportive context for development
- interrelationships with sectoral policies

+ Critical mass : a sufficient critical mass is a prerequisite for a strong research base, able through pooling of skills and alliance of disciplines to bring a wide range of possibilities to bear on any among many and diversified practical problems.

+ Supportive context for research : research in biotechnology cannot be properly implemented in the absence of extensive multidisciplinary training and without appropriate logistic support (data banks, collections of biotic materials, major centres for highly specialised expertise and technical facilities, patent counselling...).

+ Supportive context for development : progress in biotechnology and its exploitation depend upon clear regulatory regimes at all stages from laboratory development and testing through marketing to post-market monitoring.

+ Interrelationships with sectoral policies : the economic and social impacts of biotechnology on health, agriculture and industry are such that it is no longer possible to envisage an evolution of sectoral policies or strategies in these areas which could be independent of biotechnology R&D. This is particularly true within the Community for the agricultural policy, and for the public health domain which has witnessed a rapid expansion of medical costs and the substantial replacement of the private customer by the state-customer.

4. PROPOSED COMMUNITY ACTIONS

Taking into account those of its existing activities that are related to biotechnology, among which the central R&D action is the ongoing programme in biomolecular engineering, the Commission proposes the following six priorities to stimulate biotechnology in the Community and to increase competitiveness in Europe's bio-industries.

A financial statement is annexed. The tentative estimates relate to the period 1984-89, and within this period are consistent with the Framework Programme 1984-87.

I. RESEARCH AND TRAINING :

In conformity with the scientific and technical objectives of the Framework Programme 1984-87 (COM(83)260 final), the following lines of action have been identified, the elements of which will be presented in specific proposals.

Each action will include research and training aspects which are intimately linked in any advanced multidisciplinary activity.

They divide into "horizontal" and "specific" actions.

"Horizontal actions" are inherently pre-competitive. They consist of research and training actions in basic biotechnology and of contextual measures adapted to the requirements of biotechnology R&D. The projects for basic biotechnology are focussed upon the removal of bottlenecks which prevent the application of modern genetic and biochemical methods to industry and agriculture. Key areas for Community research to be carried

out in cooperation with public and private laboratories have been identified ; they cover the sequences of events and processes which man must understand and control for transforming and/or exploiting on a large scale the properties of those species, organisms, tissues, cultured cells, genes and gene products essential for new industrial and agricultural developments.

Another "horizontal" area of growing importance is that which concerns the information infrastructure and logistic support for the life sciences, R&D through databanks, collections of biotic materials and related information/communication networks ; and the sophisticated data capture technologies which are generating such information in ever-increasing quantities. Contextual measures and projects will aim to maintain and advance these essential support and logistic facilities for R & D and for its exploitation and implementation in industry, health care and agriculture.

The "specific actions" are intended to stimulate certain particular developments within well defined sectors of biotechnology which can contribute to the solution of problems related to the common policy in agriculture and in the health care sector. The targets chosen have been selected on the basis of their intrinsic importance, and in view of the fact that, under the normal constraints of commercial criteria and in the still fragmented state of the European market, it is unlikely that they can be effectively pursued by industry. With regard to agro-food and chemical industries, the basic priorities obviously lie in the necessity to lower the production costs of raw materials, to reduce current deficits in industrial feedstocks and to maintain the competitiveness of the Community in traditional and new bio-industrial processes. Typical examples of the work to be carried out through joint research are the assessment and design of new raw materials of agricultural origin and the biochemistry of poorly understood empirical production methods for agro-food processing. In the health industry sector, the substitution of the private customer by the state customer and the ever-increasing cost of health care provision, have emphasised the economic necessity for a reorientation of R&D towards new medical technologies. The major objectives of Community research should be the development of methods for prevention or rapid treatment of certain common (and socially costly) diseases, for the development of cheaper, and

more precise in vitro screening systems for the detection of pharmacological and toxicological activity, and for the definition of new non-invasive in vivo techniques for clinical diagnosis.

These research activities are to be complemented by a training programme specifically designed for reducing the present shortage of appropriately trained technicians and of scientists qualified in basic biotechnology, a multidisciplinary activity not normally taught in universities. Making use of the best experts from throughout the Community in laboratories of high scientific level, it is proposed to stimulate, through 1-2 years training contracts or short duration grants, the transfer of information and competences between disciplines, between public and private laboratories and between Member States.

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The following four priority areas are designed to create a context supportive of the adequate development of biotechnology in the Community.

