COMMISSION OF THE EUROPEAN COMMUNITIES

COM(94) 219 final

Brussels, 01.06.1994

BIOTECHNOLOGY AND THE WHITE PAPER ON GROWTH, COMPETITIVENESS AND EMPLOYMENT

PREPARING THE NEXT STAGE

Communication from the Commission to the Council, the European Parliament and the Economic and Social Committee

CONTENTS

INTRODUCTION

An innovative tool

The White Paper on Growth, Competitiveness and Employment acknowledges modern biotechnology as one of the fields offering the greatest potential for innovation and growth. Its application could be of particular benefit in areas such as healthcare, industrial chemicals, food and feeds, agriculture and environmental clean-up services. Moreover, the further development of biotechnology will require increasing investment in supplies, services and hardware. This would have a correspondingly positive effect on the employment situation.

A Community role

The European Community has been becoming increasingly involved in biotechnology since the mid-1970s. By funding research and developing a regulatory framework, it has sought to promote the competitiveness of bio-industries, whilst also ensuring the safety of man and the environment.
The Commission recognised, in its 1991 initiative, that biotechnology is a key technology for the future competitive development of the Community. As such, it will determine the extent to which Community industries remain world leaders in the development of innovatory products. Although the main responsibility for competitiveness rests with the firms themselves, the Commission also took the view that public authorities could help to stimulate competitiveness by adopting a consistent and supportive approach in relevant areas. This would entail the provision of financial support for basic and applied research and related infrastructure; the drawing up of a coherent regulatory framework, based on a number of defined principles (including protection of intellectual property); a renewed emphasis on education and training; the stimulation of technology transfer; and the facilitation of public understanding and consumer choice. A package of priority measures was subsequently approved.

A new impetus

The White Paper confirmed the outstanding promise of biotechnology in terms of growth, competitiveness and employment.

Taking account of the content and state of implementation of the 1991 package, it gave new impetus to achieving a fuller realisation of the Community's inherent strength in biotechnology and to overcoming existing constraints. Reinforcing conditions at both the R&D and marketing stages of biotechnology would increase its potential for employment creation. By taking a number of specific steps, Europe's competitiveness in this field will be further enhanced.

The present communication represents the Commission's response to the White Paper's recommendations, and its structure has been designed so as to follow the order in which these recommendations were listed. It is based on the premise that the White Paper's goals in relation to biotechnology can be achieved only through close cooperation between operators, users, Community Institutions, Member State authorities and interest groups. The Commission recognises the important interest of the European Parliament in developments in biotechnology and is ready to establish the necessary dialogue on biotechnological issues, in particular with the Parliament. It will also seek, as in the past, to organise round-table discussions.

REGULATORY FRAMEWORK

Introduction

Biotechnology involves the use of modern genetic engineering, which will affect many different products and processes. The Community's regulatory framework for biotechnology was designed, in the late 1980s, in order to provide the necessary legislation to ensure adequate protection of health and the environment, while at the same time creating the internal market for biotechnological products. It is based on a number of principles, adopted in 1991[1)], which still retain their validity (see Annex 1 for details).

The Community is putting into place both "horizontal" and product legislation containing a specific environmental risk assessment of products containing or consisting of GMOs. (An overview of the state of play regarding current legislative activities is attached at Annex 1.)

This framework has been built upon the knowledge available at that time, when there was still considerable uncertainty as to safety and the risks involved in the application of modern biotechnology. The Community adopted legislation aiming at a broadly preventative approach as regards the use of modern biotechnology.

The White Paper concluded that the Community should be open to reviewing its biotechnology regulatory framework, in order that the full potential of modern biotechnology for jobs, investment and growth can be realised.

Following this commitment, the Commission, in consultation with Member State authorities, undertook such a review. Its objective was to ensure that the safety requirements and administrative procedures are appropriate to the risks for human health and the environment and reflect acquired experience, advances in scientific knowledge and established international practices. It also took account of the existing regulatory frameworks on modern biotechnology used by its main competitors, in particular the United States.

The way ahead

In carrying out the review, the Commission paid special attention to the wider range of knowledge and experience currently available, which has increased understanding of the risks associated with genetic modifications and increased confidence among scientists in the safety of genetic engineering.

