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PROMOTING THE COMPETITIVE ENVIRONMENT FOR THE INDUSTRIAL ACTIVITIES BASED ON BIOTECHNOLOGY WITHIN THE COMMUNITY

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I. SITUATION AND PERSPECTIVES IN BIOTECHNOLOGY

A. THE IMPORTANCE OF BIOTECHNOLOGY

Biotechnology is a key technology for the future competitive development of the Community and it will determine the extent to which a large number of industrial activities located within the Community will be leaders in the development of innovatory products and processes. The recent Commission Communication on Industrial Policy stressed that only those industries in the forefront of technological process can maintain and improve competitiveness in the European economic system as a whole. The capacity of the industries which use biotechnology as a tool of production to play a leading role in research and to master industrial applications will be crucially affected by the economic environment within which these industries work. The main responsibility for industrial competitiveness rests with firms themselves.. It is, therefore, crucial that public authorities, both at the Community and Member State level, provide clear and predictable conditions for the activities of industry. This strategic dimension is important if the Community is to be in a position where it can offer a combination of factors and/or preconditions essential to the full industrial diffusion of biotechnology.

An indication of the potential size of this sector can be ascertained from an estimate, according to industry sources, that world sales of biotechnology-derived products (excluding fermented foods and drinks) were approximately 7.5 billion ECU in 1985, representing three times the volume of investment in the field made between 1980 and 1985. Industry estimates for the year 2000 vary widely between 26 billion ECU and 41 billion ECU. Even the conservative estimate yields a threefold increase in sales.

The recent increase in biotechnology products is only a beginning. It is clear that biotechnology will have a strategic significance in dealing with some of the major challenges facing the developed and developing world, ie. food, health, environment and population growth. Biotechnology will play a significant role in protecting and improving our environment. New vaccines, developed through biotechnological techniques, have already saved many lives and improved the quality of life for both humans and animals. Efforts are being directed towards the development of drought resistant plants, of great interest to many developing countries, and making certain plants unattractive to their traditional predators thus reducing the need for excessive use of pesticides. The application of biotechnology to increasing food production will be great importance to developing countries while, at the same time, having a profound impact on agriculture in the Community with major implications for the Community's agricultural policy.

At the same time, biotechnology suffers from a bad image amongst policy makers and the general public. Concerns have been expressed about the potential impact on human and animal health and the environment resulting from the incorrect use of new biotechnology. Each strategy to improve the economic framework for biotechnological techniques must be aware of these dimensions, not only as a constraint but as a challenge to balance the different aspects. Although some of the expressed fears seem exaggerated they are, nonetheless, of great political influence. It is imperative therefore that problems of public acceptability, and ethical questions

raised, be recognised and dealt with. It is suggested that there should be advice available to the Commission in the area of ethics in biotechnology.

The biotechnology revolution will ultimately have an impact on our everyday lives as profound as that of information technology but the time dependence of industrial applications must be recognized. While scientific progress is as rapid in many areas of biology as informatics, for many of the applications, especially those where added value is greater, as in the pharmaceutical industry, the time required for innovations to reach the market is much greater, largely due to the time required for registration. This cost (in terms of time as well as money) makes prenormative research in such sectors particularly important.

It is of paramount importance that the industries using biotechnology develop competitively. This need to create favourable conditions for the biotechnology industries, which are crucial to the development of the Community as a whole and which will affect competitiveness across a broad spectrum of the Community's industries, including the agricultural sector, must be combined with the protection of human, animal and plant health, safety and the environment. In fact, the need to achieve higher standards of health, safety and environmental protection do not act as limiting factors but as major opportunities for industry to develop through biotechnology more precise, effective and non-polluting products and services which will contribute to these aims. It is, therefore, the role of government to ensure that the framework which is provided for such activities is comprehensive enough to satisfy public concerns while, at the same time, encouraging the industrial development of biotechnology. **The Commission considers that the Community should be attractive to both Community and non-Community investors so that it may reap the benefits which will accrue from the industrial application of biotechnology.** The purpose of this Communication, therefore, is to examine the future perspectives for competitive biotechnology in the Community.

The Commission has been active, through Communications to the Council in 1985 and 1986, in defining a comprehensive framework for biotechnology and in identifying policies across a broad spectrum of Community activities which aim at encouraging the conditions necessary for competitiveness while ensuring the protection of health, safety and the environment. These Community activities have encouraged biotechnology firms in the Community.

The general approach to the Community's industrial policy was laid down in the afore-mentioned industrial policy communication. The Commission considers that a separate paper on biotechnology is needed due to the growing importance of biotechnology in the Community. Biotechnology is confronted with differing expectations and strategies and this paper shows the necessity to have a coherent industrial approach for competitive biotechnology in the Community.

B. MACROECONOMIC INDICATORS

1. DESCRIPTION OF THE INDUSTRIES INVOLVED

Within the Community, it is the pharmaceutical, agrochemical, food and drink sectors which have been the most active in developing the industrial applications of biotechnology. Biotechnology has potential uses across a broad spectrum of industries including energy, metal extraction, waste treatment, chemical products and bio-electronics. At the moment, however, the use of biotechnology in these industries is relatively undeveloped.

It is estimated that approximately 800 firms in the Community, 1000 in the United States and 300 in Japan, are active in biotechnological research. The vast majority of these firms are small- and medium-sized enterprises in the pharmaceutical or

chemical fields which are notable for having a high proportion of research staff specialising in contract research and contract manufacture. In addition, a significant proportion of the firms active in biotechnology in the Community are chemical and pharmaceutical multinationals, providing a broad industrial base, with significant financial and technological capacity, for the development of Community biotechnology.

The importance of biotechnology in these main areas of application can be illustrated as follows:

* *The Agrochemical Industry*

  The majority of firms active in this sector are multinational chemical companies whose agrochemical divisions only represent a small part of the total sales of the group. Product differentiation is a key factor to the competitiveness of this sector. Biotechnology has recently become a key area of research in this industry with seed and plant development, eg. drought resistant plants, dominating biotechnological developments. Attention has been focused on new products which will be environmentally safer and demonstrate stronger pest control. However these new products are not expected to be commercialised before the year 2000.

* *The Pharmaceutical Industry*

  This sector includes products destined for both human and veterinary health care. The world pharmaceutical industry as a whole is confronted with the high cost of developing new technologies and marketing new pharmaceutical products. Differences in testing requirements and standards world-wide contribute significantly to the high cost of R&D. In the Community alone, the current fragmented market, in terms of market authorisations and approval, results in significantly higher costs for European firms.

* *The Food and Drink Industries*

  The European food and drink industries are made up of a mixture of firms and sectors with very different structural and operational characteristics. (These include, for example, the agricultural sector, which produces food and non-food raw materials, and the food industry which processes these raw materials.) This variety can be attributed to the diversity of market demand, market size and the technologies and traditions particular to each country and each sector. Within these industries biotechnology has applications for new animal and plant varieties on the one hand and for new organisms, eg. for making cheeses, on the other hand.

2. EMPLOYMENT

The current Community average for employment in the above-mentioned sectors is 19.8% representing approximately 15 million jobs. All sectors expect a growth in employment levels due to biotechnology and it is estimated that approximately 2 million biotechnology-related jobs will be created in the Community in these sectors by 2000.

The identification of the exact numbers of those employed in research in biotechnology is difficult in all Member States mainly because no differentiation can be made between biologists and those biologists specialising in biotechnology.

It has to be recognised that multinational firms have great flexibility in determining the location of their research facilities so there is considerable competition to attract such investment and the resulting employment.

3. INDUSTRIAL STRUCTURE

In terms of structure, the high costs of research, testing, marketing, and patenting favour large companies. Large firms, with diversified resources, are also in a better position to afford the cash and time necessary before they can see a return on their investment in biotechnology. On the other hand, smaller start-up firms have greater flexibility and faster response times. Nevertheless there are big differences according to sector and product and it is evident that cooperation is mutually beneficial to large and small firms. This is supported by the fact that many of the SMEs which succeed in developing an innovative product either seek collaboration with established pharmaceutical or chemical firms or are taken over. The interaction between the large established firms and SMEs, eg. takeovers, encourages the development and commercialisation of innovatory products.

The industries involved in biotechnology are increasingly characterised by participation in joint ventures between European, Japanese and United States firms at an international level. Not only do the strategic alliances which have thus been formed extend across the whole spectrum of industry from small and medium sized enterprises to multinationals but also to the university and pure research sectors. From a European stand-point it is thus important that the Community remains an attractive industrial site in order to build such alliances on the basis of mutual interest rather than as a result of unilateral predominance.

4. FINANCIAL ASPECTS

The financial strength of the Community industries involved in biotechnology is an asset and the strength of these industries is illustrated by their activity in seeking strategic alliances or takeovers with US companies such as Zymogenetics and Genentech. A consequence of this activity is that some Community firms have located certain biotechnology research and production facilities in the United States.

The nature of state aids payable in respect of biotechnology R&D varies widely throughout the Member States and biotechnology R&D within the Community is fragmented when compared with the US. The Member State which devotes the most finance to R&D in biotechnology is the UK with a total outlay of 500 million ECU (public funds: 185 m. ECU; private funds: 315 m. ECU) in 1987. The total for the Community as a whole for the same year was 1630 million ECU (public only). This figure should be compared with the United States for the same year where a total of 2538 MECU (federal: 2484 MECU) was available for biotechnology R&D. Furthermore, the greater availability of venture capital is often stressed as a comparative advantage of American firms. On the other hand, long term capital seems easier to obtain in the Community and, especially, in Japan.

