Procedure file

Basic information

COS - Procedure on a strategy paper (historic)	2002/2123(COS)	Procedure completed
Life sciences and biotechnology: a strategy for Europe Subject 3.50.08 New technologies; biotechnology 4.20.02 Medical research		

Key players

European Parliament	Committee responsible	Rapporteur	Appointed
	ITRE Industry, External Trade, Research, Energy	PSE DAMIÃO Elisa Maria	19/02/2002
	Committee for opinion	Rapporteur for opinion	Appointed
	JURI Legal Affairs and Internal Market	The committee decided not to give an opinion.	
	ENVI Environment, Public Health, Consumer Policy	The committee decided not to give an opinion.	
	AGRI Agriculture and Rural Development	PPE-DE MÜLLER Emilia Franziska	19/06/2002
	CULT Culture, Youth, Education, Media and Sport	The committee decided not to give an opinion.	
Council of the European Union	Council configuration	Meeting	Date
	Competitiveness (Internal Market, Industry, Research and Space)	2467	26/11/2002
	Industry	2433	06/06/2002
	Research	2417	11/03/2002
European Commission	Commission DG	Commissioner	
	Secretariat-General		

Key events

23/01/2002	Non-legislative basic document published	COM(2002)0027	Summary
11/03/2002	Debate in Council	2417	
06/06/2002	Resolution/conclusions adopted by Council		
10/06/2002	Committee referral announced in Parliament		

21/10/2002	Vote in committee		Summary
21/10/2002	Committee report tabled for plenary	A5-0359/2002	
20/11/2002	Debate in Parliament		
21/11/2002	Decision by Parliament	T5-0566/2002	Summary
21/11/2002	End of procedure in Parliament		
26/11/2002	Resolution/conclusions adopted by Council		Summary
29/01/2004	Final act published in Official Journal		

Technical information

Procedure reference	2002/2123(COS)
Procedure type	COS - Procedure on a strategy paper (historic)
Procedure subtype	Commission strategy paper
Legal basis	Rules of Procedure EP 142
Stage reached in procedure	Procedure completed
Committee dossier	ITRE/5/16293

Documentation gateway

Non-legislative basic document		COM(2002)0027	23/01/2002	EC	Summary
Document attached to the procedure		SEC(2002)0630	29/05/2002	EC	Summary
Economic and Social Committee: opinion, report		CES1010/2002	18/09/2002	ESC	
Committee report tabled for plenary, single reading		A5-0359/2002	21/10/2002	EP	
Text adopted by Parliament, single reading		T5-0566/2002 OJ C 025 29.01.2004, p. 0223-0384 E	21/11/2002	EP	Summary
Follow-up document		COM(2003)0096	05/03/2003	EC	Summary
Follow-up document		SEC(2003)0248	05/03/2003	EC	
Follow-up document		COM(2004)0250	07/04/2004	EC	Summary
Follow-up document		SEC(2004)0438	07/04/2004	EC	
Follow-up document		COM(2005)0286	29/06/2005	EC	Summary
Follow-up document		COM(2007)0175	10/04/2007	EC	Summary
Follow-up document		SEC(2007)0441	10/04/2007	EC	

Life sciences and biotechnology: a strategy for Europe

PURPOSE : to propose a strategy for Europe in the area of life sciences and biotechnology. CONTENT : with the present initiative, the European Commission proposes a strategy for Europe to develop sustainable and responsible policies to address the following three broad questions: - Life sciences and biotechnology offer opportunities to address many of the global needs relating to health, ageing, food and the environment, and to sustainable development. How can Europe best attract the human, industrial and financial resources to develop and apply these technologies to meet society's needs and increase its competitiveness? - Broad public support is essential, and ethical and societal implications and concerns must be addressed. How can Europe deliver effective, credible and responsible policies which enjoy the confidence

and support of its citizens? - The scientific and technological revolution is a global reality which creates new opportunities and challenges for all countries in the world, rich or poor. How can Europe best respond to the global challenges, develop its domestic policies with a clear international perspective and act internationally to pursue its interests? The Commission proposes a strategy to respond with responsible, science-based, and people-centred policies on an ethical basis. This strategy aims to allow Europe to benefit from the positive potential of life sciences and biotechnology, to ensure proper governance, and to meet Europe's global responsibilities. This is a proposal for an integrated strategy - its different elements are interdependent and mutually reinforcing. Implementing this strategy requires an open, collaborative and sustained process to develop coherent and credible policies. The Commission also proposes an action plan for concrete measures by the Commission and the Community, as well as recommendations for other public and private actors, respecting the subsidiarity principle.?

