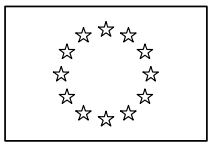

COMMISSION OF THE EUROPEAN COMMUNITIES

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COMMISSION STAFF WORKING PAPER

in support of the Communication from the Commission to the European Parliament, the Council and the Economic and Social Committee on Progress Report and Future Orientation on Life sciences and Biotechnology
{COM(2003) 96 final}

LIFE SCIENCES AND BIOTECHNOLOGY- A STRATEGY FOR EUROPE

This Working Paper has been prepared as support for the European Commission's Communication to the European Parliament, the Council and the Economic and Social Committee.

A detailed overview of the progress made in implementing the action plan set out in the Strategy is provided in the Annex.

Actions are subdivided into four headings as follows:

1) Harvesting the potential (Actions 1-12):

Actions under this heading aims at developing skills, supporting European research, providing a strong European intellectual property system, facilitating access to capital, networking all the various stakeholders working in biotechnology in Europe and increasing the proactive role of the public authorities.

2) A key element for responsible policy: governing life sciences and biotechnology (Actions 13-23):

These actions includes dialogue among stakeholders, ethical and social implications, consumers' right to choose and the legislative framework.

3) Europe in the world – responding to global challenges (Actions 24-28):

These actions highlight Europe's role in developing international guidelines and indicate the areas where Europe can support the developing world in its efforts.

4) Implementation and coherence across policies, sectors and stakeholders (Actions 29 and 30):

This final group of actions focuses on the role of the Commission in evaluating and further developing the Europe's biotechnology policy in the coming years.

In the current early phase of implementation of the action plan, this overview focuses on action undertaken by the Commission, and only provides occasional reference to other stakeholder activities.

ANNEX

PROGRESS REPORT OF LIFE SCIENCES AND BIOTECHNOLOGY:
AN OVERVIEW

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
Investing in people				
1 2003-10	The Commission will, together with Member States, ● **identify the education needs** in life sciences within the 'Ten-year objectives for learning in the knowledge society' and strengthen a **broad education and understanding** of life sciences, **and** develop and train a **skilled workforce** in life sciences by issuing recommendations for curricula and teacher training. Community support can be provided under the Comenius and Erasmus programs.	▯ **A call for proposals** under the second phase of the **Leonardo Program** (for vocational training) has been launched (2003-2004). Life Sciences and Biotechnology can be proposed specific priorities themes in the call under various actions ▯ A **detailed work program on the future objectives of education and training systems** was adopted on 14.2.2002. Work had already started on 3 priority objectives: 'basic skills', ICT and 'Math, Sciences and Technologies'	▯ While the Commission support this action through its various education programs, **recommendations for developments of curricula are strictly competence of Member States**	**Members States, Commission, private sector**
	● promote continuing education and refresh the current competence of the scientific workforce, as set out in its communication on the European area of lifelong learning. Community support can be provided under the Leonardo program	▯ The Communication on **'Making a European Area of Lifelong Learning a Reality'** includes key concrete actions to provide people of all ages with equal and open access to high-quality learning opportunities. An interim report on progress towards implementing the lifelong framework will be presented by to the 2003 Spring European Council.		
	● support discussion for specialist scientists, with the objective of stimulating an exchange across disciplines. Community support can be provided under the Erasmus program	▯ A number of **'Thematic Network Projects'** in the specific area of Biotechnology consisting of university cooperation projects have been supported under **the Socrates-Erasmus program (for education)**		

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
2 (a) **2003 onwards**	● the Commission will explore with Member States the opportunity and best way to establish efficient methods **to match a skilled workforce with job opportunities**, involving effective communication of open positions, collaboration with established companies and a labour force aware of available employment options.	▯ **high level task force** was established in 2001 to address the challenges of skills and mobility on European labour markets. ▯ On the basis of the task force's report, in February 2002 the Commission adopted an **Action Plan for Skills and Mobility**, endorsed by the Barcelona Summit in March 2002. 24 separate actions were identified with many linked directly to investing in people and ensuring skills matching. Action 2 seeks to promote maths, science and technology skills, action 4 seeks closer links between education, industry and careers guidance. Actions 23 and 24 explicitly address the issue of a one stop mobility and information/qualifications website and the existing EURES website on the classification of professions.	▯ The Commission works together with Member States via the **European Employment Strategy** to improve and enhance employment, seeking both more and better jobs. As part of this process, Member States prepare and present **National Action Plans (NAPs)** for employment on the basis of guidelines agreed at the beginning of the year. Within the guidelines for 2002, and thus in all NAPs, is action on matching jobs with skills and combating bottlenecks.	**Member States, Commission**
2 (b) **2003 onwards**	● The Commission will explore with Member States possible measures to **attract and retain scientists** and avoid brain drain.	▯ Under the specific program **"Structuring the European Research Area"(2002-2006)**, the Commission will offer ▯ increased opportunities for **mobility** across Europe and implement actions to counteract the brain drain. Researchers from third countries will be able to participate with a view to reinforce the skilled workforce in Europe ▯ **seed grants** to allow researchers to return to their own countries and establish research capacities.	▯ The **Sixth Framework Program for Research (FP6)** expands the training through research program and offers new tools well adapted to the present situation. In particular there will be new possibilities offered for **exchanges with Third Countries** and for the establishment of **new European research teams**.	**Member States, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
3 2002-06	● The Commission will enhance support for life sciences and biotechnology research, technological development, demonstration and training activities under the Sixth **Framework Program 2002-2006** aimed at ▯ **c**ontributing towards the creation of the **European Research Area**. ▯ supporting **Biotechnology research** under 5 thematic priorities ▯ encouraging SME participation, international cooperation and mobility and training of researchers. ▯ to facilitate the objectives of **Europe-wide collaborations**, attaining critical mass and simplification of administrative procedures.	▯ **The Sixth Framework Program (FP6) 2002-2006** was adopted by Council and the European Parliament on **3 June 2002** (Decision No 1513/2002/EC - OJ L232). ▯ The **5 specific programs** have been considered by European Parliament, and they were adopted by the Council on **30 September 2002** (Decisions 2002/834/835/836EC and 837/838/Euratom -OJL294) ▯ The **Rules of Participation to implement FP6** were adopted by Parliament and Council on **5 November 2002** ▯ a **call for expressions of interest** was launched in March 2002 with a deadline of 7June. Some 11,000 expressions of interest were received ▯ the Commission issued **calls for proposals** on 17 December 2002, with a closing date in **March-April 2003**.		**Members States, EIF, Commission**
	● The Commission and the Member States and in collaboration with the European Investment Fund (EIF), will develop a **competitive bioinformatics infrastructure** in support of biotechnology research and focus support for the development of research in computational biology and bio-medical informatics.	▯ Several projects supporting bioinformatics are funded under FP5, the largest being **TEMBLOR**, a 3-year project with an EU contribution of **€19,4m to 25 participants**, coordinated by the **European Bioinformatics Institute (EMBL-EBI)** ▯ The Commission and the EIB/EIF have established a **working group** to investigate the issue of the financing of infrastructure, including bioinformatic infrastructures (see action 6a)	▯ The first two calls from FP6 in the area of fundamental genomics will include ▯ developing methods and resource in bioinformatics to focus on the annotation of human and other genomes ▯ Bioinformatics and genomics grid for EU research ▯ development of an integrated software platform to tackle genomic sequence-structure-function relationships ▯ proposals for dealing with in silico prediction of gene function and for the simulation of complex regulatory framework	

