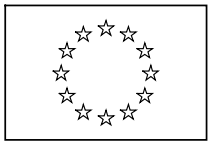

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMUNICATION FROM THE COMMISSION TO THE EUROPEAN PARLIAMENT, TO THE COUNCIL AND TO THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE

LIFE SCIENCES AND BIOTECHNOLOGY –A STRATEGY FOR EUROPE PROGRESS REPORT AND FUTURE ORIENTATIONS

{ SEC (2003) 248 }

EXECUTIVE SUMMARY

In January 2002, the Commission adopted a Strategy for Europe on Life Sciences and Biotechnology, consisting of two parts –policy orientations and a 30 point plan to transform policy into action.

The Commission intends to report regularly on the progress made. This report is the first such response. It sets out what has been achieved in policy development and on the ground, and anticipates emerging issues. Where further action is needed, this report contains future orientations, makes appropriate recommendations or announces new initiatives.

This Communication highlights a number of core issues which are fundamental to the success of the Action Plan. It is supported by a Commission Staff Working Paper which sets out both short and medium term actions to bring these about, as well as a more precise timetable for delivery by the Commission.

With this Communication, the Commission is responding to the request from the Barcelona European Council to report on progress in advance of the 2003 Spring European Council.

The Commission strategy on Life sciences and Biotechnology has been regarded as a major initiative and as an achievement ……

The European Institutions have supported the integrated approach proposed by the Commission as the way to work towards the Lisbon objective of promoting this high-technology area because of its potential to create growth and new jobs and benefit a wide range of sectors, while at the same time contributing to our broader goals, such as sustainable development. On 26 November, the Competitiveness Council adopted conclusions, which included a roadmap for Member States (and the Commission) identifying priority actions, responsibility and timetable for implementation. Together with the action plan these conclusions have established a sound framework for developing biotechnology policy Europe-wide on a collaborative basis. On 21 November, the *European Parliament* gave a strongly positive signal in support of the development of biotechnology in Europe when it adopted, by a large majority, a resolution endorsing the Commission's biotechnology strategy.

Member States and the regions, academia and the private sectors are already identifying measures and contributing to its implementation in many areas. This strategy presents an integrated policy in this area at European Union level, covering both the promotion of biotechnology development and the responsible governance of this process.

In line with the timetable set out in the Action Plan, the Commission has moved forward on a wide range of specific actions within its own jurisdiction and has supported various independent actions undertaken by the regions, academia and industrial organisations alike. In some Member States a number of measures are already in place which tie in with the Biotechnology Strategy. Although the implementation of the strategy is still at an early stage, a certain amount of progress has been made. A notable achievement has been the adoption of the 6th Framework Programme for Research & Technological Development (FP6), which will continue to *underpin* basic scientific research and help to build a European research system. Considerable progress has been made on the regulatory framework for GMOs.

……but progress in some crucial areas needs to accelerate

In some areas, including areas which might seriously risk impeding the long-term success of biotechnology in the Union, and might also have global repercussions, the picture is more mixed and is already giving cause for concern. These are the need for more research and financial resources, the need to complete the system of Intellectual Property protection and the delay in the areas of GMOs. These shortcomings have direct consequences in a number of areas, namely in innovation, competitiveness and research in European biotechnology, and in trade.

European biotechnology lags behind the US in terms of patents and collaborative R&D projects and this principal competitor of ours has a dominant lead in innovative activities, while a rapid decline in GMO field research has been reported in the EU over the last four years. This raises the risk of failing to meet the objective of the Lisbon process in the area of life sciences and biotechnology. Decisive action is now needed in a number of areas identified in this report.

Like any scientific progress, the rapid advances in life sciences create high expectations for curing diseases and improving quality of life while at the same time raising concern as to their ethical and social consequences. Public authorities at large have to take into consideration concerns about the conditions under which fundamental choices are made in this field. For its part, the Commission is committed to ensuring that the ethical, legal, social and wider cultural aspects, as well as the different underlying ways of thinking, are taken into account at the earliest possible stage in Community –funded research. In particular, the issues of *human cloning* and *human embryonic stem cell research* have provoked intense public and political debate. Ethical and social debate must continue to be a natural part of the research and development process involving society as much as possible.

Finally, there is a need for a joint effort to broaden understanding on biotechnology at international level. To this end, a multilateral consultative forum, in which a broad-spectrum dialogue on biotechnology can be engaged, will be considered.

There continues to be a need for commitments and actions from all private and public stakeholders involved in the Strategy

With the Strategy, the Commission committed itself to improving the coherence of policies and actions in order to encourage an integrated approach towards all applications of life sciences and biotechnology. The Commission is ready to continue to deliver on these commitments.

But the Commission is only one of several stakeholders in the field. Many of the proposed actions are substantially or wholly within the scope of Member States or private stakeholders. The strategy can only be successful if it is accompanied by additional activities in the individual Member States, by their setting and implementing, for example, national biotechnology strategies. The Commission, for its part, is ready to continue to play its role of facilitator and contribute to work undertaken by others with the specific task of ensuring a coherent European framework.

A clear and consistent policy within the Member States on biotechnology is crucial. Experience has shown that divergent and uncoordinated actions seriously risk reducing the impact, effectiveness and coherence of the EU strategy in this field. Attention should be drawn to the apparent inconsistency of, on the one hand, the conclusions of the Lisbon,

Stockholm, Barcelona and Seville Summits setting the objective of becoming a leading knowledge-based economy, promoting the full potential of biotechnology and calling for more competitiveness in Europe's biotech sector. On the other hand, there has not always been the same clear signal when these statements are translated into binding rules and commitments.

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1. INTRODUCTION

In January 2002, the Commission adopted a Strategy for Europe on Life Sciences and Biotechnology.[1] This was in response to the importance attached to life sciences by the European Council. It proposes a comprehensive roadmap up to 2010 and puts the sector at the forefront of those frontier technologies which are helping to take the European Union towards its long-term strategic goal established by the Lisbon European Council in March 2000 of becoming "*the most competitive and dynamic, knowledge-based economy in the world, capable of sustainable growth with more and better jobs…"* within a decade.