Much use has now been made of the technology in research laboratories and industrial facilities worldwide. From this knowledge and experience, it may be concluded that the risks involved in the contained use of GMMs are substantially less than were once foreseen. For example, the potential for horizontal gene transfer resulting in novel and harmful properties being acquired by microorganisms has not

1) SEC (91) 629

been shown to present hazards to human health and the environment. There is a growing confidence that the GMMs used in research and in industrial production can be more precisely categorised, so that they are unable to survive except in the special environment of the experiment or process in which they are used. Experience has shown that the majority of genetic modifications in contained facilities can be done safely by applying good laboratory practice.

Worldwide, there have now been many deliberate releases of GMOs, mainly with a number of well-known crop plants. This has led to an improved understanding of the behaviour of these plants and their safety in respect of human health and the environment. So far, such releases have not given cause for concern, and evidence is accumulating to the effect that genetically modified plants do not differ from non-modified plants other than in the specific character conferred by the introduced gene.

As part of its broader reflections, the Commission acknowledged that the biotechnological regulatory framework is a factor impacting on industrial competitiveness, which confirms the need for balanced and proportionate regulatory requirements commensurate with the identified risks.

It also noted the results of surveys indicating the important role that the regulatory framework has to play in building public confidence in biotechnology. This shows the need for a predictable and adaptable regulatory system.

Taking these elements into account, the Commission confirms its earlier view that, in the future, the whole network of interrelated biotechnological regulations needs to ensure that oversight is always appropriate in relation to the risks involved, the building of public confidence and to the competitive development of the industries involved, while guaranteeing the protection of human health and the environment. On this basis, the Commission is of the opinion that the following two-track approach for the future development of the biotechnological regulatory framework should be applied:

- the exploitation of existing possibilities for revising measures/procedures/degree of oversight/requirements, through use of the "light" procedure of adaptation to technical progress (regulatory Committee procedure). (internal amendment)

- the bringing forward of amendments to existing legislation in order to incorporate changes which cannot be achieved by technical adaptation while leaving the basic structure of the framework intact (external amendment)

* *
*

The Commission examined the application of the two-track approach in greater detail for specific parts of the regulatory framework, considering each such part on its particular merits. It came to the conclusions outlined below.

Directive 90/219/EEC on the contained use of genetically-modified microorganisms

The review indicated that extensive use was made during the late 1970s and the 1980s of genetically-modified microorganisms in laboratories and industrial fermenters, from which substantial experience was gained. This experience, together with the recommendations made by the OECD, forms the scientific basis of the Directive.
The Commission identified, on the basis of the substantially increased understanding of the risks associated with the use of GMMs in contained circumstances, as mentioned above, the following objectives for further action:

i) streamlining and easing of the administrative/notification/ consent requirements where this does not compromise safety;

ii) ensuring that the classification of the genetically modified micro-organisms and of the activities in which they are used are appropriate to the risks involved;

iii) ensuring that the conditions of use are appropriate to the risks involved;

iv) extension of the flexibility of the Directive so it can be more easily adapted to technical progress by regulatory Committee procedures.

In line with these objectives, this will mean that it will continue to make full use of the inherent flexibility of the Directive (regulatory Committee procedure), i.e. by:

- preparing a Decision redefining the risk categories of GMMs through the revision of Annex II;

- revising the guidelines for classification as established under Article 4.2 of the Directive as a result of the discussion undertaken for amending the criteria of Annex II (see above);

- further exploiting the possibilities to adapt safety assessment parameters, containment measures and required information for technical progress.

The increased knowledge and experience mentioned above also gives a clearer indication of the present administrative (notification) consent requirements necessary to ensure safety for the different risk categories of GMMs.

Taking into account the most up to date information, it may be concluded that the existing administrative arrangements may be lightened for activities presenting low risk to human health and the environment, without jeopardising existing safety standards. This would also allow a greater focusing of attention on higher risk

possibilities. However, as the Directive does not provide for such adaptations, a number of specific amendments must be introduced, as follows:

- replacing the consent requirements by record-keeping, or notification for information purposes, for certain low-risk activities;

- replacing the explicit consent requirements by implicit consent for certain higher-risk activities;

- reduction of time periods involved in implicit/explicit consent procedures;
- adapting the present risk classification system for GMMs, in accordance with new safety considerations.

- removal of the differentiation between activities in research laboratories and production plants.

The Commission will propose the possibility of adapting the definitions contained within the scope of the Directive via a Committee procedure, as is, for example, at present foreseen in the case of pharmaceutical legislation.

