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**REPORT FROM THE COMMISSION
TO THE EUROPEAN PARLIAMENT, THE COUNCIL, THE COMMITTEE OF THE
REGIONS AND THE EUROPEAN ECONOMIC AND SOCIAL COMMITTEE**

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

{SEC(2005)850}

1. INTRODUCTION

In January 2002, the Commission adopted a Strategy for Europe on Life Sciences and Biotechnology¹, consisting of two parts – policy orientations and a 30-point plan to transform policy into action. It sets out what is needed from the Commission and the other European Institutions, while also recommending actions for other public and private stakeholders.

The Commission intends to report regularly on the progress made. The Commission adopted its second progress report on 7 April 2004, which highlighted the progress made but also pointed out delays in some areas².

This Communication is the third such response. As last year, this report is supported by a Commission Staff Working Paper, which provides detailed information on the implementation of the action plan.

2. LIFE SCIENCES AND BIOTECHNOLOGY IN THE REFOCUSED LISBON AGENDA

In its report to the Spring European Council³, the Commission advocated refocusing the Lisbon agenda on actions that promote jobs and growth in a manner that is fully consistent with the objective of sustainable development.

The life sciences and biotechnology industry may have an important role to play in this refocused Lisbon strategy and, therefore, could contribute greatly to increasing Europe's share of the global high-tech marketplace. Life sciences and biotechnology have the potential to be leading areas of science, industry and employment over the coming decades. As well as increasing prosperity with more and better jobs, life sciences and biotechnology may have the potential to improve our quality of life through innovative medical applications and a better environment. As a leading edge technology, life sciences and biotechnology can contribute to the modernisation of Europe's industrial base.

The Commission has now decided to commence a process of reflection on the role of Life Sciences and Biotechnology in the renewed Lisbon Agenda. Understanding how the adoption of modern biotechnology in the various production sectors can contribute to the objectives of the European policy strategies on economic growth, sustainable development and environmental preservation is a recognised need.

Therefore, following the request of the European Parliament, the Commission has undertaken to carry out a study into, and conduct a cost-benefit analysis of, biotechnology and genetic engineering, including genetically modified organisms, in the light of major European policy goals formulated in the Lisbon strategy, Agenda 21, and sustainable development.

The purpose of this study is twofold. First of all, an evaluation of the consequences, opportunities and challenges of modern biotechnology for Europe, in terms of economic, social and environmental aspects, is important both for policy-makers and industry. The study would therefore constitute the primary input to the above-mentioned reflection. Secondly, this

¹ COM(2002)27

² COM(2004)250, supported by Commission Staff Working Paper SEC(2004)438

³ COM(2005)24

kind of independent study should help to increase public awareness and understanding of life sciences and biotechnology.

Priorities for future actions

The Commission will

- ▶ carry out an **independent study** aimed at providing a comprehensive assessment and cost-benefit analysis of the consequences, opportunities and challenges that applications of modern biotechnology present for Europe in terms of economic, social and environmental aspects,
- ▶ draw on both the study and an in-depth assessment of the progress achieved since 2002 to **update the Community Strategy on Life Sciences and Biotechnology** in good time for the 2007 Spring European Council.

3. OVERVIEW OF POLICY DEVELOPMENTS AND PRIORITIES FOR ACTIONS

3.1. Harvesting the potential

3.1.1. Competitiveness of European biotechnology sector and related industries

In general, 2004 seems to have been a year of consolidation rather than growth for European biotechnology.

There was no significant change in the number of companies in this field in Europe and in the US. This seems to indicate that both the US and European biotechnology sectors have reached a similar state of stability (or stagnancy).

According to a recent comparative study⁴, the European biotech industry, with approximately the same number of companies as in the American sector, employs nearly half as many people, spends one third as much on R&D, raises three to four times less venture capital and has access to four times less debt finance. Nevertheless, the US industry generates only about twice as much revenue as the European sectors.

According to the same study, the financing gap is probably the biggest single barrier to European competitiveness in biotechnology. That said, it is not the supply of seed financing or early venture capital that is holding back European biotechnology. The main obstacle seems to occur later in the business cycle. After a few years, at the time when Europe's companies ought to be taking off, most of them appear to run out of money.