This strategy set by the Commission consisted of two parts – policy orientations and a 30 point plan to transform policy into action. It set out what was needed from the Commission and the other European Institutions, but also recommended actions for other public and private stakeholders. The strategy therefore provides a framework and a reference both for action undertaken by the many stakeholders concerned within their own responsibilities and for co-operation between these stakeholders.

The Barcelona European Council examined the Action Plan and asked the Commission and the Council to develop measures and a timetable to enable Community business to exploit the potential of biotechnology while taking account of the precautionary principle and addressing ethical and social concerns. It also asked the Commission to report on progress in advance of the 2003 Spring European Council.

The Commission intends to report regularly on the progress made. This report is the first such response. It states what has been achieved in policy development and on the ground, and anticipates emerging issues. Its purpose is not to repeat the comprehensive outline for the future course of action provided by the action plan. Many measures in line with the action plan are already been developed or implemented across the EU. However, where there is a specific need for fresh political impetus in some priority areas, this report contains orientations for the future and appropriate recommendations or announces new initiatives.

This Communication highlights a number of core issues which are fundamental to the success of the Action Plan. It is supported by a Commission Staff Working Paper which sets out both short and medium-term actions to bring these about, as well as a more precise timetable for delivery by the Commission. In the current early phase of implementation, this first report focuses on action undertaken by the Commission and only provides occasional reference to other stakeholder activities.

2. REACTIONS TO THE COMMISSION'S STRATEGY

The Strategy on Life Sciences and Biotechnology has been generally welcomed. Member States and the Regions, academia and the private sectors are already identifying measures and contributing to its implementation in many areas. It presents an integrated policy in this area at European Union level, covering both the promotion of biotechnology development and responsible governance of this process. It has proven possible to arbitrate between competing interests and between different sectors to establish a common, albeit evolving approach.

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[1] COM(2002) 27 Final.

The strategy has been taken as a sign that the Community has begun to regain leadership in this sensitive area; an area which affects an increasing number of Community policies. The strategy, and the way in which it has been developed, provides a good example of European governance in practice.

A short overview of the political response of the European Institutions is provided below.

Council and the European Council

> In March 2002, the **Barcelona European Council** stressed the importance of frontier technologies as a key factor for future growth. It welcomed the Commission's strategic vision on Life Sciences and Biotechnology as a basis for the future framework. It asked Council and the Commission to develop detailed measures to implement the approach and to report on progress in good time before the 2003 European Council.
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> In Seville, the **European Council** added a request to the Council to implement the biotechnology strategy proposed by the Commission.
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> The Council responded in November 2002, with the adoption of conclusions within the **Competitiveness Council**, which welcomed the Commission's Strategy and included a roadmap for Member States (and the Commission) identifying priority actions, responsibility and timetable for implementation.

These conclusions have established a sound framework for developing biotechnology policy Europe-wide on a collaborative basis.

However, some Member States have not yet been able to transform the aims of those conclusions into action in areas which are vital to the development of biotechnology and life sciences, notably because of delays in transposing legislation concerning biotechnology patents and in progressing with the authorisation of new Genetically Modified Organisms (GMOs). There has also been only slow progress on the Community Patent proposal.

European Parliament, European Economic and Social Committee and Committee of the Regions

> The **European Economic and Social Committee** adopted its report on 24 September, welcoming the Commission strategy and considering the Action Plan to be well-constructed, precise, dynamic and pro-active.
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> On 21 November, the **European Parliament** gave a strong positive signal in support of the development of biotechnology in Europe when it adopted by a large majority a resolution endorsing the Commission's biotechnology strategy. Parliament took the opportunity to debate all aspects of biotechnology in a single text and thus supported a clear and coherent concept of the importance of life sciences. Parliament highlighted in particular the need for a Community Patent and for a progress in the authorisation of new GMOs in order to stimulate innovation in this sector.
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> The **Committee of the Regions** did not take a position on the Commission's biotechnology strategy.

These responses show that the European Institutions support the integrated approach as the way to move towards the Lisbon objective of promoting this high-technology area, realising its potential to create growth and new jobs and benefit a wide range of sectors, while at the same time contributing to our broader goals, such as sustainable development.

3. OVERVIEW OF POLICY DEVELOPMENTS AND PRIORITIES FOR URGENT ACTIONS

In line with the timetable set out in the Action Plan, the Commission has moved forward on a wide range of specific actions within its own jurisdiction and has supported various independent actions undertaken by the regions, academia and industry organisations (See supporting Commission Staff Working Paper for a detailed state of implementation of those actions, including a more specific timetable for their delivery[2]).

In some Member States a number of measures are already in place which tie in with the Biotechnology Strategy.

Although implementation of the strategy is still at an early stage, a certain amount of progress has been made.

However, in some areas, including areas which seriously risk impeding the long-term success of biotechnology in the Union, and may also have global repercussions, the picture is more mixed and is already giving cause for concern. These are the need for more research and financial resources, the need to complete the system of Intellectual Property protection and to further progress in the areas of GMOs.

These shortcomings have direct consequences in a number of areas, namely in innovation, competitiveness and research in European biotechnology, and in relations with our international trading partners, including developing countries.

This raises the risk of failing to meet the objective of the Lisbon process in the area of life sciences and biotechnology.

In the recent letter of Federal Chancellor Gerhard Schröeder, President Jacques Chirac and Prime Minister Tony Blair in anticipation to the 2003 Spring Council, the potential of biotechnology in improving European industrial competitiveness and ensure employment opportunities was recognised, while stressing the need to develop all aspects of European business as a key role in the success of the Lisbon Strategy.

a) European Research

Research is the engine that drives the development of biotechnology. Greater, better and more coherent research investments through the establishment of a true European Research Area are a prerequisite if Europe wants to succeed in the life sciences.