The Commission will conduct the necessary broad consultations with operators, users, Member State authorities and interest groups in order to propose amendments before the European Council to be held in Essen by the end of 1994.

Directive 90/220/EEC on the deliberate release of genetically modified organisms to the environment

The Commission has made a number of technical adaptations to the Directive to reflect the evidence acquired from the wide number of GMO releases in the plant area, which were shown not to pose any specific risks. These measures seek to improve uniform application, streamline and simplify the procedures and reduce the obligations on the notifiers while maintaining the appropriate protection of health and the environment. These activities are the following :

- A Commission Decision revising the notification information requirements of Annex II of the Directive, reducing them significantly for releases of plants (95% of releases) (April 94).

- A Commission Decision revising the Summary Notification Information format reducing the information required for plants (April 94).

- A Commission Decision establishing criteria for introducing simplified procedures under Article 6.5 (Oct. 93) for genetically modified plants.

- Preparation of a Commission Decision introducing specific simplified procedures for releases of plants (to be adopted by June/July 94).

The Commission concluded, on the basis of the progress made in adapting aspects of the Directive, that it is flexible enough to satisfy current needs for adaptation to technical progress and simplification of procedures. In the short term, it will fully exploit the existing possibilities in this area.

Biotechnology is a fast-moving and continually evolving technology, and the Commission recognises that there are aspects of the Directive that might be improved. It is not, however, possible at present to detail the precise nature of these improvements, as further experience is necessary in order to determine the right balance between the need for safety, public reassurance and the minimum restraint on industry and research work.

Hence, on the basis of future experience and scientific knowledge, the Commission will carry out a further review of the Directive during the first half of 1995. This review will assess the need for proposals in relation to:

- extending the flexibility of Directive 90/220/EEC, so that its scope and the procedures to be followed are always appropriate to the risks involved, and are easily adaptable;

- strengthening more uniform decision-taking between Member States in the case of research and development releases;

- introducing further opportunities for notifiers (industry and researchers), so that they can benefit more from the existence of a uniform Community system;

- facilitating the link between this Directive and product legislation.

Other legislation

The Commission has noted that, to date, one specific piece of product legislation, namely for medicinal products of biotechnology, is in force. As from 1 January 1995, this will be replaced by a centralised procedure which will result in a Community-wide marketing authorisation. This new piece of legislation is the result of a streamlining of existing marketing authorisation procedures so that patients can benefit from new innovative medicinal products simultaneously in all Member States, while at the same time safeguarding maximum standards of public health.

In respect of other product-based regulations which contain or will contain an environmental risk assessment similar to that in Directive 90/220/EEC, one other such piece of legislation (namely, additives in feeding stuffs) has been adopted - which will enter into effect as from 1 October 1994 - and a further two (on novel foods and seeds) are under discussion before the other institutions. The rapid adoption by the Council of this legislation, as an essential part of the overall framework, is seen as a matter of urgency. The Commission will continue to make efforts to arrive at this and to ensure its proper implementation, by drawing upon experience and knowledge already available.

It will, as a matter of urgency, make a proposal for an amendment to Council Directive 91/414/EEC on the placing of plant protection products on the market in order to complete the environmental risk assessment, already provided for in the Directive, with the technical complements which are necessary to cover adequately plant protection products containing or consisting of GMMs. A fast track procedure for certain low risk plant protection products, including biological plant protection products, whether derived from GMMs or not, will also be proposed.

In relation to the legislation to protect workers from the risks related to exposure to biological agents at work, the Commission will press Member States for a more rapid transposition.

The review again demonstrated the need for adequate patent protection for inventions, as an important condition for attracting investments in biotechnology. The Commission re-emphasises therefore that Community legislation, which has been under discussion since 1988 and 1990 respectively, in the area of intellectual property (patents for biotechnology inventions and plant variety rights) should be adopted as a matter of urgency. By doing so, an important gap in the regulatory framework will be closed.

The same applies to the draft modification of the seed marketing directives aiming at integrating the environmental risk assessment in the established variety acceptance procedure.

The Commission will seize opportunities - as is foreseen, at the end of 1997, for example, in the legislation for medicinal products - as regards further simplification and/or streamlining of procedures of the biotechnology regulatory framework as part of its general policy in this area as stated in the White Paper. An ongoing review of the biotechnological regulatory framework shall be carried out as new scientific knowledge and the emerging regulatory practice of major international competitors indicates that this is necessary or desirable.