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Management and legal services				
4 **2003 onwards**	To enhance the supply of specific management and legal skills: ● Member States and national biotechnology associations should examine the opportunity of creating self-sustained **networks of biotechnology company managers** at the national level. ● Member States and the Commission should promote collaboration between law schools, law firms and companies for the **development of specific legal competence** needed by biotechnology companies.	▯ In **2003** the Commission, together with Member States and national industry associations, will explore the opportunities and best ways of providing this expertise at national level .	▯ Young biotechnology companies often need better access to entrepreneurial/management skills and specific legal expertise (e.g. IPR/licensing contracts). Creation of self-sustained networks of biotechnology company managers, possibly including the involvement of specialized law schools/firms for the development of specific legal competence, might help to improve access to expertise.	**Member States, academia, professional associations, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
Exploitation of intellectual property				
5 (a) **2002 onwards**	To finalize a **strong, harmonized and affordable** European intellectual property protection system **by** ● Member States **urgently transposing** into national laws the Directive **98/44/EC** on the Legal Protection of Biotechnological Inventions.	▯ To date, **six Member States** have transposed the Directive (DK, FIN, IRL, UK, GR, ES) ▯ The Commission has launched the second stage of formal **infringement proceedings** against Members States which have not yet transposed the Directive. In the light of the recent ruling of the Court of Justice confirming the compatibility of the Directive with various legal principles and internation obligations, the Commission will consider what action is appropriate to ensure a full and speedy transposal of the Directive into national law, where this has not already been achieved.	▯ As provided for by Article 16(b) of Directive 98/44/EC, on 14 January 2002, the Commission has adopted a **report assessing of the implications for basic genetic engineering research of failure to publish, or late publication of, papers on subjects which could be patentable** as required under Article 16(b) of Directive 98/44/EC on the legal protection of biotechnological inventions **(COM(2002)2 Final)** ▯ As provided for by Article 16(c) of Directive 98/44/EC, on 7 October 2002, the Commission has adopted **a report on the development and implications of patent law in the field of biotechnology and genetic engineering (COM(2002) 545 Final)** ▯ The Commission has already set up a **group of experts** in economics, law and natural sciences to examine controversial issues linked to biotechnology patent and to help it to prepare future annual reports. The two topics to be studied **in 2003** will be i) the scope to be given to patents related to sequences or partial sequences of genes isolated form the human body, and ii) the potential patenting of human stem cells and cell lines obtained from them. These topics will be discussed by the Group in **March and May 2003** respectively. Reports from those discussion will be made available at the same time as the 2003 Commission annual monitoring report.	**Member States, Council, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
5 (b) 2002 onwards	● Council adopting the **Community Patent Regulation**.	▯ On 1.8.2000 the Commission adopted a Proposal for a Council Regulation on Community Patent **(COM(2000) 412 Final).** ▯ The **European Parliament** delivered its opinion on **10.4.2002**. ▯ The **Council** reached a political agreement on **3.3.2003**.	▯ The political agreement reached on 3 March 2003 enables the work on the details of the Regulation to continue efficiently in the Council with a view to its adoption as soon as possible,	**Member States, Council, Commission**

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1. Harvesting the potential

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
5 (c) 2002 onwards	● Member States and the Commission clarifying rules on **ownership of intellectual property** stemming from public research and monitoring the effect of implementation of patent legislation on research and innovation.	▯ The Commission has contracted out a **study** in January 2002 which will provide a detailed comparative analysis of the **Intellectual Property Research (IPR)** rules applicable to publicly-funded research, their evolution and their effects, in the 15 EU Member States, in 2 adhesion countries, as well as in the US and Japan. The final report is expected in **spring 2003**.The study will mainly focus on legislative aspects and aim at the identification of recommendations which could improve the coherence of the IPR regimes applicable to publicly funded research in the European Union ▯ In parallel, an **expert group of technology transfer and legal specialists** has been set up. This group primarily aims at identifying good practices and recommendations at user level.	▯ This action will in particular benefit the biotechnology sector, since the majority of technology transfer activity and licensing from the public research sector is in this area. The analysis of the study and expert group recommendations will allow to identify problems and good practices, and to define possible actions by the Commission and/or Member States aimed at improving the efficiency and coherence of these rules in the EU, taking into account the international context.	**Member States, Council, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
5 (d) **2002 onwards**	● encouraging awareness training in the strategic use of IPR during the entire research and innovation process and raising awareness among academics of the commercial potential of their research, encouraging entrepreneurship and movement between academia and companies.	Various initiatives have recently been launched at regional, national and Commission level, such as ▯ the **PROTON** network of technology transfer licensing offices in Europe aimed at increasing professionalism of technology transfer activities in Europe. ▯ the I**PR-Helpdesk** which provides a helpdesk on IP issues for mainly for participants of the EU RTD framework program or the "EuroBioBizz" training activity that helps potential biotech entrepreneurs in writing professional business plans . ▯ On a broader level, the **Gate2Growth Initiative** provides tools and networks for access to finance and better exploitation of knowledge.	▯ Training and awareness initiatives will be supported through the **Sixth Framework Program (FP6)**, both through specific support actions of the thematic priorities focusing on biotechnology and life sciences, as well as through measures supported through the "research and innovation" area of the specific program on "structuring the European Research Area". ▯ Movement between academia and companies is strongly encouraged through the **mobility grants** of FP6, for which the budget has been doubled in comparison to the last framework program. ▯ The **websites** of the newly established **IPR-Helpdesk** and **Gate2Growth Initiatives** may serve as an information platform for communicating the various national and regional initiatives and providing information on and links to training and awareness activities. ▯ The next edition in **November 2003** of the bi-annual **PATINNOVA conference** in Luxembourg could also be used as a communication platform for initiatives in the biotech sector.	**Member States, Council, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
5 (e) 2002 onwards	• taking steps to **promote international dialogue and co-operation** with a view to work towards a level playing field with industrialized countries in patent protection on biotechnology inventions, ensuring an effective level of protection for innovation in this field.	▯ Harmonization of intellectual property law in industrialized countries is currently being discussed at the level of the **World International Property Organization (WIPO)** in its Standing Committee on Patent Law (SCP). A number of very important issues are being discussed, such as the patentability criteria, the patentable subject matter and the grace period. ▯ In parallel, the reform of the **Patent Cooperation Treaty (PTC**) has been undertaken in order to streamline and to simplify the PCT procedure and to avoid duplication of works. The real purpose of this exercise is to solve the increasing workload of the Patent Offices. Both exercises should allow to create a more user friendly system for the applicants and to reduce the discrepancies on patent law among the Parties of WIPO	▯ The Commission prepared a **working document** on these issues which was discussed with the Member States during the General Assemblies of WIPO (23 September-1 October 2002) which decided that works dedicated to the PCT reform should be pursued. ▯ Discussion on **Substantive Patent Law Treaty (SPLT)** will continue under the auspices of WIPO	**Member States, Council, Commission**
		▯ The **"grace period"** is a particular important issue regarding research co-operation on an international level. For this reason, the Commission has organized **two workshops** on this topic	▯ The **"grace period"** discussed during the workshops could serve as a basis for defining a common European standpoint at the current SPLT negotiations	