The European research in general, but also in life sciences and biotechnology still suffers from insufficient resources and from fragmentation. National and regional research programmes are insufficiently geared up to each other and cross-border co-operation between universities and industry is not yet widespread.

The establishments of a *European Research Area* will be helped by the Union's Sixth Framework Programme for Research & Technological Development (FP6)[3]. The latters' adoption by the Council and the European Parliament in June 2002, six months before its entry into force, is the most visible and prominent achievement in the year since the launch of the strategy. . It marks a decisive step towards involving Europe's research and scientific

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2 SEC(2003) 248

3 Decision No 1513/2002/EC (OJ L232, 29.8.2002, p.1).

networks in the fulfilment of the Lisbon agenda of economic, social and environmental renewal.

The Sixth Framework Programme for Research & Technological Development (FP6)

The FP6 is the Union's principal instrument for its researchpolicy. With an overall budget of €17.5 billion covering the four-year period 2003-2006, it represents approximately 5% of total public research spending in Europe. The funding modalities have been revamped so as to enable the mobilisation of a critical mass of expertise and resources around ambitious scientific objectives and to have a better structuring impact on the research landscape in Europe. Universities, companies and research centres will work together in integrated projects and will establish networks of excellence on topics that present a European dimension. Biotechnology research is catered for in most of the FP6's 7 thematic priorities, including biotechnology for health; nanotechnologies; food quality and safety and sustainable development. Specific attention will be given to the participation of small and medium-sized companies. Additional support will be provided for international scientific co-operation, research infrastructures and mobility and training of researchers.

At the heart of FP6 is the creationof a true *European Research Area*, an internal market where researchers, knowledge and technologies freely circulate. It aims to promote scientific excellence, improve competitiveness and innovation through greater co-operation among researchers and increase co-ordinationamog those that invest in research, including national research programmes.

FP6 will help to address some of the outstanding problems hampering the development of biotechnology in Europe, such as insufficient mobility, 'brain-drain' or our researchers, fragmentation of research efforts and lagging transformation of research results into products and services. This European public research effort will complement and spur the investments made by entrepreneurial biotechnology companies, totalling€7.5 billion in researchin 2001.

Investment in research

Investment in knowledge creation is a precondition for Europe to achieve the goal set by the European Council at Lisbon of becoming "*the most competitive knowledge-based economy in the world*". However, current level of investment in R&D is insufficient to achieve this goal. The European Union invests 1.9 % of GDP in R&D compared with 2.7% invested by US and 3% by Japan. In 2000, the gap between US and EU investment in R&D reached €124 billion. It has doubled at constant prices since 1994. More than 80% of this R&D gap is due to lower funding by the EU business sector.

At the March 2002 Barcelona European Council, the EU agreed that overall spending on R&D in the Union should be increased with the aim of approaching by 2010 3% of GDP, of which two-third should come from the private sector. On 11 September 2002, the Commission Communication "*More Research for Europe - Towards 3% of GDP*" was adopted. With this Communication the Commission has engaged a debate with all stakeholders on the ways and means of achieving the ambitious goal set in Barcelona. It intends to come forward in spring 2003 with an action plan.

The Commission calls for coherent mobilisation of a wide range of policies in order to establish framework conditions that are more conducive to private investment in R&D, and to ensure a more effective use of public R&D financing mechanisms.

Priorities for future actions

The life sciences and biotech industry has and will continue to have its roots in public research. Actions agreed at European level must be matched by a solid nationally funded research effort that delivers results at national and local levels, and that allows for unhampered cross-border co-operation between the best researchers from public and private sectors in dedicated fields.

b) Science and Society

Like any scientific progress, the rapid advances in life sciences have created high expectations for curing diseases and improving quality of life but have at the same time raised concerns as to their ethical and social consequences. Public authorities at large have to take on board concerns about the conditions under which fundamental choices are made in this field.

For its part, the Commission is committed to ensuring that the ethical, legal, social and wider cultural aspects, as well as the different underlying ways of thinking, are taken into account at the earliest possible stage in Community–funded research.

Fostering informed public dialogue

As in the past, the Commission will, in the implementation of FP6 and in other action, ensure that ethical and social debate continues to be a natural part of the research and development process, involving society as much as possible.

In order to encourage scientists managing their projects in such an inclusive way and dialogue with the public, the Commission calls for initiatives that integrate discussion platforms as a strategic element of the work. Large research clusters like one on the safety assessment of GMOs or another on probiotics have designed new ways of conducting research, with NGOs participating as partners in the projects.

Through the FP6, the Commission supports measures to help researchers become communicators and debaters, caring for the conditions in which all parties in society can be involved and embarking in new ways of collective learning. One concrete example is the "Science-Generation" project, which creates partnerships between local communities, the media and scientists in France, Italy and Sweden.

In addition and for the first time, the FP6 now includes a Science and Society programme which supports comparative, foresight and technology impact research linked to ethical questions emerging in new fields of science and their applications.

Recently, two issues have provoked intense public and political debate: *human cloning* and *human embryonic stem cell research.*

Human reproductive cloning

Recent speculation on the possibility of *human reproductive cloning* has reignited the debate on its acceptability from an ethical as well as a scientific point of view. A number of initiatives on this issue have been taken, both at national and at international level. A Franco-German initiative on a world convention banning the reproductive cloning of human beings

has been announced and is being discussed in the United Nations. Japan has recently indicated its wish to join other countries in drawing up a world treaty prohibiting human reproductive cloning.