STRENGTHENING OF SCIENTIFIC ADVICE

The White Paper recognised the importance of scientific advice available to the Commission, which is particularly relevant in the field of biotechnology with applications in a broad range of areas. At present, it is therefore assessing whether there is a need for reinforced scientific input to regulations, for example, in view of an appropriate implementation of product legislation containing a specific environmental risk assessment for products consisting of or derived from GMOs. This assessment will also take account of the work of existing advisory scientific committees at Community level and that carried out by a number of national advisory Committees on biosafety or genetic modification providing advice at national level. A meeting will be organised between the Commission and the chairpersons of these scientific committees to share experiences and to identify whether there are further needs in the area. A European Science and Technology Assembly is being set up to assist the Commission in the conception and implementation of all Community research and technological development policies, including those relating to biotechnology. This will further strengthen the links between the Commission and the research world.

RESEARCH AND DEVELOPMENT

One of the greatest resources for the European biotechnology industry is ready access to a well-established science base and a highly-skilled workforce. A recent survey of some 400 new biotechnology companies indicated that, generally speaking, they have grown up around areas of academic excellence. This vital resource of innovation and skills, much of it funded by governments, is also readily available to Europe's large pharmaceutical and chemical companies, either via strategic partnerships or directly-funded research. Experience, however, has shown that, despite this, Member States need to give greater recognition to the importance of the science base for biotechnology, as has been done elsewhere. Furthermore, increased coordination is needed between and within Member States' research programmes to minimise wasteful duplication and to maximise collaboration, with the aim of improving the efficiency of R&D expenditure.

Community initiatives

To these ends, the Commission has recently proposed considerably expanded research programmes activity within the area of Life Sciences and Technologies: biotechnology (552 MECU), biomedecine and health (336 MECU) and agriculture and fisheries (684 MECU) under the Fourth Framework Programme. This total proposed expenditure of 1572 MECU signifies an increase in budget of 741 MECU in comparison to the relevant programmes as included in the third Framework Programme.
The Commission realises that the European Union as a whole is not matching research and development expenditure made elsewhere. However, it is compensating for this by focusing on the most vigorous R&D areas and on increasing coordination between the Member States' and the Community's research programmes.

To improve these aspects, the three Specific Programmes in the Life Sciences and Technologies area propose three mechanisms:

- Areas offering the highest potential returns on R&D in the short to medium term will receive special priority for funding (concentrated financial support). This will often involve a multi-disciplinary and integrated approach.

- Areas which are strategically important, but where limited financial support is available, will be supported by the establishment of networks aimed at coordinating and building upon Member States' research programmes.

- Areas which are essential to the exploitation of the life sciences, but which may require special attention in respect of other factors such as socio-economic or ethical issues, will be addressed by horizontal activities. These will involve the key players and users in dialogue aimed at socially acceptable solutions and a well-informed public.

By the rapid adoption of the three specific programmes and through the implementation of the above mentioned mechanisms, the Commission expects to achieve a fuller realisation of the Community's inherent potential in biotechnology R&D.

BIOTECHNOLOGY AND SMES

As shown by previous major technological advances, small and medium sized enterprises play a vital role in the early stages of technological innovation and diffusion. This sector is growing, and a number of important firms have been established. In terms of numerical importance, SMEs specialising in modern biotechnology are located in the UK, France, the Netherlands, Denmark and Germany, and focus primarily on the therapeutic and diagnostic fields of research and production.

Community support

A recognition of the important role of small and medium sized enterprises has led many Member States to encourage the development of the SME sector. Building on this, the White Paper has set out guidelines for an integrated programme, whose focus is on three major themes: improving access to finance and credit facilities, support for cooperation between firms and support for improvements in management quality.

These objectives respond in large measure to the needs of the small and medium sized biotechnology enterprises. Like other SMEs, these firms face difficulties in accessing private sector sources of funds, whether from financial intermediaries, equity market or venture capital. Small and medium sized biotechnology firms have a particular need for industrial and financial partners when starting up.