C. COMPETITIVENESS OF THE COMMUNITY'S BIO-INDUSTRIES

The recently adopted Communication on Industrial Policy stresses that the principal responsibility for competitiveness lies with industry itself. A number of factors determine this competitiveness, many of which are particular to individual markets, eg. the size of the market, public perceptions, and, not least, company investment policy. Two factors in particular will affect the competitiveness of the bio-industries:

- international policy strategies,
- intellectual property rights.

The strategies applied by firms in the market are particularly important given the fact that Community firms compete on the national, Community and international levels. In international competition Community firms are faced with comprehensive industrial strategies to which they must be able to react. The competitiveness of Community firms will be better improved if the Community's competitive

environment enables the completion of the internal market, the improvement of R&D and encourages cooperation both at the Community and international levels.

As biotechnology becomes a major priority for industry and governments throughout the developed and developing worlds, the Community is participating in the related international scientific and technical cooperation. By maintaining scientific excellence, technological leadership and appropriate social policies (eg for training and human resource development), the Community can manage and can benefit from the structural adjustments which the new knowledge and technology will require and facilitate.

The following factors, many of which fall within the responsibilities of the public authorities, are also considered as potentially important in determining the competitiveness of countries involved in biotechnology:

* financing and tax incentives for firms;
* government funding of basic and applied research;
* personnel availability and training;
* the legislative framework;
* intellectual property law;
* university/industry relationships;
* anti-trust law;
* international technology transfer, investment, and trade;
* government targeting policies in biotechnology;
* public perception and consumer choice.

The interplay of the factors which stimulate world-wide economic growth, much of which relies on the interaction between research, industry and trade, is complex. Although it is difficult to measure competitiveness by a single figure one indication could be the flows of direct investment representing investment by EC firms in the United States. (Table 2 shows that US and Japanese firms seem reluctant to invest in the Community with the same vigour.)

1. INTERNATIONAL COMPARISONS OF POLICY STRATEGIES

Biotechnological research and development is currently concentrated, although not limited, to three main geographic zones: the United States, Japan and Europe (including the EFTA countries). Smaller developed countries (eg. Australia, Canada, Israel) also have significant capabilities and many newly industrialising countries, particularly South Korea, Taiwan, Singapore, Brazil, India, and China, are giving high priority to biotechnology developments. Moreover, the markets for the products of biotechnology are geographically world-wide, eg. recombinant vaccines in Indonesia or the Sahel, and are of particular interest to developing countries.

Biotechnology is perceived as a strategic sector for international competitiveness, especially in the United States and Japan, and support by the public authorities has manifested itself in various different approaches:

* **United States**

  In order to provide guidelines for the future regulation of biotechnology the Office of Science and Technology Policy published principles, in 1990, relating to the scope of oversight for the planned introduction into the environment of organisms with deliberately modified hereditary traits. This initiative develops and refines the principles laid down in the 1986 Coordinated Framework for the Regulation of Biotechnology.

  In the United States it is estimated that approximately 1000 firms are active in biotechnology research and the industrial application of the results of this research. Since 1975 more than 200 established firms have diversified into biotechnology.

The United States, because it possesses the world's major biotechnology information infrastructure involving both data bases and specialist software, currently has the potential of controlling the sources and flow of information in biotechnology. Furthermore, federal support levels for biotechnology research are steadily increasing and in 1991 are estimated to represent approximately 2850 MECU. The positive climate for biotechnology is supported through close links between industry and universities. This means of supporting the diffusion of technological innovation is a characteristic advantage of R&D in the United States.

* Japan

In 1981 MITI identified biotechnology as a key technology of the future. Under the auspices of MITI Japanese companies set up the Bio-industry Development Centre in 1983 with the intention of assuring cooperation in promoting R&D and commercialisation of biotechnology. Furthermore, MITI has published guidelines which relate to the industrial application, manufacturing of medicines and the agricultural use of recombinant DNA technology.

It is estimated that approximately 300 firms are engaged in biotechnology research and more than 150 of the larger industrial Japanese companies are currently engaged in the industrial application of this research to biotechnology.

A solid competitive base is provided by the Japanese market which, according to the Japanese Industry Development Centre, could grow from 1.5 billion$ in 1985 to 35 billion$ in 2000.

Japanese industrial strategy for biotechnology is coordinated by MITI with particular emphasis being placed on the integration of new process technologies into Japan's fermentation and chemical industries. The real value of such a strategy is that company research into new and important technical areas is stimulated.

* The European Community

Many of the world's leading pharmaceutical and chemical companies which are involved in biotechnology are Community based.

Key issues of our policy approach in favour of biotechnology are evidenced by the wide range of Community research programmes supporting R&D and the importance attached to ensuring that the raw materials used in biotechnological processes (sugar and starch) are available to Community producers at world competitive prices.

Environmental and public health considerations as well as the completion of the internal market for biotechnology products has had the highest priority as shown by the type of legislation adopted by the Community in this area (see annex 1).

Furthermore, it is evident from an examination of the leading universities and institutes engaged in biotechnology R&D, that the intellectual basis for a competitive industrial structure in the Community is strong. But data bases in the Community are often fragmented and not comprehensive. Researchers within the Community therefore rely on access to the comprehensive data bases which exist in the United States. Therefore, the Community must support an open scientific information infrastructure for biotechnology within the Community and world-wide, coherent with international developments in

bio-informatics (including data banks, software, and electronic networks and services);

2. INTELLECTUAL PROPERTY

The **economic importance attached to the protection of intellectual property in the field of biotechnology should not be underestimated** since firms will only invest in long-term high-risk projects if they can be guaranteed adequate protection for the results of their research. In this regard it is absolutely necessary that industry within the Community benefit from similar levels of protection as their international competitors and that trade barriers resulting from differing levels of protection be avoided. These principles are being actively negotiated by the Community in GATT.

Differences in the length of the period of exclusivity granted under existing patent protection legislation, notably in the pharmaceuticals sector, adversely affects Community industry in comparison with its international competitors. This lack of a sufficiently tight patenting system could have a negative effect on investment. Companies take into account the patent systems in operation when assessing potential investment decisions. If biotechnology patent protection is weaker in the Community than outside of the Community then the profitability expectations for European firms will be less than for their competitors.

Industrial research activity is reflected in the number of patent applications made to the European Patents Office (EPO). Biotechnology is not, of course, a specific sector of scientific activity but is more the application of a range of processes across a range of sectors. This breadth of activity is reflected in the different classes of patents which are granted by the EPO. Between 1986 and 1988 the average breakdown of applications for patents at the EPO, in relation to biotechnology, was the following: 38.5% of American origin, 31% of European origin and 19.5% of Japanese origin. These levels are more easily appreciated when looked at in the overall context (patent applications across <u>all</u> technological sectors) where we see that between 1984 and 1989 the average level of applications lodged of US origin was 26% and of Japanese origin was 17.5% Therefore the level of penetration in Europe of US and Japanese patent applications in biotechnology is considerably greater than the average for all industrial sectors.

II. <u>A COMMUNITY FRAMEWORK FOR BIOTECHNOLOGY</u>

The Community's public authorities are responsible for ensuring that the regulatory and industrial frameworks relating to biotechnology which exist within the Community are conducive to the competitive development of the industries involved. It is therefore the role of the national authorities and, where necessary, Community authorities to address themselves to the factors necessary to achieve a single market for biotechnology, to achieve a competitive position in so far as the protection of intellectual property is concerned, to provide the necessary framework for encouraging research and development, and to ensure protection of human, animal and plant health and the environment. The need to achieve these goals is recognition of the fact that the completion of the internal market in the immediate future is the best industrial policy for the competitive development of industry.

In common with other industrial sectors, it is necessary to avoid market fragmentation caused by unilateral actions by Member States in so far as they erect new trade barriers within the Community. The importance to industry of having a harmonised and transparent approach to regulation is underlined by the high investment cost of research in biotechnology.

Community firms need a strong and competitive home market so that they are strong enough to face international competition and in order that the Community itself is interesting for investors. Therefore, in order to provide clear and more common rules, both for industry and for national legislators, and to fulfil the commitments proposed in earlier Communications, the Commission has launched a wide range of complementary vertical and horizontal initiatives which take into account the objectives of Community policies. These initiatives play an important interactive role towards the provision of a stable regulatory environment for the industrial development of biotechnology.

A. ACHIEVEMENT OF THE INTERNAL MARKET FOR BIOTECHNOLOGY

The achievement of the internal market for biotechnology will mainly depend upon the application of two tools at the Community level: the legal framework and the industrial use of standards.

1. THE REGULATORY FRAMEWORK

Not all products derived through biotechnological methods will require a specific assessment and/or authorisation procedures. Currently the vast majority of biotechnology products are produced through traditional methods (eg. cheeses, malt extracts, beers and yeasts). As far as new biotechnology products are concerned, which involve gene manipulation, each product will have to be considered on a case-by-case basis and assessed as necessary.

Those products which do require governmental activity may be assessed and authorised under the regulatory framework for biotechnology which has been developed by the Community. This regulatory framework, which is based upon scientific analysis and evaluation, covers horizontal (environmental and worker protection) and product legislation. This latter is based on the three criteria of safety, quality and efficacy (1), which are also applied when assessing whether a product can be authorised for distribution on the open market. The horizontal framework ensures that all stages of pre-industrial development and environmental aspects are covered.

The approach now applied by the Community, based upon the correct and thorough application of the criteria of safety, quality and efficacy, in conjunction with relevant horizontal legislation, ensures consumers" safety and economic interests and permits the protection of human, animal and plant health and of the environment. Furthermore, in order to ensure that the consumer protection aspect is covered, the impact on consumers' information and choice needs to be taken into account.

