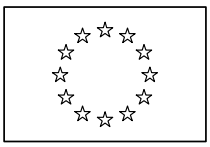

COMMISSION OF THE EUROPEAN COMMUNITIES

Brussels, 7.4.2004
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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 Second Progress Report and Future Orientation on Life sciences and Biotechnology

{COM(2004) 250 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 1**.

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.

The full text of the first report of the **Competitiveness in Biotechnology Advisory Group with Industry and Academia** (CBAG), appointed by the Commission in accordance with Action 10b of the Action Plan, is provided in **Annex 2**.

ANNEX 1

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) was launched (2005-2006). The different measures of this programme allow for project development in this field. ❒ 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.** Most Member States have instituted measures to revamp science education, with an emphasis on new technology.	**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 was presented by to the 2003 Spring European Council.	⇨ In several Member States (F, UK, DK, IRL, German länder) the needs and options for continuing education are mapped and strengthened.	
	● 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.Some Member States try to facilitate career movements between academia and the private sector.	**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.	❒ In the framework of the **Mobility Strategy for the European Research Area,** (COM(2001)331) ►"**The Researcher's Mobility Portal**" (http://europa.eu.int/eracareers) was launched in summer of 2003. ► Dedicated **national Mobility Centres** have become in part operational in 2003, and ► the **European network of Mobility Centres** will formally be launched in the spring of 2004. ❒ In the communication **"Researchers in the European Research Area: one profession, multiple careers"** (COM(2003)436) the Commission is addressing for the first time at European level, the issue of the researcher profession and researchers careers.	⇨ A specific **"Life Sciences Mobility Consultance"** aiming to help researchers in the life sciences to find funding opportunities, training programmes and vacancies, will be linked to the Researchers Mobility Portal. ⇨ the "**European Researcher's Charter"**, a framework for the career management for human resources in R&D, based on voluntary regulation and a "**Code of Conduct for the recruitement of researchers**" based on best practise, to improve recruitment methods will be launched **in the course of 2004.**	**Member States, Commission**

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N° Action/ Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
		❑ in order to make Europe more attractive for researchers, a **Commission proposal for a Directive and an Action Plan on the entry and stay of third country researchers within the E**U was adopted on 16 March 2004 **(COM(2004) 178)** ❒ Under the specific program **"Structuring the European Research Area"**, the Commission offers increased opportunities for mobility across Europe and implement actions to counteract the brain drain. As a result of the first calls for **Marie Curie-actions** under the Human Resources and Mobility programme **47 life sciences and biotechnology related actions** (including 10 training networks, 12 excellence grants, 6 inter European fellowships, 4 reintegration and 8 international fellowships, 3 technology transfer fellowships that allow companies to host fellows, 4 conferences and training courses) have been selected for funding to a total amount of just under **€ 47 million** (representing 13% of a total indicative budget of € 356 million for Marie Curie actions for the first calls)	⇨ **studies** to assess and benchmark the multiple career paths of researchers will be launched **in 2004**. ⇨ **New calls for Marie Curie** actions will be launched **in 2004-2005**	

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
Research				
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 ◆ to facilitate the objectives of **Europe-wide collaborations**, attaining critical mass and simplification of administrative procedures.	❒ The results of the first calls for proposals under the Sixth Framework Program(FP6) have among others resulted in the funding of : ► **103 research projects** with an initial EC contribution of **€604 million** under the Thematic Priority 1 " Life Sciences, Genomics and Biotechnology for health ", The projects, involvinvolving **more than 2020 laboratories including 274 SME's.** The second call for proposals deadline **13 November 2003** has an indicative budget of €**415 million**, ► **36 research projects** awarded an initial EU contribution of **€ 206 million** in the Thematic Priority 5" Food Quality and Safety". The projects involving some **685 laboratories including 103 SME's.** A second call for proposals have been published **5 November 2003** - deadline 5 February 2004- indicative budget **192 million Euro**. These research projects will be complemented with **11 actions (EU contribution of € 8.1 million)** supporting the programme cooperation and the coordination of research activities carried out at national or regional level in the areas of health and food research.	⇨ **New calls for proposals** will be published **in 2004 and 2005** for the various Thematic Priorities including Thematic Priority 1 and 5. ⇨ A **European technology platform on plant genomics and biotechnology** is currently being set up with the aim to develop an EU wide strategy to re-build and strengthen the S&T base in plant genomics and biotechnology , taking into account the needs of the different industrial sectors (food, chemicals, pharmaceutical etc). It is expected to be officially launched **in spring 2004**.	**Members States, EIF, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
	◆ encouraging **SME participation, international cooperation and mobility and training of researchers**.	❒ As a result of the first call for proposals about **13% of the budget will be allocated to SMEs** under the thematic priorities and 52 Specific SME activities (Co-operative and collective research) and research and innovation activities (Economic and Technological Intelligence actions) will be implemented to support a large community of SME's to develop innovation in healthcare, food quality and safety, agriculture and aquaculture. ❒ Nearly **20 Specific support actions** will be implemented to facilitate co-operative research and innovation partnership in life sciences and biotechnology with INCO target countries (including Developing countries, Mediterranean partners, Western Balkans, Russia and NIS).	⇨ **New calls for specific activities** promoting the participation of SME's , international collaboration and coordination of national activities will be launched **in 2004 and 2005**,	
	● 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 work of this group is continuing. ❒ The **European Strategy Forum on Research Infrastructures (ESFRI)**, set up by Member States in 2002, concluded in its firts annual report published in September 2003 that the body should extend its activities and address specific needs for scientific areas such as life sciences.		