Other specific characteristics of biotechnology SMEs are the need for and availability of high-tech scientific input and the need to overcome hurdles quickly in bringing inventions and innovations onto the market. In view of this, the Fourth Framework R&D Programme opens up opportunities:

- for facilitating the participation of SMEs, irrespective of their RTD capability, in Community R&D programmes, via the implementation of a special procedure based on the experience of CRAFT activities;

- for encouraging the establishment of industrial platforms. These consist of groups of European companies associated with specific projects under the Community research programmes, with preferential access to their results;

- for demonstrations. The application of the innovative results of research in the life sciences area will be addressed through well targeted and pre-competitive demonstration activities. This will enhance the attractiveness of new biotechnology applications;

- for helping SMEs to find suitable partners to carry forward innovative applications of biotechnology and to establish trans-national networks for technology transfer.

Science parks

The characteristics that biotechnology SMEs share with other science-based SMEs underlie the emergence of science parks at the combined initiative of the SMEs themselves and universities, in collaboration with local and regional authorities. Up to one-third of biotechnology SMEs in the Community are located in science parks. With the steady entry of new biotechnology firms, some 59 of the 250 science parks in the Community now contain an important biotechnology component.

Science parks facilitate the process of technology innovation and diffusion and offer a number of advantages for SMEs. For example, they provide easy and close access to science facilities, which enables the SME to have a "window on the technology" and to be informed on the most up-to-date developments. The costs involved in seeking venture or investment capital partners are considerably reduced for firms and investors alike; sourcing of intermediates and laboratory materials is facilitated; and labour mobility can be encouraged between academic work and research applications.
This evident trend of growth, in the Community, of science parks with a biotechnology component, mirrors a development already witnessed in the USA in the past decade, where, by 1992, there were 81 dedicated biotechnology centres, with some 730 firms, specialising primarily in applied research.

Under the Programme for Innovation and Technology Transfer, SPRINT 1989/93 (Council decision 89/286/EEC), modest Community funding was envisaged to support feasibility studies and expert assistance in creating science parks that serve a market need and that are able to attract firms. Presently the Commission is, following the recommendations of the Communication on Cohesion and RTD Policy , undertaking a study to evaluate the need to create networks, the type of network most conducive to the optimal functioning of science parks and collaboration between Technology Parks within the European Union. This would allow a fuller exploitation of opportunities for increased cooperation between firms operating on the internal market, and hence would contribute to realising the objectives of the integrated programme for SMEs.

THE INVESTMENT CLIMATE

The importance of the investment climate to the transfer of applied research and product development to the commercialisation stage is fully recognised. In general, the allocative mechanism in market economies is efficient in shifting investment flows and factors towards sectors experiencing, or likely to experience, high growth, as with certain areas of application of biotechnology.

While, in a number of products derived from modern biotechnology, market-driven growth is evident, there are others of major long-term potential such as bioremediation products and new ranges of biosensors, where growth is variable or modest. The result is that medicinal products of biotechnology is the target domain of over 60% of the current modern biotechnology firms, while bioremediation product development occupies less than 5% of the existing firms. Investment incentives in particular by Member States, within the existing Community framework, to improve the investment climate in these areas are recommended. This would cover support for R&D activities, or the start-up or expansion of business activities, together with the establishment of sound technological clusters and a business-friendly tax climate. In doing so, Member States would strengthen Europe's competitiveness in high-value added future growth markets. For its part, the Community will, through the implementation of a newly-proposed specific programme on the diffusion and exploitation of R&D results (involving expenditure of 293 MECUs), help to overcome barriers preventing the conversion of scientific achievements into commercial successes.

PUBLIC UNDERSTANDING

The introduction of any new technology, whether in the past or at present, has raised critical reactions from the general public. This is especially true of biotechnology, as it raises value-laden issues. Surveys indicate that understanding of biotechnology varies widely within the Community, as does the perception of the risks and benefits of different applications.
The Commission has helped to bring about a number of initiatives to raise public awareness, although it recognises that other public and private bodies have primary responsibility in this area. The focus for the Community's activities has been the Life Sciences and Technologies Research Programmes. The following actions will be reinforced:

- analytical work concerning public attitudes, including the Eurobarometer surveys. This is necessary in order to understand the scale of the problem and the factors which lie behind it. Such work will guide future awareness activities to be undertaken by the Commission, Member State governments and other interested parties from the public and private sectors.