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
Capital base				
6 (a) **2002 onwards**	The Commission should, together with the European Investment Bank (EIB) and the European Investment Fund (EIF), strengthen the **capital base** for the biotechnology industry, by: ● seeking to stimulate investments in research and technological innovation via complementary financing on the basis of the co-operation agreement signed in June 2001 between the Commission and the EIB group.	**Three workings groups** chaired by the Commission, European Investment Bank (EIB) and European Investment Fund (EIF) have been set up to investigate the issues of **support R&D financing** via direct financing and guarantee mechanisms; **financing of infrastructures**; **availability of risk capital and support to incubators**.	The financing instruments of the **EIB**, including information on recent projects and case studies, will be actively promoted by the Commission and EIB, e.g., through their **websites** and through information contained in the "**INFO PACK**" to the new framework program. Concrete results and recommendations for further collaboration and the development of new financing instruments is expected by the launch of Sixth Framework Program. In addition, the Commission will target appropriate industrial partners who are currently project participants of the framework program to evaluate the interest for and potential of complementary financing instruments of the EIB.	**EIB group, Commission**
		Since June 2001, the EIB has made R&D the centerpiece of its ongoing **"Innovation 2000 Initiative" (i2i)**, one of the two pillars of the co-operation agreement between the Commission and EIB with the Framework Program for Research and Technological Development (FPRTD). EIB has substantially increased its financing of research and innovation. From 1990 to 1999, EIB had loaned 245 million € . From 2000 to present, under i2i, EIB approved 9.1 billion € in loans, of which **4.2 billion for research**.	R&D will remain a key objective for EIB lending in the years to come. A particular focus will be on supporting private R&D by SMEs, large companies as well as "mid-caps" and on fine-tuning EIB financial instruments to each sector. The EIF will continue to support universities and research centers in the creation of investment funds and new vehicles. Furthermore, EIF is currently setting up a consultancy operation. In doing so, EIF aims to bridge the gap between research and product development.	

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
6 (b) **2002 onwards**	● seeking to stimulate investments in business incubators through the **EIF Start Up Facility**	▯ In the year 2001, the EIF has done major investments in biotech VC funds linked largely to regional clusters and bioincubators, such as **"Heidelberg Innovation"** in Germany, **"BioAm"** in France and **"Symbion"** in Denmark. These commitments have been done through EIB funding, which represent 90% of the EIF VC resources. Altogether, **8 funds** have been created that devote 100% of their capital to the biotech sector. Through 55 general funds, **223 biotech start-ups** have been financed. Another €49 million were invested in smaller and regional start-up funds through the ETF start-up facility.	▯ Through the **multi-annual action plan (MAP)**, €317 million of financing will be available for the ETF start-up facility for the 2001-2005 period, with a focus on incubators and seed-capital funds. ▯ A **working group** comprising venture capital fund managers, banks, industry, bio-cluster managers, research organizations and research and industry ministries could be established to investigate how other regional actors could be involved in public-private partnerships, together with the EIF, to improve early stage financing for biotech start-ups. ▯ **Increase of the EIB VC funds** will be investigated.	**EIB group, Commission**
6 (c) **2002 onwards**	● studying measures to support technology transfer mechanisms, such as financing of patent pools or other methods for patent exploitation.	▯ A specific **working group** will be set up at the **beginning of 2003**, initiated through the Biotech and Finance Forum, comprising the PROTON network of European technology transfer offices and researchers, industry, financiers from the biotech sector to identify best practices in financing of technology transfer related to biotechnology. The objective of this group is to give policy recommendations for Member States, regional authorities and public research organization on how to best support the process of technology transfer. Best practices such as successful examples of public-private partnerships involving universities and regional financiers (banks, industry, etc.), co-operation of universities with private technology transfer firms or other novel examples of technology transfer initiatives should be identified and widely promoted.	▯ The US experience has shown that professional technology transfer structures are a major success factor for the exploitation of publicly funded research through licensing and start-up generation. Professional structures do not exist widely across Europe at the desired level, although some member states have recently initiated actions to support and increase technology transfer from the public sector, e.g. by supporting patent applications from the public research sector. Europe therefore needs to increase its support for the establishments of new or the professionalisation of existing structures, through regional or national initiatives, with sufficient private involvement and financing to guarantee a market driven approach.	**EIB group, Commission**

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6 (d) **2002 onwards**	● studying measures to encourage commercial financing of companies based on a medium-term investment perspective.	▯ On recommendation of the Biotech and Finance Forum (BFF - see action 7 for further details), the Commission set up a small **ad-hoc working group** comprising members of the BFF board, experts from biotech focused large VC companies and the EIB/EIF to investigate new financing instruments. A **report** was delivered in November 2002, recommending a stronger EIB/EIF/EC support for late stage investments and consolidation funds to support the further growth of the EU biotechnology industry. ▯ The Commission finalized the terms of reference for a **"Biotech finance study"** that should investigate financing gaps in the various Member States and other countries.	▯ The EIB and EIF, with the support of experts from the BFF group, will examine ways of implementing the recommendations of the working group, in particular raising support for later stage investments and consolidation funds, by **spring 2003**. ▯ The **Biotech Finance Study** will examine in detail, on a country-by-country basis, the respective ease of access to capital that biotechnology companies have: (a) at each stage of finance, (b) take-up/usage of EIB/EIF finance, and (c) in general, relative to other innovative companies.	**EIB group, Commission**
7 **2002**	● To strengthen the work of the **Biotechnology and Finance Forum** by the inclusion of relevant major stakeholders to provide advice into policy development in the field of capital supply.	▯ The **Biotechnology and Finance Forum (BFF)** was set-up as a joint initiative between the European Commission and the European Association of Security Dealers in 1997 to promote networking between researchers, entrepreneurs, industry and finance and support financing of biotech ventures. The BFF has organized **4 conferences** in recent years, which attracted on average around 300 participants. A total of 200 investment presentations by biotech companies have been done and numerous important financing deals have emerged from these meetings. On **22.4.2002**, the first meeting of the **new BFF advisory board** took place. This board includes all relevant biotech stakeholders in Europe, such as EuropaBio, the European Federation of Biotechnology (EFB), the European Venture Capital Organization (EVCA), the EIB, EIF and Eureka. Representatives of major bio-clusters, venture capital firms, consultants, etc. in the biotech sector are also present.	▯ An **ad-hoc working group** will be set up **at beginning 2003** to look into financing of professional technology transfer and medium term financing mechanisms (see action 6c). ▯ The **BFF board** will meet in **early 2003** to review the activities and to set priorities for working groups and other activities for 2003. ▯ A **BFF conference** is planned for **February 2003.**	**Commission**