Life sciences and biotechnology: a strategy for Europe

The aim of this report is to analyse the 316 contributions received in response to the points and questions in the consultation document 'Towards a strategic vision of life sciences and biotechnology'. The wide range of opinions and proposals made reflects the extent of the areas covered by the consultation document. The chosen structure is based on the most commonly expressed ideas and could certainly be challenged; without claiming to be exhaustive, the document tries to reflect, as objectively as possible, the richness and variety of the contributions received. In its desire for transparency, the Commission plans to make these contributions available to the public. This report lists the ideas most often mentioned and classifies them under three headings: points of consensus, points of debate and points of conflict. The consultation was received with interest, because the debate suffers from an extreme level of polarisation. Some people thought that the consultation had been conducted too late, concomitant with other consultations and over far too short a period. Some thought that the consultation document did not take the ecological dimension sufficiently into account, that the precise objective of the future European strategy had not been explained in enough detail, that the scope was too wide, or that the term "genetic sciences" would have been more appropriate than "biotechnology". The "secrecy" of the consultation - because the Commission had not publicised it sufficiently - was also criticised by several respondents. Six countries provided by far the greatest number of contributions: Belgium, Germany, France, the UK, Austria and Italy. The over-representation of Belgium is probably linked to the presence of many professional organisations and NGOs in Brussels and their European outlook. It should be noted that the number of contributions from the four 'cohesion countries' (Spain, Portugal, Ireland and Greece) was extremely low. The classification of arguments all into three categories: points of consensus, points of debate, points of conflict. - Points of consensus : the points grouped under this category are those ideas and suggestions that tended to be universally shared. They include 'common sense' arguments and some technical suggestions that are not controversial. To a certain extent, they represent the viewpoint of the "honest man" who recognises the potential benefits of technical progress but also the need to provide a framework for it; to strengthen the mobility of scientists and research policy; developing SMEs in the biotechnology sector; improving competitiveness (developing centres of excellence, creating a favourable and stimulating environment for innovation, start-ups, make the patent system cheaper and more effective; reinforce the role of education; improving public information and consultation; amending the regulatory framework; step up research in the medical field; prevent contamination of organic crops by GMOs; application of the precautionary principle; support for developing countries; individual freedom and restricting the use of the test result. - Points of debate : these concern the benefits and the risk of biotechnology. There were about as many contributions in favour of the biotechnology as against them. A large majority of the contributions received called for the ethical aspects to be takenon board. In addition, the role of the experts should be defined and risk evaluation should be stepped up. The debate also centres on the way of funding research, the division of responsibilities between Member States and the EU, its purpose and organisation. - Points of conflict : the contributions here concern very sensitive matters relating to the systems of values and ethical and moral principles (patenting and the genome; economic competitiveness versus ethical issues) with regard to the which positions tend to be more entrenched and more resistant); experiments on embryos; patenting life and genetically modified animals; European trade policy. The Commission has taken note of certain questions and suggestions, which will be discussed in greater depth and tackled later on. The Commission also intends to launch an inter-institutional consultation designed to take into consideration ethical questions at European level and to evaluate the role, composition and modus operandi of the European Group on Ethics.?