The European Parliament has adopted a number of resolutions on the cloning of human embryos and the ethical and legal problems of genetic engineering.[4] An EP own-initiative report on the ethical, legal, economic and social implications of human genetics was rejected in plenary.[5]

Human reproductive cloning is prohibited by Article 3 of the Charter of Fundamental Rights of the European Union[6]. The European Group on Ethics in Sciences and New Technologies (EGE) has also spoken out against such procedure.[7] Accordingly, the European Community's Sixth Framework Programme has excluded from funding any research that involves human reproductive cloning.

> The Commission reaffirms its full support for a worldwide ban on human reproductive cloning.

Human embryonic stem cell research

The issue of *human embryonic stem cell research* was highlighted in the process of adopting FP6 and its implementing measures.[8] In particular, the final discussions in the Council and Parliament on the specific programme "Integrating and Strengthening the European Research Area (ERA)" implementing FP6 focused on this specific issue.

> ***Council position on research on stem cells***
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> In the Council meeting of 30th September 2002, the Council and the Commission agreed that detailed implementing provisions concerning research activities involving the use of human embryos and human embryonic stem cells which may be funded under the FP6 have to be established by 31 December 2003.Furthermore, in that occasion, the Commission stated that, during that period and pending the establishment of detailed implementation provisions, it will not propose to fund such, with the exception of banked or isolated human embryonic stem cells in culture.

The Commission is constantly monitoring scientific advances and needs as well as the evolution of international and national legislation, regulations and ethical rules regarding these issues. In so doing, it takes into account the opinions of the European Group of Advisers

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4 EP Resolution of 16 March 1989 on the ethical and legal problems of genetic engineering, EP Resolution of 28 October 1993 on the cloning of the human embryo, EP resolution B4-0209 of 12 March 1997, EP resolution B4-0050/98 of 15 January 1998 and EP resolution B5-0710 of 7 September 2000 on the cloning of human beings.

5 Report on the ethical, legal, economic and social implications of human genetics – A5-0391/2001, voted and rejected in plenary on 29.11.2001.

6 OJ C 364, 18.12.2000, p.1.

7 "Ethical Aspects of Cloning Techniques" Opinion No 9 of 28 May 1997. Information concerning the EGE can be found at the following site: http://europa.eu.int/comm/european_group_ethics

8 Council Decision 2002/834/EC (OJ L 294, 29.10.2002, p.1), Council Decision 2002/835/EC (OJ L 294, 29.10.2002, p.44), Council Decision 2002/836/EC (OJ L 294, 29.10.2002, p.60), Council Decision 2002/837/Euratom (OJ L 294, 29.10.2002, p.74), Council Decision 2002/838/Euratom (OJ L 294, 29.10.2002, p.86).

on the Ethical Implications of Biotechnology (1991-1997) and the opinions of the European Group on Ethics in Science and New Technologies (as from 1998).[9]

Priorities for future actions

In accordance with the Council declaration on the specific programme "Integrating and strengthening the European Research Area", the Commission will

- in Spring 2003, present a report on human embryonic stem cell research to the European Parliament and to the Council which will form the basis for discussion at an inter-institutional seminar on bioethics, and is expected to contribute to a Europe-wide discussion on the ethical issues of modern biotechnology, particularly on human embryonic stem cells;

- submit a proposal, based on Article 166(4) of the Treaty, establishing further guidelines on the principles for deciding on possible Community funding of research projects involving in particular the use of human embryonic stem cells.

c) Competitiveness, innovation and intellectual property

There have been encouraging signs of dynamism: a wave of entry of new dedicated biotechnology firms entering the market in a number of European countries. The European biotech industry is a late starter and still at an early stage in terms of size of companies, revenues and product pipeline. There is now an urgent need for further industry development and consolidation. Biotechnology is a global, highly capital-intensive and knowledge-based industry. Its development will thus depend on progress in overcoming the three fundamental issues of *fragmentation, access to finance* and *intellectual property protection.*

Fragmentation and access to finance

The fragmentation that characterises research is also reflected in European industry. This is partly due to general regulatory, entrepreneurial, fiscal and financial factors, but more specifically also to the traditionally national nature of research spilling over to the companies created out of that research. There is little co-operation across Member States and it has been shown that European companies are more likely to enter into research collaboration with US companies than with Europeans counterparts. In addition, the interface between the public research system and industry is insufficiently developed.

Innovation and competitiveness in European Biotechnology

A study[10] shows that European biotechnology lags behind the US in terms of patents and collaborative R&D projects and that this principal competitor of ours has a dominant lead in innovative activities.

Underpinning public basic scientific research and the ongoing establishment of a European Research Area offers the most effective means of counteracting this fragmentation.

It is a fact that none of the biotechnology clusters in Europe at present are as dynamic in developing companies and products as the leading US biotechnology clusters in New England

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9 Opinion No 15 of 14 November 2000 on the ethical aspects of human stem cell research and use; Opinion No 16 of 7 May 2002 on the ethical aspects of patenting inventions involving human stem cells.

10 This study provides details on the competitiveness of the European biotechnology industry. Innovation and competitiveness in European Biotechnology, Enterprise Papers No 7, 2002, European Commission.

and California. A forthcoming innovation scoreboard study of biotechnology shows that the top performers of the EU are competitive with the US but that many have not reached a critical mass. In the time since the Commission issued the Communication on Biotechnology strategy there have been an increasing number of initiatives and meetings involving regions, clusters, companies and research institutions. Europe's regions are developing a network based on an open membership structure and co-operation between interested parties on specific issues. There have also been a number of other promising initiatives from the private and academic sectors and NGOs to promote dialogue between stakeholders and the general public. The Commission welcomes this type of activity and above all its bottom-up approach, which should ensure that activities correspond to the priorities of the participants. Following a recently concluded evaluation of proposals, a European biotechnology web hub will be established in 2003 with Commission support, the aim being to provide a central linkup function between the stakeholders in the biotechnology community.