Recent debate has focussed on the introduction of broader socio-economic needs in addition to the three traditional criteria when assessing biotechnologically derived products. The debate is on-going and the preoccupations involved differ. To some the concept includes a broader analysis of health and environmental aspects, to others it should focus on social and/or economic impacts (for example, consequences on agricultural production). The Community must, above all, avoid a situation creating uncertainty. As a rule, decisions have to be based upon objective assessments using clearly identified criteria. Uncertainties about product acceptance and authorisation could result in a diversion of investment and could act as a disincentive for innovation and technological development by industry. The Community must however guarantee the public that the industry is properly controlled. The dynamism of the industry and the confidence of public opinion depend on the ability of the Community to reassure both parties.

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(1) It should be noted that these three criteria are nowadays considered to include impact on nature and safety for the environment.

Where a biotechnological product is assessed, the three traditional criteria, based on scientific evaluation apply. By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right however to take a different view in the light of its general obligation to take into account other Community policies and objectives. This might, in exceptional cases, lead to requirements for further information. It might equally, in exceptional cases, lead the Commission to propose that other policies be modified in the light of biotechnological developments.

2. STANDARDS

Following the principles of subsidiarity and Community policy on the use of standardization the Commission considers that it is appropriate to mobilize the considerable technical expertise available in industry to support the targets of the legislation already adopted at Community level.

The use of standards complements and fulfils the regulatory framework and accords with both the policies expressed in the White Paper on the internal market and with the principle of subsidiarity. This was recognised in the conclusions of the Council meeting on 16 July 1984, which pointed out that European standardization not only helps to create a standard technical environment but also improves competitiveness, on both Community and external markets, especially in new technologies. The Council has established as a general principle that **standards should be used in support of the legislative programme.** Such support can make a significant contribution to the development of biotechnology.

The Commission has noted that, as in the United States and Japan, standardization projects have been launched in the Member States in a variety of fields, but without following a consistent approach. This lack of a consistent approach results in increased costs to industry and it would, therefore, be more beneficial for industry if standardization were to be coordinated at a European level.

Since biotechnology is beginning to find its way into industrial applications priority should be given to standardization of those industrial aspects which support Community legislation but which are not covered by it in order to make the most of the results of research undertaken and the experience gained to date. Furthermore, in order that high levels of safety may be guaranteed, the maximum use should be made of quality assurance and certification procedures within the global approach to certification and testing.

In industrial areas other than biotechnology, the regulatory approach complements the self-regulatory activities of industry. In the different issues raised by biotechnology, however, industry has an interest in the legislator indicating from the beginning the scope and orientations for standardization in order that confusion is avoided.

B. PROTECTION OF INTELLECTUAL PROPERTY

In recognition of the need to ensure that the Community's industries and agricultural producers are in a position to be competitive at the international level, the Commission has proposed two measures concerning the legal protection of biotechnological inventions and Community plant variety rights, both of which should go far towards improving the current situation:

* *the legal protection of biotechnological inventions*

  The fact that differences in the legal protection of biotechnological inventions exist even within the Member States, and that such differences could create

barriers to trade and to the creation and proper functioning of the internal market, has called for a harmonised legislation concerning the legal protection of biotechnological inventions. The harmonisation of patent protection in the Commission's proposal for a directive represents an essential element in the Community's multi-faceted strategies for biotechnology.

* *plant variety rights*
  The objective of the Commission proposal for a regulation on Community plant variety rights is to assure plant breeders that, through a single decision, they may acquire direct and uniform protection throughout the entire Community rather than with the existing fragmented approach.

It is difficult to discuss the form of the final interface between these two proposals since they are still being discussed in the various Community fora. Nevertheless, the Commission should ensure that its approach will be comprehensive and will be coherent with international developments in this field.

The development of harmonized Community legislation in the protection of biotechnological inventions is taking place at a time of rapid technological change and of ongoing international negotiations and discussions (UPOV, GATT, the European Patent Convention). This conjuncture represents an opportunity to strengthen and improve the basis for innovation within the Community while simultaneously addressing the need for greater international harmonisation on issues such as burden of proof, "grace periods", "first to invent versus first to file", and access to deposited strains.

C. RESEARCH, DEVELOPMENT AND INNOVATION

The Commission recognises that strengthening the scientific and technological base of industry is essential for the Community's industries to become more competitive at international level. The Community's principal role is to furnish the necessary dynamism and coherence, to contribute to the definition of joint projects, to the coordination of the various interests involved, to the exchange and diffusion of results and to the harmonisation of actions lying within its competence. The Single European Act, which brought research and technological development for the first time explicitly into the EEC Treaty, has provided new impetus towards an overall strategy for research and competitiveness in the bio-industries.

The recently adopted **3rd Framework Programme** will further develop significant new areas for Community research activity in biotechnology and other aspects of life sciences and technologies, in particular through specific programmes on

- biotechnology
- agricultural and agro-industrial research
- biomedical and health research
- life sciences and technologies for developing countries.

The Commission's contribution to biotechnology should be reinforced and this should be reflected in the next review of the R&D framework programme.

The long term strategic objective is to contribute in a coherent way to the development of Europe's potential for understanding and using the properties and structure of living matter. Such basic biological knowledge is the essential foundation needed for applications in agriculture, industry, health (human, plant and animal), nutrition, and the environment. Sectors which ignore this new knowledge and its potential cannot long remain competitive.

In emphasizing the several programmes relevant to biotechnology, the Community recognizes that biotechnology is much more than the application of recombinant

DNA technology. Areas such as tissue and single cell culture, receptor biology, and immunology are no less important to industry and, where appropriate, are being stimulated and strengthened through Community R&D programmes.

Reference has been made to the particular importance of registration activities in sectors such as pharmaceuticals and food, the objects of careful regulatory oversight for well-known reasons.

The methods of prenormative research, building upon elements of earlier and current programmes (see Annex 2) will be expanded as a contribution to the joint development of scientific basic elements for regulations and in contact with corresponding international activities. Through modern biotechnology, it will be possible to increase the speed and precision of product development and testing, and hence simultaneously improve services, reduce costs and sharpen competitiveness.

It is essential that the Community activities in biotechnology and related research stretch beyond the laboratory, through development and demonstration, to stimulus and support for innovation in industry. In this respect the current activities of the VALUE programme are important, in promoting the dissemination and utilization of the results of scientific and technical research, with special consideration to the needs of small- and medium-sized enterprises - vital elements for a dynamic development of industrial biotechnology.

Ethical issues arise in biotechnology (as discussed below) and in the biotechnology research programmes all necessary importance is attributed to the ethical implications of such work and to their relevance to industry. In biomedical research too, ethical issues arise, and a research activity in biomedical ethics is expected to form part of the next programme in this area. Within the current programme on human genome analysis, the ethical, social and legal aspects of this work form a significant element; a specific expert working group has been constituted, its first meeting in April 1991.

D. ETHICS AND OTHER ISSUES

Biotechnology, through its wide ranging implications for food, health and the environment, and through the new knowledge and technologies it offers, will have considerable positive impacts on our way of life. It also offers specific new possibilities for information and interventions affecting human life, and raising or reinforcing basic ethical issues. For both these general and ethical reasons, it attracts considerable public interest and debate, some of it confused. This is important for industry as such confusion can adversely influence the whole climate for industrial development of biotechnology.

The questions arising in public debate belong to distinct categories and debate will continue to be ill-defined (and for public policy purposes, ineffectual) so long as a clear differentiation is not made between these issues:

(i) **ethical considerations** relating to human life and identity, which may arise (for example) in medical practice and counselling, or in research on human embryos and the human genome;

(ii) **other value-laden issues** which may be raised by biotechnology, including:

> **animal welfare issues** concerning, inter alia, novel methods to enhance the productivity of agricultural animals and the development of new animals by biotechnological methods for medical research, agricultural or other purposes;

* issues relating to the **limits of intellectual property rights** (patents, plant breeders' rights) and concerning a mixture of economic and ethical aspects - eg. patenting human beings might be universally rejected, patenting of modified microorganisms widely accepted.

(iii) **environmental** issues about the potential impacts of release of living genetically modified organisms into the environment. There is a Community framework for the protection of the environment and it is important that this is implemented. Issues relating to protection of health, safety and the environment are to be satisfied.

(iv) **health and safety** related issues, either concerning worker safety vis-a-vis biological agents, or consumer and public safety issues such as are addressed by applying the usual criteria of quality, safety and efficacy to products of biotechnology;

(v) issues related to transparency and information to allow for well-informed **consumer choice.**

(vi) issues relating to the **socio-economic impact** (eg. on production and employment) of new biotechnology-aided methods of production in agriculture.

It is essential that a clear distinction be made between ethical questions, related mainly to the first and partly to the second of the above categories and other issues raised by the applications of biotechnology. All of these concerns are important and both national and Community policy makers must ensure that legislative and other measures (agricultural, environmental, consumer protection, research, product safety, protection of human rights) respond to the concerns expressed. The Commission is aware that its responsibilities in this area extend beyond the borders of the Community.

On bio-ethical issues, the Community has been seriously involved in the succession of international conferences, from the first at Hakone, Japan, in 1985 to that held in Rome in 1988 (on ethical issues in human genome sequencing) and that hosted by the Commission in 1989 on environmental ethics. Reference has been made to ethical elements of research programmes in biotechnology and human genome analysis (and to the latter's working group on ethical, social and legal aspects); similarly the future programme of environmental research will include ethical aspects of environmental policy and management.

