



COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 07.04.2004  
COM(2004)250 final

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

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

{SEC (2004)438}

## 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 in implementing this Strategy. It states what has been achieved in policy development and on the ground, anticipates emerging issues - namely tissue engineering, genetic testing and animal biotechnology – and indicates elements of a policy response. It also incorporates, to the largest possible extent, the elements listed in the roadmap within the conclusions adopted by the Competitiveness Council of 26 November 2002. It is supported by a Commission Staff Working Paper providing further detailed information and timing on implementation of the action plan.

*Since last year's report was issued, further progress has been made in the implementation of the Strategy .....*

The 6<sup>th</sup> Framework Programme for Research (FP6) provides a major incentive for research in this area. The Commission, together with all other interested stakeholders, has continued its effort to bring science and society closer together and to develop an understanding of and an information exchange on life sciences and biotechnology. The review of the pharmaceutical legislation was adopted early this year. The regulatory framework on Genetically Modified Organisms has been completed and guidelines on co-existence in agriculture have been published.

Member States have chosen different strategies to provide the policy underpinning of biotech development and have opted for different instruments to support biotechnology development. They have also responded effectively to the challenge of education. Most have revamped the life sciences curricula and added new courses and material. Several Member States have in addition established relationships between academia and industry/society.

There are also a number of actions in the Member States intended to obtain “brain-gain” by making the European Research Area (ERA) more attractive for scientists in and outside the Union.

*...However, there is obviously still much to be done to improve the situation for European biotechnology.*

Public and private **investments in research urgently needs** to be increased. There is a need to continue to improve **biotechnology companies' access to finance**. The number of European companies has remained stable, while the number of pharmaceutical compounds in clinical trials (a common measure of research activity) has continued to increase. This growing maturity of the industry will put much higher demands on the European system for financing innovation and growth than was previously the case.

Member States still need to make progress on the implementation of measures to which they are already committed. One major example is **intellectual property**. The delays incurred in the **implementation of Directive 98/44/EC**, on the legal protection of biotechnological inventions leaves companies engaged in innovative biotechnology research uncertain as to whether they are fully entitled to the commercial fruits of their work. This is severely hampering the industry's development, discouraging not only innovators themselves but also

the potential investors whose finance is so desperately needed. The slow progress in adopting a **Community patent** has also led many companies to adopt a strategy of primarily securing patents in the US and a few European states. Resolving these two issues will be important for the growth of the biotechnology industry.

More active co-operation from all Member States is also needed in the **implementation of the new legislation governing GMOs**. Having demanded—and subsequently committed themselves to—a more rigorous framework, it is now imperative that all Member States implement the basic Directive 2001/18/EC on the authorised release of GMOs into the environment and the two regulations on traceability/labelling and GM/food and feed.

*The next stage in the strategy is for the various authorities and organisations to make commitments and to begin delivering the new policy measures according to the responsibilities set out in the action plan.*

The Commission is directly responsible for some actions but it is also determined to do what it can to keep up the general momentum and to play a facilitating role.

Against the background of the renewed political debate on the Lisbon agenda of task to revamp Europe's competitive position, there is an acknowledged need to step up the measures to meet the Lisbon commitments. The Biotechnology Strategy includes many subjects and stakeholders and the Union has to ensure that the coherence of its efforts is maintained. This calls for a **greater coordination and cooperation between Member States and the Commission**, with the aim of improving Europe's competitiveness. Consequently, the Commission proposes to reinforce the role of the existing Biotechnology network with Member States.

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## 1. INTRODUCTION

In January 2002, the Commission adopted a Strategy for Europe on Life Sciences and Biotechnology.<sup>1</sup> This sets out a comprehensive roadmap up to 2010 and puts the sector at the forefront of those frontier technologies which should move the European Union towards its long-term strategic goal established by the Lisbon European Council in March 2000.

This strategy set by the Commission consisted of two parts – policy orientations and a 30 point plan to transform policy into action. It sets out what was 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. On 5 March 2003, the Commission adopted its first progress report<sup>2</sup>, highlighting the progress made but also pointing out delays in some areas. It invited Member States to provide the necessary impetus to carry the strategy forward.

This Communication is the second such response. It states what has been achieved in policy development and on the ground, and anticipates emerging issues. It also incorporates to the largest possible extent the elements listed in the roadmap within the conclusions adopted by the Competitiveness Council of 26 November 2002.

As last year, this report is supported by a Commission Staff Working Paper providing further detailed information and timing on the implementation of the action plan.

## 2. REACTION TO THE COMMISSION'S FIRST PROGRESS REPORT

While highlighting the progress made in the implementation of the Strategy, the Commission pointed out in its first progress report that the picture was more mixed in some areas and was already giving cause for concern. This was down to 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**. The Commission concluded by calling on Member States to develop a clearer and more consistent policy on biotechnology to avoid the risk of reducing the impact, effectiveness and coherence of the EU's strategy in this field.

In its opinion of 16 July 2003, the **European Economic and Social Committee** shared the Commission's views, noting with a degree of pessimism that the Member States have not taken sufficient steps to swiftly achieve the goals laid down in the conclusions adopted by the Competitiveness Council on 26 November 2002. It asked the Commission to include a detailed analysis of achievements, failings and delays with respect to the approved plan in the next annual report.

At the **Competitiveness Council** of 22 September 2003, EU Ministers welcomed the first progress report on the implementation of the European Biotechnology Strategy and agreed with the broad lines of its analysis and adopted a set of conclusions.

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<sup>1</sup> COM(2002)27 final.

<sup>2</sup> COM(2003)96 final. It was supported by Commission Staff Working Paper SEC(2003)248

#### The Council

- stressed the need for “significant efforts to be made to move from the conceptual and planning stage to the implementation of the Strategy and of the roadmap contained in the Council conclusions of 26 November 2002 in order to contribute effectively to the achievement of the EU competitiveness objectives set by the Lisbon European Council,
- encouraged Member States and the Commission to step up their co-operation and to regularly exchange information on progress made in order to advance in the priority areas for future action already identified and, in particular, to improve conditions for access to finance for biotechnology companies and to complete and implement the general regulatory framework.

The **European Convention on Life Sciences and Biotechnology** organised by the Italian Presidency on 21-22 November 2003 further stressed the need for greater cooperation amongst various parties and for better co-ordination to be achieved in the national policies of Member States.

#### Priorities for future actions

##### **Commission and Member States**

- ▶ to increase their co-operation and exchange of information in order to enhance coherence and disseminate best practices. To this end, reinforcement of the existing Biotechnology network with Member States should be considered.