Given the emergence of new competitors, particularly in the Asia-Pacific region, some justified concerns exist as to the long-term competitiveness of the European biotech industry, although currently Asian competitors are still less mature than their European counterparts.

In order to address this issue the Commission has adopted a proposal for a Competitiveness and Innovation Programme⁵ with a total budget of 4.2 billion € for 2007-2013. It is designed to provide instruments to develop and sustain a supportive environment for innovative firms, encouraging clusters, strengthening access to finance. Secondly, the Commission has, within

⁴ "Biotechnology in Europe: 2005 Comparative study" by Critical I

⁵ COM(2005)121

its proposal for the 7th R&D Framework Programme⁶, outlined a new financing instrument, the “risk-sharing finance facility”, which could provide loans for larger research and infrastructure projects.

3.1.2. The Competitiveness in Biotechnology Advisory Group

The **Competitiveness in Biotechnology Advisory Group** with Industry and Academia (**CBAG**) was appointed by the Commission in 2003 in accordance with Action 10b of the Strategy. It gathers representatives from all the various industry segments and from companies at every stage of company development together with entrepreneurial academics and has the role of issuing recommendations to the Commission and contributing to this annual report.

In its second report⁷, the group reviews its first set of 2003 recommendations, the progress made towards them last year and any remaining or new barriers to be tackled. The Commission welcomes this second report and invites the CBAG to continue its contribution in view of the announced future update of the Strategy.

The CBAG confirms its support for the 2002 European Strategy for Life Sciences and Biotechnology. It suggests that discussion of the progress reports issued by the Commission at the level of the relevant ministerial Councils would help to ensure that their contents are properly considered and acted upon by Member States.

At the same time, the CBAG notes that implementation of the strategy has been patchy and there remain some serious concerns. In order to address those concerns, 10 key recommendations have been issued. This report responds to some of them. The remaining recommendations will be addressed in the broader Commission reflection in the light of the announced future update of the Strategy.

3.1.3. Intellectual property protection

The CBAG considers it essential for a **simplified, workable and affordable Community patenting system to be introduced as soon as possible**. The lack of progress on implementation of Directive 98/44/EC on the protection of biotechnological inventions erects a further barrier to effective innovation.

To date, twenty Member States⁸ have transposed Directive 98/44/EC⁹ on the legal protection of biotechnological inventions into their national legal systems while the other Member States are currently at varying stages of progress.

On 9 July 2003, the Commission referred eight Member States to the European Court of Justice for their failure to transpose the Directive into national legislation. Among those, three infringement procedures are still pending¹⁰. In December 2004, two other infringements procedures were launched against Latvia and Lithuania.

⁶ COM(2005)118

⁷ the full text of the Group’s report is available at http://europa.eu.int/comm/dgs/enterprise/index_en.htm

⁸ Denmark, Finland, Ireland, United Kingdom, Greece, Spain, Portugal, Sweden, the Netherlands, France, Germany, Belgium, Estonia, Czech Republic, Slovakia, Cyprus, Poland, Hungary, Malta and Slovenia.

⁹ OJ L 213, 30.7.1998, p.13.

¹⁰ Luxembourg, Austria and Italy.

For its part, the Commission has considered two questions identified in 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 provided for by Article 16c of Directive 98/44/EC¹¹, namely the scope of patents relating to sequences or part-sequences of genes isolated from the human body, and the patentability of human stem cells and cell lines obtained from them. These two topics have been addressed in the Commission report under Article 16c of the Directive.

Priorities for future actions

Member States

- ▶ to fully and swiftly transpose and implement Directive 98/44/EC.

Commission

- ▶ to continue to monitor whether there are any economic consequence of possible divergences between Member States' legislation on the issue of scope of patents of gene sequences.

3.1.4. Networking Europe's biotechnology

The informal **network of Member States officials on competitiveness issues**, as established in accordance with action 10a of the Strategy, has continued to operate and has played an effective role in the **benchmarking exercise of European Public Biotechnology Policies**.