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Networks in Europe				
8 (a) **2002-03**	● The Commission will support creation of a **commercial biotechnology web portal for Europe** that will help free access to information and networking available Internet platforms.	▯ Following the launch of a **call for proposals**, five responses have been received and they are currently being evaluated	▯ The web site(s) would be expected to be fully operational by the **end of 2003.**	**Commission**
8 (b) **2002-03**	● the Commission will develop its **newly created Commission web site** to provide a broad entry platform into the Commission's work on biotechnology.	▯ A thematic portal on Europa website under 'Biotechnology' is currently available.	▯ Further developments of the structure and contents of this site are currently under evaluation. The web site is expected to be developed and operational by **end of 2003**	**Commission**
9 (a) **2003-06**	● Member States, their regions, the Commission and the EIB will support **stronger interregional co-operation**, e.g. through a network of biotechnology regions. Crossborder and interregional co-operation can receive funding from the Interreg programs (notably Interreg IIIB and IIIC).	▯ While the Commission through its regional policy supports this action, the procedures of selection of concrete projects are matter for the Member States.	▯ Stronger interregional co-operation in the life sciences and biotechnology area is developing in a number of European regions. These activities, such as interregional networks, can be considered eligible for financing under the **INTERREG III initiative**. The INTERREG III programs (strands A, B and C) are now operational in all Member States. In particular, the INTERREG III C program launched its first call for proposals of projects on 10 October 2002, which closed on 10 January 2003. All relevant information about this program can be found on the following website: **www.interreg3c.net**	**Member States, regions, EIB, Commission**
		▯ The Commission, through the 5th Research Framework Program, has recently funded the **"Baltic Biotech Forum"**, an accompanying measures out of which the **SCAN BALT** initiative has evolved, which aims at networking biotechnology activities and clusters around the Baltic Sea. The Baltic Sea region has also recently received support for transnational collaboration from the Interreg III program		

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9 (b) 2003-06	● Member States, their regions, the Commission and the EIB will support **networks of biotechnology clusters**. In addition, the Commission will organize a European competition between Biotechnology Innovation clusters, to highlight their capability to develop a cluster with a focus of excellence in a specific scientific field.	▯ **Networks of biotechnology clusters** have been and are being developed in Europe. Examples are the **BioValley network of clusters** covering Rhone-Alp (FR), Freiburg (DE) and Basel (CH), as well as the **Medicon Valley** covering both Danish and Swedish regions around Copenhagen and Lund. ▯ The Commission has recently funded the **"Baltic Biotech Forum"** (see action 9a)	▯ Networking of biotechnology clusters can be actively supported within the **6th Framework Program** through specific support actions in the life science thematic priorities as well as through measures financed through the specific program on **"structuring the European Research Area"**. It is planned to organize a **workshop early 2003** that will bring together managers of biotech clusters to discuss possible new networking initiatives and highlight funding opportunities of the framework program and other sources, such as structural funds or those of the EIB/EIF. This workshop will also discuss the needs of biotech clusters to develop specific scientific, management and other competencies throughout Europe. This reflection could serve as a basis for developing specific targeted calls within the 6th Framework Program.	**Member States, regions, EIB, Commission**
A proactive role for public authorities				
10 (a) 2002	● the Commission will **establish** a **competitiveness monitoring function and a contact network with Member States ministries with responsibility for competitiveness in biotechnology**. Monitoring should include impact on European competitiveness of legislation and policy measures.	▯ The **contact network** has been established with 12 out of 15 Member States participating. It met for the first time in July 2002. A further meeting is planned for the next months	▯ The network has so far positively contributed to the developments of national positions	**Member States, Commission**
10 (b) 2002	● the Commission will establish a **Competitiveness in Biotechnology advisory group** with industry and academia to assist in identification of issues affecting European competitiveness. The Group will provide input into the Commission's regular reports on Life Sciences and Biotechnology.	▯ Reflections on terms of reference and composition of the group have started.	▯ A first meeting of the group should be envisaged for **May 2003**	

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
11 **2003 onwards**	Transparency in the administrative process: ● The Commission and Member States should **aid applicants,** especially from start-up companies and SME's, requesting approval through the regulatory process. ● the Commission should issue a **guide to Community regulation** for users and for entrepreneurs who have limited staff and expertise in the regulatory and legal fields. Such a guide should also benefit non-EU (e.g. developing world) applicants and the general public.	▯ The Commission already provides various but spread and selective information on Community biotechnology legislation/its management, such as ▯ the information it provides about the various **"dossiers"** concerning applications for EU authorization of GMOs; ▯ **web-site on pharmaceutical legislation**; ▯ **SMEs User Guide on biotechnology**	▯ The main aims of this action are to facilitate comprehensive information on biotechnology-relevant legislation, and ultimately, long-term investment in biotechnology that is in compliance with the developing regulatory framework in the EU, and public understanding of the development of that framework. The **new Guide** will be drafted **in 2003/2004**, when the new legislative framework will be in place, and will be the main instrument for access to information. It will be published on the Commission's biotechnology web-pages and regularly updated.	**Member States, Commission**
12 **2003 onwards**	● In collaboration with the involved actors, the Commission will **benchmark good practices in clustering biotech companies and in the work of business incubators** and disseminate results. ● The Commission will establish with Member States a program for **benchmarking** relevant elements of **biotechnology policies**, in addition to existing benchmarking structures.	▯ a **benchmarking program** involving interested Member States was endorsed by the Council and included in the road map adopted on 26 November.	▯ the possible contents of the benchmarking program will be discussed in **early 2003** within the contact network with Member States ministries with responsibility for competitiveness in biotechnology (see action 10a) on the basis of the roadmap.	**Commission**

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N° Action / Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
Societal scrutiny and dialogue				
13 (a) **2002 onwards**	● The Commission will propose a framework for a process of **dialogue and follow-up with stakeholders** as a result of the European strategy for life sciences and biotechnology. The framework will notably include a broadly based **Stakeholders' Forum**.	▯ The preparation of the **Stakeholders' Forum** is underway and it is planned to be set up in **2003**, when new key legislation is expected to be in place and Council/European Parliament will have given their response to the Commission's proposed strategy.	▯ The **Stakeholders' Forum** will be composed of representatives of all main stakeholders and societal groups (consumers, environmentalists, industry, trade union, academia, ethicists, etc.) and institutions (EP/national parliaments, regions…). Candidate countries and Third countries will also be invited to participate. While the scope of its debate should be broad (regulatory framework and underlying principles, role of science, main ethical issues), the Forum should not duplicate, but complement discussions in other, mostly more specialist or expert fora.	**Member States, industry, academia, civil society, EFSA, EMEA, Commission**
13 (b) **2002 onwards**	● the Commission will promote **awareness of key scientific paradigms** underlying regulatory oversight, within their respective fields, the **European Food Safety Authority** and the **European Agency for the Evaluation of the Medicinal Products** will play an important role in general risk communication	▯ The European Agency for the Evaluation of the Medicinal Products is undertaking a broad risk communication effort with an informative and accessible **website (www.emea.eu.int)**	▯ the **European Food Safety Authority** has been established and it will be fully operational by the **first half of 2003**	**Member States, industry, academia, civil society, EFSA, EMEA, Commission**