### **3. OVERVIEW OF POLICY DEVELOPMENTS AND PRIORITIES FOR ACTIONS**

#### **3.1. Harvesting the potential**

##### **Competitiveness of European biotechnology sector and related industries**

The biotechnology industry world-wide has continued to develop, although at a slower rate than previously due mainly to the lower confidence of investors in high-technology sectors since 2000. However, there seems to have been some recovery in biotechnology in 2003, particularly in the US but increasingly also in Europe.

The number of European companies has remained stable, while the number of pharmaceutical compounds in clinical trials (a common measure of research activity) has continued to increase. This growing maturity of the industry will put much higher demands on the European system for financing innovation and growth than was previously the case. The slow progress in adopting a Community patent has also led many companies – specifically SMEs – to adopt a strategy of primarily securing patents in the US and a few European states. Resolving these two issues will be important for the growth and competitiveness of the biotechnology industry.

As highlighted in a recent letter of Prime Minister Tony Blair, President Jacques Chirac and Federal Chancellor Gerhard Schröder in anticipation to the 2004 Spring Council, life sciences and biotechnology are amongst the key growth technologies for a more innovative and

competitive Europe. Critical to the success of the innovation process is the ability of business to transform research initiatives into commercially viable processes and products.

It is well known that Europe has more biotechnology companies than the US. It is also often repeated that the US industry employs far more people and has a much higher turnover. A more careful analysis highlights some interesting aspects of this seeming paradox.

The innovative and economic performance of small European biotechnology companies is comparable to their US counterparts. There does not seem to be any fundamental limitations on European companies at that level. Interestingly enough, neither does there seem to be much difference in the performance of medium-size companies. Europe does however have far fewer of those companies compared to the US. Undoubtedly, this can partly be ascribed to Europe's younger industry, but there are clear indications that difficult access to later-stage finance and the absence of liquid stock markets for technology shares have contributed.

As noted in the Strategy, there is a strong potential for the use of biotechnology in industrial processes and new materials. This so called "white biotechnology" may well represent a significant portion of the whole biotechnology industry in the coming years, but is also a sector where European companies hold a strong position. One of the main challenges to European policy-makers will be to put the conditions in place to ensure that bio-based solutions become mainstream options for industrial development.

Member States have chosen different strategies to provide the policy underpinning of biotech development. In Finland a ministerial working group coordinates the work while in other Member States the task is done by individual ministries or through government agencies.

In similar fashion, Member States have chosen different instruments to support biotechnology development. Some have introduced fiscal benefits or deferred social security payments (France, Italy), some are encouraging inward investment (Ireland, Spain), yet others stress technology transfer (Italy). There is no single measure that is universally applicable, but continuing exchanges of views and collaboration will help to policymakers to choose the mix of measures that is most beneficial given the local circumstances.

Member States have also responded effectively to the challenge of education. Most have revamped the life sciences curricula and added new courses and material. Several Member states have in addition established relationships between academia and industry/society. It is likely that there is much to be learned from an exchange of experiences.

There are also a number of actions in the Member States intended to obtain "brain-gain" by making the European Research Area more attractive for scientists in and outside the Union. Tax treatment and better conditions for leading edge research are being introduced in Austria, Denmark, Germany, Italy and other Member States.

### ***The Competitiveness in Biotechnology Advisory Group***

In accordance with Action 10b of the Strategy, in 2003 the Commission appointed a **Competitiveness in Biotechnology Advisory Group** with Industry and Academia (CBAG). 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 first report, the group chose to concentrate on the issues of **access to finance and regulation**.

The Group highlighted that entrepreneurial biotechnology companies are faced with the same pressures as other innovative companies, except that for biotech companies these pressures are often more acute. It identified **three main areas** that require attention to boost the financial environment for biotech companies, namely

- protecting **intellectual property rights**,
- boosting **finance, liquidity and capital markets** in Europe, and
- **research funding through public/private partnerships**.

The Group stressed that, for fast and effective improvements, the entrepreneurial biotechnology community expects policy changes mainly at national level rather than at EU level. Therefore, many of its recommended actions target Member States rather than the Commission.

The full text of the Group's report can be found in the Commission staff working paper.

### ***Intellectual property protection***

The CBAG calls for a **speedy and full implementation and application of adopted Community legislation** and criticises the delays in some Member States in transposing already agreed legislation, in particular the Biotechnology Patent Directive. The Group recommends **enhanced communication between regulatory authorities and between such authorities and applicants**.

After receiving the opinion of the European Parliament, the Commission proposal for a Regulation on the Community Patent<sup>3</sup> is being discussed in the Council, where, on 3 March 2003, a common political approach was agreed on a number of issues. This approach provides useful guidance for the finalisation of the regulation.

To date, only seven Member States<sup>4</sup> have transposed Directive 98/44/EC<sup>5</sup> 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 the other eight Member States to the European Court of Justice for their failure to transpose the Directive into their national legislation. The lack of transposition of the Directive leaves companies engaged in innovative biotechnology research uncertain as to whether they are fully entitled to the commercial fruits of their work. This is severely hampering the industry's development, discouraging not only innovators themselves but also the potential investors whose finance is so desperately needed.

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 16(c) of Directive 98/44/EC<sup>6</sup>, 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.

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<sup>3</sup> COM(2000)412.

<sup>4</sup> Denmark, Finland, Ireland, United Kingdom, Greece, Spain and Portugal.

<sup>5</sup> OJ L 213, 30.7.1998, p.13.

<sup>6</sup> COM(2002)545 final, 7.10.2002.



These two topics have been studied and analysed by a group of independent experts. The Commission is drafting the second report provided for in Article 16© of the directive, taking into account the comments made by the experts.

### **Priorities for future actions**

#### **Council**

- ▶ to resolve the remaining difficulties following the political agreement of 3 March 2003, and to adopt the Community Patent Regulation in 2004,
- ▶ to take a decision in good time on the creation of the centralised Community patent court, for which the Commission has presented a proposal<sup>7</sup> to the Council in December 2003,
- ▶ to agree on changes to the European Patent Convention in order to allow the European Patent Office to grant Community Patents.

#### **Member States**

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

### *Access to finance*

The biotechnology industry, with its long development times and high costs, is uniquely dependent on effective access to finance.

The CBAG stresses that **lack of capital and the fragmentation of the European securities markets** is impeding the industry's development and recommends swift harmonisation of securities regulations, to enable multiple listings and mergers of markets. The Group agrees with the conclusions of the Biotechnology and Finance Forum as mentioned below and recommends the **establishment of funds to cover the gap between traditional venture capital (VC) financing and the IPO stage.**

In general, the financial community has retained confidence in the industry, but in 2002-2003 the overall retrenchment of risk capital and the arrival of a large number of companies at the point where they need new financing to continue their expansion combined to threaten a substantial segment of the industry.