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N° Action/ Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
		❒ Under the specific program "Structuring the European Research Area"(2002-2006) specific support is provided to research infrastructures. **Four projects (EU contribution of 48,7 M€)**, currently under negotiation, will provide access for the European research community to synchrotron radiation sources and free electron lasers; to museum collections of micro-organisms, fungi, plants, animals and fossils, to mouse strains including transgenic strains; to network of European seed banks. ❒ The **first call** for proposals in the area of functional genomics under Thematic priority 1 resulted in the funding of" **A European Network for Integrated Genome Annotation"**	⇨ The **4th call for research infrastructures** under the specific programme " Structuring the European Research area" (**deadline 4 March 2004**) includes constructions of new infrastructures, feasibility studies and technical preparatory work for new infrastructures and actions to promote a more co-ordinated approach to research infrastructures in Europe. ⇨ The **second call** (deadline **13 November 2003**) in the area of functional genomics under Thematic priority 1 invited proposals for Bioinformatics grid for European genomics research and development of an integrated software platform to tackle genomic sequence-structure-function relationship.	

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N° Action / Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
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 **2004** 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. Such networks have been created in several Member States (A, S, F, I,).	**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, **seven Member States** have transposed the Directive (DK, FIN, IRL, UK, GR, ES, PT). ❒ The Commission has launched the **third 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 has decided to sue an action before the ECJ against Member States which have not transposed the Directive into their national law.	⇨ 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, the Commission is currently preparing its **second annual report** on the development and implications of patent law in the field of biotechnology and genetic engineering (the first annual report was adopted in 2002 - **COM(2002) 545**). ⇨ 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. Two topics were studied **in March and May 2003** respectively 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. Minutes from those discussion and reports prepared by experts will be made available at the same time as the Commission second 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**
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.	❐ A Commission **study** that provides 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,as well as in the US and Japan, has been finalised and will be published soon. The study is currently being analysed in view of proposing recommendations or guidelines which could improve the coherence of the IPR regimes applicable to publicly funded research in the European Union ❐ An **expert group of technology transfer and legal specialists** has produced "Management of Intellectual Property in Publicly-funded Research Organisations : towards European guidelines", http://europa.eu.int/comm/research/era/pdf/iprmanagementguidelines-report.pdf	⇨ 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. ⇨ Through the method of open coordination, wider IPR issues will be discussed with Member States as part of the "3% action plan" (COM(2002)499)	**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. ❒ A workshop to explore the establishment of a **EU network of managers of public intellectual property resources in agriculture** took place in January 2004. ❒ 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.	⇨ A **project analysing IP management** within and consortium agreements of FP5 biotech research projects will,by the end of 2004, produce guidelines and best practise for IP management in collaborative research projects. ⇨ 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.	**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) meet on an ad hoc basis 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 EIB has increased the capital available to EIF for investvents in high tech venture capital by 500 million Euro. ⇨ 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 **Biotech and Finance Forum** working group established in 2003 will continue its work in 2004 to identify best practices in financing of technology transfer related to biotechnology and propose new financing instruments for technology transfer (proof of concept funds, patent pools etc.). ❒ A workshop to explore the establishment of a **EU network of public intellectual property resources in agriculture** took place in January 2004. The network should provide technology packages and patent pools in particular for small European speciality breeders and for humanitarian use in developing countries.	⇨ 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. A majority of the $1b of royalties earned by US and Canadian public research institutions in 2002 have originated from inventions in life sciences and biotechnology, mainly through license income from SMEs. A similar potential in the EU is largely untapped and needs to be exploited through national and EU initiatives.	**EIB group, 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**
6 (d) **2002 onwards**	● studying measures to encourage commercial financing of companies based on a medium-term investment perspective.	❒ Recommendations of the Biotech and Finance Forum working group delivered in 2002 on "Financing of biotech companies" have been discussed with institutional investors and the EIB/EIF early 2003. The EIB has decided to provide an additional 500 million euros to the EIF to provide further venture capital to innovative SMEs, which will be particular beneficial for follow-up investments in biotech companies. ❒ 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 EIF will make available an additional €0,5b for VC funds focusing on innovative SMEs. The potential for joint initiatives of the EIF and Member States should be explored. ⇨ 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**

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State of implementation of action plan [1]

N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
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 **6 conferences** in recent years, featuring investment presentations by biotech companies, from which numerous important financing deals have emerged. The **BFF advisory 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 **BFF working group** in **2004 will** look into financing of professional technology transfer (see action 6c). ⇨ The **BFF board** will meet in **early 2004** to review the activities and to set priorities for working groups and other activities for 2004/2005. ⇨ A **BFF conference activities** will continue and seek to consolidate with other EU events.	**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
		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 **2004.**	**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 **2004**	**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. ❒ A project have been partially co-financed by the European Fund for Regional Development. The project will promote the growth of the **Scottish Centre for Genomic Technology and Informatics (GTI)** which is dedicated to providing specialist genomic and computational resources necessary for the escalating number of life sciences and biotechnology researchers who utilise microarray (DNA chip) technology. GTI will act as a catalyst in the formation of post-genomic based SMEs, provide necessary advice and expertise which will further stimulate growth in the biotechnology cluster industries being generated in the East of Scotland.	⇨ 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**