G10 Medicines and review of the pharmaceutical legislation

In May 2002 the High Level Group on Innovation and Provision of Medicines (G10 Medicines) delivered its report[11] on ways to improve the competitiveness of the European-based pharmaceutical industry within the context of achieving social and public health objectives. Given the important role of biotechnology in developing tomorrow's pharmaceutical products, the Report underlined the importance of the Commission's biotechnology strategy and referred, in particular, to the need to complete the implementation of the Directive on biotechnological inventions. The Commission will respond to the report's recommendations in the form of a Communication that is likely to be adopted in the summer of 2003.

Many important steps to improve the innovative capacity of European pharmaceutical industry are taken on board in the ongoing revision of the Community's pharmaceutical legislation as laid down in Regulation No 2309/93 and Directive 2001/83/EC. Key elements in the Commission's efforts to overcome the current fragmentation of the markets and to establish the necessary intellectual property protection are certain adaptations of the so-called centralised procedure including increased scientific advice of the companies and harmonised data protection periods.

The biotechnology industry is dependent on access in particular to risk capital.

Companies will have to manage a very long and costly research and development process before they have a marketable product or in some cases fail. Public and private investors have to be prepared to invest with a longer perspective in high-risk companies. During the last five years Europe has been very successful in creating new biotechnology companies, but a large proportion of those companies are now facing the need to renew their financing in a very difficult financial market.

There is no doubt that a number of biotechnology companies are going to disappear in the consolidation process, as some would not be viable even in good market conditions. Others will find a future through mergers or as divisions of larger companies. This does not lessen the fact that Europe runs the risk of losing not only a number of potentially viable companies but also a generation of researchers and its resulting intellectual property. Europe risks losing knowledge assets already acquired. It has therefore been realised that the main problem lies in financing more mature companies. The Commission's advisory Biotechnology and Finance Forum estimated a potential funding gap of up to $1 billion during 2003.

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[11] Available on "http://pharmacos.eudra.org"

Priorities for future actions

There is some indication of the scope and urgency of the financial situation in the entrepreneurial biotechnology industry. The Member States, the Commission and financial institutions now have to consider their response to ensure that Europe does not lose what knowledge assets it has.

Intellectual property protection

A clear, equitable, affordable and effective patent regime applied consistently across the EU is crucial if we are to exploit fully the medical, environmental and economic potential of biotechnology in line with high ethical standards, while taking due account of public concerns on the issue of patents granted for biotechnological innovations.

This objective involves

– the Community Patent, and

– the Directive on biotechnological inventions.

Patent protection in the EU is currently ensured by two systems, neither of which is based on a Community legal instrument: the European Patent System and the national patent systems. As a result, patenting in Europe is expensive and fraught with legal uncertainty. A Community patent of a unitary nature valid in all Member States remains utterly desirable, particularly in a field of global application like biotechnology. With this in mind, the Commission has submitted a proposal for a Regulation on the Community Patent,[12] which, after receiving the opinion of the European Parliament, is being discussed in the Council, where, on 3 March 2003, a political agreement has been reached.

Directive 98/44/EC[13] on the legal protection of biotechnological inventions was adopted after a long and constructive debate which lasted about ten years in both the Council and the European Parliament. During those negotiations, it was fully recognised that biotechnological inventions are a sector in full expansion and need a sound legal framework to allow European businesses to develop and market the resulting products and processes. New techniques of great promise for cures, industrial processes and foodstuffs are becoming established very rapidly, and the European legislator considered it essential not to hamper their development.

This Directive, which is crucial for both scientific progress and innovation and competitiveness, has been applicable since 30 July 2000. The European Patent Organisation, a non-Community Body which grants patents having effect, among others, in the territory of the Member States, amended its implementing regulation in 1999 in order to take account of the provisions contained in Directive 98/44/EC.

As provided for by Article 16(c) of Directive 98/44/EC, the Commission adopted the Annual Report of the Commission to the European Parliament and the Council on the development and implications of patent law in the field of biotechnology and genetic engineering,[14] the aim being to monitor developments and prevent any malfunctioning in this sector. In particular,

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12 COM (2000) 412.

13 OJ L 213, 30.7.1998, p.13.

14 COM (2002) 545 Final, 7.10.2002.

the report highlights the key provisions of the Directive in the light of the judgement of the Court of Justice of the European Communities of 9 October 2001.[15]

In its **judgement the Court** dismissed the action for annulment brought by the Netherlands, reiterating de jure the essential principles of the Directive and casting new light on a number of specific provisions. In particular, the Court confirmed the scope of the Directive and its compatibility with existing international agreements in the field of biotechnology.
The Court pointed out that the Directive complies with the fundamental rights relating to the respect of human dignity and human integrity.
Finally, the Court also recalled the patentability of inventions relating to plants.

Despite the above, to date, only six Member States[16] have transposed Directive 98/44/EC into their national legal systems while the other Member States are currently at varying stages of progress. Reasoned opinions, the second stage of formal infringement proceedings under Article 226 of the EC Treaty have been sent to the Member States concerned asking them to transpose Directive 98/44/EC into national law.

Transposition of this Directive is a legal obligation under the Treaty and is essential in order to avoid any discrepancies between the legislations of the Member States. This situation is considerably hampering the development of biotechnology in Europe in comparison to our competitors.

Priorities for future actions

- Following the political agreement of 3 March 2003, the Commission invites the Council to resolve the remaining difficulties and to adopt the Community Patent Regulation before the end of 2003. The Council is furthermore invited to take a timely decision for the creation of the centralised court, for which the Commission is now able to present a proposal to the Council in due course. Changes to the European Patent Convention will also have to be agreed in order to allow the European Patent Office to grant Community Patents.

- In the light of the judgement of the Court, the Commission strongly calls upon the Member States concerned to fully and swiftly transpose and implement Directive 98/44/EC.

- For its part, the Commission will consider the following two questions identified in the report:

a) the scope of patents relating to sequences or part-sequences of genes isolated from the human body;

b) the patentability of human stem cells and cell lines obtained from them.