The Commission organised in 1988, in conjunction with the German Ministry of Research and Technology, the first "European Bioethics Conference" on human embryos in modern medical and biological research. During the conference, the scientific and technical aspects relating to this issue were presented and discussed by biologists, physicians, sociologists, philosophers and theologians, as well as legal experts and legislative authorities. A common position was reached on basic considerations: rejection of commercial exploitation; protection of genetic information; and establishment of multidisciplinary ethical committees.

Following a meeting of Ministers of Research at Kronberg in March 19990, the Commission has now established a working group on human embryos and research, which held its first meeting in Brussels in March 1991. In this field it is seen as particularly important to maintain close contact with the substantial and continuing work of the Council of Europe (as it has already done, for example, in the field of animal welfare conventions).

Regarding the other, less directly ethical, issues listed above, the Commission has been and remains actively involved. Some are treated elsewhere at appropriate points in this communication.

The Commission will continue to carry out social, economic and technological assessment studies to accompany its policy initiatives and research programmes in biotechnology, as it has done for many years through programmes such as FAST (Forecasting and Assessment in Science and Technology), and through the work of the European Foundation for the improvement of Living and Working Conditions (who have accorded to biotechnology the highest priority in their work on social assessment of technology).

III. ACTIONS

At present the sectors involved do not suffer from any structural weakness in terms of R&D, production facilities, investment, financial capability, market penetration in both Community and world markets. However, in order to have the competitive environment for biotechnology in the Community reinforced some problems should be solved:

- insufficient patent protection

- fragmentation of the Community market

- the bad image that biotechnology sometimes has for both policy makers and the general public.

A number of initiatives are required on a broad range of fronts if the competitiveness of the industries using biotechnological techniques is to be encouraged. Further action must be taken in the development of the legal framework, the use of standards, the protection of intellectual property and financial support for research and development. Furthermore, at the national and Community level, the ethical questions raised by biotechnology must be addressed.

A. THE LEGAL AND REGULATORY FRAMEWORK

The Commission intends to ensure that the wide range of initiatives relating to biotechnology which emanate from the numerous services involved are cohesive and complementary. The recent establishment by the Commission of the Biotechnology Coordination Committee, a high level inter-service committee, underlines the recognition of the need for a cohesive approach.

The problems of ensuring policy coherence between different ministries and agencies is no less of a problem at Member State level than at Community level. It is in the interests of the Member States, just as it is necessary at Community level, that channels of communication operate well both within their national administrations and to the European institutions.

The Community has "horizontal" directives which relate specifically to the environment and to the protection of workers in the workplace. These directives have provisions relating to adaptation to technical progress and the Commission will make full use of these provisions in order to guarantee that unknown risks are assessed at an early stage. There are also "vertical" directives which relate specifically to sectors and products affected by biotechnology, eg. pharmaceuticals.

The Community endeavours not to create unnecessary regulatory burdens to industry. The Commission will examine whether existing product legislation is appropriate and can be applied as it is, or slightly amended, to take into account any particular aspect related to biotechnology.

Existing horizontal legislation will continue to safeguard situations not covered by sectoral product legislation.

Biotechnology represents dynamic innovatory techniques for a wide range of industries. Therefore, it poses a challenge for legislators who need to be able to respond to its rapid development. This means a constant assessment of the appropriateness of existing and proposed legislation. The Community should, at the same time, ensure that excessive demands are not made on industry, and with consequent cost to the consumer, by unnecessary duplication of testing procedures relating to product authorisation. In this regard the Community will ensure that testing and authorisation procedures are streamlined and that one assessment and notification procedure covers all that is required for product authorisation.

The Commission considers that the legal and regulatory framework which now exists, or is proposed, is adequate to ensure protection of health and the environment. It has also identified that further consideration will have to be given to the risk assessment of biological agents and to implementing existing Community legislation on worker protection, health, safety and the environment while taking into account the state of scientific knowledge and technical progress. Furthermore, in order to contribute to public acceptability and to ensure consumer protection, the impact on consumers' information and choice needs to be taken into account. The Commission will ensure that the Community does not over-regulate and that the Community's legislation for biotechnology is coherent.

B. STANDARDS

Europe's standardization bodies, CEN (the European Committee for Standardization) and CENELEC, by virtue of their structure, their composition, their common rules of procedure and their relations with their international counterparts ISO and IEC, are in a position to draw up harmonized European technical specifications for certain aspects relating to the industrial application of biotechnology, eg. equipment, and codes of good practise on subjects supporting Community legislation but which are not covered by it.

The Commission intends to pursue a dialogue with CEN with the intention of drawing up a clear and precise mandate for CEN's activities in biotechnology by identifying those aspects which can be most effectively and usefully developed by CEN.

The initiative and responsibility of industry is crucial to the success of the use of standards in biotechnology. If the problems relating to the identification of harmonised technical standards cannot be resolved by CEN then the determination of technical standards will fall back to the legislators for inclusion in the legal framework.

C. RESEARCH, DEVELOPMENT, INNOVATION AND INVESTMENT

The Community must remain attractive to investment in biotechnology, not only between Member States but also from third countries, since direct investment is an invigorating competitive element by which technical know-how and industrial expertise are exchanged and international economic integration put on a broader

basis. An integrated approach is imperative so that the Community is attractive from the point of view of R&D, production and manufacture, and marketing.

Certain Member States of the Community, as well as some third countries, have recognised the future importance of biotechnology to economic competitiveness and have identified varying strategies to realize this goal. Current Community support for R&D is very limited when compared with the level of support provided by the Member States on an individual basis or, indeed, with the level of federal support in the United States. Within the Community only Germany, France, Netherlands and the UK, out of 15 countries surveyed by the OECD, had endeavoured to achieve vertical/lateral coordination of R&D policies and programmes in biotechnology.

The Commission will continue the progressive development and implementation of a policy for R&D in biotechnology which is relevant to the future needs of industry, strengthening the scientific base and infrastructure in consultation with Member States, and with effective coordination between the programmes required at Community level, and national programmes.

There is a need for biotechnology in the context of large integrated projects, addressing targets of strategic importance to the Community, and requiring contributions from two or more specific research programmes. Examples could be found in decentralised networks of laboratories, collaborating in applying the methods of molecular biology and genetic engineering to agriculture; on the advanced use of biotechnology for biomass energy, through integrated projects including high value co-products, or on research to provide the scientific and technical background for modifying the protocols of various classes of drugs, such as cardiovascular.

The wider international dimension demands new responses and the Commission is exploring appropriate mechanisms for scientific collaboration with other countries, focussing on topics such as biotechnology information infrastructure, and pre-normative research in biotechnology. Of importance in this respect are existing fora such as the EC-US Task Force for Biotechnology Research, the broader EC-US Joint Consultative Group on Science and Technology, the EC-US High Technology Group and Permanent Technical Working Group on biotechnology and the environment..

Care will be taken to ensure that state expenditure contributes to the competitiveness of the industries affected and does not become a mechanism inhibiting competitiveness. Therefore, financial support by public authorities must continue to be rigourously examined and controlled.

With the exception of pre-competitive R&D, the industrial strategy of Community firms has failed to take sufficient account of the Community dimension and long-term prospects. Opportunities for cooperation with Community and international partners have not been sufficiently exploited. As regards innovation and production, European firms have failed to take full advantage of the opportunities for cooperation created by the major Community technology programmes and have not put long-term global strategies in place early enough. In this context we should consider whether R&D policy has not been too limited to the precompetitive area. It has, however, been Commission policy up to now to leave near-market research to the companies themselves so as to maintain the incentive for them to compete through innovation.

The Commission through its general policies - above all for completion of the internal market - seeks to promote innovation and investment in biotechnology and will, in addition, expand in future such initiatives as the VALUE programme, and stimuli to innovation such as the SPRINT activity. The VENTURE CONSORT action is also particularly relevant in this context.

Through these and other initiatives, in conjunction with the concertation action of the BRIDGE programme, the Commission is developing an approach to stimulate the formation and growth of small companies in biotechnology.

D. INTELLECTUAL PROPERTY

Questions of ensuring **adequate protection for biotechnological inventions** within the Community are being addressed. The recently proposed directives on the legal protection of biotechnological inventions and Community plant variety rights represent essential measures in this direction. Nevertheless, a number of the provisions contained within the legal framework laid down by the European Patent Convention (for example, the exclusion from patent protection of plant and animal varieties) might need to be reconsidered for improved adaptation to advances in biotechnology. Given the rapidity of progress in biotechnology it is clear that certain principles retained in the Convention should be adapted if the Convention is to accurately reflect the requirements of a modern economy as well as developments in science and technology.

The Community's industry currently suffers from differences in the length of protection granted under existing patent protection legislation in comparison with that of its international competitors. It is therefore essential that the Community have a strong system of patent protection in place if investment in biotechnology is to be encouraged.

E. ETHICS

The Commission realizes that it is not possible to find general solutions for ethical issues which can be applied as a universal rule and that ethical issues need to be identified on a case by case basis. Recent debate has focussed on ethical and other aspects of human genome analysis, of human embryo research, of environmental research, of animal welfare, and of intellectual property law.

It is desirable that the Community have an advisory structure on ethics and biotechnology which is capable of dealing with ethical issues where they arise in the course of Community activities. Such a structure should permit dialogue to take place where ethical issues which Member States or other interested parties consider require resolution could be openly discussed. It would also enable recognised experts from relevant groups to participate in guiding the legislative process. The Commission considers that this would be a positive step towards increasing acceptance of biotechnology and towards ensuring the achievement of the single market for its products.