This problem first surfaced in countries, such as Germany, where the success of the BioRegio programme in the nineties had led to a large number of companies at the same stage of development, but other Member States where the industry has made a significant start shortly face the same problem. It should be noted that the present problem is a consequence of the large-scale success in developing an industry, not of failure

The Commission's advisory **Biotechnology and Finance Forum**, reporting early in 2003 on the issue, identified a number of problems and several Member States and the European financial institutions have worked to find appropriate solutions.

Germany and the European Investment Fund (EIF) have created a common fund to tackle this acute situation, while other Member States, such as France have acted by reviewing their fiscal and social contributions policies. In October 2003 the European Investment Bank (EIB) decided to commit half a billion € for the EIF to invest in funds in high-technology

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<sup>7</sup> COM(2003)827 and 828

companies. This measure can be expected largely to benefit biotechnology companies. The EIF investment rules have also been changed to allow investments in later stage entrepreneurial companies. This provision is of great importance given the long development times of most biotech products.

The biotechnology industry will always be characterised by the creation and disappearance of entrepreneurial companies, but it may be hoped that the recent measures will help to retain companies with good products and good management that would otherwise find the situation impossible. This is of vital importance to the consolidation and development of an industry with a critical mass also composed of medium-size companies.

### ***Networking Europe's biotechnology***

Fragmentation is still a crucial issue for Europe's biotechnology stakeholders. There is still too little cross-national collaboration between researchers and companies, and too little awareness of developments in other European countries. There are many regional biotechnology clusters, although co-operation between them is under-developed; this is a particular problem considering that many of them lack critical mass.

In consequence, networking is vital for the effective further development of biotechnology in Europe. The Commission is supporting the creation of an external **European Biotechnology Web Portal**, with the aim to successfully link up companies, the academic world and interested lay people. The portal will be available in 2004.

The informal **network with Member States officials on competitiveness issues**, established in accordance with action 10a of the Strategy, is operating successfully and has now been expanded to the accession countries. This network will play an important role in the benchmarking of European Biotechnology Policies that has just been launched and has already made a constructive contribution to the previously mentioned finance issue.

#### **Priorities for future actions**

##### ***Commission and Member States***

- ▶ to develop, in 2004-2005, a **benchmarking programme** as a tool for policymakers to develop the right mix of policies, given their Member State's circumstances, and to repeat the benchmarking at intervals to provide a basis for an exchange of best practices and fine-tuning of policies.

### **Research and Technological Developments**

In its report to the Spring European Council<sup>8</sup>, the Commission indicated that the Union is still far from achieving the objectives set at the Lisbon European Council. An analysis of progress has highlighted the **lack of investment in knowledge sectors, namely research, innovation, education and training**. High priority should now be given to improving the framework conditions and public support for research investment and ensuring consistency and synergy in Europe through the open method of co-ordination.

This requires a determined and co-ordinated efforts by all interested parties - EU Member States and public and private sector stakeholders - to implement the **Investing in Research action plan**<sup>9</sup> setting out initiatives to give Europe a stronger public research base and to make

<sup>8</sup> COM(2004)29 final, Delivering Lisbon: Reforms for the enlarged Union

<sup>9</sup> COM(2003)226 final, Investing in research : an action plan for Europe

it much more attractive to private investment in research and innovation. Key actions include setting up European technology platforms, strengthening links between industry and public research, redirecting public spending towards research and innovation, making research careers more attractive and developing better fiscal incentives for research.

#### **Priorities for future actions**

##### ***Member States, public and private sector stakeholders***

- ▶ to implement the action plan "Investing in Research".

#### **Funding research in Europe**

For its part, the Commission has enhanced its support for Life Sciences and Biotechnology research under the **6<sup>th</sup> Framework Programme for Research (FP6)**. Implementation of this Programme has in fact increased the Commission's financial contribution to research in this area by some 20% compared with the 5<sup>th</sup> Framework Programme for Research. As a result of the first call for proposals more than €810 million was allocated to actions in the 2 thematic priorities "Life sciences, genomics and biotechnology for health" and "Food Quality and Safety", mobilising more than 2700 laboratories, including about 400 SMEs.

Disciplines are converging and life sciences and biotechnology are now permeating many areas of research including nanotechnology, informatics, social sciences and engineering. Therefore, other thematic priorities such as Nanotechnology, Sustainable Development, Citizen and Governance as well as research in ethics under Science and Society, will contribute to generating progress in life sciences and biotechnology.

Funding has been concentrated on a **few selected priorities** and the new funding instruments (Network of Excellence and Integrated Projects) provide top researchers with a critical mass of resources and skills to be at the leading edge of science and technological developments. The new instruments foster linkage between basic scientists and clinicians, between academia and industry, between disciplines (physicists, geneticists, computer scientists, etc.), involving both the natural sciences and experts in ethics and social sciences, and between the scientific communities and consumer and patient organisations, etc. The goal of stimulating these interactions is not unique to Europe, but the European experience may benefit the international scientific community and serve as a model for other nations.

As a result of the first call for proposals, about 10% of the budget (approximately €80m) will be allocated to **SMEs**. In addition, 52 Specific SME activities (Co-operative Research, Collective Research) and research and innovation activities (Economic and Technological Intelligence actions) will be implemented to help a large community of SME's develop innovation in healthcare, food quality and safety, agriculture and aquaculture.

In order to improve the access to biological resources and large-scale high technology facilities essential for both the research and commercial development of biotechnology, actions on **access to research infrastructures** are supported under the specific programme "Structuring the European Research Area" (2002-2006) (EU contribution of €48.7m).

Amongst the numerous areas holding much potential in the area of Life Sciences and Biotechnology, the following are being promoted:

➤ *Genomics research*

The **BioSapiens Network of Excellence** brings together 24 bioinformatics centres in 14 countries throughout Europe. Bio Sapiens aims to address the current fragmentation of European bioinformatics by creating the “European Virtual Institute for Genome Annotation”<sup>10</sup>. The Institute will establish a permanent European School of Bioinformatics.

➤ *Biotechnology for health*

As one of the measures geared towards the European Research Area (ERA), the Commission has called together the Forum of Genomes Programme Managers to help find synergies between national research activities in the field of genomes research in Europe.

**CO-ORDINATION OF GENOMES RESEARCH ACROSS EUROPE ( COGENE)**

**COGENE**<sup>11</sup> aims to promote the development of synergies between national genome research programmes related to human health in Europe. It acts on behalf of the Forum of Genomes Programme Managers with representatives from 25 European countries. At the moment COGENE is mapping major national research funding sources and the most important infrastructures for genomes research within the COGENE forum member countries. COGENE workshops, which brought together research managers from national funding agencies, academia and industry, have yielded recommendations for further actions to co-ordinate research in strategically important fields, such as pharmacogenomics and population genomics.