II. CONCERTATION OF BIOTECHNOLOGY POLICIES. Biotechnology is a broad subject, because of its multi-disciplinary bases, and the multiplicity of sectors and policy areas involved in its development. It is therefore essential for coherence, and for maximum effectiveness in each of the policy areas related to biotechnology, to have a central activity of concertation : inter-service, international, and between Community and Member States. Such concertation demands active monitoring and assessment of strenghts, weaknesses, and emerging opportunities and challenges.

The principal tool to be used in the monitoring function will be an expanded series of networks, established in cooperation with the Member States to provide an ad-hoc system of collaboration between individuals, specialized groups and institutions. This will be coupled with an information base, regularly updated by scanning, selecting, interpreting and storing in an organized way the incoming flow of information.

In particular these activities will relate to the 4 domains identified as being of fundamental importance for the future of European biotechnology :

- a) Foundation capabilities - strategic strength in biotechnology rests on a relatively large number of fundamental disciplines and practical capabilities. These capabilities must be present, and there must be active monitoring to ensure their continued strength in a rapidly changing situation.

- b) Land use - as noted in the Commission's recent communication to Council (COM(83)500), biotechnology will offer a growing number of new opportunities for the improvement of agricultural production, and for increasing the quantity and range of non-food products (timber, animal feeds, chemicals, fuel...).

- c) Relations with the Developing World - Community actions in biotechnology can make significant contributions to the needs of the developing world: both through the programme of Science and Technology for Development, and through contributing specialist advice on relevant aspects of the Community Development Policy (including, for example, assessment of the risks of substitution for major Third World commodity products, and the elaboration of policy responses).

- d) Health care - pharmaceutical and basic health research are of fundamental importance to all biotechnology for the scale and significance of their research efforts; the pharmaceutical industry represents the technological leading edge, particularly in the all-important translation of scientific breakthroughs into pure, tested, economically produced, marketable products.

Each of these strategic domains is of course the predominant concern of a particular ministry (in Member States) or service (within the Commission); but the rich and proliferating interactions arising from biotechnology demand a horizontal view, if opportunities are to be seized (cf. the fertilisation of life sciences by information technology : bio-informatics), problems avoided (e.g. uncompetitive pricing of raw materials for the fermentation industry), and coherent policies adopted (e.g. between promotion of innovation and protection of established producers or consumers).

Action : the Commission therefore proposes a reinforcement of its resources for effective assessment and concertation of the new and existing activities which bear upon the 5-year biotechnology action plan. Tasks will be defined, in consultation with Member States, as necessary to enhance effectiveness of both Community and national actions in biotechnology, to improve contextual conditions (e.g. disseminating knowledge to raise the quality of public debate on acceptance), and to promote its development in all useful applications and the supporting capabilities.

III. NEW REGIMES ON AGRICULTURAL OUTPUTS FOR INDUSTRIAL USE :

Continuing research and development in biotechnology is giving industry the possibility to manipulate raw materials and to produce existing products by new methods as well as new products. Opportunities are thus being created to adapt agricultural outputs to market needs, including non-food uses and feedstocks for the chemical industry. It is therefore essential that the regimes for raw materials for biotechnology offer a free choice at competitive price level so that industry can establish a long term investment policy.

Action : in its Communication on the Common Agricultural Policy (COM(83)500 final 2.10) the Commission has underlined the necessity "to provide Community raw materials for biotechnology on the same conditions of competition as for external competitors".

The Commission intends to propose to the Council new regimes for sugar and starch for industrial use which will attain this objectives.

IV. A EUROPEAN APPROACH TO REGULATIONS AFFECTING BIOTECHNOLOGY

IV.1. Biological Safety

Public and parliamentary opinion is divided between admiration of the new discoveries in biotechnology, and concern about some of the possible implications or conjectural risks of their use. This concern is reflected in the extensive discussions, studies and reports on the need for regulation and control of various aspects of the life sciences; a debate vigorously pursued throughout the developed industrial world.

Given the continued level of widespread public and political concern, reflected in the many fora mentioned, and in the similarly persistent concern with issues such as animal welfare and their use in tests, which also impinge on biotechnology, it is clearly a normal role for the Commission to ensure regulatory provision to maintain rational standards of public safety; to this end, monitoring the social dimensions of biotechnology and their interfaces with policy.

Action : in order to maintain awareness of evolving pressures for new policies or regulations, a monitoring function is needed, to collate at Community level the evolving views of national regulatory bodies and interested international organisations (OECD, WHO, Council of Europe etc.), and hence to advise the Community on regulatory initiatives or international negotiations. This function can be appropriately combined with the concertation role described in item II above, and provision for it is included in the budget estimates.

IV.2. The consumer and the bio-industry

The roles of the public authorities, at both Community and Member State level, impinge at several points upon the "bio-industries" (pharmaceuticals, agro-food etc.) and the consumer. The Commission seeks to encourage innovation, harmonize regulatory regimes, create a genuine

common market, and ensure that regulations are based on rational assessment and well-informed debate; while seeking always to maintain high standards of nutrition and safety.