The Commission is profiting from, and collaborating with, the important work of the Council of Europe in this area.

The Commission considers that through addressing explicitly the ethical challenges, it is helping to improve the climate of public understanding and opinion concerning the responsible development of biotechnology; hence facilitating the acceptance of its benefits, and ensuring a single market for its products.

F. THE STATISTICAL BASE

One of the major problems relating to an accurate analysis of the real impact of biotechnology to the industrial structure of the bio-industries is the lack of information. Reliable biotechnology-specific statistics on these new aspects of

industrial activity is extremely difficult to find for several reasons: the manufacture and sales of biotechnologically-derived products tend to be integrated with the overall industrial production figures for the sectors concerned; many cases involve the development of completely new products for new markets for which there is currently no competition and, therefore, no issue of competitiveness. This lack of biotechnology-specific information also makes it difficult to assess the impact of Community actions which are directed towards biotechnology. It is therefore necessary that the Community compile a statistical base on the industries and products relating to biotechnology in order that accurate and useful analyses may be conducted.

IV. CONCLUSIONS AND RECOMMENDATIONS

The Community will continue to promote the beneficial application of biotechnology while ensuring safety for man and the environment. In doing so it will avoid creating undue burdens for industry.

A. The legislative framework:

Within the overall goals of ensuring adequate protection of health and the environment, environmental and health legislation has been adopted at Community level. This should be implemented as a matter of urgency.

The Commission will continue to ensure a coherent regulatory approach and an efficient and simplified interaction between sectoral and horizontal legislation.

New biotechnology products involving gene manipulation may need to be considered and assessed. The Commission foresees, therefore, that in the future a number of biotechnology products, will have to be regulated under Community existing sectoral legislation. The Commission will only do so where a thorough case-by-case examination in the light of characteristics inherent to specific biotechnological products or processes indicates that this is necessary.

Sectoral legislation may require adaptation to technical progress and the progress of scientific knowledge in order to deal with advances in biotechnology. Review of existing legislation will be ensured to reflect rapid developments and technical progress. In the exceptional cases where legislation does not provide for adaptation to technical progress the Commission will keep this legislation under review.

Where a biotechnological product is assessed, the three traditional criteria, based on scientific evaluation apply. By their nature, socio-economic aspects need to be considered in a different way. It is not the intention to have another systematic assessment in addition to the three criteria. The Commission will normally follow scientific advice. The Commission reserves the right however to take a different view in the light of its general obligation to take into account other Community policies and objectives.

Duplication of testing and authorisation procedures will be avoided. In this regard the Commission will ensure that testing and authorisation procedures are streamlined and that one integrated assessment and notification procedure covers all that is required for product authorisation.

Adopted Community legislation in the field of public health and the environment will continue to provide adequate protection in cases not covered by sectoral legislation.

B. Measures to enhance competitiveness and public acceptability:

The Commission proposed that priority be given to the following:

(i) the Community's contribution to research and development in the area of biotechnology should be reinforced. This will be undertaken in the review of the R&D framework programme;

(ii) the Community will through its research programmes, information market policy, and international collaboration, contribute to the development of a biotechnology information infrastructure within the Community and world-wide (including data banks, software, and electronic networks and services);

(iii) in order that work in the field of standards may fully complement the Community's legislative work, a clear and precise mandate shall be prepared by the Commission's services, in consultation with CEN;

(iv) Community legislation currently under discussion in the area of intellectual property should be adopted, and Community legislation already adopted should be transposed into the legislation of the Member States, as a matter of urgency in order that the Community will have a coordinated approach which will strengthen its position in international negotiations.

(v) statistics specific to biotechnology should be compiled in order that statistical monitoring of developments in the industrial application of biotechnology may take place;

(vi) Bilateral and multilateral international contacts must be further strengthened. In addition to this the Community should pursue, within the context of international bilateral working groups, GATT, the OECD, EFTA and, where appropriate, other international bodies, the establishment of environmental and health objectives and should ensure that these are integrated into economic and other policy decisions.

(vii) to enable ethical issues to be clearly identified and discussed, the appropriate advisory structure at Community level should be established.

(viii) the Commission will regularly evaluate the progress and competitiveness of the biotechnology industries in Europe in order to make sure that the agreed framework remains appropriate. Success in this regard will, essentially, depend on the strategies adopted by the industries concerned.

ANNEX 1

REGULATORY ACTIONS

LEGISLATION ALREADY ADOPTED (in reverse chronological order)

*** Council Directive 90/679/EEC on the protection of workers from the risks related to exposure to biological agents at work:**

The purpose of this directive is the protection of workers against the risks to their health and security from exposure to biological agents and to promote the harmonisation of the regulation applied by Member States in this area.

The text sets out "levels of confinement" which are a series of technical measures which must be applied to ensure the most efficient barrier between the biological agent and the exposed worker. These special measures were related directly to the classification of biological agents having regard to their degree of intrinsic danger (group 1 to 4) according to the definition set out in the Directive.

This Directive covers, in one measure, all work with biological agents and advocates the medical surveillance of workers exposed to biological agents in such a manner so as to evaluate the general state of the worker to be so exposed.

It should be noted that the Directive, in parallel to the general types of protection such as signs of biological danger, also list special measures applicable to industrial procedures, in laboratories and animal research centres, and, in addition, to certain medical services and certain diagnostic laboratories

The Directive covers biological agents. that is to say, micro-organisms, including those subjected to genetic manipulation, cellular cultures and human endoparasites.

*** Council Directive 90/220/EEC on the deliberate release of genetically modified organisms:**

This Directive covers the deliberate release of live genetically modified organisms (micro-organisms, plants and animals) at all the stages of release to the environment, from small scale to large scale experimental introductions, as well as release through product marketing, where the products contain or consist of live genetically modified organisms.

In adopting this Directive, the Council recognised that the intentional release of organisms having a combination of traits that nature may have never produced increases uncertainty as regards the behaviour of the organisms and the possibility of an adverse impact of the environment, and that it was therefore necessary to proceed with releases of GMO's in a careful manner, and only under conditions of human and environmental safety which are as high as reasonably practical. A case-by-case and step-by-step approach to the evaluation and approval of releases was therefore adopted in line with the international consensus reached in the OECD in 1986.

The Directive foresees that an environmental risk assessment must always be carried out before any release of GMOs to the environment whether for an experiment or in a product and that no releases may be carried out without the consent of the competent authorities.

A national approval procedure is foreseen for experimental releases, while a Community approval procedure is foreseen for approval of releases made by marketing a product. Once cleared, however, a product can circulate freely throughout the Community, without the need for any further environmental risk assessment.

It is foreseen that the Commission, with the assistance of a Committee composed of Representatives of the Member States, will have the role of an arbitrator in case any disagreements arise between competent authorities as regards the Community approval for a product, and in this case, the Committee will take its decision by qualified majority.

*** Council Directive 90/219/EEC on the contained use of genetically modified microorganisms:**

The Directive on contained use, formally adopted by the Council of Ministers on 23.4.90, addresses the use of genetically modified micro-organisms in all systems where barriers are used to restrict dissemination of live material to the external environment, both for the purposes of research and in industrial production.

In adopting this Directive, the Community has recognised that installations carrying out work with genetically modified microorganisms should do this in a manner which prevents or minimises any potential risk to human health and the environment, and that the use of GMMs should be undertaken with the degree of preventive control appropriate to the potential risk involved.

The Directive establishes a framework for the case-by-case risk assessment of activities. Differentiation is made between degrees of risk involved in various operations by taking into account both the type of operation envisaged and the type of GMM used, and this is reflected in a flexible notification procedure.

Working practices and containment measures are established corresponding to the risk posed by the micro-organism. In case of higher risk micro-organisms explicit consent for certain operations is needed, and measures must be taken to prevent accidental release of GMMs and limit the consequences of such accidents where they occur.

*** Council Directive 89/381/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC on the approximation of provisions laid down by law, regulations or administrative action relating to proprietary medicinal products and laying down special provisions for medicinal products derived from human blood or human plasma;**

*** Council Directive 89/342/EEC extending the scope of Directives 65/65/EEC and 75/319/EEC and laying down additional provisions for immunological medicinal products consisting of vaccines, toxins or serums and allergens;**

*** Council Directive 87/22/EEC on the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology;**

* **Council Directive 87/21/EEC amending Directive 65/65/EEC on the approximation of provisions laid down by law, regulation or administrative action relating to proprietary medicinal products:**

In the interest of public health, and in order to promote the free movement of medicinal products, the European Community has adopted a series of legislative measures harmonizing the conditions of manufacture, testing and marketing authorization of medicinal products, including these directives, with application to biotechnological and high technology products.

For biotechnology/high technology products, directive 87/22/EEC requires that the national competent authorities consult each other within the Committee for Proprietary Medicinal Products (CPMP) or the Committee for Veterinary Medicines (CVMP) before taking any decision to authorize such products. It also provides for Community coordination before any national decision on suspension or withdrawal is taken, save in exceptionally urgent cases.

Furthermore, a special EEC Biotechnology/Pharmacy Working Party has been set up to advise the CPMP on individual applications for marketing authorization relating to biotechnology/high technology medicinal products. This Working Party establishes specific, harmonized guide-lines for the production and quality control of these products. The development of such guide-lines is an on-going task which must constantly take into account the latest scientific knowledge.

Biotechnology/high technology medicinal products benefit from a certain form of protection against copies for a period of ten years, running from the date of the first authorization to market the product in the EEC.

In accordance with Directive 87/22/EEC, the Council adopted in 1989 two directives to extend the scope of the pharmaceutical legislation to cover two important categories of biological medicines, immunologicals, and medicinal products derived from human blood and plasma.