➤ *Plant genomics and biotechnology*

Although progress on GMO’s has been made in recent years and new non-GM technologies (e.g. marker-assisted breeding and high-throughput identification of mutations in genes of interest) are being developed and applied, it will take a joint effort on the part of all stakeholders to regain ground in plant science and strengthen the competitive position of EU research and industry in the world.

The **Integrated Project “New strategies to improve grain legumes for food and feed”**, involving 52 participants from 18 countries, will mobilise and integrate European scientific research on grain legumes (e.g. peas, lupins, lentils, chick peas) in particular it will contribute to the sequencing of the genome of the model legume *M. truncatula* and generate extensive functional genomics tools for *M. truncatula* as well as for grain legumes of economic importance for Europe. In yet another step towards creating a true European Research Area, the Commission is also supporting an **ERA-NET on Plant Genomics**<sup>12</sup> aimed at coordinating the national research programmes in this area of ten EU member states and Norway.

This ERA-NET is expected to be an important part of a future **European technology platform on plant genomics and biotechnology**, which is currently being set up. The aim of this platform is to develop an EU-wide strategy to re-build and strengthen the S&T base in plant genomics and biotechnology, taking into account the needs of the different industrial sectors (food, chemicals, pharmaceuticals etc.). The platform will involve key stakeholders from research, biotech, - food and feed- industry, farmers, regulators and consumers. Based

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<sup>10</sup> ‘Annotation’ is the process by which features of the genes or proteins stored in a database are extracted from other sources, defined and interpreted.

<sup>11</sup> <http://www.cogene.net>

<sup>12</sup> <http://www.cordis.lu/coordination/era-net.htm>

on a common vision for the development of plant genomics and biotechnology in Europe, one of the key objectives of this platform will be to formulate **a strategic research agenda for 2005-2010** defining, for both medium and long-term targets, priorities, and building up the necessary public-private-partnership, including the mechanism to mobilise private and public investments which will be required for the implementation of the research and development strategies.

#### Priorities for future actions

##### Commission

- ▶ to launch the European technology platform on plant genomics and biotechnology in Spring 2004.

#### *Industrial biotechnology*

The potential of industrial biotechnology in terms of competitiveness, growth and environmental sustainability has been reflected in a series of OECD reports<sup>13</sup>. Despite the funding of this area under the various EC Framework Programmes and strategic research programmes in a number of Member States, large scale practical applications of industrial biotechnology in Europe seem to be limited, while in the US and in Japan a strategic research agenda for the development of industrial biotechnology has been formulated.

The importance of industrial biotech for sustainable development has been highlighted in the recent Commission **Communication on “Environmental Technology Action Plan”**<sup>14</sup>.

#### Priorities for future actions

##### Commission

- ▶ to launch a series of roundtables in Spring 2004 bringing together stakeholders from research, industry, NGOs, regulators and representatives from Member States with the aim to prepare by mid 2004 a vision paper for European industrial biotechnology.

#### **Human resources in R&D: Researchers**

Human resources are vital to R&D. The need to take action has been acknowledged. The Commission has taken a proactive role, from promoting and financing several initiatives to attempting to streamline legislations, in an attempt to improve the researchers' environment and to make the European Research Area more attractive to scientists in and outside the Union. As part of the implementation of the **Mobility Strategy for the European Research Area**<sup>15</sup>, the Commission has launched several initiatives, in close cooperation with the Member States, including the **“The Researcher’s Mobility Portal”**<sup>16</sup>, which provides web-based national and Community information on a European scale, specific job and fellowship opportunities for researchers, and the **European network of mobility centres( ERA-MORE)** which will provide researchers and their families with customised assistance in all matters relating to their working and daily lives when undertaking a mobility experience.

<sup>13</sup> E.g. "Biotechnology for Clean Industrial Products and Processes: Towards Industrial Sustainability", 1999; and "The Application of Biotechnology to Industrial Sustainability", 2001; OECD, Paris.

<sup>14</sup> COM(2004)38 final “Stimulating Technologies for Sustainable Development: An Environmental Technologies Action Plan for the European Union.( <http://europa.eu.int/comm/environment/etap>)

<sup>15</sup> (COM(2001)331 final of 20.06.2001)

<sup>16</sup> <http://www.europa.eu.int/eracareers>

The budget for the Structuring Activity “**Human resources and mobility**” under the 6<sup>th</sup> Framework Programme for Research has been almost doubled from the 5th Framework Programme value<sup>17</sup>. Research training opportunities in Europe for researchers have been reinforced. Specific grants providing return opportunities for those European researchers who have spend long periods outside Europe as well as **International Marie Curie Fellowships** and **Marie Curie Excellence Grants and Chairs** to attract world-class researchers to Europe have been introduced. As a result of the first calls for proposals €47 million (13% of the budget) has been allocated to “Human resources and mobility”/”Marie Curie” actions in Life Sciences and Biotechnology.

In its Communication “**Researchers in the European Research Area: one profession, multiple careers**”<sup>18</sup>, the Commission addresses for the first time at European level the issue of the researcher profession and researchers’ careers.

A proposal for a Directive on the entry and stay of third country researchers within the EU and an associated action plan was adopted by the Commission on 16 March 2004<sup>19</sup>.

The Commission is launching a series of initiatives, which will be implemented in the course of 2004, in order to open a structured dialogue between the different stakeholders.

#### Priorities for future actions

##### *Commission*

- ▶ to propose Recommendations on a “**European Researcher’s Charter**”, a framework for the career management of human resources in R&D, based on voluntary regulation, as well as on a “**code of conduct for the recruitment of researchers**” to improve recruitment methods, and to launch **studies** to assess and benchmark the multiple career paths of researchers.

#### Future Research Policy Initiatives

The Commission is now starting to reflect on the design of the next European Research Framework Programme. A vision for future research activities is vital in order to maintain and increase momentum towards an effective knowledge-based economy and society. Taking current initiatives as a basis and identifying the needs and expectations of the scientific community, policy-decision-makers and society, an orientation document will be presented to initiate a debate engaging all stakeholders.

#### Priorities for future actions

##### *Commission*

- ▶ to present a Communication regarding future research policy initiatives in May 2004.
- ▶ to prepare a revision of the Community framework on **state aid for R&D**.

<sup>17</sup> Human capital web site: [http://www.europa.eu.int/comm/research/fp6/mariecurie-actions/home\\_en.html](http://www.europa.eu.int/comm/research/fp6/mariecurie-actions/home_en.html)

<sup>18</sup> COM(2003)436 of 18.07.2003

<sup>19</sup> COM(2004)178 final

## 3.2. Governing life sciences and biotechnology

### Social scrutiny and dialogue

Uncertainties about social acceptance of biotechnology have continued to weaken the EU's capacity for innovation. With the exception of medical applications, public expectation of biotechnology, with particular reference to agricultural applications, remains moderate. Therefore, the Commission, together with all interest stakeholders, has continued its efforts to bring science and society closer together and to develop an understanding of and information exchange on life sciences and biotechnology. However, it is imperative that industry should openly explain and document the benefit and potential of this technology in all its fields of application, and the initiatives to a broader dialogue by the industry and by the European Federation of Biotechnology are to be welcomed.