Action : as with the previous section on the social dimension and biological safety, the need is to maintain in the Commission the capacity to monitor the situation, and hence to concert necessary policy discussions and initiatives across the services, with Member States, and with other relevant groups (e.g. consumer associations).

IV.3. The Regulation of Products and their free Circulation

The bio-industries, given the high entry costs and long time scales (for both R&D work, and regulatory approval), have great need of the full dimensions of the European, and indeed the world, markets for their products or innovative processes.

From a first review of the situation, it would appear that the application of current Community regulations in the various fields (pharmaceuticals, veterinary medicines, chemical substances, food additives, bioprotein feedstuffs) will meet current regulatory needs, provided that there is close cooperation between the competent authorities in the Member States and the Commission. Such cooperation can be achieved by greater recourse to the existing institutional or scientific committees and, as necessary, use of the new information procedure for technical standards and regulations adopted by Council in its directive 83/189/EEC of 28th March 1983.

Action : on the basis of its experience deriving from the use of these various instruments, the Commission will put forward general or specific proposals appropriate to create a regulatory framework suitable for the development of the activities of the bioindustries and for the free circulation of goods produced by biotechnology. In its proposals, the Commission will be careful to introduce at Community level measures meeting urgent needs, and pursuing the common interest in line with Article 36 of the EEC Treaty.

V. A EUROPEAN APPROACH TO INTELLECTUAL PROPERTY RIGHTS IN BIOTECHNOLOGY.

The role of industrial property is to secure the commercial exploitation of proprietary R&D-results in highly competitive markets and simultaneously to permit the beneficial dissemination and exchange of knowledge in the field of activity concerned. Biotechnological R&D and bio-industry are rapidly evolving and expanding at the international level, and it is therefore indispensable that the industrial property laws and instruments available in the Common Market match the need of science and industry and of the Community's goals.

Failure to provide such protection for intellectual property will drive firms to protect themselves by commercial secrecy. Such secrecy will inhibit precisely the collaborative patterns of activity which are needed in this complex inter-disciplinary field, if maximum benefit is to be obtained from the individual developments.

Major unresolved issues include :

- the patentability of biotechnological inventions as such ;
- the implications and conditions associated with the rules of practical protection requirements and procedures (e.g. associated with the deposit of microorganisms and conditions for release to third parties);
- the additions to the existing problems concerning plant and animal variety protection, of complex new relations with patent law.

Action :

- the Member States should be invited to share with the Commission information about the aims and content of ongoing and planned work, national and international, regarding the protection of biotechnological inventions or achievements (e.g. as most have recently submitted to the OECD);

- the Member States and the Commission should seek common principles and guidelines for the management and dissemination of biotechnological information and knowledge arising from publicly financed R&D in biotechnology.

The industrial property issues in biotechnology reinforce the need for all Member States to ratify both the European and the Community Patent Conventions, as a first but necessary step towards a basis for commonly accepted regulations.

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It is the intention of the Commission to complement as necessary the R&D activities in biotechnology by :

VI. DEMONSTRATION PROJECTS :

designed to facilitate the transition between research developments and full scale exploitation on a commercial basis. These will be framed to relate also to the other Community actions bearing on the implementation of biotechnology. Since they will be contingent upon the outcome of the R&D actions, their precise scale, status and timing will be estimated in due course.

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The challenges and the opportunities presented by the new biotechnology are clear. An effective response by the Community and the Member States demands coherence and concertation, themselves depending upon an act of political will.

The Commission requests the agreement of the Council on the lines of action proposed, in order to set in motion the more detailed definition of programmes and procedures which will inspire and reinforce a Community policy for biotechnology in Europe.

RESOURCE REQUIREMENTS

The Biotechnology Action Plan defines the overall objectives and coherence of a combination of measures and actions which are diverse in their nature, resource requirements and timing. Certain elements - particularly of R&D and assessment/concertation actions - are already fully defined and costed; others must at this stage be seen as probable requirements, whose detailed costing must await either further investigation, or the outcome of the R&D itself.

The following table summarises the estimated requirements for the 5-year period July 1984-June 1989 :

	<u>MioECU</u>
R&D and Training programme	106
Assessment, concertation and non-R&D contextual :	6,6
Preparatory actions and training, on commercial and intellectual property	2,4
Demonstration projects in the later years of the plan, :	80
Administrative reinforcement related to regulations, market regimes and development policy	5
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Provisional order-of-magnitude total for the Biotechnology 5-year Action Plan	200
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	(i.e.average 40 Mio ECU p.a.)