* **Council Regulation 1010/86/EEC laying down general rules for the production refund on certain sugar products used in the chemical industry;**

* **Council Regulation 1009/86/EEC establishing general rules applying to production refunds in the cereals and rice sector;**

PROPOSALS NOT YET ADOPTED

* **Legal protection of biotechnological inventions**

* **Supplementary protection certificate for medicinal products**

* **Community plant variety rights**

* **Pesticides**

* **Community authorisations for biotechnology products/European Medicines Evaluation Agency:**

The Commission has transmitted to the Council in November 1990 (COM(90)283) several proposals for the future system for marketing authorisations in the Community. Under current Community procedures, the opinions of both the CPMP and the CVMP are not binding on the Member States. Therefore, in spite of the wide scope of harmonization of legal,

technical and administrative requirements, differences may occur in the final national decision on the same product.

Extensive consultations with the Member States and with industry have been carried out for over two years, on how to frame the future system for marketing authorisation of medicinal products after 1992. A common trend has emerged, according to which the future EEC system for marketing authorisation of medicinal products would result in the establishment of a centralised, binding EEC system for biotechnology/high technology products and performance enhancers with the support of a small central EEC Medicines Evaluation Agency. This would ensure more rapid access to the whole EEC market for innovative medicinal products.

SOME PROPOSALS UNDER CONSIDERATION

- **Novel food food ingredients and novel food processes**
- **Genetically modified animals**
- **Transport of biotechnological organisms and microorganisms**
- **Classification of biological agents**
- **Silage additives**

ANNEX 2

COMMUNITY R&D PROGRAMMES IN SUPPORT OF BIOTECHNOLOGY

The Community's research activities in biotechnology have a long history: starting from radiation biology in EURATOM, arguments in the 1970s about recombinant DNA regulation, and the long debate which led in 1981 to adoption of a first and modest (15 MECU, 1982-86) "Biomolecular Engineering Programme (BEP)", covering elements of genetic engineering and enzymology. At that time, for European scientists the word "international" was synonymous with "American".

Closer and stronger collaboration with US science remains a current and important preoccupation; but the first objective, and major achievement, of BEP was to develop in biotechnology the habit of transnational collaboration between laboratories within Europe.

Following the 1983 debate the need to reinforce the Community's R&D effort in biotechnology was recognised in the 1985-89 "Biotechnology Action Programme (BAP)", overlapping BEP and with resources of 55 MECU. The programme was not only larger in resources, but wider in scope. Where BEP had addressed obstacles to the application of modern biological techniques in the agriculture and food sectors. BAP reflected increasing industrial interests by focussing, for example, on aspects and micro-organisms of industrial interest. In response to recommendations from the first FAST programme (Forecasting and Assessment in Science and Technology, 1978-83), it also incorporated "contextual measures" for infrastructure such as databases and culture collections; and the first "concertation action" (see below).

In 1987, a 20 MECU amplification of BAP not only enabled Spanish and Portuguese laboratories to join the activity in mid-programme, but allowed for two significant developments:

- amplification of safety assessment work, to involve over 50 laboratories throughout the Community: to cope with rising political concerns about conjectural risks (especially in the agricultural and environmental use of modified organisms). and to provide a scientific basis for possible regulation;

- reinforcement of bio-informatics activities in Europe (eg. the DNA sequence library at the European Molecular Biology Laboratory, Heidelberg), in response (along with the AIM programme, of Advanced Informatics in Medicine) to recommendations arising from the BICEPS initiative of exploratory studies and workshops (Bio-informatics: Collaborative European Programmes and Strategy).

BAP saw the fuller development of the concept of "European Laboratories Without Walls (ELWW)", and the rapid growth of industrial interest, paralleled by demands from both industry and Member States for greater industrial involvement. relevance and co-finance.

Such co-finance was formally required in the Community's first programme of biotechnology-based agro-industrial research, "ECLAIR": European Collaborative Linkage of Agriculture and Industry through Research (80 MECU, 1988 to 1993). launched to respond to new opportunities arising across the agro-industrial interfaces. and to encourage the development of new, competitive activities for European agriculture. Such development depended also on the changes to sugar and starch

prices. The integration of agro-industrial with agricultural and other related research will be further developed in the FP3.

The BRIDGE programme will consolidate the developments achieved in BAP - industrial involvement, contextual measures, concertation action - but has other novel features, of which three can be briefly mentioned:

- the programme is open to COST-participant countries and EFTA, thus strengthening collaboration with the biotechnology - strong European countries.

- in line with advice from industry, and the very positive Evaluation Panel report on BEP and BAP, the programme has both "N-projects", network-based activities of typically more academic character and modest financial scale, and "T-projects", more targeted in character, multimillion ECU;

- building on a small start in BAP, genome analysis work will be pursued on both yeast and the plant Arabidopsis - both ideal models for study - in conjunction with world-wide collaboration.

The existing VALUE programme (38 MECU) stimulates the transfer of the fruits of Community co-financed research towards commercialisation; and in FP3, this will be amplified by devoting 1% of each programme's budget through VALUE for this purpose. In the context of innovation, mention should be made of the SPRINT programme (90 MECU, 1989-93), which has a wider mandate to stimulate and support innovation and technology transfer throughout the Community.

The MONITOR programme is contributing to biotechnology through three sub-programmes:

1. MONITOR/FAST
   The FAST group has prepared a report on "European Chemical Firms and Biotechnology". It emphasizes the role of biotechnological innovations as a restructuring process of the industry.

2. MONITOR/SAST
   The "Strategic Analysis in Science and Technology Programme" is supporting several studies on the role and place of biotechnology research to meet the challenges facing the Community in agro-industrial development.

3. MONITOR/SPEAR
   SPEAR, which deals mainly with activities in support of the evaluation of R&D, is currently looking at the use of patents as indicators of biotechnology research in agriculture.

MONITOR is also conducting a survey amongst Member State's administrations of understandings and perceptions of biotechnology and Community activities in biotechnology in various ministries.

ANNEX 3

TRAINING IN BIOTECHNOLOGY

* *Training under the research programmes BEP, BAP and BRIDGE*

Training through research represents a permanent priority in each of the three successive previously mentioned programmes: BEP, BAP, and BRIDGE, which the Commission elaborated in the past or is presently carrying out to foster the expansion of biotechnology R&D in Europe. The total budget committed to training activities in these three programmes amounts to 22 Mio ECU (3 in BEP, 9 for BAP and 10 foreseen in BRIDGE) and corresponds, for the period 1982-1994, to the requirements for approximately 800 man/year in specialised training and for the organisation of 20-30 summer schools in Member States which recently joined the Community or where stronger foundations in basic biotechnology must be prepared. This figure of 22 Mio ECU is certainly out of proportion with the size of Western Europe and with the dimensions of the combined effort which the Member States need to accomplish for bridging present gaps with the USA and Japan. It nevertheless is an example of a major effort, through the pooling of competences and of infrastructures, for large-scale transnational training in a specific area of modern technology.

Statistics and studies on the requirements of employers show that the need for intensive training is particularly important in research sectors of relatively recent emergence (molecular biology of crop plants, rheology of bioreactors, kinetics of immobilised catalysts, protein design...) and with a strong multidisciplinary basis. An analysis by the Commission services of 500 advertisements published in the West-European press indicated, in this relation, that multidisciplinarity was sought by the employers through the constitution of mixed teams and not through the association of multiple expertise within single individuals. Proposals for positions in research or in its management were in most instances, in 1985, channelled towards university graduates with a relatively narrow specialisation in a branch of the natural sciences (genetics, microbiology, molecular biology, biochemistry ...).

The training activity essentially aims at providing young scientists from the Member States with the possibility to acquire specific knowledge and know-how in one or several of the complex disciplines which constitute modern biotechnology.

Training under BAP required transnational mobility. The host-laboratories receive a benchfee which contributes to the running costs of the training activity. In BAP, by 1 January 1989, 320 scientists had received grants for "training through research" for periods ranging from several weeks to a maximum of two years.

All possible combinations occur in the relationship between the "origin of trainee" and "the geographic location of host-laboratories" but there is a clear trend for trainees to be nationals of southern Member States and for host-laboratories to be located in the centre and in the North of the Community. France, Spain, Italy, the Federal Republic and Greece provide the largest numbers of trainees: the United Kingdom and, to a lesser extent, France, the Federal Republic and the Netherlands contribute the vast majority of host-laboratories.

In order to complement these actions of training through research, BAP also supported in 1980 summer schools and workshops in Spain, Portugal and Greece.

The initiative has concentrated, up to now, on the most essential features and laboratory techniques of molecular biology, genetic engineering and process engineering.

Training activities in BRIDGE are pursued on the BAP model.

* *COMETT*

A total of 876 projects were selected for 1990. Of these, 158 represent supports for the so-called UETPs (University-Enterprise Training Partnerships), 244 involve transnational student work experience (representing 3,731 students), 13 are advanced student placements, 65 are staff exchanges. 124 are short-training courses and 190 are joint training actions.

The COMETT projects accepted in the first Application Round of COMETT II represent more than 1,400 European universities and institutions of higher education, almost 4,000 enterprises and some 2,100 professional bodies in the private and public sectors, such as chambers of commerce and professional associations. It should be noted that 76 % of the enterprises participating in these projects are SMEs.