As envisaged in Action 13(a) of the Strategy, the Commission organised the first stakeholder conference entitled “**Risk perception: Science, Public Debate and Policy making**” in December 2003. The objective of the conference was to explore the effect of human perception on risk assessment and risk analysis and its significance and implications in promoting key scientific paradigms underlying regulatory oversight and governance.

The emergence of “**Technology Platforms**” is expected to add a new dimension of dynamism to societal dialogue by bringing together all interested stakeholders - research organisations, industry, regulators, user groups, etc. – around key technologies, in order to devise and implement a common strategy for the development, deployment and use of these technologies in Europe.

The importance of research communication, openness and researchers contact with society has been recognised and Member States as well as the Commission have taken actions to identify measures and tools to improve communication. Within FP6 research communication to the general public is an integral part of the research projects.

#### Priorities for future actions

##### **Commission and Member States**

- ▶ to engage in exchange of experience in order to establish a more comprehensive strategy for communicating research.

We can not neglect that at the same time as research in Life Science and Biotechnology is demonstrating its vast potential for improving quality of life, weapons engineered to attack humans, animals or plants is becoming an increasing concern.

It is clear that a central component of the debate is to raise the awareness of the global scientific community also about this **dual-use “tension”** and the responsibility to mitigate any possible risks associated with research in Life Science and Biotechnology. As a first initiative to stimulate an international dialogue, the Commission organised a conference 3-4 February 2004 on the “*Ethical implications of scientific research on bioweapons and prevention of bio terrorism*”. The participants appeared to agree that concerning the restriction of release of scientific results, the benefits of releasing scientific information outweighs the risk of its misuse.

## ***Developing life sciences and biotechnology in harmony with ethical values and societal goals***

The immediate responsibility of the Commission is to ensure public trust and confidence in its research projects. The application of the **ethical review system** in the FP6 has been made more consistent and systematic for research project involving human beings, human tissue, private or personal data, genetic information and/or animals. A reporting system has improved the governance and transparency of such EC funded research. It also acts as a mean for raising the awareness of research regarding ethical issues.

Several specific actions have been undertaken in the context of implementation of the **Science and Society action plan**<sup>20</sup>. In particular, a **Forum of the Presidents of the National Ethics Councils** has been established, allowing for an exchange of positions and views about important topics of bioethics and ethics in research in Europe. A **directory of local ethics committees** has been collected in the 33 countries of ERA.

### **Priorities for future actions**

#### **Commission**

- ▶ to establish a **documentation and information system on ethics in research** in 2005. The system will be based on a FP5 project and a feasibility study launched in February 2004. It will provide information on the different legislation, debates and important literature in ERA

The **European Group on Life Sciences (EGLS)** has been continuing its activities towards facilitating broad communication and societal dialogue on life sciences and biotechnology. An Encounter - *Modern Biology and Visions of Humanity* - gathering scientists, humanists and scholars from the arts to reflect on the reciprocal impact of life sciences, our cultures and societies, took place on 22-23 March 2004.

In accordance with the statements to the minutes of the Council of 30 September 2003 on the specific programme “Integrating and strengthening the European Research Area” and in order to contribute to the current debate within the context of deciding on the funding of **human embryonic stem cell research** under the FP6, the following steps were taken by the Commission:

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<sup>20</sup> COM(2001)714 final



- a **report** on human embryonic stem cell research was published on 3 April 2003 (SEC(2003) 441);
- an **inter-institutional seminar** was organised on 24 April 2003 on the same subject;
- **procedural modalities for research activities involving banked or isolated human embryonic stem cells in culture** to be funded under FP6 were adopted by the Commission on 11 November 2003 ( C(2003) 2952). These modalities clarify the procedure which the Commission will follow when evaluating selecting and supporting research projects involving such research activities;
- 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 within the framework of FP6, was submitted to the Institutions in July 2003. Although supported by the European Parliament, **these guidelines were not adopted by the Council.**

## Confidence in science-based regulatory oversight

### *Review of the pharmaceutical legislation*

The review of the pharmaceutical legislation was adopted on **11 March 2004**. There are three elements of particular importance for the development of stronger entrepreneurial biotechnology, namely a series of provisions to develop and reinforce the system of giving scientific advice through the creation of expert panels and permanent working groups in the EMEA, the introduction of a fast-track marketing authorisation procedure for products with a major public health interest for European patients, and a conditional marketing authorisation.

In parallel, the G10 process, launched in 2001, has already passed some significant milestones. Following the Council Conclusions on the Communication<sup>21</sup>, the G10 process has now entered its implementation phase.

Most of the Recommendations will be implemented through existing EU programmes such as the Pharmaceutical Review, the FP6 and the Public Health Programme. However, it will be supplemented by specific exercises to take forward recommendations on benchmarking, patient information, pricing and relative effectiveness. To make progress in these areas will require both the Commission and Member States to take joint action building on the consensus developed through the G10 process.

### *Genetically Modified Organisms (GMOs) legislation*

On 28 January 2004, the Commission held an orientation debate on GMOs and related issues to take stock of the progress made in recent years in building a comprehensive EU regulatory framework on GMOs, in close dialogue with Member States and all stakeholders<sup>22</sup>.

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<sup>21</sup> Communication from the Commission to the Council, the European Parliament, the Economic and Social Committee and the Committee of the Regions 'A stronger European-based Pharmaceutical Industry for the Benefit of the Patient – A Call for Action COM(2003)383 final

### Regulatory Framework on GMOs

- **Directive 2001/18/EC**<sup>23</sup>, which provides for a more complete authorisation procedure for GMOs, has been fully applicable since **17 October 2002**;
- the **two new Regulations 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, have been adopted by the Council and EP and will be fully applicable by **April 2004**<sup>24</sup>; Regulation (EC) No 1829/2003 covers GMOs for food and feed use as well as food and feed containing, consisting of, or produced from GMOs. The Regulation is based on the “one door-one key” principle. Thus, it is possible to file a single application for obtaining both the authorisation for the deliberate release of a GMO into the environment, under the criteria laid down in Directive 2001/18/EC and the authorisation for use of this GMO in food and/or feed under the criteria laid down in Regulation 1829/2003. This authorisation, valid throughout the Community, is granted subject to a single risk assessment process under the responsibility of the European Food Safety Authority and a single risk management process involving the Commission and the Member States through a regulatory committee procedure.