Life sciences and biotechnology: a strategy for Europe

The committee adopted the report by Elisa DAMIÃO (PES, P) welcoming the Commission's strategy for life sciences and biotechnology. It wanted to see a specific political agenda for the next few years in the field of biotechnology, along with efforts to convince the public of the opportunities offered by biotechnology, not only in the field of medicine but also in sectors such as agriculture, industry and alternative energy. The report then looked at the various 'strands' that the strategy would involve and made a series of recommendations: - Member States should improve education in the field of biology in general so that consumers can take informed decisions; - given that the cautious attitude of consumers towards GMOs was largely attributable to insufficient provision of information about GMO technology, there should be improved public information and debate in the field of biotechnology; - the precautionary principle should be applied in a rational manner so as to provide consumer and environmental protection, while not serving as a barrier to political decision-making and technological innovation; - as regards international cooperation, biotechnology, if applied prudently, could contribute towards finding genuine solutions to problems such as sustainable development and food sufficiency. Developing countries themselves must decide if and to what extent they want to use GMOs, and technology transfer should be one of the preconditions for sustainable development; - regarding legislation, there was a need for a harmonised ethical legal framework for biotechnology companies and farmers and for the introduction of a European patent which meets the requirements of researchers and innovators in both public research institutes and industry; - as regards R&D and the business environment, the EU should continue research into the development of foodstuffs that are beneficial to consumers and into the improvement of risk assessment. SMEs should be given easier access to innovation, training and risk capital and active support should be provided for the setting up of bio-clusters; - concerning the environment and agriculture, there should be support for research into biotechnology uses offering clear social or environmental benefits. Legislation on fuels should be reviewed to enable products from biological energy sources to be placed on the market in the short term. There should also be an end to the existing de facto moratorium on GM foods in order to increase consumer choice and benefits and to promote innovation. At the same time, the committee wanted products to be clearly and unambiguously labelled and traceability to be ensured; - on health and reproductive medicine, the Commission should come up with a proposal on the introduction of a standard for genetic tests, ensuring that they were conducted under clear rules covering medical, ethical, social, psychological and legal aspects. Genetic testing data should remain confidential and should be used only for the benefit of the person requiring such tests, with the exception of tests undertaken for clearly defined scientific or criminal investigation purposes. The committee also wanted to see an EU-wide

regulation on DNA-testing, with a legal basis which left Member States free to introduce more stringent protection measures. Finally, it stressed that no woman should be compelled to have prenatal diagnosis and that determination of sex in connection with prenatal diagnosis should only be permitted if there is a risk of serious gender-specific hereditary diseases.?

Life sciences and biotechnology: a strategy for Europe

The European Parliament adopted a resolution on biotechnology drafted by Elisa DAMIAO (PES, P). (Please refer to the document dated 21/10/02). Parliament called for primary responsibility for coordinating the biotechnology strategy to be conferred on one Commissioner in particular and on a directorate-general created to that end so as to ensure greater consistency in Community activities. It felt that there is a need to enhance and broaden public debate and access to objective information. Consumers must have the opportunity to address questions to scientists and to receive answers from them. On international cooperation, Parliament stated that biotechnology alone will not help to overcome hunger in the world and that other methods, for example a better distribution of available food, are currently more important. However, given the ever-increasing world population it might also be necessary to use genetically modified crops to produce enough food. Should a developing country wish to use biotechnology, the EU and Member States ought to provide support so that it can strengthen its own capacities. Parliament called on the Commission and the Member States to promote the Johannesburg process for sustainable development and include technology transfer as one of the preconditions for sustainable development in the developing countries. Biotechnology, if applied prudently, can contribute to sustainable development because it helps to save energy and raw materials and can lead to less pollution. Parliament repeated its insistence that there should be a universal and specific ban at the level of the United Nations on the cloning of human beings at all stages of formation and development. On the question of the environment and agriculture, Parliament supported the establishment of legal thresholds for the adventitious presence of GM foods and feeds which enable consumer choice, are set at practically appropriate levels and are based on scientific assessment, provided these products have been established as safe by EU standards. It called for the immediate implementation of Directive 2001/18/EC on the deliberate release of GMOs into the environment. This must take place within the framework of an overall strategy for green genetic engineering in which products containing or produced from genetically modified material or must be unambiguously labelled and traceability ensured in order to give consumers the greatest possible transparency and full freedom of choice.?