The benchmarking exercise aimed primarily at providing European policy-makers with a set of tools that will assist them in formulating their policies on biotechnology. The general objective of the project was to identify types of public policies that affect the development of biotechnology in Europe and assess their effectiveness against a background of verifiable data. Analysis of the first round of benchmarking has identified both the benefits and the limitations of this exercise, which should be repeated at regular intervals, together with the necessary improvements in methodology.

A comparison of the national portfolios between the countries and between the different periods considered (1994/95 and 2004) reveals a general increase in public policies in favour of biotechnology.

¹¹ COM(2002)545

Priorities for future actions

Commission and Member States

- ▶ to continue cooperation and exchange of information through the existing Biotechnology network with Member States.

Member States

- ▶ to repeat, in 2006, the **benchmarking programme** to provide a basis for an exchange of best practices and fine-tuning of policies. The results of this exercise should also contribute to the future update of the Strategy
- ▶ to report to the Commission on progress in implementation of the biotech strategy as part of the benchmarking exercise

3.2. Funding research in Europe

The **6th Framework Programme for Research** is continuing to give a strong impetus to Life Sciences and Biotechnology research in Europe, in particular in terms of the critical mass of human and financial resources, sharing of knowledge and facilities, strengthening of scientific excellence, coordination of national activities and support for EU policies.

The 6th Framework Programme for Research has also continued to attract industry and in particular **SMEs**. However,

The CBAG recommends that the proposed 7th Framework Programme should be designed with a streamlined administration system to encourage greater participation, and radically increase the number of participating SMEs.

On 6 April, the Commission adopted a proposal for the Seventh EC Research Framework Programme 2007-2013 (FP7)¹². A Key priority of FP7 will be to make the way it operates much simpler and to make participation in the programme easier, through measures addressing the procedures, plus a streamlining of instruments.

By focusing more on themes and less on instruments, the programme should become more flexible and adaptable to the needs of industry, as well as more straightforward for its participants.

Life sciences and biotechnology research for medical applications will remain an important priority in FP7. The Commission intends to bring together the relevant technologies and sectors to develop a European **Knowledge-Based Bio-Economy**, which will provide the necessary critical mass, synergies, and outputs to meet social and economic demands for the sustainable and eco-efficient production and utilisation of renewable biological resources and their transformation into health, food, energy and other industrial products. This, in turn, will provide an incentive for increased growth and employment.

¹² COM(2005)119 final

Priorities for future actions

The Commission will

- establish a network with EU Member States to help coordinate the development and implementation of a European research policy for a **knowledge-based bio-economy** in co-ordination with the Standing Committee on Agricultural Research.

3.3. Confidence in science-based regulatory oversight

3.3.1. *Review of pharmaceutical legislation*

The CBAG indicates that problems remain with the licensing of medicines derived from biotechnology. In particular, some of the registration procedures used by the European Medicines Agency (EMA) are both complex and expensive and may act as a major disincentive to the introduction of new products by SMEs.

Following the adoption of the new Community Pharmaceutical legislative framework and its publication on 30 March 2004, work has focused on implementing this legislation and thus introducing implementing measures and guidelines. These measures include a Commission Regulation on incentives for Small and Medium-sized Enterprises (SMEs) in their dealings with the European Medicines Agency (EMA).

In addition, the Commission adopted a proposal for a Regulation on paediatric medicines on 29 September 2004. This will provide industry with a number of incentives to develop medicines specifically for use in children, including enhanced intellectual property rights.

3.3.2. *Genetically Modified Organisms (GMOs) legislation*

Although the CBAG welcomes the Commission's lead in recent months in introducing EU legislation on GMOs and approving GMO products, it takes the view that it is for **the Member States themselves to implement the comprehensive EU legislation on GMOs adopted BY Parliament and Council.**

At its orientation debate on 28 January 2004, the Commission agreed on the way forward regarding pending decisions on Genetically Modified Organisms (GMOs) and the upcoming application of the new regulatory framework.