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13 (c) **2002 onwards**	• the Commission encourage **public debates on biotechnology** between scientists, industry and civil society	Specific measures have been taken by the Commission in this regard. In particular: ▯ An advisory group has been established in 2000, the **European Group on Life Science (EGLS)**, with a mandate that includes promoting and supporting science communication/debate strategies involving society at large. Under the guidance of the EGLS, the Commission is regularly organizing a series of **Life Sciences Discussion Platforms**	▯ The role of the **EGLS**, providing examples of multistakeholders platforms for the discussion of life sciences, should be reinforced through the development of systematic mechanisms of exchange of good practices, and amplification thereof, between Countries and organizers of all kinds.	**Member States, industry, academia, civil society, EFSA, EMEA, Commission**
		▯ Several projects involving consumers platforms and/or other public discussion forums are ongoing under the Quality of Life FP5 program	▯ The creation of a « **European network of citizens**», as a forum for informed reflection on biosciences issues, should be a final goal of on-going pilot initiatives.	
		▯ Initiatives of public perception monitoring have been regularly supported, starting from FP4	▯ Furthermore, the planned **European web-portal and the Commission's web-site** that should provide a broad entry platform into the Commission's work on biotechnology (see Action 8), should present an improved opportunity for stakeholders and citizens to express their views.	
		▯ in the context of the creation of the European Research Area, the Science and Society Action Plan is also developing a number of actions directly beneficial to the life science and biotechnology issues.		

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Developing life sciences and biotechnologies in harmony with ethical values and societal goals				
14 **2002-06**	The Commission will ● strengthen and focus Community **support for research into socio-economic and ethical issues** and dissemination of results, including criteria for assessing the benefits of using biotechnology in agri-food production, to facilitate future reporting and to provide a good basis for societal decisions on the application of biotechnology and life sciences. ● program research support to a more systematic **mapping of benefits and disadvantages/risks** which should include a strong component for dissemination of information and debate. ● ensure that **ethical, legal and social implications** are taken into account at the earliest possible stages of Community supported research by means of funding bioethics research and of providing an ethical review of research proposals received.	▯ The specific program **"Quality of Life and Management of Living Resources "** under the Fifth Framework Research Program (1998-2002) has so far ensured that the ethical dimension of research in Life Sciences and Biotechnology is addressed by: ▯ **Supporting research in Bioethics**, which has allowed to analyze the ethical issues linked to biotechnology and to better understand the ethical and cultural divergences in Europe, to develop proposals for codes of conduct as well as to establish a database in bioethics; ▯ **Fostering ethical awareness in research**, an obligation is put on the applicants to describe the potential ethical aspects of the proposed research regarding its objectives, the methodology and the possible implications of the results, and to justify the research design. An ethical assessment takes place for all proposals during the scientific evaluation and a specific ethical review has been implemented for proposals dealing with sensitive issues; ▯ **Improving the awareness of scientists**. To this end a **study on national, international and professional training material for ethics in research** was launched in 2002; such material will be largely disseminated; Furthermore, a **study on training programmes in ethics in research established in scientific faculties** across Europe has been launched. Those programmes will be connected across Europe.	▯ The policy developed under the Fifth Framework Program will be reinforced in the **Sixth Framework Program for Research (FP6)** by ▯ Promoting the integration of the analyses of the ethical, legal and social spects into research projects: **research in bioethics** will be an integrated part of research projects in relation to the thematic priorities 1 " Life Sciences, genomics and biotechnology for health" and 5. "Food quality and safety" ▯ Encouraging **public dialogue and participation of stakeholders** in research projects ▯ Fostering **ethical awareness and foresight attention** in research ▯ Supporting specific actions to **promote the debate on ethical, legal, social and wider cultural aspects** of life Sciences and Biotechnology ▯ Addressing via the specific programme "Structuring the ERA3 cross-cutting questions through comparative research, foresight and impact studies on ethical issues in relation to sciences and technological developments.	**Commission**
			▯ Following the Council conclusion on the five specific programs implementing FP6, the Commission will publish a **report on the evolution of stem cells research** and will organize a **public institutional seminar** on the subject by **Spring 2003**.	

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N° Action / Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
15 **2002**	The Commission will ● propose to enhance the role of the **European Group on Ethics**	▯ The role of the **European Group of Ethics (EGE)** has been enhanced **by** establishing closer collaboration with Commission services, and by increasing exchanges with other institutions namely with EP (e.g., participation of MEP to the round tables organized by the Group, hearing of the Group by the EP temporary commission on genetics, etc…).	▯ Following the EP resolution of the Commission strategy on life sciences and biotechnology, the Commission intends to propose a **modification of the mandate of the EGE** to allow the EP and Council to be involved in the nomination of the members of the group.	**ethical bodies, legislatures, Commission**
	● launch a separate consultation of the other Community institutions on possible structural and procedural improvements	▯ The Group is involved in the ongoing discussion on how to integrate ethical consideration in decision making process within EU, which also implies to carry out an in depth reflection on the evolution of its role (e.g., participation of EGE to the workshop within the framework of the Danish Action	▯ The EGE will actively participate to the public institutional **seminar on bioethics** to be organized by the Commission following the Council conclusion regarding the specific programs of the FP6 (see action 14).	
	● promote collaboration between Community, national and local levels by promoting networking of national and local ethical bodies and elected representatives	▯ Contacts and exchanges between the EGE and the national instances of ethics are regular and facilitated by the fact that several EGE members also are members of such national instances. Furthermore, the Group systematically meets every six months the national instances of the Member States in charge of the presidency	▯ The EGE will create a **News Letter** on the activities carried out by national ethics instances; such regular publication will improve the diffusion of informations and facilitate contacts and collaboration between ethics committees. Furthermore, in view of the preparation of its future opinion of genetic testing in the work place, the EGE	
	● organize a network of academic and professional experts for ad-hoc advice on specific socio-economic aspects.	▯ Networks of academics and experts have been set up by the Commission to address socio-economic aspects of biotechnology, as the **European Group on Life Sciences** set up in April 2000, to meet the need of high level advice on Life Sciences and Biotechnology.		

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16 **2002 onwards**	The Commission ● will develop, jointly with the European Parliament, outreach **measures to inform about the analysis of ethical issues** at the EU level.	▯ The opinions issued by the **European Group on Ethics in Science and New Technologies** play a relevant role in the ethical debate at European level. ▯ A **web-site** is currently under construction to promote the dissemination of the results of **multidisciplinary research** projects into the ethics of life science and biotechnology funded and coordinated under FP5, and to contribute to inform the ethical debate. ▯ In 2002 a **workshop** was organised with existing networks in the field of "ethics in research" to explore the possibility to create a "**European Information and Documentation system on ethics in science"**, in order to improve the generla access to regulation and ethical debates in the EU. A feasibility study is expected.	▯ The **participation of all stakeholders in research projects** under Sixth Framework Program, in particular under the thematic priorities 1. " Life Sciences, genomics and biotechnology for health" and 5. "Food quality and safety" will be encouraged in order to engage in an interactive dialogue between scientists, physicians, industry, patients, consumers, farmers, animal welfare organizations, ethicists, lawyers and the public at large – for socially responsible choices, shared understanding and greater public participation.	**European Parliament, Member States, regions, industry, institutions, Commission**
	● will work with public and private partners, to identify areas where it is possible to establish consensus on ethical guidelines/standards or best practice. Areas might include stem cell research, biobanks, xenotransplantation, genetic testing and use of animals in research. Such guidelines could, when appropriate, take the form of self-regulatory initiatives in the scientific community and industry.	▯ The Commission has during the last 12 months conducted **3 surveys** regarding national legislations in relation to xenotransplantation, human embryonic stem cell research and biobanks. These surveys allows to analyze best practice and provide a first step towards preparations of guidelines. ▯ The opinions of the **EGE** and the work in **Council of Europe** are other important documents in this respect.	▯ Transnational, multidisciplinary and pluralistic focus groups may be established in a first step to develop guidelines for research funded under FP 6 regarding areas such as animal experimentation biobanks, xenotransplantation, genetic testing and human stem cell research.	