These two topics will be studied and analysed by a group of independent experts (specialising in the fields of economics, law and natural sciences). This group will also help the Commission to identify priority topics to be covered in future reports.

[15] Case C-377/98.
[16] Denmark, Finland, Ireland, United Kingdom, Greece and Spain.

d) Genetically Modified Organisms (GMOs)

Regulatory framework and public perception

The regulatory framework in place since 1990 on the deliberate release into the environment of GMOs (Directive 90/220/EEC) and since 1997 on novel food and novel food ingredient (Regulation (EC) No 258/97) have already provided for a high level of protection for human and the environment.

Considerable progress has been made in further advancing in the ***regulatory framework for GMOs***, namely:

- **Directive 2001/18/EC**[17], which provides for a more complete authorisation procedure for GMOs, has been fully applicable since 17 October 2002. This Directive improves legislation on the deliberate release of GMOs into the environment, providing a solid base for transparent and responsible management of the use of GMOs. Furthermore, **implementing measures**[18] needed for the applicability of that Directive at that date, including guidance notes on risk assessment and monitoring, are also in place;

- the reaching of political agreement in the Council on first readings in the European Parliament of the **two Commission proposals on genetically modified organisms (GMOs)**, establishing a comprehensive Community system to trace and label GMOs and to regulate the placing on the market and labelling of GM food and feed;[19,20]

- steps forward in the **implementation of the Cartagena Protocol,** which guarantees all signatory countries the freedom to carry out a risk assessment prior to accepting import of a new GMO. On 17 October 2002, political agreement was reached in the Environmental Council on the Commission proposal for transposing the Cartagena Protocol into EU legislation, which will govern exports of GMOs.[21]

Furthermore, the ***European Network of GMO Laboratories (ENGL)*** was set up to contribute more effectively to the uniform enforcement of legislation across the Community through the harmonisation and standardisation of means and methods of sampling, detection, identification and quantification of GMOs or derived products in a wide variety of matrices, covering seed, grains, food, feed and environmental samples.

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17 OJ L 106, 17.4.2001, p.1.

18 Council Decision 2002/813/EC establishing the Summary Notification Information Format Part B(OJ, L 280, 10.8.2002, p.62), Council Decision 2002/812/EC establishing the Summary Notification Information Format Part C (OJ L 280, 10.8.2002, p.37), Commission Decision 2002/623/EC establishing guidance notes supplementing Annex II to Directive 2001/18/EC (OJ L 200, 30.7.2002, p.22), Council Decision 2002/811/EC establishing the guidance notes supplementing Annex VII to Directive 2001/18/EC (OJ L 280, 10.8.2002, p.27).

19 Proposal for a Regulation of the European Parliament and of the Council concerning traceability and labelling of genetically modified organisms and traceability of food and feed products produced from genetically modified organisms. (COM (2001) 182 Final).

20 Proposal for a Regulation of the European Parliament and of the Council on genetically modified food and feed. (COM (2001) 425 Final).

21 Proposal for a Regulation of the European Parliament and of the Council on the transboundary movement of GMOs (COM (2002) 85 Final).

The **ENGL** set out to act as a scientific and technical European Union network of excellence within the context of EU GMO regulation.

The network was inaugurated in Brussels on 4th December 2002 and currently consists of 44 EU enforcement laboratories, plus Norway and a number of observers such as Accession Countries. The GMO laboratory of the Commission's Joint Research Centre (JRC) will co-ordinate ENGL's activities. It will act as the EU reference laboratory for GMO food and feed legislation.

The EU regulatory framework on GMOs and GM food and feed is one of the most thorough and transparent regulatory framework on GMOs in the world. It aims to provide a high level protection of human health and the environment, legal certainty for operators, address public concerns, including ethical concerns, facilitate consumers' choice,and thereby fosters further public confidence on the use of GMOs.The Commission considers that it has met its commitments to create the conditions for making the GMO authorisation procedure operational and it is ready to play its role in managing the new procedure. Member States should equally assume their responsibilities in order to ensure that progress is made on authorisations. However, in spite of the improvements in the regulatory framework, public and political concerns with GMOs continue. Whilst medical applications involving the use of GMOs have continued to make progress, this is not the case for the use of GMOs inagriculture, where so far there are no obvious perceived benefits for consumers.

Since October 1998, progress in the authorisation of new GMOs have been limited. However, food products produced from GMOs have been placed on the market in the Community under the Novel Foods Regulation,[22] on the basis of their 'substantial equivalency' to the conventional products.

The deadline for transposition of Directive 2001/18/EC was 17th October 2002. To date only Denmark and Sweden have fully communicated its implementation measures for this Directive. The Commission had already addressed Letters of Formal Notice to 13 Member States for non-communication of transposition measures and is considering sending one to the UK for partial communications of transposition measures.

The most recent in the series of ***Eurobarometer surveys*** on what the European public thinks about biotechnology indicates that, although there may be a softening of attitudes towards biotechnology in general, GM foods are still seen as having no benefits and to carrying risks.

Whilst public authorithies are responsible for providing a clear and predictable legal framework for the approval of GMOs and derived products, it is primarily for the biotech industry to openly explain and document the benefits of the use of GMOs.

The lack of progress on the authorisations of new GMOs is having a direct impact on ***research activities on GMOs and GMO field trials*** in Europe.

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[22] Regulation (EC) No 258/97 of the European Parliament and of the Council of 27 January 1997 concerning novel foods and novel foods ingredients (OJ L 43, 14.2.1997, p.1)

Impact on research activities and development in GMOs

A survey among private companies and research institutes active in the field of GMOs was conducted in order to get an overview of basic and applied research activities on GMOs in Europe.[23] The survey reveals that **39% of the respondents have cancelled R&D projects on Genetically Modified Organisms (GMOs) over the last four years** giving as the main reasons the unclear regulatory framework and uncertain market situation. The tendency to cancel R&D projects is low for the public sector (23 % of respondents have cancelled projects) and higher in the private sector (61 % of respondents having cancelled projects).