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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, through the FP6, will support the **SCAN BALT initiative**, which aims at networking biotechnology activities and clusters around the Baltic Sea.	⇨ Networking of biotechnology clusters can be actively supported within the **FP6** 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".** A **workshop** will take place in Zurich in March 2004, before the annual BioSquare conference, which will bring together managers of biotech clusters to discuss the pros and cons of networking of bioregions through "virtual clusters" or "meta-regions", identify added value of networking and to make policy recommendations for incentives at regional, national and EU level.	**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.	⇨ A reflection on the possible **reinforcement** of the role of the contact network will start in **2004.**	**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.	❒ The **Competitiveness in Biotechnology Advisory Group** has been appointed by the Commission in **2003**. It has delivered its first report.	⇨ The first report concentrated on the issues of **access to finance and regulation** (see annex 2 of the staff working paper).	

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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 commissioned **in 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 2002.	⇨ the possible contents of the benchmarking program will be discussed in **2004** within the contact network with Member States ministries with responsibility for competitiveness in biotechnology (see action 10a) on the basis of the roadmap. The supporting study has been commissioned.	**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**.	❑ In **December 2003** the Commission organised the **first stakeholder conference** with the objective of to explore the effect of human perception on risk assessment and risk analysis and its significance and implications in promoting key scientific paradigms underlying regulatory oversight and governance. In particular, the conference addressed the issues of risk assessment and risk analysis, and how such processes could be improved.	⇨ The conference, entitled **'Risk Perception: Science, Public Debate and Policy Making'**, attracted considerable Community and international attention. Expert panels comprising senior political leaders, eminent scientists, international experts, leading decision and opinion formers from across European government and civil society engaged in presentation and debate over two days, with more than 500 participants representing a wide spectrum of stakeholder views and expertise from across Europe. The conference proceedings will be published on-line, with a follow up focus group on the way forward planned for **early 2004** .	**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** is now fully operational and has commenced its work on risk communication		**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: ❑ In the framework of the European Group on Life Science (EGLS)'s **Life Sciences Discussion Platforms,** the Commission has organised the conference **'Towards Sustainable Agriculture for Developing Countries: options from Life Sciences and Biotechnology'**	⇨ A call for **SSAs** to support life sciences discussions platforms, citizen's networks as well as initiatives to improve the science communication process with the involvement of the media, is currently open.	**Member States, industry, academia, civil society, EFSA, EMEA, Commission**
		❑ Several projects involving consumers platforms and/or other public discussion forums, including pilot citizen's networks, are ongoing under the Quality of Life FP5 program ❑ Under the aegis of the EGLS, the encounter **Modern Biology and Visions of Humanity** was organised in Genoa on **22-23 March 2004**.	⇨ A citizen's network and experts **Symposium** on **"Biotechnology: possibilities, risks, ethics and society"** will be organised in the frame of the Science Generation project in **August 2004.**	
		❑ Initiatives of public perception monitoring have been regularly supported, starting from FP4	⇨ 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.	
		❑ Under the Science and Society Action Plan, a study was launched and a conference Governance of the European Research Area: The Role of Civil Society took place in **June 2003**. Findings of the study and inputs from the conference were merged into Commission's work programme for 2004.	⇨ Following the recommendations of the EGLS workshop Life Sciences and the Media, a series of specific support actions towards improving the science communication process with the involvement of the media are being called. In the **first part of 2004**, **training courses for Journalists** (established journalists and students/young professionals) on the topic of Risk Governance and Risk Communication will be organised. The courses are organised jointly by the Commission and the European Journalism Centre.	

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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.	❑ **A network on ethical, legal and social aspect in food research** has been established among projects funded under Priority 5 Food quality and Safety in order to exchange best practice for integrating ELSA in research projects, develop joint activities across projects, promote ELSA in food and agriculture research in candidate countries and develop links to local, regional, national and international activities. ❑ **Experts in ethics and social sciences** are actively participating in research projects . It allows for mutual education and dialogue and ensures that ethicists have the means to continuously assess the societal relevance and adequacy of their analysis and evaluation; ❑ A **study on national, international and professional training material for ethics in research** was launched in 2002. ❑ A **study on training programmes in ethics in research** established in scientific faculties across Europe has been conducted.	⇨ **Stakeholders' conferences** will be organised providing at European level a bottom-up approach to help the process of consensus –forming around best ethical conduct involving academia, the professional networks and societies, industry, consumers, patient organisations etc;	**Commission**
	● 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.	❑ All applicants under FP6 are requested to address, the potential ethical aspects of the proposed research regarding its objectives, the methodology and expected results.	⇨ A **specific ethical review** has been implemented for proposals dealing with specific and sensitive issues such as the use of banked or isolated human embryonic stem cells in culture, human foetal tissue or cells, non human primates, animal cloning, human beings, genetic information etc. The **recommendations from the ethical review are taken into account in the negotiation of the projects.**	

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N° Action/ Timeframe	**Description of the Action**	**State of play**	**Comments/ Further follow-up**	**Implementer**
		❑ In accordance with the Council minutes of 30.9.2002 several actions have been taken by the Commission ► a **report on human embryonic stem cell research was published on** 3 April 2003(SEC(2003)441) and a **public institutional seminar** on the subject was organised on 24 April 2003. ►in July 2003 **guidelines on human embryonic stem cell research** in the context of FP6 were proposed, however these guidelines were not adopted by the Council. ► procedural modalities for research activities involving banked or isolated human embryonic stem cells in culture to be funded under FP6 were adopted		