The Regulation extends the labelling provisions to all genetically modified food and feed irrespective of the detectability of DNA and protein. The applicability of this requirement is ensured through the provisions laid down in Regulation 1830/2003 on traceability and labelling. In order to ensure the feasibility and practicability of the Regulation, provisions regarding derogation for adventitious or technically unavoidable presence of GMOs in food/feed have been foreseen.

- a number of **implementing measures and guidelines** for the above legislation have been adopted or are in preparation with a view to completing and ensuring full applicability of the new regulatory framework by **April 2004**;
- **Regulation (EC) No 1946/2003 on transboundary movements of GMOs** was adopted on 15 July 2003 by the Council and the EP and is applicable as of **25 November 2003**<sup>25</sup>. This Regulation complements the above regulatory framework on GMOs, in particular as regards exports, and aligns it with the provisions of the Cartagena Protocol on Biosafety, which entered into force on 11 September 2003.

On that occasion, the Commission reconfirmed its approach on GMO authorisation procedures and agreed on a number of actions in the short term.

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

Regrettably, to date **only seven Member States** have fully communicated their implementation measures for Directive 2001/18/EC<sup>26</sup>. These are currently being assessed by

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<sup>22</sup> Communication to the Commission available at:  
[http://www.europa.eu.int/rapid/start/cgi/guesten.ksh?p\\_action.gettxt=gt&doc=IP/04/118|0|RAPID&lg=EN&display=](http://www.europa.eu.int/rapid/start/cgi/guesten.ksh?p_action.gettxt=gt&doc=IP/04/118|0|RAPID&lg=EN&display=)

<sup>23</sup> OJ L 106, 17.4.2001, p.1.

<sup>24</sup> Regulation (EC) No 1829/2003 of the EP and of the Council of 22.9.2003 on genetically modified food and feed (OJ L 268, 18.10.2003, p.1; Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC (OJ L 268, 18.10.2003, p.24)

<sup>25</sup> Regulation (EC) No 1946/2003 of the European Parliament and of the Council on the transboundary movement of GMOs (OJ L 287, 5.11.2003, p.1).

<sup>26</sup> UK, Denmark, Sweden, Portugal, Italy, Spain and Ireland.

the Commission for their conformity. The Commission has referred the eight Member States that have still not adopted national transposition measures to the European Court of Justice.

#### **Priorities for future actions**

##### **Member States**

- ▶ to fully and swiftly transpose and implement Directive 2001/18/EC,
- ▶ to withdraw national measures invoked under the novel food regulations and under environmental legislation and to lift the relevant restrictions.

##### **Commission**

- ▶ to complete the adoption of implementing measures and guidelines,
- ▶ to adopt labelling thresholds for the adventitious or technically unavoidable presence of authorised GM seeds in seeds of non-GM varieties under Article 21(2) of Directive 2001/18/EC. Similar thresholds will then be adopted under the Seeds Directives.

#### *Co-existence of GM crops with conventional and organic crops*

The cultivation of GM crops may have implications for the organisation of agricultural production. Co-existence refers to the ability of farmers to make a practical choice between conventional, organic and GM crop production in compliance with the legal obligations for labelling and purity standards.

At its meeting on 5 March 2003, the Commission agreed that it should be up to the Member States to develop and implement management measures concerning co-existence, in accordance with the **subsidiarity principle**. The **Round Table** hosted by the Commission on 24 April 2003 to examine the latest research results on the co-existence of GM and non-GM crops concluded that any approach needs to take account of the diversity in regional conditions, which argues against a unified Community approach towards co-existence.

In the light of the above, on 23 July 2003, the Commission adopted a Recommendation setting out **guidelines for the development of national strategies and best practices to ensure the co-existence**<sup>27</sup> of GMOs with conventional and organic farming.

The guidelines provide a list of general principles and elements for the development of national strategies and best practices as well as an indicative catalogue of measures that can be used to reduce or avoid the accidental mixture of GM and non-GM crops. The basic principle underlying the guidelines is that **no form of agriculture, be it GM, conventional or organic, should be excluded in the EU in the future**. Measures for co-existence should be efficient, cost-effective and proportionate and should not go beyond what is necessary to ensure that the adventitious presence of GMOs stays below the tolerance thresholds.

The subsidiarity approach was endorsed by the Council and the European Parliament last July, when a new Article specifically authorising Member States to take appropriate measures to avoid “the unintended presence of GMOs in other products” was introduced in the environmental legislation (i.e. Article 26(a) of Directive 2001/18/EC on the deliberate release into the environment of GMOs). This Article also establishes that the role of the Commission is to gather and co-ordinate information and observe developments regarding co-existence in

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<sup>27</sup> Commission Recommendation 2003/556/EC on co-existence.

the Member States. In the Recommendation itself, the Commission committed itself to coordinating the exchange of information on measures, experiences and best practices supplied by the Member States.

Many Member States are now seeking clarification as to what sort of co-existence measures would be legally acceptable.

The Commission recommendation on co-existence was discussed in the Council of Agricultural Ministers of 29 September 2003, where Member States and acceding countries were split between supporting the subsidiarity approach and requesting that rules on co-existence be established at Community level.

Furthermore, on 18 December 2003, the EP plenary adopted an own-initiative report calling for uniform and binding rules on co-existence to be established at Community level, including Community-wide liability rules and insurance in respect of possible economic damage in connection with co-existence.

Several Member States have been considering their policies on co-existence. Following public debate, science review and studies on the costs and benefits of GM crops. National debates were organised, amongst other initiatives, in the **UK**<sup>28</sup> and **Denmark**. National co-existence strategies are in advanced stage of adoption by **Denmark** and **Germany**.

While a number of draft “co-existence” measures have already been notified to the Commission, the Commission is also aware of non-notified co-existence measures, taken at national, regional or local level, which might contradict Community legislation and could prompt infringement procedures.

#### **Priorities for future actions**

##### **Member States**

- ▶ to ensure an exchange of information on successful approaches and best practices and to notify national or regional measures on co-existence to the Commission.

##### **Commission**

- ▶ to enhance its co-ordination role as defined in Directive 2001/18/EC, in order to smooth any potential problems linked to the development of co-existence strategies by Member States,
- ▶ to report to the Council and the European Parliament, 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 evaluation and assessment of all possible and necessary steps to be taken.

### **3.3. Europe in the world - responding to global challenges**

#### **A European Agenda for international cooperation**

The Commission has continued to play an active role in developing international guidelines, standards and recommendations in the relevant sectors and within established international forums such as UN-organisations, OECD, the Council of Europe Steering Committee on Bioethics. Now that the Community has become a full member of the **Codex Alimentarius**

<sup>28</sup>

Further details are available on the "GM Nation" web site - <http://www.gmnation.org.uk/>

**Commission**, the Commission intends to contribute in full to the development of Codex guidelines relating to food produced from biotechnology.