- raising awareness among the main players. Building upon the experience of analytical work, increased information will be provided in a balanced and impartial way to raise awareness in industries where the commercial potential of the emerging technology may not be well understood; in the public sector, including government institutions, where policies and strategies are developed; among the media communicating biotechnology to the public; among scientists increasing public understanding of science; and public interest groups and educators.

- raising awareness and providing information to the general public. A European Initiative in Biotechnology Education has been launched and will be reinforced to provide teaching materials and expertise to school teachers throughout the European Union. Other specialised materials will be prepared and workshops, conferences and meetings will be held to encourage dialogue and to aid openness.

The Commission recognises that modern biotechnology comprises many varying applications. In view of this, it is important that all parties concerned develop reliable information on all aspects of these applications, especially as regards their potential benefits and risks. This involves illustrating innovative advantages as well as addressing issues such as safety, ethics and environmental protection. It would, however, like to stress that, ultimately, it is the market place which decides the successful commercialisation of individual biotechnological applications.

ETHICS

General

Developments in biotechnology may raise questions of an ethical nature in certain areas. There is concern about tampering with nature and life, and the White Paper stressed the need to ensure that these questions are addressed and identified properly. In response to this, the Commission has reinforced the profile of the Group of Advisers on the Ethical Implications of Biotechnology, thereby building on the results achieved during the first two year term of the Group.

This group, established in 1991, is concerned with:

- the identification and definition of ethical issues raised by biotechnology;
- the appraisal of the ethical aspects of Community activities in the field of biotechnology, and their potential impact on society and the individual;

- and advising the Commission as regards the ethical aspects of biotechnology, with a view to improving public understanding.

So far, the group has given three opinions on the ethical implications of the use of performance enhancers in agriculture and fisheries, of medical products derived from human blood and plasma, and of legal protection of biotechnological inventions. These opinions have greatly assisted the Commission in formulating its policy in these areas.

The Group's mandate has been renewed recently to increase the number of advisers, and hence to make available a broader range of advice. It consists of independent leading experts from several different branches of science. It is the Group's intention to step up its contacts with the general public and international organisations. At the same time, it has also intensified its work programme and its Secretariat has been reinforced. At present, opinions are under preparation on the ethical aspects related to transgenic animals, gene-therapy and pre-natal diagnosis, all of which will be finalised before the end of this year. Because of its terms of reference, the Group has a unique place in the European Union. It is closely involved, in a consultative capacity, in the elaboration of relevant Community policy, but is completely independent. It is also able, at its own initiative, to examine any topic touching on biotechnology.

Several activities such as workshops and seminars on legal and ethical aspects related to biotechnological and biomedical research including their application in the agricultural sector are proposed under the Fourth Framework Programme. These activities are related to more general issues concerning biotechnology (patents, biodiversity, animal models) and the application of classical rules of medical ethics (informed consent, confidentiality, ethical review of research protocols) to new fields of biomedecine like brain research, gene therapy and neurotransplantation.

Biomedical ethics

In the past, the Commission has taken a number of initiatives to clarify ethical issues in relation to biomedical and health research. For example, the human embryo and research (HER) working group has monitored the legal and practical aspects of research on human embryos in the Member States and identified sectors where a consensus could be reached. Two reports, on embryos before and after implantation, have been published, and the state of legislation on embryo research was reviewed. Protection of embryos and specific issues like pre-implantation diagnosis will be the next tasks of this working group.

Moreover, the ESLA (Ethical, Social and Legal Aspects) working group under the human genome analysis research programme, has encouraged public discussion and made recommendations to the Commission on the legal or other initiatives to be taken in this field.

Research in all areas of biomedical ethics has been initiated under the first Biomedical and Health research programme, and the Commission has proposed to continue this under the new second specific Biomedical and Health research programme. To this end, it intends to organise working groups to prepare reports and surveys for the European Parliament and Council of Ministers on relevant biomedical ethical issues. Targeted workshops are to be held to identify and debate issues requiring clarification and debate at an international level.

International

An increasing number of international organisations have undertaken initiatives to clarify the ethical issues related to the different kind of applications of biotechnology. In this respect the Commission attaches importance to the work of the Council of Europe towards the preparation of a Convention on Bioethics. The Commission is preparing a Communication to the Council on its participation in this Convention.