Throughout 2004, the Commission has implemented the approach, and has progressed with the pending decisions concerning the placing on the market of new GM products and the lifting of national safeguard measures through the relevant comitology procedures, in accordance with the provisions of the relevant EU legislation.

Three decisions concerning the placing on the market of GM products have been adopted by the Commission following the failure of Member States to provide a qualified majority in the Regulatory Committee or Council.

The Commission also listed 17 plant varieties derived from an authorised GM maize line (MON810) in the Common Catalogue of Varieties of Agricultural Plant Species, meaning that the seeds of such GM varieties can be marketed throughout the Community.

Moreover, the Commission has contributed to the enforcement of the Community legislation on GMOs by adopting a measure preventing the import of non authorised GM products into the Community.

Further draft decisions continue to make progress through the administrative procedures, but, in spite of improvements in the new regulatory framework, public and political concerns about GMOs continue.

In its most recent orientation debate on 22 March 2005, the Commission confirmed its full confidence in the existing regulatory framework on GMOs and concluded that it would continue to comply fully with its legal obligations and proceed with the approval of pending authorisations as appropriate.

The Commission now expects more active cooperation from all Member States in ensuring correct implementation of the new, more rigorous legislation governing GMOs, which they themselves demanded—and subsequently committed themselves to.

Priorities for future actions

Member States

- ▶ to play their role in the implementation of the new regulatory framework on GMOs

The Commission will

- ▶ continue to ensure that the EU regulatory framework on GMOs is fully implemented,
- ▶ finalise its work on the establishment of **labelling thresholds** for the adventitious or technically unavoidable presence of authorised GM **seeds** in seeds of both conventional and organic varieties.

The Commission has also decided to step up its efforts to address all the outstanding issues identified, which could increase cooperation in decision making and ultimately result in a wider consensus amongst institutions and other stakeholders.

Priorities for future actions

European Food Safety Authority

- ▶ to promote and make full use of the **networking of national scientific bodies**, in line with Article 36 of Regulation (EC) 178/2002 on food law, and thus to increase the possibility of resolving diverging scientific opinions among the Member States

The Commission will

- ▶ enhance its coordination role on co-existence issues, as defined in Directive 2001/18/EC, through the establishment of a **coordination network** designed to facilitate the exchange of information on co-existence with and between Member States,
- ▶ report to the Council and the European Parliament **by the end of 2005**, using information from the Member States, on the experience gained in the Member States concerning the implementation of measures to address co-existence, including, where appropriate, an assessment of all possible and necessary steps to be taken.

3.4. Newly emerging issues

3.4.1. *Tissue engineering*

The CBAG stresses the importance of Europe having **a clear regulation for human tissue engineered products**. Current Member State regulations are not harmonised, are contradictory, are subject to monopolies by state-controlled institutes in certain Member States, and, in general, do not promote innovation in the field.

Together with other biotechnologies, such as gene therapy and somatic cell therapy, these advanced therapies represent a fast-growing sector, which holds great promise for improved treatment opportunities and enhanced quality of life across Europe. To develop this potential, the Commission has been working on a proposal for a regulatory framework on human tissue engineered products.

Following the public consultations that took place in 2002 and 2004, the principles and main elements of this legislative proposal have now been agreed upon. Stakeholders will be consulted on this draft in May-June 2005. Adoption of the Commission proposal is scheduled for the last quarter of 2005.

Priorities for future actions

The Commission will

- ▶ finalise legislation to harmonise the authorisation procedures for marketing products/processes from human tissue engineering, while guaranteeing a high level of protection for patients, to be presented to Parliament and Council **before the end of 2005**.

3.4.2. Genetic testing

Genetic testing, and its scientific, ethical, legal and social implications, have continued to be debated both nationally and internationally. Discussions on the need for new legislation or, in some cases, a review of existing legislation have been initiated across Europe¹³.

The Commission is conscious of the far-reaching consequences that the lack of an adequate quality assurance system for genetic testing might have for the person tested and his/her family. Without wishing in any way to interfere with Member States' competence regarding genetic testing, the Commission intends, in addition to the priority actions identified in the 2nd progress report, to continue its efforts to ensure the highest quality of genetic testing in the EU and beyond.