In 1990, 23 Projects are dealing with biotechnology, representing a 55% increase compared to the average of COMETT I. These projects are granted by a Community contribution of 2,8 MECU. Biotechnology is one of the 10 sectors which are receiving an annual Community financial support higher than 2,5 MECU this year. An analysis of these biotechnology projects shows that 50% are concerned with student and staff exchanges. This could easily be explained by the fact that biotechnology is currently in a phase of active technology transfer between university and enterprise. However, it is worth nothing that in financial terms the projects concerned with courses and training material development are the most significant since they represent 85% of the amounts allocated. Altogether, these projects are proposing courses and advanced training (some of which using specialized software, interactive videos and even satellite communications) covering most of the topics relevant to the biotechnology industry. Biotechnology is one of the sectors in which the projects show a very important multimedia component.

The biotechnology projects involve 150 universities, 91 other organizations and 106 enterprises, out of which an outstanding proportion (93%) are SMEs.

The COMETT 1991 Call for Applications was restricted to projects under the following Strands: Ba (students' placements), Bc (university and enterprise staff exchanges), Ca (short courses) and D (preparatory visits). In 1991, out of 414 projects submitted, 18 are dealing with biotechnology and 32 with agro-food. In relative terms, these figures represent a significant increase compared to last year since the 1991 projects in biotechnology account for more than 4% of the total number of projects (compared to 2% in 1990). As observed for last year, biotechnology projects are concerned mainly with student and staff excanges. This connfirms that biotechnology is still in a phase of active technology transfer between university and enterprise.

LIST OF TABLES

U.S. REPORT CARD: TRENDS

	Versus Japan	Versus Europe
Losing Badly	Advanced Materials Biotechnology Digital Imaging Technology Superconductors	Digital Imaging Technology Flexible Computer Integrated Manufacturing
Losing	Advanced Semiconductor Devices High-Density Data Storage High-Performance Computing Medical Devices and Diagnostics Optoelectronics Sensor Technology	Medical Devices and Diagnostics
Holding	Artificial Intelligence Flexible Computer-Integrated Manufacturing	Advanced Materials Advanced Semiconductor Devices High-Density Data Storage Optoelectronics Sensor Technology Superconductors
Gaining		Artificial Intelligence Biotechnology High-Performance Computing

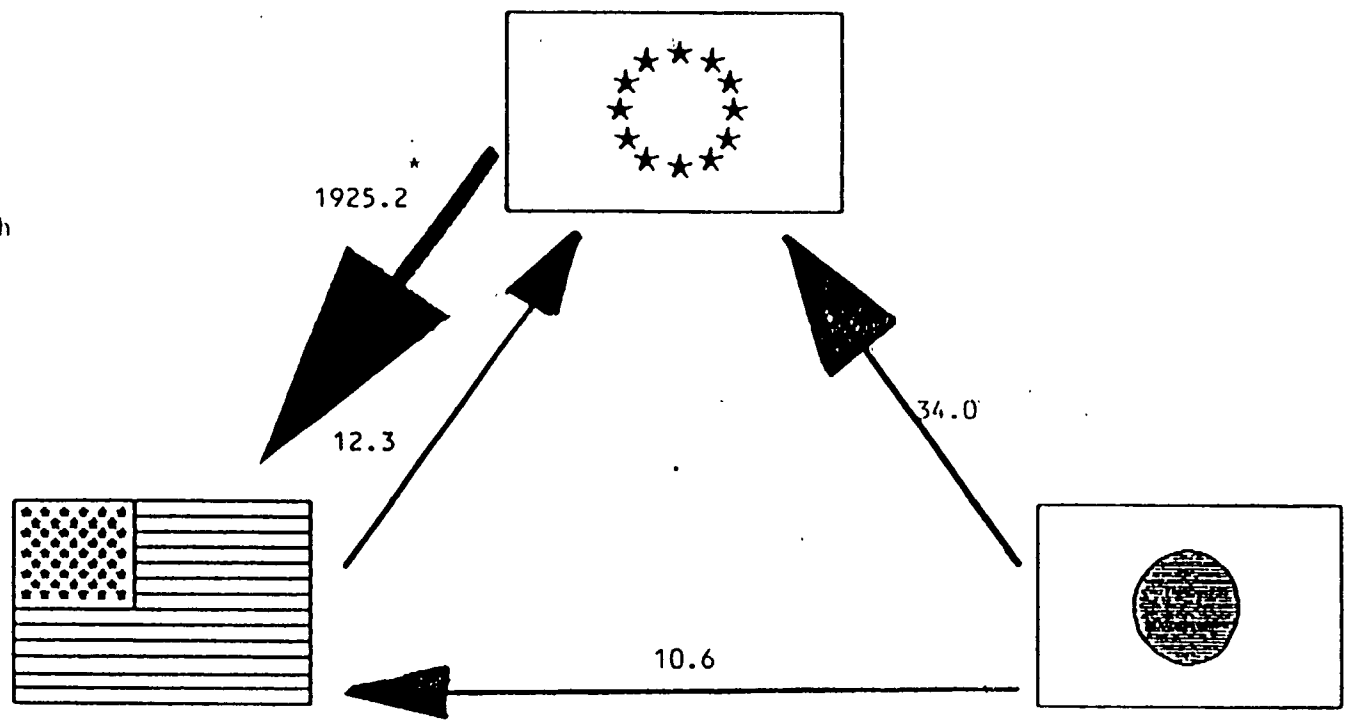
TABLE 1

Source: FAST Report on the European Chemical Industry and Biotechnology, 1990

EC-US-JAPAN

1989 million ECU

COMMERCIAL BIOTECHNOLOGY INVESTMENT ACTIVITY

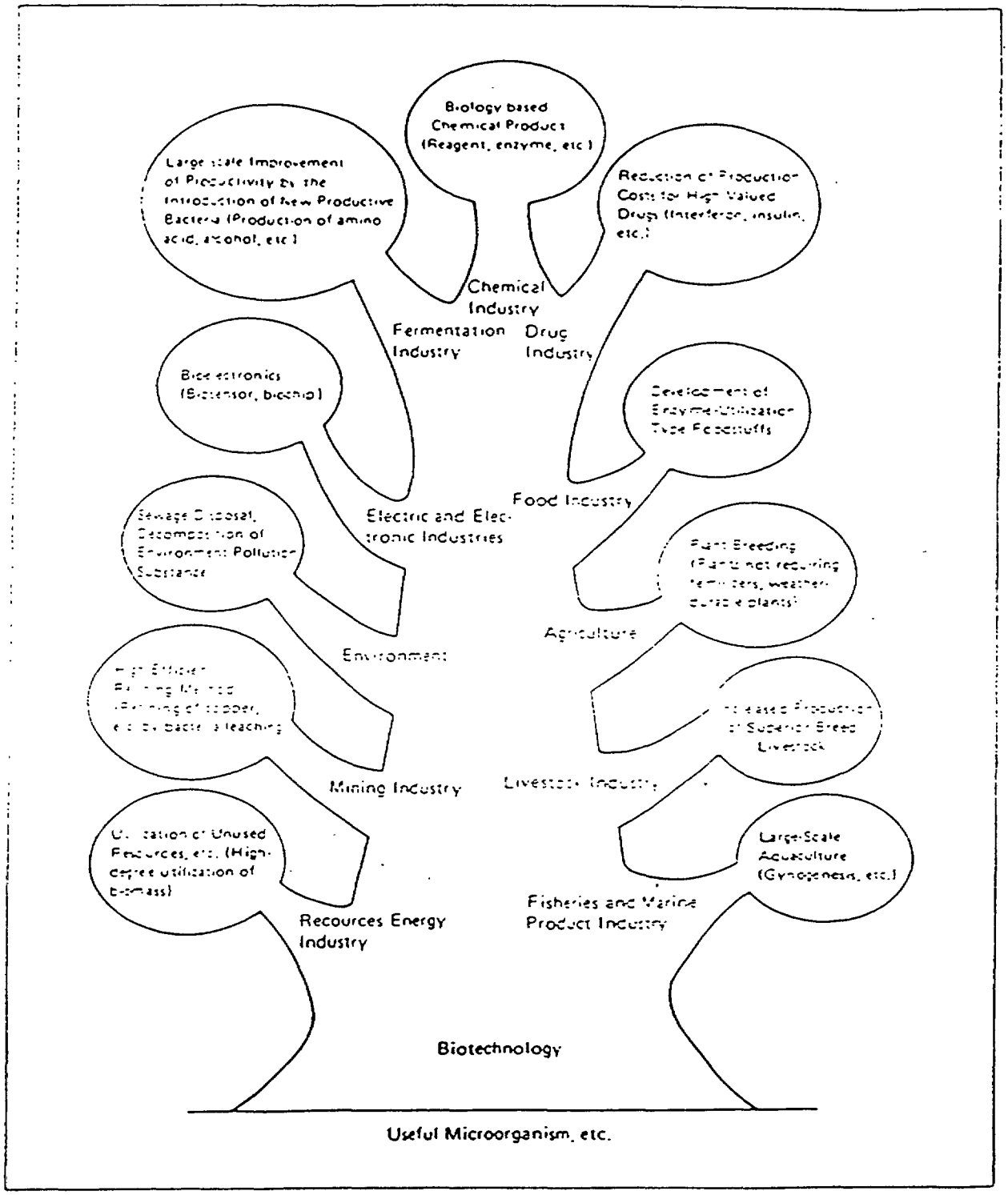


* This includes the Hoffmann-La-Roche purchase of Genentech

Source: Original SAGB compilation via Predicasts (Data-Star)