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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** ● launch a separate consultation of the other Community institutions on possible structural and procedural improvements	❑ 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.	⇨ 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**
	● promote collaboration between Community, national and local levels by promoting networking of national and local ethical bodies and elected representatives	❑ The **EGE** concretely reinforced exchanges and collaboration with national ethics committees (NEC) by: ► publishing a **newsletter "Ethically speaking"** reporting on recent activities of NEC and facilitating contacts, ► **inviting NEC at EGE meetings** to present their reflection on issues of common interests, ► organising each semester a **common working meeting with the NEC of the country chairing the Presidency**, ► intiating **bilateral meetings** with NEC of acceding countries ❑ In the context of the Science and society action plan the **Forum of the Presidents of the National Ethics Councils** has been created in December 2002 and met for the first time in Athens in July 2003 and again in Rome in December 2003. ❑ A **directory of local ethics committees** has been collected in the 33 countries of ERA.	⇨ The Forum of the Presidents of the National Ethics Councils will meet again in 2004 under the Irish and Netherlands Presidency. ⇨ A **conference** for and with Local ethics committees is planned for end 2004.	
	● 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.	⇨ A **network of local animal welfare committees** is currently being established. ⇨ A **conference on animal experimentation** is planned for **2005** . The Council of Europe is expected to join this initiative.	

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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 **biosociety web-site** (http://europa.eu.int/comm/research/biosociety/index_en.htm) has been constructed to promote the dissemination of the results of EC funded research projects into the ethics of Life Science and Biotechnology, and to contribute to inform the ethical debate. ❑ **European Information Network Ethics in Medicine and Biotechnology " EURETHNET"** (http://www.eureth.net.) has been funded under the Quality of Life Programme" (FP5) ❑ **a feasibility study** has been launched under the Science and Society action plan to explore how to further develop an efficient "European Information and Documentation system on Ethics in science"		**European Parliament, Member States, regions, industry, institutions, Commission**

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	● 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 continues to up-date the **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. ❑ A **High level Strata Group** has been set up in 2003 to discuss methodologies to analyze underlying ethical values in the ERA. ❑ A **high level Strata Group on Genetic testing**, composed of representatives from industry, NGO, in particular patient organizations and scientists and social scientists, was set up in 2003 to discuss the ethical implications in genetic testing. ❑ The **opinions of the EGE** and the work in **Council of Europe** are other important documents in this respect.	⇨ The High Level Strata Group will deliver a **report by the beginning of 2004**. A proposal for a **EUROBAROMETER on ETHICS** is under consideration. ⇨ The high level Strata Group on Genetic testing will publish a **report early 2004** and a stakeholder conference will take place in **spring 2004.**	

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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 **round table on co-existence** was organised by the Commission **in April 2003**. ❑ a Commission **Recommendation 2003/556/EC on guidelines concerning co-existence** was adopted on 23 July 2003. ❑ A 1st **European Conference on the co-existence of Genetically Modified Crops with conventional and Organic Crops** took place 13-14 November in Denmark. ❑ A **national debate** was organised in UK. Details are available at www.gmnation.uk	⇨ A **new study on co-existence** is on-going, aimed to analyse new cases studies on this issue, with special focus on seed production. The study includes analysis of the economic costs related to the introduction of different farming practices. Final results are expected by **end 2004**. ⇨ the Commission will enhance its **co-ordination role** as defined by Directive 2001/18/EC. ⇨ the Commission will **report** to the Council and to the EP on experience gained in the MS, including, as appropriate, necessary steps to take.	**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.	❑ The **Community programme** on the conservation, characterisation, collection and utilisation of genetic resources in agriculture has been adopted, with an estimated overall cost up to €10 million for the period 2004-2006 **(COM(2003) 817)**	⇨ This programme aims to help maintain biological diversity, improve the quality of agriculture products, contribute to diversification in rural areas and reduce inputs and agricultural production costs by promoting sustainable and rural development.	

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Pharmaceutical legislation				
18 **2002**	● to speed up the adoption of the **three legislative proposals**, revising the Community **pharmaceutical legislation**	❑ On **17.12.2003**, the European Parliament has adopted the **compromise amendments** negotiated with the Council on the Pharmaceutical Review package (COM(2001)404 Final). This paves the way for its adoption in the first months of 2004.	⇨ The review consists of 3 proposals, i.e. one regulation dealing with the Community centralized procedure for the authorisation and supervision of medicinal products and establishing the European Medicines Agency, and two directives modifying the existing codes in the field of human and veterinary medicinal products which were adopted by the Commission on 26.11.2001	**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 Labelling of Genetically Modified Organisms and Traceability of Food and Feed derived from Genetically Modified Organisms.** ▪ Proposal for a European Parliament and Council Regulation on **Genetically Modified Food and Feed**.	❑ The two proposals were adopted by the European Parliament and Council: ► **Regulation (EC) N° 1830/2003 on traceability and labelling of GMOs and of food and feed produced from GMOs** ► **Regulation (EC) N° 1829/2003 on GM food and feed**	⇨ see action 21 for implementing measures of both Regulations.	**European Parliament, Council**

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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). The Council and the EP reached an agreement in February 2004.. ❑ **Regulation (EC) No 1946/2003 of the European Parliament and the Council on the transboundary movements of GMOs** was adopted on 15 July 2003. It is applicable as of **25 November 2003**.	⇨ The final approval by the two institutions is scheduled in **March 2004**.	**European Parliament, Council, Commission**
		❑ The **Cartagena Protocol on Biosafety** entered into force on **11 September 2003**.		
			⇨ **Thresholds for the adventitious presence of authorised GMOs in non-GM seeds** will be finalized under Article 21(2) of Directive 2001/18/EC during 2004. Similar thresholds will be then adopted under Seeds Directives.	