Furthermore, **the number of notifications for GMO field trials in the EU increased rapidly from 1991 to 1998, and declined sharply thereafter (76 % decrease by end 2001)**. In 2001, the Commission's Joint Research Centre (JRC) database, which keeps a register of EU field trials, received just 61 notifications for field trials with GM plants, compared with over 250 in 1998. Such a marked decrease in the number of GMO field trials has not taken place to this extent outside Europe (e.g. in the US). According to the study, there is a response effect to the lack of progress in new commercial release of GMOs as well as the widespread tendency of the European public to reject GMOs.

This situation underlines the importance of a clear and predictable regulatory framework not only for fostering consumer acceptance and providing legal certainty for operators in the production and distribution chain, but also for reversing the rapid decline in GMO field research in the EU.

Priorities for future actions

Against the above background, the Commission calls upon

- the Member States concerned to fully and swiftly transpose and implement Directive 2001/18/EC and not to withold new authorisation on GM products which fulfil current legal requirements, and
- the European Parliament and the Council to adopt of the two Commission proposals on the traceability and labelling of GMOs and on GM food and feed, at the earliest

in order to provide a modernised legal framework based on transparency and efficiency and facilitating the freedom of choice of consumers as well as providing legal certainty for operators.

e) International issues

Biotechnology has been increasingly adopted in the world. In the agriculture/food sector, biotechnology has spread very quickly and continues to spread. In 2002, up to 58 millions hectares were planted with GM crops. While the US still dominates the production of GM food, several developing countries grew GM crops or started to authorise GMOs in agriculture.

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23 "Review of GMOs under Research and Development and in the pipeline in Europe", an ongoing study of the Institute of Prospective Technological Studies (IPTS-JRC) and the European Science and Technology Observatory (ESTO)".

Existing international forums and initiatives

Discussions on biotechnology and issues related to biotechnology take place today in a multitude of international forums. A number of international organisations have direct competence in dealing with issues relating to biotechnology – biosafety is addressed by the Cartagena Protocol, biodiversity by the Convention on Biological Diversity (CBD), agriculture by the Food and Agriculture Organisation (FAO), intellectual property rights and technology transfer by the World Intellectual Property Organisation (WIPO) and World Trade Organisation (WTO), trade by the WTO, risk analysis of foods derived from modern biotechnology in Codex Alimentarius under the World Health Organisation (WHO)/FAO, plant protection under the International Plant Protection Convention (IPPC), and the development of consensus documents by the Organisation for Economic Co-operation and Development (OECD).

Recently, new initiatives have been launched and other organisations have also taken up the issue of biotechnology. The OECD organised two conferences on GM crops and feed in 2000 and 2001 with world-wide participation, the UNIDO intends to organise a Global Biotech Forum later in 2003, the WHO is working on GM food safety, and the World Bank has launched a consultative process on the proposed international assessment of the role of agricultural science and technology in reducing hunger, improving rural livelihoods and stimulating environmentally sustainable economic growth.

Need for improved dialogue

The increasing number of international initiatives reflect the different concerns and current controversy surrounding biotechnology and raises a more fundamental question relating to international governance. Each of the above organisations plays an essential role in their specific area. However, none appears to provide an adequate forum for promoting an open and transparent dialogue between all the stakeholders concerned. Such a dialogue, on all the issues at stake in biotechnology, would facilitate mutual understanding of the concerns and objectives of the different countries and regions. Without it, there is a risk that the approach to biotechnology in the international system will become too fragmented, incoherent and overlapping. It is also increasingly difficult for developing countries to afford the resources to participate in all of the on-going activities.

Improved dialogue is particularly important where regulatory requirements and the concerns of countries and regions are going in different directions. In particular, the current developments in the EU regulatory framework are being closely followed by a number of third countries, some of which have expressed strong reservations regarding the implementation of existing legislation and the design of future rules.

The economic stakeholders and interests involved in the production of GM- crops extend well beyond national frontiers. Therefore, governing biotechnology innovation means finding a way of laying down common rules and principles on a global scale while still respecting the pursuit of legitimate approaches in different parts of the world. This is proving to be a difficult challenge. Resorting to legal challenges or showing disrespect for the legitimate rights of governments is not going to solve the public concerns expressed in different countries, and would most likely lead to more controversy and polarisation.

The current divergence of views between the EU and some of its trading partners is adding to the perception of a lack of "international governance" in the field of biotechnology, particularly for agricultural biotechnology.

The most salient example is the reported threat from certain Third Countries of a WTO challenge against the EU biotechnology legislation.

Threats of a WTO legal challenge

At the November 2002 meeting of the World Trade Organisation (WTO) Committee on Sanitary and Phytosanitary Agreement (SPS), the US, Canada, Argentina and the Philippines again raised their concerns regarding the EU's continued handling of the approval of new GMOs and on the WTO compatibility of new and forthcoming European legislation, namely the Commission proposals on the traceability and labelling of GMOs and on GM food and feed.

The introduction of GMOs in agriculture raises several issues among which human health, environment, the economically viable co-existence of different agricultural production systems, intellectual property rights and trade.

Many developing countries have not yet developed a policy to address these issues and several still lack the capacity to develop and enforce biotechnology legislation.

GM crops and developing countries

The recent food crisis in Southern Africa and the GMO- content of related food aid supplies has once again brought to the public attention the issue of the introduction of GMOs into certain developing countries.

The recent controversy has been sparked by the US supply of substantial amounts of food aid as a response to the serious food shortage in Southern Africa. US-supplied maize contains grain from varieties which are genetically modified.

Some countries in the region[24] initially refused to take the maize for several reasons, among which human health concerns, environmental considerations, intellectual property rights concerns, the risk of spread of transgenes into their own maize production, and the repercussions such a spread could have on regional and international trade.