Priorities for future actions

Commission and Member States

- ▶ to enhance an EU-wide exchange of information on best practice and cooperation on the development and use of genetic testing through the open method of coordination. In particular, an evaluation of the clinical validity/utility of genetic tests and the establishment of a referral system at EU level for genetic testing of rare and complex diseases will be addressed in 2005- 2006
- ▶ to take whatever action appropriate or required, as arising from the coordination

The Commission will

- ▶ launch an initiative on the protection of workers' personal data in the employment context, taking account of the European Group on Ethics in Science and New Technologies Opinion No 18 "Ethical Aspects of Genetic Testing in the Workplace". The initiative will also address the processing of genetic data,
- ▶ analyse the possibility of setting standards on genetic testing under Article 152 or 153 of the Treaty and the appropriate legal instrument.
- ▶ Analyse the Directive 98/79/EC on in vitro diagnostic medical devices in the context of genetic testing and in particular regarding quality and performance assurance of genetic test devices.
- ▶ Launch a mapping and networking exercise on public health aspects of genetic testing.

3.4.3. Pharmacogenetics

Pharmacogenetics is still in the research and development phase, but its application in drug development and evaluation is expected, and appropriate measures should be prepared in time for this evolution. The potential impact of pharmacogenetics on health care and its ethical, legal and socio-economic implications are still uncertain. The European Medicines Evaluation Agency (EMA) organised an expert meeting in November 2004, which stressed that no legislative provisions should be made before a wide-ranging consultation process with all the relevant stakeholders has taken place, and highlighted the importance of ensuring high quality and validation methods for pharmacogenetic tests. The research projects funded under the 6th Framework Programme for Research and the newly established Technology Platform for Innovative Medicines are expected to give incentives to this field and enhance cooperation between all the stakeholders concerned.

¹³ E.g. Austria, Belgium, Czech Republic, Finland, Germany, Netherlands, Slovakia, Spain, Sweden - Add website link to the survey conducted by DG RTD

Priorities for future actions

The Commission will

- ▶ launch initiatives on the potential benefits, risks and possible new policy issues associated with the application of pharmacogenetics, including a prospective study, and consider the need for an opinion from the European Group on Ethics on the ethical implications.

3.4.4. Biobanks

An increasing number of population-based biobanks have been established worldwide. At the same time, this has led to new ethical issues being discussed in ethics committees at national and international levels. New specific laws regarding biobanks have been implemented or are under discussion at national level. The ability to optimise the use of biobanks across Europe is an important basis for ensuring progress in European biomedical science, including in the development of genetic testing and pharmacogenetics. However, effective collaboration is becoming increasingly difficult in a complex world where the principles governing public and private biobanks differ from one country to another.

Priorities for future actions

Commission and Member States

- ▶ to launch initiatives to establish recommendations for general principles governing biobanks, which will optimise data and sample-sharing for research purposes across the EU. The activities should take account of ongoing work at national and international level, such as the activities of the Council of Europe and OECD

The Commission will

- ▶ consider the need for an opinion from the European Group on Ethics regarding the ethical implications, some of which were covered in their Opinion No 19 "Ethical aspects of umbilical cord blood banking".

4. CONCLUSIONS

As described in more detail in the accompanying staff working paper, further progress has been made since last year's report on implementation of the Strategy and roadmap on Life Sciences and Biotechnology at Community level.

As last year, it is acknowledged that the situation regarding European biotechnology and its competitiveness still needs to be improved.

Regrettably, delays are still reported in the transposition of Directive 98/44/EC on the legal protection of biotechnological inventions. There is also a need for more active cooperation from all Member States in the implementation of the new legislative framework governing GMOs.

Against the above background, the Commission will, for its part, commence a process of reflection on the role of Life Sciences and Biotechnology in the renewed Lisbon Agenda and on the identification of the most appropriate measures needed to fulfil the Lisbon commitments. This process will draw on the results of a comprehensive biotechnology study and on an assessment of the progress achieved since 2002.

The Commission invites the Council and all stakeholders involved to participate in this reflection process.