Life sciences and biotechnology: a strategy for Europe

The Council held an exchange of views on the basis of the Commission's communication "Life sciences and biotechnology - a strategy for Europe" and adopted the following conclusions: - The Council welcomes the Commission's communication on a life sciences and biotechnology strategy action plan that provides a comprehensive basis for implementation of a roadmap. It agrees with the main lines of the Commission's analysis of strengths and weaknesses of the EU biotechnology sector and of policies and actions related hereto, as well as the identification of main areas that need action to improve further policy coherence. The Council also recognises that life sciences and biotechnology offer a considerable potential in areas such as health care, agriculture/food, industrial products and processes and environmental protection, and may contribute to sustainable development. It underlines that this potential should be continuously assessed on the basis of benefits and risks anticipating health, economic, social and environmental consequences and ethical aspects and that the successful development of a competitive biotechnology sector in the EU requires a comprehensive and co-ordinated approach covering all major areas of application of biotechnology. The Council acknowledges that any effective approach which would allow harvesting the potential of biotechnology in Europe should engage all Member States and encompass all policy areas and instruments available for the sectors' promotion taking into account international aspects, be balanced, including a continuing societal dialogue, a high-standard regulatory framework which is science-based, and respect diversity of views and freedom of choice. Based on a yearly report from the Commission the Council once a year should hold an in depth discussion, beginning in 2003, on the implementation of the following roadmap for the strategy on life sciences and biotechnology, on the basis of the following points: 1) Human resources : Member States should keep under review and assess, before mid-2003, future requirements in specific skills in the EU for scientists, technicians, engineers and managers within the various life science specialities. These measures should be operational by 2004. 2) From knowledge to market: The Council invites the Member States and the private sector to increase or continue to increase the research resources allocated to life sciences and biotechnology. The Council recognises the vital importance of the proposed Community Patent for a dynamic biotechnology sector and will resolve the outstanding issues as soon as possible and invites Member States to continue the transposition of Directive 98/44/EC on the legal protection of biotechnology inventions. The Member States and the Commission should in 2003 establish an inventory of best practises for the promotion of technology transfer and subsequent support of the dissemination through networks and pilot projects. 3) Networking and Clusters : the Council welcomes the Commission support for the creation of a self-financed biotechnology portal for Europe, providing free access to information on available networking Internet platforms. This portal and the entry platform should be operational before the end of 2003. In order to create mutual learning and develop best practices, representatives frombiotechnology clusters are encouraged to exchange experiences yearly. The Commission is invited to monitor the process and the development of clusters and co-operation between clusters and report yearly to the Council beginning in 2003. 4) A proactive role for public authorities : Member States and the Commission should prepare and implement on a voluntary basis a benchmarking programme in 2003, highly focussed on areas of special relevance, to assist the development of biotechnology policy through identification and exchange of best practices. Such a programme may for example include measurement of the extent of commercial development of biotechnology: the resource base (human and financial), public policies (national and sub-national) to promote the development of commercial biotechnology (e.g. technology transfer and SME support), regulatory factors including transparency and other (national and sub-national) factors affecting the business climate for commercial biotechnology, and the use of the precautionary principle. The programme should make full use of already existing measures and involve all interested stakeholders. 5) Participation of society : the Council joins the Commission's commitment to support an open and transparent as well as comprehensive, structured and focussed dialogue and information exchange, including all stakeholders, notably through a broadly-based Stakeholders Forum starting at the latest in 2003 as well as other targeted measures, as indicated in the Commission Science and Society Action Plan. 6) Regulatory Framework : the Council welcomes the Commission's efforts to improve the regulatory framework for medicinal products. The recommendations made by the High-Level Group on Innovation and Provision of Medicines, and the Commission's reaction to the recommendations should provide a basis to arrive at operational conclusions to be presented by 2003. In this context, the Council is considering the outcome of the ongoing work concerning further GMO related legislation. The Commission is invited to, as it has indicated, periodically - beginning in 2003 - publish a rolling regulatory work programme to further improve coherence, predictability, transparency and quality of the regulatory framework, applying notably the principles of: - product authorisation on the basis of scientific risk management; - precautionary principle; - risk management measures also taking into account other legitimate factors as appropriate; - proportionality of risk management measures; - transparency of procedures

assessments and, as foreseen by the Aarhus Convention, public participation; - consumer information and choice; - testing and validation of control methods; - regular reviews of legislation; - the functioning of the approval system. 7) International cooperation : Member States and the Commission should provide strong EU support in order to enable developing countries and countries with economies in transition to assess and use the potential of biotechnology and to develop their own capacity for the adequate policy response, according to their needs and to the local conditions. Support should include international scientific cooperation, such as the establishment of effective research partnerships between public and private research organisations in developing countries and the EU. By the end of 2003, the Commission should report on results in this respect.?