CONCLUSIONS

The Commission considers that the application of modern biotechnology will have a major impact on the development of a wide range of sectors. Whilst naturally committed to guaranteeing maximum standards of safety for man and the environment, it is of the opinion that, by taking a number of specific steps, as a follow-up to the White Paper's recommendations, it will encourage the competitiveness of Europe's bioindustries. It counts upon the other Institutions, Member States and interest groups to give force to these measures. The Commission recognises the important interest of the European Parliament in developments in biotechnology and is ready to establish the necessary dialogue on biotechnological issues, in particular with the Parliament. It will also seek, as in the past, to organise round-table discussions.

Taking account of the considerations outlined above, it has decided upon the following:

- to implement a two-track approach as regards the future development of the biotechnological regulatory framework i.e. to exploit fully, where they exist, the inherent possibilities to adapt to technical progress (via regulatory Committee procedure). At the same time, it will bring forward amendments in order to incorporate changes which cannot be achieved by technical adaptation while leaving the basic structure of the framework intact. In line with this approach it will, as regards :

    . directive 90/219/EEC on the contained use of GMMs, continue to review Annexes II to V and conduct the necessary broad consultations with operators, users, Member State authorities and interest groups, in order to propose amendments in the indicated areas before the European Council at Essen so that the wide ranging available knowledge and experience is incorporated in that directive. By doing so, its functioning will be improved without jeopardising existing safety standards.

    . directive 90/220/EEC on the deliberate release of GMOs, make full use of the possibilities to adapt to progress and in particular to simplify procedures. On the basis of ongoing

experience and scientific and technological developments, in the first half of 1995 an evaluation will take place following the objectives set out, whereby an assessment will be made of the need for bringing forward amendments.

. other parts of the regulatory framework, continue to press for a rapid adoption of the intellectual property protection legislation as well as of product legislation containing an environmental risk assessment similar to that of directive 90/220/EEC. It will ensure adequate implementation of such legislation by preparing guidelines drawing upon already available expertise. The Commission, for its part, will, as a matter of urgency, make a proposal for an amendment to Council Directive 91/414/EEC, in order to complete the environmental risk assessment of plant protection products derived from or consisting of genetically modified microorganisms. A fast track procedure for certain low risk plant protection products, including biological plant protection products, whether derived from GMMs or not, will be proposed.

  The rapid transposition of the workers' protection legislation by the Member States is a matter of urgency.

. An ongoing review of the biotechnological regulatory framework shall be carried out as new scientific knowledge and the emerging regulatory practice of major international competitors indicates that this is necessary or desirable.

- to identify and remedy the needs for strengthening scientific advice at its disposal.

- to enhance the rapid adoption of, in particular, the proposed specific programmes for biotechnology, biomedecine, health and agriculture and fisheries within the Life Sciences and Technologies area. The concentrated financial support for areas offering the highest potential returns on R&D and the establishment of networks to build upon Member States' research programmes are guarantees of further developing Europe's inherent strength in the area;

- to facilitate the development of small biotechnology firms, given their inherent advantages for developing new ideas and products. The Fourth Framework R&D Programme opens up opportunities for facilitating the participation of SMEs and for helping them to carry forward innovative applications of biotechnology, both within and outside science parks. Currently, the Commission is evaluating the need to create networks, and the type of networks most conducive to the optimal functioning of science parks. The continued development of a favourable investment climate, following existing Community guidelines, is also essential;

- to facilitate public understanding of biotechnology through the reinforcement of a number of outlined initiatives;

- to reinforce the profile of the Group of Advisers on the Ethical Implications of Biotechnology in order to clarify further value-laden issues related to biotechnology. Biomedical ethical issues will be similarly identified and debated.

STATE OF PLAY OF THE BIOTECHNOLOGICAL REGULATORY FRAMEWORK

The Community's regulatory framework is composed of both "horizontal" and product legislation (medicinal products, additives used in animal nutrition, plant protection products, novel foods, seeds). Legislation on intellectual property protection also forms part of this framework, which is founded upon the following underlying principles:

- Necessity: the Commission will propose legislation in this area only if it is shown to be necessary by a thorough examination, on a case-by-case basis, of the characteristics inherent in specific biotechnological applications.

- Efficient interaction: biotechnologically-derived products will be subject to only one authorisation and assessment procedure before being placed on the market.

- Evaluation criteria: product evaluation will take place in accordance with the three established criteria of safety, quality and efficacy. The Commission will normally follow scientific advice. In exceptional cases, however, it reserves the right to take a different view in the light of its general obligation to take into account other Community policies and objectives.