The Commission considers that all countries have the right to take the measures they deem appropriate to control the intentional or unintentional dissemination of genetically modified organisms in their territory. However, regulations should, as a general principle, take into account the current degree of scientific knowledge, be transparent and predictable, and should not be more trade-restrictive than is necessary to fulfil their objectives, taking into account the level of protection sought. There is a need to improve international governance in the field of biotechnology and to ensure that different regulatory mechanisms can co-exist.

To date, the EU-US Biotechnology Consultative Forum, launched by President Prodi and President Clinton in May 2000, remains as a unique example of an independent group of experts representing diverse views on the two sides of the Atlantic. The Forum was a useful exercise in promoting understanding of, and consensus on some of the difficult and contentious issues that underlie the different points of view on biotechnology within the EU and the US and between the respective governments. Because of the background and causes of the controversies surrounding biotechnology and its rapid evolution, the Forum made a

[24] At the beginning of October, Lesotho and Swaziland were accepting GM grain, and Malawi, Zimbabwe and Mozambique agreed to retract their ban, provided that the GM grain was milled before distribution, thereby removing the potential for outcrossing of GM maize with indigenous crops. Zambia is still refusing the GM grain.

number of recommendations including further work and analysis. The Commission has made its position on the Forum's recommendations public[25] and is willing to continue dialogue towards a co-operative solution to the issues at stake.

The initiative of an international process designed to engage a broad range of stakeholders has indeed been considered in the recent past. In fact, at the Okinawa Summit in July 2000, the G8 agreed "to explore, in consultation with international organisations and interested bodies including scientific academies, the way to best integrate the best scientific knowledge available into the global process of consensus building on biotechnology and other aspects of food and crop safety". After the tragic events of 11September 2001, the G8 has been preoccupied with combating terrorism and, thus, the issue of food safety and biotechnology has been deferred.

On 30 and 31 January 2003, the Commission organised a conference in Brussels on the subject of biotechnology in agriculture in developing countries. The conference attracted more than 900 participants from all over the world, including scientists, government representatives, NGOs, industry, media.

Priorities for future actions

It is time to give further consideration to the need for **a *multilateral consultative forum*** to facilitate open and balanced dialogue, including all stakeholders and to promote better consistency of the agreements achieved in the different forums.

Such a consultative body should be capable of fostering a wide spectrum of interests, including scientists and a cross section of civil society, the aim being to contribute to the process of international consensus building on issues relating to biotechnology without duplicating on-going work in established international forums. Such an initiative should be intended as an essential step towards a better global understanding of the issues relating to the application of biotechnology and the differences in regulatory approaches amongst regions and countries.

The Commission will pursue this matter further with a view to verifying the feasibility of such a forum and the willingness of our trading partners to engage in such a dialogue. The Commission will also support an independent review of existing scientific knowledge concerning agricultural biotechnology in the context of developing countries.

4. Overall conclusions

– The Commission strategy on Life sciences and Biotechnology has been widely regarded as a major initiative and as an achievement.

– With the Strategy, the Commission committed itself to improving the coherence of policies and actions in order to encourage an integrated approach towards all applications of life sciences and biotechnology. The Commission is ready to continue to deliver on these commitments.

– Progress has been made in some areas, but others are suffering from serious delays. There is a need for commitments and actions from all private and public stakeholders involved in the Strategy. The Commission is only one of several stakeholders in the field. Many of the proposed actions are substantially or wholly within the jurisdiction of the Member States

[25] http://europa.eu.int/comm/external_relations/us/biotech/ec_commentary.htm.

or private stakeholders. The strategy can only be successful if it is accompanied by additional activities in the individual Member States, by setting and implementing, for example, national biotechnology strategies. The Commission, for its part, is ready to continue to play its role of facilitator and contribute to work undertaken by others with the specific task of ensuring a coherent European framework. The Council conclusions of November 2002 are a major contribution to this framework. A concerted effort is now needed to continue the process of implementation.

– A clear and consistent policy in the Member States on biotechnology is crucial. Experience has shown that divergent and uncoordinated actions seriously risk reducing the impact, effectiveness and coherence of the EU strategy in this field. Attention should be drawn to the apparent inconsistency of, on the one hand, the conclusions of the Lisbon, Stockholm, Barcelona and Seville Summits setting the objective of becoming a leading knowledge-based economy, promoting the full potential of biotechnology and calling for more competitiveness in Europe's biotech sector. On the other hand, there has not always been the same clear signal when these statements are translated into binding rules and commitments. In particular, the maintenance of a situation of legal uncertainty, notably the delay in progress in the area of GMOs, and the non-transposition of EC legislation on patents along with the delay in setting up a unitary Community patent, is having an impact on competitiveness, research capabilities and trade. Decisive action in now needed in a number of areas identified in this report.

– The regulatory framework on GMOs, including the Commission's proposals on traceability and labelling of GMOs and on GM food and feed provides for a high level of protection for human health and the environment, legal certainty for operators, addresses public concerns and facilitates consumers' choice, and thereby fosters further public confidence on the use of GMOs. It is also important that the regulatory framework is clear and predictable if the rapid decline in GMO field research in the EU is to be reversed.

– Like any scientific progress, the rapid advances in life sciences create high expectations for curing diseases and improving quality of life while at the same time raising concerns as to their ethical and social consequences. Public authorities at large have to take on board concerns about the conditions under which fundamental choices are made in this field. For its part, the European Commission is committed to ensuring that the ethical, legal, social and wider cultural aspects, as well as the different underlying ways of thinking, are taken into account at the earliest possible stage in Community–funded research. Ethical and social debate must continue to be a natural part of the research and development process, involving society as much as possible.

– Finally, there is a need for a joint effort to broaden understanding on biotechnology at international level. To this end, a multilateral consultative forum, in which a broad-spectrum dialogue on biotechnology can be engaged, will be considered.