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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, ❑ several **implementing measures** have been adopted ► Council Decisions **2002/812 and /813/ EC** establishing the Summary Notification Information Format Parts C and B, ► Commission Decision **2002/623/EC** establishing guidance notes supplementing Annexes II and VII to Directive 2001/18/EC, ► Council Decision **2002/811/EC** establishing the guidance notes supplementing Annex VII to Directive 2001/18/EC, ► Council Decision **2003/701/EC** establishing a format for presenting the results of the deliberate release into the environment of GM higher plants ► Commission Regulation No **65/2004** on the establishment of unique identifiers ► Commission Decision **2004/204/EC** laying down detailed arrangments for the opeartion of the registers for recording information of genetic modifications in GMOs	Other implementing measures required by the new legislative framework are under consideration: ⇨ **Guidance for sampling and detection of GMOs and GM food and feed**. A formal Commission Reccomendation will be adopted in early 2004 ⇨ **Implementing rules for Articles 5, 8, 17, 20 and 47 of Regulation 1829/2003** ⇨ 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.	**Commission**

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		❑ 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.**	⇨ The proposal for GM Food/Feed establishes that the **JRC is the Community Reference laboratory** to be assisted by the **"European Network of GMO laboratories"**	
	● 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	
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 **study** was launched on **30 July 2003**.	⇨ 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 **working group** for the development of specific sets of monitoring criteria for individual groups of GMOs and for different transgenic phenotypes has been set up.	⇨ **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.	❑ The Commission continues to play a leading role in **Codex Alimentarius**, where it has become a full member, **OECD** and under the **biosafety protocol** with a view to develop international guidelines, standards and recommendations on food safety and biotech issues. ❑ An **EC-OECD colloquium** was organised - jointly by the Commission and the OECD, in Brussels on **6 October 2003** – as an international forum for early discussions towards a world-wide harmonisation of **genetic testing quality assurance**.	⇨ Specific support actions are being call for under FP6 to facilitate bi-regional dialogues and bi-lateral international cooperations in life sciences and biotechnology.	**Commission**

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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/outputs/ard/ard.pdf ❑ 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 Conclusions and recommendations are available at the following address:http://europa.eu.int/comm/research/conferences/2003/sadc/index_en.html ❑ As a follow-up of the above Discussion Platform, the Commission has invited for a specific support action aiming at contributing to an International consultative forum on life sciences and biotechnologies for 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 **programme** will be signed by **mid-2004** with the **Global Forum on Agricultural Research (GFAR)** aiming at enabling greater stakeholder participation. The Commission is funding a project titled "Strengthening the Functional Linkages between Civil Society Organizations (CSOs) and National Agricultural Research Institutions (NARIs) for Effective Agricultural Research for Sustainable Development". This initiative focuses on capacity building of participating farmer's organisations and NGOs involved in ARD in sub-Saharan Africa and at reinforcing the involvement of the participating beneficiaries in ARD activities and decision-making processes at the national and regional levels.	**Member States, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
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). ⇨ The **5th Global Forum on Bioethics** will take place in **April 2004** in Paris. The Commission is participating in the steering committee together with the MRC, the Welcome Trust, NIH Fogarty Centre, INSERM, WHO. The topic will be **"Sharing the benefits from research in developing countries: equity and intellectual property"**	**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**. ❑ the list of CGIAR projects to be financed by the EC in 2004 has been reviewed with the EU Member States in **September 2003**.	⇨ 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 at http://www.cc.cec/home/dgserv/dev/body/theme/docs/B4/ARD%20CGIAR%20Strategy%20FR.pdf) ⇨ The next 3-year allocation to the CGIAR (2005-07) is under preparation.	**Member States, Commission**