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Demand-drive applications through informed choice				
17 **2002 onwards**	● to develop research and pilot projects to clarify the need, and possible options, for agronomic and other **measures to ensure the viability of conventional and organic farming** and their sustainable **co-existence** with genetically modified crops.	▯ A **study on scenarios co-existence of GM, conventional and organic crops in European agriculture** was carried out by the Commission. It provided the first results on this issue. ▯ A **strategy paper** is under development	▯ The following **actions** are envisaged for the elaboration and implementation of the strategy: ▯ **follow-up** of the study on co-existence planned for **2003,** aiming to confirm and to enlarge the preliminary first results of the study ▯ **round table** on co-existence to be organized in **April 2003** ▯ future **studies and research** within the FP6	**Member States, professional associations, other operators, Commission**
	● To launch a new action program for the conservation, characterization, collection and utilization of genetic resources in agriculture in the Community.		▯ A proposal for a Regulation on the conservation, characterization, collection and utilization of genetic resources the proposal of a new regulation is in preparation	

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Pharmaceutical legislation				
18 2002	● to speed up the adoption of the **three legislative proposals**, revising the Community **pharmaceutical legislation**	▯ The review consists of **3 proposals**, i.e. one regulation dealing with the centralized procedure and two directives modifying the existing codes in the field of human and veterinary medicinal products**(COM(2001)404 Final),** which were adopted by the Commission on 26.11.2001 ▯ The **EP** concluded its first reading on 2 October 2002 ▯ Discussion in the **Council** is progressing slowly.	▯ A **political agreement** is expected to be reached under the Greek Presidency.	**European Parliament, Council**
Short-term regulatory action				
19 2002	● To speed up the adoption of the two following legislative proposals: ▯ Proposal for a European Parliament and Council Regulation on **Traceability and Labeling of Genetically Modified Organisms and Traceability of Food and Feed derived from Genetically**	▯ The **European Parliament** completed its first reading on 3 July. ▯ The Environmental Council reached a political agreement on **9 December**.		**European Parliament, Council**
	▯ Proposal for a European Parliament and Council Regulation on **Genetically Modified Food and Feed**.	▯ The **European Parliament** completed its first reading on **3 July**. ▯ The Agriculture Council reached a political agreement on **28 November**.		

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20 **2002-03**	● To finalize the **legislative proposals** which have already been announced, such as initiatives concerning **GM plant propagating material**, **environmental liability** and the implementation of the **biosafety protocol**.	The Commission has adopted ▯ a Proposal concerning the **environmental liability** (COM(2002)17 final of 23 January 2002). ▯ a Proposal for a Regulation of the European Parliament and the Council on the **transboundary movements of GMOs**	▯ Both proposals on the environmental liability and on the implementation of the Biosafety Protocol are under examination by other Community Institutions.	**European Parliament, Council, Commission**
		▯ a Proposal for a Council Decision on the **conclusion of the Biosafety Protocol** on the behalf of the European Community (COM(2002)127 final), which was adopted by the Environment Council of 25 June 2002	▯ On **27 August 2002** the European Community deposited its instrument of **ratification** to the Secretary General of the United Nations in New York	
			▯ The proposal for establishing **thresholds for the adventitious presence of GMOs in conventional seeds** is to be finalized in the light of the developments on the proposals on food/feed and traceability. ▯ the proposal for including the **environmental risk assessment of seeds in the seeds legislation** will be considered once the discussions on the proposals on GM food/feed and traceability are finalized and at the latest in the context of the report to Council and EP on the feasibility to improve further the consistency and efficiency of the framework for authorizing GMOs (see action 22).	

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Implementation and enforcement activities				
21 **2002-03**	● To ensure that legislation is enforced in a uniform and effective way across the Community and to adopt **appropriate implementing measures** required under relevant legislation, including the necessary guidance for detection and sampling methodology	In order to ensure uniform and effective enforcement of EC legislation, ▯ **four implementing measures** have been adopted **1)** Council Decision **2002/813/EC** establishing the Summary Notification Information Format Part B(OJ, L280) **2)** Council Decision **2002/812/EC** establishing the Summary Notification Information Format Part C (OJ L280) **3)** Commission Decision **2002/623/EC** establishing guidance notes supplementing Annex II to Directive 2001/18/EC (OJ L200), **4)** Council Decision **2002/811/EC** establishing the guidance notes supplementing Annex VII to Directive 2001/18/EC (OJ L280)	▯ The Commission is considering **other implementing measures** required by Directive 2001/18/EC ▯ The proposal for GM Food/Feed foresees the JRC to become **Community Reference laboratory** to be assisted by the "European Network of GMO laboratories ▯ A proposal for a Commission Regulation on a **protocol for sampling and testing of seed lots** of non-GM varieties for the presence of GM seed will be put forward together with a proposal for a Commission Directive amending the annexes of the different seed Directives, setting additional conditions and requirements concerning the adventitious or technically unavoidable presence of GM seeds in seed lots of non-GM varieties	**Commission**
		▯ the JRC of the Commission continues to co-ordinate a **network of laboratories** responsible for GMO testing from Member States and third countries. The main objective of this network is to contribute effectively to the European harmonization and standardization of means and methods for sampling, detection, identification and quantification of GMOs and GM products. The JRC is also providing **certified reference materials.**		
	● To establish a **molecular register** that is accessible to the public, containing information on events of genetic modification.		▯ The creation of a **molecular register** of known GMO molecular and biological data has begun	

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Specific long term regulatory action				
22 **2003**	● To report on the feasibility of options **to improve further the consistency and efficiency of the framework for authorizing GMO's for deliberate release into the environment**, including a centralized Community authorization procedure.	▯ A call for tender for a **study** is being launched.	▯ This study is aimed at preparing the **Commission's report to the other EU institutions.**	**Commission**
23 **2002 onwards**	● To support the development of methodologies for monitoring **potential long-term environmental impacts of GMO's** as compared with conventional crops, and methodologies for the **monitoring of effects of genetically modified food and feed as compared with conventional food and feed**. With the establishment of the European Food Safety Authority, the work on the early identification of emerging risks will be reinforced and upgraded.	▯ a **study** for the development of specific sets of monitoring criteria for individual groups of GMOs and for different transgenic phenotypes has been envisaged for **end 2003/mid 2004**	▯ **Short and medium term actions** concerning the development of methodologies for post-marketing will be developed in consultation with **European Food Safety Authority by 2003** ▯ Council Decision **2002/811/EC** (see action 21) will contribute to monitor potential long-term environmental impacts of GMOs.	**Commission**