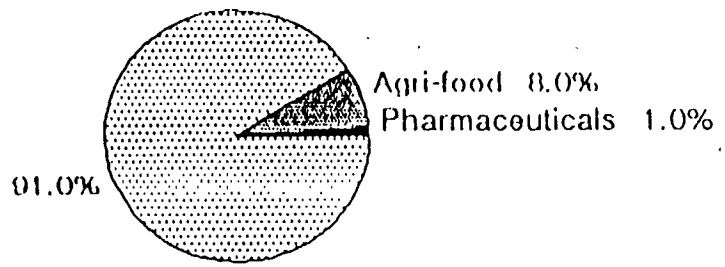
TABLE 2

System Diagram of Biotechnology Application

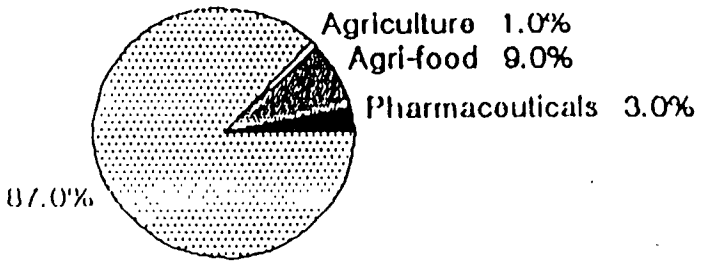


Source: MITI
(from: FAST Report on the European Chemical Industry and Biotechnology, 1990)

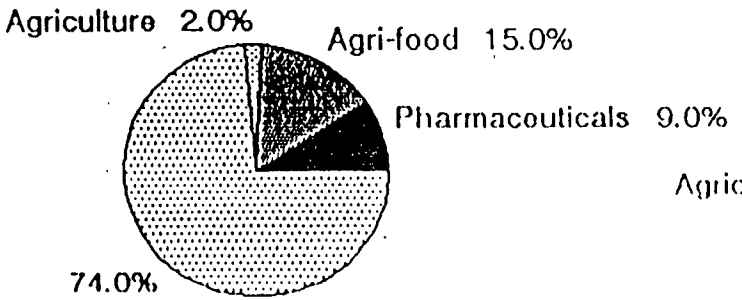
Part of the World market held by Biotechnologically produced products



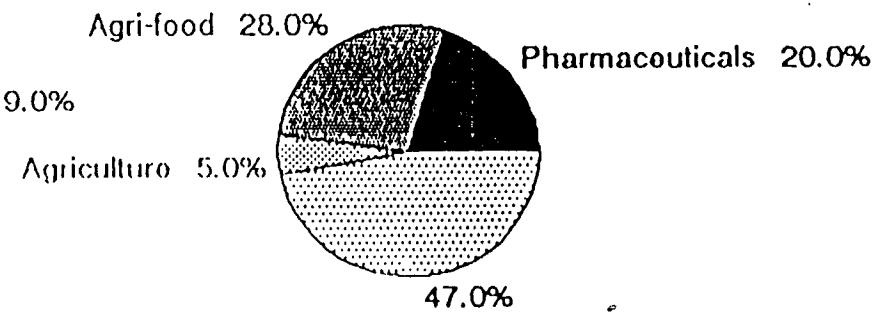
1985



1990



1995



2000

Source: "Atlas: la Puissance Economique"
Hachette, 1990

TABLE 4

PATENT APPLICATIONS IN BIOTECHNOLOGY, 1986-1989

CLASSES LPC	PAYS D'ORIGINE											TOTAL EN NOMBRE DE DEMANDES
	US %	JP %	Etats CEE Total approx. %	Etats CEE (détail)							Autres %	
				GB%	DE%	FR%	BE%	NL%	DK%	IT%	ES%	
A0 1G	15	8	56	10	15	13	1	7	2	8	1	21	118
A01 H	50	17	11	0	0	11	0	0	0	0	0	22	18
A61 K39	40	9	34	6	8	10	2	4	1	1	0	17	268
C12 N	40	20	30	6	11	6	2	2	2	2	0	10	1.517
C12 N15	42	19	29	6	9	6	2	3	2	1	1	10	996
C12 P	31	31	30	5	12	6	1	4	2	2	0	8	616
C12 Q	54	14	24	7,5	10	4	0,5	1	0,5	0,5	0	7	390

Source OEB (Office Européen de Brevets)

A0 1G: fabrication de produits laitiers
A01 H: nouveauté végétale ou procédé pour leur obtention
A61 K: médicaments
C12 N: biotechnologie générale
C12 N15: technique de manipulation en génie génétique
C12 P: procédé de fermentation
C12 Q: procédé de mesure de recherche ou d'analyse faisant intervenir des micro-organismes

PATENT APPLICATIONS (ALL TECHNOLOGICAL SECTORS), FROM U.S., JAPAN, EPO CONTRACTING STATES AND OTHERS

	Source of Application	Year of Filing (Calendar Year)					
		1984	1985	1986	1987	1988	1989
EPO Statistics	EPO Contracting States Resident	18,239 (55.1%)	17,966 (53.2%)	20,013 (54.4%)	24,298 (52.9%)	26,986 (51.6%)	29,302 (50.7%)
	Non-EPO Contracting States Resident	14,853 (44.9%)	15,762 (46.8%)	16,770 (45.6%)	21,662 (47.1%)	25,326 (48.4%)	28,463 (49.3%)
	U.S. Resident	8,833 (26.7%)	8,709 (25.8%)	9,500 (25.8%)	12,206 (26.6%)	13,565 (25.9%)	15,053 (26.1%)
	Japanese Resident	4,845 (14.6%)	5,795 (17.2%)	5,966 (16.2%)	7,177 (15.6%)	9,099 (17.4%)	10,840 (18.8%)
	Other	1,175 (3.6%)	1,278 (3.8%)	1,304 (3.6%)	2,279 (4.9%)	2,662 (5.1%)	2,570 (4.4%)
	TOTAL	33,092	33,748	36,783	45,960	52,312	57,765

TABLE 6

Source: Statistical Report of the Trilateral Cooperation

LES FINANCEMENTS NATIONAUX DE LA R & D EN BIOTECHNOLOGIE POUR L'ANNEE 1987

Pays	Public MECU	Privé MECU	Total (estimations moyennes MECU
Etats-Unis	Fédéral: 2.484 Etats : 54 Total : 2.538	1.360	3.898
Canada	Fédéral: 46 (hors salaires)	94	140
Royaume-Uni	172 à 201	315	500
France	132 à 215	229	401
RFA	157 à 215	372	559
Italie	40 à 63	143	201
IR, NL, DK, B, E, P	130	nd	-
CEE	306	-	-
Japon	229	157 (génie génétique seulement)	entre 573 et 716
Australie	97	140	229

Si ces chiffres ont un sens, c'est-à-dire s'appliquent à des activités comparables dans les différents pays, sur quelque 6.590 MF de R & D publique et privée investis en 1987, 60% l'ont été par l'Amérique du Nord, 28% par l'Europe et 10% par le Japon. A noter que si aux Etats-Unis 65% de l'effort est fourni par les pouvoirs publics, au Japon et en République fédérale allemande, c'est le secteur privé qui en assure l'essentiel.

Source: BIOFUTUR - Mai 1990 - (taux d'échange - avril 91)

STATISTIQUES CONCERNANT LES ACCORDS DE COOPERATION FUSIONS ET ACQUISITIONS DANS LES BIOTECHNOLOGIES

La banque de données du MERIT-CATI utilisée par M. Hagedoorn et M. Schakenraad fournit les statistiques suivantes:

-Statistiques annuelles

	avant 70	70-74	75-79	80	81	82	83	84	85	86	87	88	TOT.
Nombre	2	9	92	59	70	104	71	88	157	152	166	142	1124
%	-	1	8	5	6	9,5	6,5	8	14	14,5	15	12,5	100

Il est possible de distinguer trois périodes:

- Avant 1979, les accords comme les prises de participation étaient peu nombreux.
- De 1980 à 1984, leur nombre s'accroît fortement pour être compris entre 70 et 100 par an.
- De 1985 à 1988, ils augmentent de nouveau pour atteindre un nouveau palier à un niveau moyen de 150.

- *Statistiques par types*

Pour la période 1970-1988, plus les sept premiers mois de l'année 1989, la répartition est la suivante:

	Joint-venture	Vente de technologie	Echange de technologie	Investissement direct	Relation fournisseur-client
%	13,5	15	7	19,5	15

La technologie est donc comme le principal objet des accords et des prises de participation.

-Statistiques par régions

Europe de l'Ouest	Europe de l'Ouest E.U.	E.U.	E.U.- J.	J	J-EUROPE	Autres
18,5	20	35,5	13	5	3	5

Les Etats-Unis apparaissent comme le centre de gravité. Néanmoins, ces statistiques ne tiennent pas compte du nombre d'entreprises par régions ou pays, ce qui peut entraîner un biais.

Par ailleurs, M. R.T. Yuan a diffusé des statistiques concernant les accords entre des sociétés des Etats-Unis et d'autres pays pour la période de 1981- 1er trimestre 1986.

%	Investissement	Recherche	Licence	Distribution	Nombre
Europe	19	31	16	34	227
Japon	13	27	19	41	203

Les accords entre les entreprises américaines et les entreprises européennes semblent relativement plus axés sur l'investissement direct et la recherche-développement que ceux entre les entreprises américaines et japonaises.

Source: Hagedoorn, J. et Schakenraad, J. "Partnerships and Networks in Core Technologies". Communication présentée à la Conférence on "The Economies of Technical Change", Maastricht, 2 November 1989.
Yuan, R.T. "An Overview of Biotechnological Transfer in our International Context" Genetic Engineering News, Mars 1987.

From: FAST Report on the European Chemical Industry and Biotechnology, 1990