An important example of this commitment is the Commission's role in the works of the Cartagena Protocol on Biosafety which entered into force on 11 September 2003. At the First Meeting of the Parties to the Cartagena Protocol, held in Kuala Lumpur (23-27 February 2004), a consensus was reached in relation to documentation requirements for the transboundary movement of GMOs, on an action plan to help developing countries implementing the Protocol, on a compliance mechanism and on a fully operational internet-based Clearing House for the international exchange of information related to GMOs.

At the same time, it has promoted and participated in initiatives aimed at improving dialogue with our trade partners towards a better understanding of the issues relating to the application of biotechnology and its governance.

The Commission actively participated in the **UNIDO Global Biotechnology Forum**, which took place in Chile 2-5 March 2004.

Constructive and fruitful **bilateral dialogues with Japan**, which, like the EU, also launched a strategy for life sciences and biotechnology in 2002, have taken place within the framework of the EU-Japan Industrial Policy Dialogue and within the industry-led EU-Japan Business Dialogue Round Table.

However, on 29 August 2003 the long-standing divergence of views between the EU and some of its trading partners culminated in the establishment of a **WTO panel**, at the request of the US, Canada and Argentina, to rule on the matter of **GMOs**.

The Commission has always made it clear that a WTO challenge is an inappropriate and regrettable move. At a time when most countries are developing appropriate legal frameworks to deal with the modern techniques of genetic modification, the decision to start a WTO case is in stark contrast with the spirit of co-operation that should herald the global trend towards more comprehensive and better regulation. While it is only right and proper for states to raise their legitimate trade concerns through the appropriate channels, the Commission views the WTO challenge on GMOs as an obstacle to the search for common, trade-enhancing approaches to biotechnology.

The Commission will continue to promote international and bilateral cooperation in the field of biotechnology. The Commission considers that there are important political and technical issues that need to be addressed at international level and remains committed to discussing those issues with any parties willing to enter into a constructive dialogue.

## **Europe's responsibilities towards the developing world**

### *Agriculture and Genetic Resources*

The EC is the main contributor to the new **Consultative Group on International Agricultural Research (CGIAR)** Challenge Program "**Unlocking Genetic Diversity in Crops for the Resource-Poor**", which is developing *a unique platform involving public, private and civil society partners* for accessing and developing new genetic resources using new molecular technologies and traditional means. Through the programme, an unprecedented array of genomic and genetic resources, ready for direct use in plant improvement, will be made available as public goods in the form of enabling technologies

and intermediate products for crop improvement programmes. Tolerance to drought will be the first issue to be considered for proof of concept.

### *Health*

In February 2003, the Commission adopted a **Communication** reviewing progress achieved under the Programme for Action entitled "**Accelerated action on HIV/AIDS, malaria and TB in the context of poverty reduction**" and putting forward recommendations for further actions<sup>29</sup>.

In terms of '*increasing investment in research and development*', substantial resources have been allocated from the Research Framework Programmes for HIV/AIDS, malaria and TB research, including the establishment of the new ***European and Developing Countries Clinical Trials Partnership (EDCTP)*** initiative which is the first joint programme to bring together the efforts of several Member States aimed at developing and evaluating new vaccines and drugs against those diseases. The EDCTP clearly constitutes a new step forward as it provides a unified voice to represent European research contributions in the fight against the three diseases in developing countries. Additional direct and indirect incentives for **research** and development of specific global public goods to fight the three diseases will require primary focus in the coming years.

#### ***European and Developing Countries Clinical Trials Partnership (EDCTP)***

The EDCTP was adopted **in June 2003** and will be fully operational during the first half of 2004. It is an independent legal entity with its own operational procedures, including calls for proposals and appropriate selection of the clinical trials to be fully or partially funded. The EDCTP has a target budget of € 600 million. The Community will contribute one third of the budget via the 6<sup>th</sup> FP, whereas another € 200 million will be provided by Member States and Norway. The remaining € 200 million will be sought from private sources, R&D industry, foundations, charities and Community development funds (e.g. EDF).

A carefully balanced management structure ensures that developing countries are equal partners in strategic decisions.

In addition, financial support for research projects under FP6 in the area of poverty-related diseases (HIV/AIDS, malaria and tuberculosis) is significantly increased. Support will be given to ***Preclinical and early clinical testing of new drugs, vaccines and microbicides for HIV/AIDS, malaria and TB***. Support will be given in particular to large research consortia that integrate different disciplines and approaches and can generate a critical mass between the different players involved. Active participation of partners from endemic, developing countries is specifically encouraged. The first call for proposals under FP6 resulted in funding projects, among others, for the development of a new TB vaccine and for preclinical testing of vaccines and microbicides targeting HIV.

Finally, the Commission will also continue to support research on further ***neglected tropical diseases***, such as "sleeping sickness".

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<sup>29</sup> COM(2003)93 final

### 3.4. Newly Emerging issues

#### *Tissue engineering*

Tissue engineering is a young and emerging multidisciplinary biotechnology sector which promises to change medical practice profoundly, regenerating diseased tissues and organs instead of just repairing them. However, as highlighted in a report of the Commission's Joint Research Centre (JRC)<sup>30</sup>, the size of the tissue engineering market and the commercial range of applications is still in its infant phase, mostly because the first products (skin, cartilage and bone) have "conventional" alternatives firmly rooted in the market. This situation may change if tissue engineering begins to produce applications with life saving properties, and targets conditions with no conventional counterparts. Several significant scientific and technological challenges still have to be met. Meanwhile the regulatory framework applied differs from Member State to Member State. The lack of a clear and uniform regulatory framework leads to legal uncertainty and to a fragmentation of this emerging market. This might in the long term undermine EU competitiveness in the sector.

In its report, the CBAG has called for **new market authorisation legislation for biotechnology-based healthcare applications** that are not considered medicines or medical devices, such as human tissue engineering.

#### **Priorities for future actions**

##### **Commission**

- ▶ to prepare 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 summer 2004.

#### *Genetic testing*

Genetic testing is a most relevant example of leading-edge research and development - showing potential for the benefit of society - and at the same time having policy implications for research, public health, regulation, fundamental rights, ethics and international cooperation beyond the EU.

A growing number of laboratories in Europe and the world are offering a wide and varied array of genetic testing and analysis services. These practices are becoming increasingly frequent, highly variable in quality, and available across national boundaries and some genetic tests are becoming the subject of uncontrolled "mass marketing", including via the Internet. In a recent statement, the **European Group on Ethics (EGE)** warned against the risks of advertising **genetic testing via the Internet**<sup>31</sup>.