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A European agenda for international collaboration				
24 **2002 onwards**	● The Commission should continue to play a **leading role in developing international guidelines**, standards and recommendations in relevant sectors, based on international scientific consensus and, in particular, push for the development of a consistent, science-based, focused, transparent, inclusive and integrated international system dealing with food safety issues.	▯ In the **G8**, the Commission has over the last two years actively pushed for a consistent, science-based, focused, transparent, inclusive and integrated international system dealing with food safety issues. ▯ The Commission continues to play a leading role in **Codex Alimentarius**, **OECD** and under the **biosafety protocol** with a view to develop international guidelines, standards and recommendations on food safety and biotech issues.	▯ After 11 September 2001, the **G8** has been preoccupied with combating terrorism and the issue of food safety and, as a consequence, biotechnology has not been on their agenda.	**Commission**
Europe's responsibilities towards the developing countries Agriculture				
25 (a) **2002 onwards**	● the Commission will in cooperation with Member States **support** the redefining of national research towards **an appropriate mix of traditional techniques and new technologies**, based on priorities developed with local farmers.	▯ This action is addressed in the Commission **Agricultural Research for Development (ARD) strategy** document, elaborated in close collaboration with the Member States, available at the following address: http://europa.eu.int/comm/development/rurpol ▯ A **meeting** with other **donors** (World Bank, FAO, USAID, IFAD, African Development Bank, EU Member States), African Sub-Regional Organizations , Forum Africain pour la Recherche Agronomique and Global Forum on Agricultural Research took place on **24-26 June 2002**, on Competitive Funds, providing for concrete recommendations ▯ On **30-31 January 2003**, the Commission organized a **Life Sciences Discussion Platform: Towards sustainable Agriculture for Developing Countries,** aiming to address the potential, benefit and risks of life sciences and biotechnology for sustainable agriculture in developing countries	▯ Implementation of this approach through the Sub Regional Organizations **SADC** / **SACCAR program** is under preparation (estimated amount: 15M€) with the participation of the Member States through European Initiative for Agriculture Research for Development ▯ A **program** is under preparation with NGOs, farmers associations, private sector, extension services, etc., through Global Forum on Agricultural Research**,** aiming at supporting the participation of all stakeholders at all stages of Agricultural Research for Development in ACP countries. Its expected starting date is **beginning of 2003**.	**Member States, Commission**

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25 (b) **2002 onwards**	▯ the Commission will in cooperation with Member States support the establishment of effective **research partnerships** between public and private research organizations in developing countries and in the EU, and the adequate **capacity and infrastructure for developing countries** to enter into such partnerships, in accordance with international commitments under the Conventions.	▯ Partnerships, capacity building and physical infrastructures are being provided through various financial instruments, such as on-going Commission research support projects and ARD programs. The FP6 will pursue these efforts, particularly through its international dimension.	▯ **South-South** and **South-North Partnerships** will be strengthen through the implementation of **Competitive Funds** at national level, subregional level (see action 25a), regional level (FARA, FONTAGRO, etc.), and at global level (GFAR, CGIAR challenge programs).	**Member States, Commission**
25 (c) **2002 onwards**	● the Commission will in cooperation with Member States support **sub-regional, regional and international organizations**, in particular the International Agricultural Research Centers.	▯ The Commission and the Member States are working together through **European Initiative for Agricultural Research for Development (EIARD)** to elaborate common positions on and participation in the **Consultative Group On international Agricultural Research (CGIAR)** policy, governance and management structures, as well as to co-ordinate respective supports. ▯ The **proposed EC support to the CGIAR** for the period 2002-2004 has been endorsed by the EU Member States in the Foods Aid / Food Security Committee at the end of May 2002 and will amount to **22 M€ per year**.	▯ Regular participation of the Commission in the **European Initiative for Agriculture Research for Development (EIARD) meetings** is ensured. ▯ **Annual contracts** will be prepared and signed by the Commission with the **Consultative Group On international Agricultural Research (CGIAR) Secretariat** / **World Bank** for the mobilization of the EC support 2002-04. ▯ **Priority areas** of EC support and implementation modalities are detailed in EC strategy document "GCRAI: éléments de stratégie" available on Commission website ▯ The modalities to select the **CGIAR projects** that will be supported by the EC have been reviewed with the EU Member States in October 2002, as well as the lists of projects to be financed in 2003.	**Member States, Commission**

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Europe's responsibilities towards the developing countries Genetic resources				
26 (a) **2002 onwards**	The Commission and the Member States will support the **conservation and sustainable use of genetic resources** in developing countries and their equitable sharing of benefits arising from their use by: ● supporting the development and enforcement of effective **measures to conserve, to use sustainably and to provide access to genetic resources and traditional knowledge,** as well as to share equitably the benefit arising from them, including income generated by intellectual property protection. Support for local communities is vital to **conserve indigenous knowledge and genetic resources**.	▯ At the **WTO** : Commission actively participated in review of **Article 27.3(b) of the Trade Related Intellectual Property (TRIPs) Agreement** and, in the context of the DDA, in the working program mandated by para. 19 of the Doha Ministerial declaration. A **Communication** on these issues, which was submitted by the Commission to the TRIPs Council on 16 September 2002 (ref. IP/C/W/383), was welcomed by several deveoping countries as a useful contribution ▯ At the **CBD** : the Commission was an active participant in several expert and working groups which prepared the **Bonn Guidelines on Access to Genetic Resources and Benefit-sharing** adopted at the 6th Conference of the Parties in The ▯ At the **FAO** : Commission and Member States played key role in the adoption of **the International Treaty on Plant Genetic Resources** and provides input to the current dialogue on the conditions for ABFS in the context of the IT with an aim to agree on a standard **Material Transfer Agreement**.	▯ The Commission will continue its active participation in the debate on TRIPS and Biodiversity in the WTO.	**Member States, Commission**

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26 (b) **2002 onwards**	● supporting the **participation of delegates from developing countries in the negotiations of relevant International Conventions**.	▯ **Financial resources** are available in the envelope **"Intra-ACP resources 9th European Development Fund (EDF 9)** to contribute to this objective.	▯ A **Commission Interservice Steering group on issues related to the WTO-Sanitary and Phytosanitary Agreement (SPS)** has been created to co-ordinate actions and financial support in this objective	**Member States, Commission**
26 (c) **2002 onwards**	● supporting measures to **promote greater regional co-ordination in legislation** to minimize disparities in access, benefits and also trade in products derived from genetic resources, in accordance with international commitments	▯ A Commission's study **"Benefits, needs, constraints and recommendations for development and use of biotechnology in developing countries"** is under preparation. The objective of this study is to list recommended standards and guidelines to promote the safe and effective development and use of green, white and red biotechnology in developing countries, based on their autonomous choice and on their national development strategies. Stakeholders will be consulted on the terms of reference of the study at the **beginning of 2003**	▯ **Several African sub-regional research organizations** (e.g. ASARECA, SACCAR and CORAF) could be well placed to work on these subjects (i.e. national and regional policy processes and coherence). ▯ EC **financial resources** mobilized for Agricultural Research for Development (ARD) at sub-regional level (respectively 28, 19 and 20 M€), in close collaboration with the Member States mainly through European Initiative for Agricultural Research for Development (EIARD), could be partly utilized for this purpose	**Member States, Commission**