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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
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 and the MS were pro-active negotiators, under the Convention on Biological Diversity, of the **Bonn Guidelines on Access to Genetic Resources and Benefit-sharing** adopted on 19 April 2002. On 23.12.2003, the Commission adopted a **Communication** on the implementation of the above Guidelines and is currently working on its follow-up measures. The Commission has also been an active negotiator of the **terms of reference for an International Regime on Access and Benefit-sharing**, at the 7th Conference of the parties of the CBD (Kuala Lumpur, 22-27.2.2004). ❑ At the **WIPO** : Commission and Member States are active participants in the Intergovernmental Committee on Intellectual Property, Genetic Resources, Traditional Knowledge and Folklore.	⇨ The Commission will continue its active participation in the debate on TRIPS and Biodiversity in the WTO. ⇨ An international action contributing to the implementation of the Convention on Biological Diversity for international equitable access and benefit sharing of microbial resources is being negotiated under FP6 and the Commission has invited for a specific support action aiming at establishing **Networking of European and International Research** on issues related to conservation, management and sustainable use of genetic resources for food and agriculture (deadline 5 February 2004) ⇨ The Commission will streamline the issue of access and benefit-sharing in the on-going revision of the EC Biodiversity Action Plan on Economic and Development Co-operation.	**Member States, 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**
		❑ 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**.		
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.	⇨ An additional limited contribution for supporting capacity building and the participation of ACP Representatives in International Conventions is under consideration. ⇨ Ad hoc contributions for the participation of delegates from developing countries to specific meetings of the Convention on Biological Diversity and of the Cartagena Protocol on Biosafety are provided for in 2004.	**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 in **2004**.	⇨ **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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N° Action/ Timeframe	Description of the Action	State of play	Comments/ Further follow-up	Implementer
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.	❑ The **European and Developing Countries Clinical Trials Partnership (EDCTP)** was adopted in **June 2003** and will be fully operational during the first half of 2004, whereupon it will consider applications for funding or co-funding of clinical trials from the private and public sectors, including industry, organisations and individuals from Europe, developing countries and elsewhere.	⇨ Improved co-ordination of research activities between Member States will increase the impact and efficiency of research efforts. With the establishment of the EDCTP the fragmentation of European research efforts can be overcome and also be translated into clinical interventions that are applicable in the Developing Countries. The EDCTP has a target budget of **€ 600 million**. The Community will contribute one third of the budget via the 6th FP, whereas another € 200 million will be provided by Member States and Norway. The remaining € 200 million will be sought from private sources, R&D industry, foundations, charities and Community development funds (e.g. EDF).	**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/Bamako and in Kampala/Uganda. A teaching manual for conducting clinical trials in developing countries have been prepared in the context of an EC funded project (http://www.ethica.uib.no/level/ctc.html).	⇨ A further workshop is planned in Egypt.	
		❑ The **Program for Action** against **AIDS, malaria and tuberculosis** has progressed on the main issues of impact, affordability and research.		

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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) ❑ The Commission has been actively involved in the works of the Intergovernamental Committee of the Cartagena Protocol (ICCP) in preparation of the entry into force of that Protocol. The Protocol sets out simple requirements which allow countries to make informed choice on the import of GMOs. ❑ the Commission will finance in 2004 a **workshop on capacity building concerning the documentation requirements for the transboundary movements of GMOs** under the Cartagena Protocol of Biosafety.	⇨ A **platform for bi-regional co-operation with Asia** in the field of food quality and safety research is being negotiated and the Commission has invited for a specific support action aiming at establishing Bi-regional co-operation platforms for food quality and safety research with Latin America and/or African-Caribbean-Pacific ACP countries. ⇨ The Commission will streamline the ratification/implementation of the Cartagena Protocol on Biosafety in the on-going revision of the EC Biodiversity Action Plan on Economic and development Co-operation.	**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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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, published in 2003 **two prospective studies** on emerging biotechnology applications and issues: **Human tissue engineering** and **quality assurance and harmonistaion in genetic testing**.	⇨ IPTS foresight and anticipation studies on **animal cloning, aquaculture, pharmacogenomics, nanodevices in medical diagnostics and therapeutics, the use of GMOs in agriculture** are on-going or will start in 2004.	**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	❑ The Commission **Biotechnology Steering Committee (BSC)** consisting of the most directly involved cabinets and services has been set up and has met regularly since 2001. The mandate and composition of the BSC has been recently reviewed in order to reinforce continuous co-ordination amongst the 17 Commission services which have an interest in Life Sciences and Biotechnology.		**Commission, Member States**

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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.			**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 first annual Report was adopted on 5 March 2003 **(COM(2003) 96)**.	⇨ 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**

(1) COM(2002) 27 of 23 January 2002

4. Implementation across pol.

ANNEX 2

Competitiveness in Biotechnology Advisory Group – Report 2003

Introduction

The Commission has appointed the Competitiveness in Biotechnology Advisory Group with Industry and Academia in accordance with Action 10b of the Action Plan. The Group's mandate is to assist the Commission in identifying issues affecting Europe's competitiveness. The members of the Group represent all major fields of biotechnology and the spectrum from entrepreneurial companies to large companies. In addition, they also stem from different European regions.

The Group has the mandate to provide input into the Commission's annual report on the implementation of the Strategy. In 2003 the group chose to concentrate on **financial and regulatory issues**. The following report is the outcome of those deliberations. It is the advice of the Group and does not represent the views of the Commission.

I. Financial opportunities, issues, obstacles

Entrepreneurial biotechnology companies are faced with the same pressures as other innovative companies, but which for biotech companies are often more acute. Three main areas require attention to boost the financial environment for biotech companies: protecting intellectual property rights, boosting finance, liquidity and capital markets in Europe, and research funding through public/private partnerships.

For fast and effective improvements, the entrepreneurial biotechnology community expects policy changes at a national level rather than at an EU level. Many of the recommended actions are directed therefore to Member States rather than the Commission.

Intellectual Property Rights

No other business area is as dependent on protecting their intellectual property as biotechnology. Strong and stable IP protection of biotechnological inventions is a prerequisite for any type of funding at any stage. It is a **key decision-making factor for** investors seeking to protect their investment, particularly in the start-up phase. It is also key in a company's valuation as it is looking to go public. Investors will keep judging the value of biotechnology ventures by the quality and robustness of their IP.

There are three major issues in intellectual property vital to the development of biotechnology in Europe: the Community Patent, the Biotech Patent Directive (98/44) and the patenting policy of universities and other public research centres.