Life sciences and biotechnology: a strategy for Europe

The European Commission has published a progress report on life sciences and biotechnology - a strategy for Europe. In 2002, the Commission adopted a Strategy for Europe on Life Sciences and biotechnology, consisting of 2 parts - policy orientations and a 30 point plan to transform policy into action. The Commission intends to report regularly on the progress made. This report is the first such response. It sets out what has been achieved in policy development and on the ground, and anticipates emerging issues. Where further action is needed, this report contains future orientations, makes appropriate recommendations or announces new initiatives. The report states that while progress has been made in some areas, other are suffering from delays such as the need for more research and financial resources, the need to complete the system of intellectual property protection and the delays in the areas of GMOs and finally a need for a joint effort to broaden the understanding on biotechnology at international level. In line with the Action Plan timetable, the Commission has made progress on a wide range of specific actions and has supported various independent actions undertaken by European regions, academia and industry alike. In some Member States a number of measures are already in place, which tie in with the Biotechnology Strategy. Although strategy implementation is still at an early stage, a certain amount of progress has been made. A notable achievement has been the adoption of the 6th EU Research Framework Programme (FP6 2003-2006), which will continue to underpin basic scientific research and help to build the European Research Area in this and other fields. FP6 devotes EUR 2.225 billion to life sciences, genomics and biotechnology for health. A further EUR 685 million will be dedicated to food quality and safety. However this is a relatively small amount compared to private investment in this field. European biotech companies invested EUR 7.5 billion in research last year, and biotech-related industry, such as pharmaceuticals and chemicals, substantially more. These companies are making a bigger contribution than other sectors to achieving the Barcelona European Council target, to allocate 3% of Gross Domestic Product (GDP) to research in Europe. If the current trend towards moving biotech research outside Europe continues, this contribution will decrease. To foster competitiveness and innovation in this field, the Commission calls for better co-ordinated research across Europe, better access to finance, in particular to risk capital, and for clear, equitable, affordable and effective intellectual property rights regime in Europe. This requires the swift adoption of the Commission proposal for a Community Patent, and transposition into national legislation of the Directive on biotechnological inventions (directive 98/44/EC) by non-compliant Member States. Considerable progress has been made on the legislative framework surrounding GMOs. The new regulatory framework on GMOs, including the Commission's proposals on traceability and labelling of GMOs and on GM food and feed, provides legal certainty for operators. It also addresses public concerns and aids consumer choice, thereby encouraging further public acceptance of GMO use. It is also important that the regulatory framework is clear and predictable if the rapid decline in European GMO field research is to be reversed. Rapid advances in life sciences have created high expectations for curing diseases and improving quality of life, while raising concerns as to their ethical and social consequences. The Commission is committed to ensuring that ethical, legal, social and wider cultural aspects are taken into account in policy-making and research funding. Sensitive issues include human reproductive cloning. The Commission supports a worldwide ban on this issue. On human embryonic stem cell research, the Commission will present a report to the European Parliament and Council shortly, as the basis for an inter-institutional seminar on this kind of research. Biotechnology is currently discussed in many international fora. This is a reflection of the different concerns and objectives surrounding biotechnology, but raises a question of international governance. It is therefore essential to create an adequate forum for promoting an open and transparent dialogue between all stakeholders concerned, facilitating mutual understanding of the concerns and objectives of the different countries and regions. Therefore the Commission recommends giving further consideration (together with our trading partners) to the need for a multilateral consultative forum to contribute to building international consensus on biotechnology. ?