- Adaptation to progress: the regulatory framework will be kept up to date with scientific and technical progress. This is of particular importance in a rapidly developing field such as biotechnology.

- Standards: the development and existence of standards may be used to complement legislation, particularly on technical details of good practice and safety procedures.

- International obligations: the Commission will ensure that all decisions in the field of biotechnology will be in conformity with international obligations, in particular with the provisions resulting from the Uruguay Round negotiations.

The state of play regarding relevant legislation is as follows:

A. LEGISLATION ALREADY ADOPTED

- "Horizontal" legislation

Council Directive 90/219/EEC of 23 April 1990[2] which covers any contained use of genetically-modified microorganisms (GMMs), both for research and commercial purposes;

Council Directive 90/220/EEC of 23 April 1990[3] on experimental and marketing-related aspects of genetically-modified organisms (GMOs),

2) OJ No L 117, 8.5.1990, p. 1
3) OJ No L 117, 8.5.1990, p. 15

which covers any R&D release of these organisms into the environment and contains a specific environmental risk assessment for the placing of any product containing or consisting of such organisms onto the market;

Council Directives 90/679/EEC of 31 December 1990[4] and 93/88/EEC of 29 October 1993[5], which provide a minimum requirement designed to guarantee a better standard of safety and health as regards the protection of workers from the risks of exposure to biological agents.

Member States have transposed or are at the final stages of transposing Directives 90/219/EEC and 90/220/EEC, and competent authorities have been appointed in all Member States. Legislation has yet to be adopted in Greece and Luxembourg, and has nearly been completed in Spain. In Ireland, the specific regulations putting into effect the framework enabling legislation have still to be adopted. Over 250 research and development releases have been notified under Directive 90/220/EEC to the Commission and have taken place, the vast majority of which concerned plants. These releases were in Belgium (60), Denmark (11), Germany (10), Spain (8), France (78), Italy (18), the Netherlands (32), Portugal (4) and the United Kingdom (35).

Three products have so far been cleared under the 90/220/EEC system.

As regards Directives 90/679/EEC and 93/88/EEC, the transposition has yet to be widely realised.

- Product legislation

In respect of the other main part of the regulatory framework, namely, specific product legislation, the situation is as follows:

Council Directive 93/114/EC, amending Directive 70/524/EEC on additives in feeding stuffs. This amendment introduced new categories of additives, including, among others, additives containing or consisting of GMOs into the existing legislation: the amendment will enter into effect as of 1 October 1994[6];

Council Directive 93/41/EEC, repealing Directive 87/22/EEC on the the approximation of national measures relating to the placing on the market of high-technology medicinal products, particularly those derived from biotechnology: the legislation will enter into effect as of 1 January 1995[7]. Under the 1987 procedure about 50 medicinal products of biotechnology have been approved ;

Proposal for a Directive to amend Directive 91/414/EEC[8] on the placing on the market of plant protection products: this Directive provides for a specific procedure for evaluating the environmental risk of GMM plant protection products to be included in the Directive. The Commission is preparing a Proposal to that end.
The Commission has proposed to the Council to extend, for the lifetime of the milk quotas, the present moratorium on the placing on the market

4) OJ No L 374, 31.12.1990, p. 1
5) OJ No L 268, 29.10.1993, p. 71
6) OJ No L 334, 31.12.1993, p. 24
7) OJ No L 214, 24.8.1993, p. 40
8) OJ No L 230, 19.8.1991, p. 1

and administration of bovine somatotropin (BST). The Council has adopted a Decision extending the moratorium for one year, to allow time for a detailed examination of all of the available information on BST[9].

B. PROPOSALS NOT YET ADOPTED

Proposal for a Council Regulation concerning novel foods and novel foods ingredients[10];

Proposal to modify existing seed marketing directives, and in particular Directives 70/457/EEC and 70/458/EEC on the acceptance of varieties[11];

Draft Council Directive on Legal Protection of Biotechnological Inventions[12];

Draft Council Regulation on Community Plant Variety Rights[13].

9) OJ No L 332, 31.12.93, p. 72
10) COM (92) 295 and COM (93) 631 Final
11) COM (93) 598
12) OJ No C 10, 13.1.1989, p.3 and COM(92) 589 final
13) COM(90) 347 and COM(93) 104