The Community Patent, as currently proposed, will be better than before but not good enough by far to outclass our competitors. Furthermore, crucial aspects of it are unlikely to come into force until after 2010, when the EU is already supposed to be the most competitive economy in the world.

Recommendation
CBAG calls for the introduction of an EU-wide Community Patent system which is legally secure, cost-effective and simple-to-obtain. • A unitary jurisdiction at first and second instance, with highly qualified expert judges, so as to reach legal certainty and streamlined enforcement. • A language regime that is restricted to an absolute maximum of the three EPO official languages, English, German and French, with one single authentic text, that of the language in which the patents was granted. • A system where patent applications are fully processed by the European Patent Office (EPO) • Transition periods reduced to an absolute minimum so that entrepreneurs may reap immediate benefit from the simpler and cheaper procedures offered by the regulation.

The Directive 98/44 on the protection of biotechnological inventions was adopted in 1998 after lengthy discussions and was to be implemented in all Member States by 30 July 2000. Yet to date just eight Member States have implemented it.

Discussions mostly relate to the clause on gene patenting (Art. 5). The European Parliament, for instance, considers recommending that the Commission amend Article 5 to exclude from patentability the total or partial sequence of an isolated human gene. Yet, the Directive as it currently stands does not go further than any US or Canadian rules. It protects the dignity of the human body while allowing useful inventions to be developed. It prohibits making profits from the human body and its elements, as stated by Article 3 of the Charter of Fundamental Rights. It is clear in what it does and does not permit and no basic deficiencies have been documented to date.This sends the wrong signals to companies and investors, casting doubt over whether a useful invention might be held up, or worse may not be granted at all.

Recommendation
CBAG calls for the swift and loyal, one-on-one implementation of the EU Directive on the legal protection of biotechnological inventions (Directive 98/44)

The patenting effectiveness of European public research is lagging that of the US. Recent findings at Leuven University show that US patents borrow much more from European science than the other way around. Yet it is through patents rather than publications that value is created for the institution and the inventor and, eventually, for environment, people and jobs. Rules governing who benefits in Universities from a patent are an important issue. Granting personal or collective ownership to university researchers of the intellectual property they generate and entitling them to commercialise their findings are an important incentive for entrepreneurial biotech in the countries where these principles are applied (e.g. *Finland, Sweden*).

Recommendation
CBAG calls for better understanding within the Academic community of how to turn applied research into innovative products. Best practice from Sweden and Finland in academic incentives to patent should be rolled out across Europe.

Financing, liquidity and capital markets

Half of all economic growth is generated by research and innovation, which spur employment and economic wealth. Public and private sector research needs to be stimulated to achieve this growth. To raise its level of innovation, Europe must increase R&D spending to 3% of GDP and drastically raise employment levels between now and 2010 (Lisbon goal). The public sector will not achieve this alone and Europe needs to boost private sector research, especially in areas with a high growth potential. Young innovative biotech companies have that growth potential and remain a largely untapped source of innovation and employment growth.

Lack of funding is a major obstacle to the development of entrepreneurial biotech companies. Low exit opportunities for investors keep them from feeding follow-on funds and seed funds alike, thus causing a vicious circle. Europe must create optimal conditions for investors to cash in their investments and liberate funds for new ones. Policies stimulating investment in young innovative companies should be jointly prepared by the entrepreneurial community and the government.

Young Innovative Company (YIC) status, with tax and labour tax exoneration, represents an investment with a high economic return. A French study shows that the resulting economic growth would yield net fiscal revenues in just 3 years.

There are huge disparities between Member States, in social costs and in the cost of doing business in general. If applied throughout Europe, YIC would put innovative companies at a stroke on the same starting block.

A specific YIC law is discussed in the French parliament for implementation as early as 1.1.2004. To qualify, companies must be less than 8 years old and spend more than 15% of their total expenses on R & D. The key features of the law would be:

- social contributions (for all staff, not only R&D workers) waived for 6 years and reduced by half for a further 3 years
- no corporate tax for the first 3 years, reduced by half for a further 2 years
- no local taxes
- no capital gains tax
- tax reduction on stock options

EuropaBio's Emerging Enterprises Board members are discussing similar measures with other national governments.

Several successful EU biotech ventures in Europe have spun out of large life science companies and that origin has been a main factor for their success. Where fiscal incentives for YICs are formulated, it is crucial that they also apply to this type of new business, even when the company which they spun out from is keeping a (temporary) high equity share. Entitlement to Young Innovative Company status will stimulate venture capital funds to complete and/or replace the originator company's equity share.

Recommendation
The CBAG calls on EU governments to create a specific status for young innovative companies, providing tax exemptions to entrepreneurs, employees, investors and companies across Europe to reward risk with incentives and benefits.

Insufficient liquidity for innovative companies is a major obstacle to private investment in research based industries. Venture capital trapped in companies ready to go public should be freed up for re-investment in early stage ventures, but the only way to do so is through an IPO, trade sale or financial sale- a dwindling opportunity in Europe.

Rather than multiplying competing initiatives, Europe needs to build a powerful European capital market with fund raising, investment and exit opportunities for companies, entrepreneurs and investors. US biotech has largely been helped by an integrated stock market with a critical mass of companies, investors and analysts. In 2002, US public companies had twice the market capitalisation of EU companies.