Life sciences and biotechnology: a strategy for Europe

The European Commission has prepared this report in follow-up to the 2002 "Strategy for Europe on Life Sciences and Biotechnology". The aim of the report is to keep the Member States and biotechnology stake-holders abreast of European developments in the field of biotechnology and life sciences. Since the publication of its first report on biotechnology and life sciences last year, the European Commission states that further progress has been made in the implementation of the strategy, but that much mores needs to be done to improve the situation for European biotechnology. Success stories include: - The completion of the Pharmaceutical review legislation. - Finalisation of the GMO regulatory framework. - Increased funding for biotechnology and life sciences in the 6th Framework Programme. There are, however, a number of shortcomings in the biotechnology strategy as set out in 2002. The most significant of which is failure to adequately implement the 1998 Directive on the legal protection of biotechnological inventions. Delays in its implementation have left researchers unsure as to whether they can profit from their innovation and potential investors uncertain of whether they should risk financing a sector whose IPR is sketchy. This problem is exacerbated by the continuing deadlock in adopting practical regulations governing a Community patent. Failure to agree on a Community patent has resulted in a number of companies going elsewhere (notably the US) to secure their patents. Similarly, the Commission notes unsatisfactory implementation of the new legislation governing GMO's. Bearing the above in mind, the Commission suggests that the next stage should be for the various authorities and organisations to commit themselves to implementing the strategy more consistently and to begin delivering on the new policy measures. More concretely speaking, the Commission calls for enhanced coordination and co-operation between the Member States and the Commission. Other measures proposed include greater public and private investment in research as well as improved access to finance biotechnology companies. Such a strategy, it is argued, would not only improve the chances for successful biotechnology innovation it would also be instrumental in securing Europe's competitiveness in this fast evolving field of research.?

Life sciences and biotechnology: a strategy for Europe

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. It set out what is needed from the Commission and the other European Institutions, while also recommending actions for other public and private stakeholders.

The Commission reports regularly on the progress made and this Communication is the third report.

In its report to the Spring European Council, 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.

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

Policy overview and identification of priorities for action:

1) Harvesting the potential

- 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 stagnation). 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. To address this, the Commission has adopted a proposal for a Competitiveness and Innovation Programmewith 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, within its proposal for the 7th R&D Framework Programme, the Commission outlined a new financing instrument, the ?risk-sharing finance facility?, which could provide loans for larger research and infrastructure projects.

- The Competitiveness in Biotechnology Advisory Group with Industry and Academia (CBAG) was appointed by the Commission in 2003. 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. 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 but, at the same time, notes that implementation of the strategy has been patchy and there remain some serious concerns.

- 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.

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

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. 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. 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.

3) Confidence in science-based regulatory oversight

- 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 (EMEA) are both complex and expensive and may act as a major disincentive to the introduction of new products by SMEs.

- 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. 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.

4) Newly emerging issues

- Tissue engineering: The CBAG stresses the importance of Europe having 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.

- 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 Europe.

- 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 EMEA 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 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.

- 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.

Life sciences and biotechnology: a strategy for Europe

The European Council and the European Parliament have recognised the importance of life sciences and biotechnology, and the Commission has put forward an action plan to address the challenges and opportunities involved. This Strategy on Life Sciences and Biotechnology, adopted by the Commission in 2002, proposed a 30 point action plan involving the Commission, the other European Institutions and other stakeholders. It runs until 2010. The implementation of the Strategy is now at its mid point. It is time to evaluate the progress achieved since 2002 and update the Strategy, to reflect new analysis of how this fast-moving sector could contribute to EU policies. This is the purpose of this Communication and the annexed Staff Working Paper.

Life sciences and biotechnology have grown to be central to certain sectors of the EU economy: in healthcare and pharmaceuticals, but also in the fields of industrial processing and primary production/agro-food. Overall, modern biotechnology relates to the generation of about 1.56% EU gross value added (GVA, 2002 values), to which could be added positive impacts of biotechnology such as a healthier population. The recent adoption of an ambitious energy policy for Europe is likely to stimulate the contribution of biotechnology to another sector, alternative energy. Secondly, life sciences and biotechnology make a significant contribution to core EU policy goals such as health, economic growth, job creation, the ageing society and sustainable development.

The annexed Commission Staff Working Paper contains a detailed report on the implementation of the Action Plan. It has been elaborated on the basis of contributions from Commission services, Member State authorities and stakeholders. It is complemented by a summary chart of the main achievements in the implementation of the 30 actions.

The main conclusions of this review exercise are that:

- the Strategy has been successful and is still relevant. The list of achievements, such as research activities and regional integration of clusters, clearly highlights the role that the Strategy has played in terms of integrating the "biotech dimension" in other policy areas, as well as inspiring national biotech plans. The strong support enjoyed by the Strategy from stakeholders is evidence of its success;

- a small number of actions have already been completed. This mainly relates to the adoption of the new legal framework on GMOs, which has been very significantly revised since 2002;

- a few other actions have become obsolete, mainly because of lack of interest by the audience they targeted (e.g. Action aiming at creating networks of biotechnology company managers);

- there is a strong case to continue a majority of the actions, ensuring coherence with other horizontal initiatives (e.g. education, IPR?) and in accordance with the EU's international commitments (e.g. contribution to Multilateral Environmental Agreements);

- some actions need to be refocused and given a special priority, given their importance and biotechnology-specific character.