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Europe's responsibilities towards the developing countries Health				
27 **2002 onwards**	● The Commission and the Member States should work with the international community to **concretize the commitment to research to combat HIV/AIDS, Malaria, TB and other main poverty-related diseases** and also identify effective measures to support developing countries in establishing the structures needed to deploy a health policy.	▯ Over the last decade the Commission has substantially invested in research on Poverty-Related Diseases. In the 5th Framework Program alone more than **110 million €** have been contributed to 90 projects on HIV/AIDS, malaria and TB. In addition Member States invest at national level more than **200 million €** in research for the development of new interventions against these diseases. Improved co-ordination of research activities between Member States will increase the impact and efficiency of research efforts. With the establishment of the **European and Developing Countries Clinical Trials Partnership (EDCTP)** the fragmentation of European research efforts can be overcome and also be translated into clinical interventions that are applicable in the Developing Countries.	▯ Fifteen European countries, encouraged and supported by the European Commission, have initiated the establishment of the **EDCTP**. For the initial period of 5 years a contribution of 200 million € assigned by the 6th Framework Program for Research (2002-2006), is requested from the Community to serve as a catalyst to start the activities of the Joint Program of the EDCTP. The Commission will submit a **proposal** to the Council and Parliament to apply Article 169 of the Treaty **to allow for participation of the Community in the EDCTP Joint Program**. The EDCTP should be operational in **early 2003**.	**Member States, Commission**
		▯ An **international dialogue and training courses** have been organised, together with the National Institute of Health (NIH), aiming to assist in capacity building for the ethical assessment of research projects and clinical trials in developing countries In 2002 and 2003 workshops have been organised Seoul/South Korea and in Mali/Africa.	▯ Further workshops are planned in Egypt and Uganda.	
		▯ The **Program for Action** against **AIDS, malaria and tuberculosis** has progressed on the main issues of impact, affordability and research.	▯ The Commission will present its **progress report** to the EP and Council **beginning 2003**. Progress will be monitored by the annual and mid-term country reviews and by periodic meetings of the interservice group on the progress of the program for Action.	

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LIFE SCIENCES AND BIOTECHNOLOGY - A STRATEGY FOR EUROPE
State of implementation of action plan (1)

N° Action / Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
Europe's responsibilities towards the developing countries Responsible and careful use				
28 (a),(b),(c),(e) **2002 onwards**	To support: ● the **safe and effective use of modern biotechnologies** in developing countries, based on their autonomous choice and on their national development strategies. ● **measures to increase the capacity of developing countries to assess and manage risk** for man and the environment, under conditions prevailing in the country. ● the development of appropriate administrative, legislative and regulatory measures in the developing countries, for the **proper implementation of the Cartagena Protocol**. ● that the **international regulatory requirements** remain manageable by developing countries, so as not to impede their trade and production prospects.	▯ A Commission's study **"Benefits, needs, constraints and recommendations for development and use of biotechnology in developing countries"** is under preparation. (See action 26c)		**Commission**
28 (d) **2002 onwards**	● that **international research on social, economical and environmental impacts** are effectively adapted to take into account conditions prevailing in developing countries and that the findings are subsequently disseminated to them in an appropriate format.	▯ Impact monitoring and subsequent recommendations are fully integrated in the **EC supported research programs**, being at national, sub-regional, regional and global levels		**Commission**

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LIFE SCIENCES AND BIOTECHNOLOGY - A STRATEGY FOR EUROPE State of implementation of action plan (1)				
N° Action / Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
Implementation and coherence across policies, sectors and actions				
29 (a) **2002 onwards**	The Commission will enhance: ● the general **foresight function** across Commission services, and in particular its role in technology foresight through its Institute for Prospective Technological Studies (IPTS), for early identification of newly emerging issues and of elements of a policy response	▯ The Commission's Joint Research Center (JRC), to which IPTS belongs, has enlarged foresight activity in its **multiannual work program (MAWP, 2003-2006).** One of the MAWP's four priorities focus explicitly on biotechnology and includes the biotechnology foresight exercise **BIOFOR**. The first round of BIOFOR is scheduled to start in the **second half of 2003**, with completion and dissemination of results by the **end of 2004**. ▯ Other IPTS **foresight and anticipation studies** in certain biotechnology applications (namely in genetic testing of humans, on tissue engineering, on the use of GMOs in agriculture, etc.) are on going and will feed into BIOFOR. ▯ A study on **genetic engineering in aquaculture** will be funded in **2003**.	▯ starting point will be biotechnology development as enabling technology. The following application sectors might be included: ▯ Human and animal health (e.g. drug discovery, pharmacogenomics, envirogenomics, diagnosis, tissue and organ engineering), ▯ Agriculture and food production, nutraceutical production sector and personal nutrition (nutrigenomics), ▯ Fisheries and aquaculture. ▯ Environmental applications and bioremediation, ▯ New industrial processes and substitution processes, ▯ Applications in security and defense, ▯ Horizontal developments: in-silico biotechnology; bioinformatics, data management and protection.	**Commission, Member States**
29 (b) **2002 onwards**	● its **monitoring and review function** to assess - the relevance, coherence and effectiveness of legislation and policy - the extent to which policy objectives are achieved and legislation enforced - the societal and economic impact of legislation and policy measures In pursuit of these objectives and to further strengthen policy coherence, the Commission	▯ In 1991, a single inter-departmental co-ordination body, the **Biotechnology Co-ordination Committee (BCC)**, was established in order to ensure the continuos co-ordination between Commission services and the monitoring and review function of the Commission in this area. The BCC comprises all services with an interest in biotechnology and consists of high-level officials from those Commission services. ▯ Furthermore, for the preparation of the Commission strategy on Life Sciences and Biotechnology and in order to monitor the implementation of such a strategy, a **Commission Steering Committee** consisting of the most directly involved cabinets and services has been set up and has met regularly since 2001.		**Commission, Member States**

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4. Implementation accross pol.

LIFE SCIENCES AND BIOTECHNOLOGY - A STRATEGY FOR EUROPE State of implementation of action plan (1)				
N° Action / Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
29 (c) **2002 onwards**	● will reinforce continuous co-ordination between its services and calls upon Member States to also provide enhanced foresight/review functions and a coordinated interface for a dialogue on these issues.		▯ A reflection is on how internal Commission co-ordination on biotechnology could and should be enhanced is ongoing. Results are expected by **mid 2003**	**Commission, Member States**
30 **2003 onwards**	● The Commission will present a **regular Report on Life Sciences and Biotechnology** to monitor progress and indicate possible specific proposals to ensure policy and legislative coherence. The report will draw on the conclusions under actions 10 and 29.	▯ The current **report** is the document referred to by this action.	▯ In its conclusions, the **European Council in Barcelona** asked Council and the Commission to develop the detailed measures to implement the approach proposed and report on progress in good time for the 2003 Spring European Council.	**Commission**

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4. Implementation accross pol.