As yet no EU Member State is self-sufficient in testing for rare diseases, and cross-border co-operation remains suboptimal, highlighting the need to encourage a broader exchange of information and samples through trans-national networking, which is essential for ensuring the development of tests as well as for accessibility to genetic testing.

<sup>30</sup> The JRC report "Human tissue-engineered products. Today's markets and future prospects" may be downloaded at: <http://www.jrc.es>

<sup>31</sup> [http://europa.eu.int/comm/european\\_group\\_ethics/docs/statgentest-en.pdf](http://europa.eu.int/comm/european_group_ethics/docs/statgentest-en.pdf)

Although genetics specialists and professional organisations have made many moves to promote quality assessment, genetic testing services are provided under widely varying conditions and regulatory frameworks in different countries, including in the EU. The recent **prospective study from the Commission's JRC**<sup>32</sup> identifies shortcomings and measures to ensure the highest quality of such services, including

- ▶ harmonised **quality control genetic tests and the counselling** that accompanies them,
- ▶ development of a common range of **certified reference materials**,
- ▶ better cross-border co-operation, and
- ▶ the establishment of a **European database of genetic testing centres**

In view of the increasing international trade in genetic tests and services (60% of genetic test specimens are circulate across borders), and the policy issues this raises, the Commission and the OECD jointly organised an *EC-OECD Colloquium on Genetic Testing Quality Assurance*, held in Brussels on 6 October 2003. As a result of the discussions the OECD is now considering drafting “codes of conducts” for quality assurance of genetic testing.

A high level expert group “**ETAN-STRATA**”, composed of representatives from pharmaceutical companies, NGOs (in particular patient organisations), scientists and social and legal experts has been discussing the ethical, legal and social implications of genetic testing for a year now. A final report including actions and recommendations to be undertaken will be published in April 2004. It should provide the basis for a wider discussion on these recommendations at a stakeholder conference planned for 6-7 May 2004.

Furthermore, the Commission organised, in collaboration with the “European Association of Mutualities” a conference on the impact of genetic testing on the health insurance system “New genetic applications and access to healthcare” in Brussels, 24-25 March 2004.

Following a request from the Commission, the **EGE** gave an opinion in July 2003 on **genetic testing in the workplace**<sup>33</sup>, recommending that legal measures should be taken at EU level to preserve the confidentiality of genetic data, including in the event of transborder movement of employees/employers, i.e. in the context of free movement of workers within the EU. A **proposal for a Directive on the protection of workers' personal data in the employment context** is currently under preparation.

The various activities undertaken regarding genetic testing at European and international level have indicated the need for a co-ordinated approach to this emerging field.

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<sup>32</sup> The JRC report “Towards quality assurance and harmonisation of genetic testing services in the EU” may be downloaded at: <http://www.jrc.es>

<sup>33</sup> The EGE opinion “Ethical aspects of genetic testing in the workplace” may be downloaded at: [http://www.europa.eu.int/comm/european\\_group\\_ethics/index\\_en.htm](http://www.europa.eu.int/comm/european_group_ethics/index_en.htm)



#### Priorities for future actions

##### Commission and Member States

- ▶ to engage in **EU-wide co-ordination of efforts** to ensure the highest quality of genetic testing in the EU and beyond EU-25,
- ▶ to establish **EU-wide networking of national centres** for exchanges of information regarding quality assurance of genetic testing, including training activities, and **EU-wide networking for genetic testing of rare diseases**.

#### *Animal biotechnology*

Animal biotechnology, like many other categories of biotechnology, covers a wide range of applications. As much as any other category, it may become economically significant but also controversial. Its technological development seems to be approaching the point where the commercialisation of startling innovations is starting to attract public attention.

The EU's case-by-case approach to the deliberate release of GMOs into the environment applies to both GM animals and GM plants. Thus authorisation to place any GM variety of animal species on the market would require a rigorous scientific assessment of possible risks to the environment and human health before the marketing of the animal is authorised. Similarly, the marketing of food and feed products produced from such GM animals would be subject to cases by cases authorisation based on a rigorous scientific risk assessment. The existing regulatory framework for GMOs appears to be satisfactory at EU level.

Another emerging issue is the application of **cloning technology in animals**, and in particular the introduction of products obtained from cloned livestock into the food chain. It may raise ethical and social and safety concerns.

#### Priorities for future actions

##### Commission

- ▶ to launch initiatives on the potential benefits, risks and possible new policy issues associated with the application of animal cloning, including a prospective study.

#### 4. OVERALL CONCLUSIONS

Since last year's report, further progress has been made on implementation of the Strategy and roadmap on Life Sciences and Biotechnology. The review of the Pharmaceutical legislation and the GMO regulatory framework have both been completed, guidelines on coexistence in agriculture have been published, and FP6 provides a major incentive for research in this area.

However, there is no doubt that there is a lot to be done to improve the situation for European biotechnology and its competitiveness:

- public and private investment in research needs urgently to be increased,
- biotechnology companies' access to finance needs to be further improved.

The next stage in the strategy is for the various authorities and organisations to make commitments and to begin delivering the new policy measures in accordance with the responsibilities set out in the action plan.

This involves not only the European Institutions; it also seeks to include measures that are more the responsibility of the Member States and other public authorities and the private sector. The Commission is directly responsible for some actions but it is also determined to do what it can to keep up the general momentum and to play a facilitating role. For their part, the Member States are now actively working with the Commission to flesh out the details of how some of the actions should be implemented. However, they also still need to make progress on the implementation of measures to which they are already committed.

One major example is **intellectual property**, where delays have occurred in the implementation of Directive 98/44/EC, on the legal protection of biotechnological inventions. The slow progress in adopting a practical Community Patent Regulation is also a source of concern.

Member States and the Commission will also have to continue their collaboration to ensure that the follow up of the G10 process moves forward effectively in all its aspects.

More active co-operation from all Member States is also needed in the **implementation of the new legislation governing GMOs**. Having demanded—and subsequently committed themselves to—a more rigorous framework, it is now imperative that all Member States should implement the basic Directive 2001/18/EC on the authorised release of GMOs into the environment and the two regulations on traceability/labelling and on GM/food and feed.

Against the background of the renewed political debate on the Lisbon agenda of task to revamp Europe's competitive position, there is an acknowledged need to step up the measures to fulfil the Lisbon commitments. The Biotechnology Strategy includes many subjects and stakeholders and the Union has to ensure that the coherence of its efforts is maintained. This calls for **strengthened coordination and cooperation between Member States and the Commission**, with the aim of improving Europe's competitiveness. The Commission suggests that on the basis of this Report, the Council discuss the state of implementation and what further measures may usefully be taken to achieve these objectives. Against this background, the Commission also proposes to reinforce the role of the existing Biotechnology network with Member States.