The original design of the Strategy was consciously wide in scope, to give an initial mapping of the situation and to identify the full range of linked policy areas. With this phase complete, the mid term review offers an opportunity to refocus in order to maximise the impact of the Strategy. This implies pursuing actions which are still relevant according to their original design, reinforcing synergies with other horizontal policies and reviewing priorities which are specific to the sector of biotechnologies. These biotech-specific priorities can be regrouped under five main interdependent themes:

1) Promote research and market development for life sciences and biotechnology applications and the Knowledge Based Bio-Economy (KBBE). Research remains a precondition for the development of biotechnology and the Action Plan needs to be adapted to the new FP7. Europe's basic biotech research is advanced but Europe does not excel in turning research into commercial applications. The Action Plan should be refocused in order to foster market development for bio-based products and improve the uptake of new technologies;

2) Foster competitiveness, knowledge transfer and innovation from the science base to industry. Europe's dedicated biotech companies are mostly SMEs with limited resources whose growth and economic sustainability are held back by three main constraints: Europe's fragmented patent system, the insufficient supply of risk capital and shortcomings in the cooperation between science and business. The Commission has identified the lack of a clear and coherent legal framework for IPR protection as an obstacle to innovation in Europe14, and will propose concrete steps toward a modern and affordable framework. In addition to this, refocusing the Action Plan can contribute to addressing some framework conditions relating to competitiveness specific to the biotech sector.

3) Encourage informed societal debates on the benefits and risk of life sciences and biotechnology. The uptake of biotechnology is also conditional on its societal and market acceptance. Ethical concerns are also more prevalent than in other forefront technologies. There is a clear prerequisite for actions aiming at associating the public and stakeholders as closely as possible to the decision making process, taking into account the benefits and risks of life sciences and biotechnology, on the basis of harmonised data and statistics, as well as ethical considerations.

4) Ensure a sustainable contribution of modern biotechnology to agriculture. Biotechnology in the field of primary production and agro/food has a huge potential for development, in particular the replacement of chemical processes and fossil fuels. Nonetheless, some of the technologies

involved need close scrutiny. The legal framework on GMOs takes into account possible long-term effects on the environment and health, the safety of the food chain and respects other modes of agricultural Production. Nonetheless, in certain cases risk management measures for products which are specifically designed for industrial uses should be further developed.

5) Improve the implementation of the legislation and its impact on competitiveness. The EU has probably the most developed, and sometimes most stringent, legal framework on life sciences and biotechnology. Nonetheless, stringent rules should not hinder competitiveness and innovation.

The way the Commission intends to refocus its implementation of the Strategy in light of the above five priority themes is detailed in the attached "Refocused Life Sciences and Biotechnology Action Plan".

The potential of biotechnology to support EU policies is real and has been proven by numerous practical examples. Consequently, there is a strong need to continue promoting the development of life sciences and biotechnology in the EU, in particular by increasing research and promoting competitiveness. The main EU instrument for this is the Strategy.

Whilst the technology is promising, there is also a call for a reasoned use of some of its applications, in particular in the agro-food area, as well as for closer public scrutiny and forward looking regulatory control. With biotechnology evolving at a rapid pace, there is an absolute necessity for policy makers to maintain a flexible forward looking approach in order to anticipate developments and adapt to new challenges. Recent examples include the potential use of cloned animals or of their offspring in the agro/food sector, or the use of genetically modified chicken for the production of pharmaceutical substances in their eggs.

The original broad scope of the Strategy has offered a full picture; now a refocusing would ensure effective implementation, with more precise goals and enhanced coherence with other policies.

For these reasons, the Commission will:

Continue the implementation of the action plan up to 2010, while putting a specific emphasis on a focused set of biotech specific priority actions;

- include biotechnology in the implementation of innovation strategies;
- in cooperation with Member States and stakeholders;
- improve the implementation of the Strategy.