The CBAG therefore welcomes the European Commission's efforts in creating a harmonised equities market in Europe through the implementation of the Risk Capital Action Plan (RCAP)[1]. European equity market fragmentation deprives entrepreneurs of a potent investment motor, like NASDAQ in the US. A key cause is the existence of different and often conflicting national rules. Their harmonisation is therefore an urgent priority. It will attract additional capital, create greater liquidity, allow for automatic multi-listing of companies and eventually a merger of existing exchanges.

Recommendation
CBAG calls on the EU governments to achieve harmonized securities regulations by 2004 and to work with Euronext, LSE and national markets to offer automatic multi-listing of companies, or mergers of existing stock markets.

Scarce Venture Capital is mainly used to support established businesses or bail out existing investments. The result is a lack of first round financing. Investment companies who see this as the shape of things to come, are restructuring their operations to assume market risk rather than technical risk, and prefer investing at post-development stage. Most investors expect at least one drug in a company's pipeline to work so that they can exit and reinvest takings in new ventures, but this is rendered increasingly difficult : 40 IPO in 2000, 6 in 2001, 3 in 2002 and no revival in sight. In addition, in many countries, a lack of confidence-inspiring national lead investors deters local would-be investors to join in.

Consolidating smaller ventures into larger entities creates higher quality portfolios, but other means are needed to lift promising companies to an attractive level. One such solution would be increased investment by institutionals, in particular by pension funds, whose funding possibilities are presently limited by law, despite the promise of superior or equivalent returns. Pension funds portfolios should therefore be allowed to also include VC investments in innovative companies. With 5% of pensions funds' money invested in this way, this would add nearly 1% to GDP. As importantly, it would strongly encourage other investors to join.

Recommendation
The CBAG calls for greater investment possibilities for pension funds in innovative companies across Europe

The European Commission Biotech and Finance Forum (BFF) found that **the gap between seed funding and IPO** is critical in several countries (e.g. Germany). With an estimated 2003

[1] COM(2003)654 final, 4 November 2003

funding gap of up to €1 billion for EU biotech companies, an urgent solution is required to avoid destruction of value and momentum, built up during the past decade.

Mid to late stage companies with costly clinical development programmes run the greatest risk and distract management from the daily task of running the business. Expansion capital provision needs to be addressed at all stages of company development and different skill sets will be required to deploy capital at different stages. Public companies for their part are often trading below their cash per share valuations, creating the impression that the technology/products are worthless and that management is destroying value.

Funding cycles for public and private companies are interrelated and should be addressed simultaneously.

Recommendations
The CBAG supports the conclusions of the Biotech and Finance Forum WG For private companies • Conventional lead investing of larger rounds • Providing 'top up' funds for 'inside' co-investment rounds • Bridge financing in the form of convertible loans For public companies • Consolidation funds to foster public-public, public-private or private-private transactions • Cross-over funds to "arbitrage" valuation gaps between public and private companies and support consolidation

Research funding and public-private research partnerships

Public research is a major contributor to new ideas, jobs and economic growth, but many national research councils and similar bodies are seriously under-funded and need a drastic budget increase. Stagnating government funding gives the wrong signal to private companies that are considering increased R&D spending.

Under-funding is not the only obstacle, though. University structure and culture may also hamper entrepreneurial off-shoots and academia-industry collaboration, two essential factors for turning research into marketable products and services.

Joint projects between academia and start-ups, key to the successful take-off of many start-ups, should be encouraged. The Finnish national technology funding agency, for instance, provides special support to joint projects between academia and start-ups. It is no surprise that this country is one of the world's most competitive nations in the OECD ranking.

However, private/public agreements are by their nature very different from private/private industry agreements. The proposed new Technology Transfer Block Exemption Regulation (TTBER), revising the current Regulation (240/96) on technology licensing under EU competition law, will have an impact on the biotech industry and on the academia/industry licensing agreements. Such revision must take adequate account of academia/industry licensing agreements, so as to encourage such partnerships to develop.

Recommendation
CBAG calls for technology transfer programmes modeled on best practices to increase the number of private/academia spin-offs and licensing agreements and to ensure that such practices are adequately taken account of when considering new or amended EU legislation.

Gear EU research funding programmes to SMEs. Research funding programmes are often too bureaucratic, long and cumbersome for young companies, with too many partners to manage a project. Too much effort is needed for too small a return. If grants were aimed to increase the competitiveness of SMEs and drive growth, then research projects should be much more business driven with clear milestones. SMEs need to be in full control to develop strategic research projects for business growth, as academic led projects often fail to adequately meet the business growth objectives of companies.

Recommendation
CBAG calls for the EU Commission and Member States to make research funding conditions more suitable to SMEs, to focus SME research funding programmes on building growth and competitiveness in industry and not to mix these goals with political, social, and ethical objectives which can be covered through other projects with appropriate funding.

II. Regulatory issues and requirements

In the Commission Communication **Life sciences and biotechnology – A strategy for Europe** [COM(2002)27], a bold and comprehensive strategic action plan is spelled out, which includes the drafting and completion of various pieces of legislation aimed at enhancing Europe's competitiveness in the global marketplace, in line with the Lisbon 2010 goals. However, in order to truly raise competitiveness, new or improved EU legislation must be as good or better than that of our main competitors, and cannot satisfy itself with being merely better than what was in place before. In addition, requirements for industry to comply with legislation should be proportionate with the objectives pursued and should strike the right balance between the enabling and controlling objectives. In particular, legislation should take due account of SMEs, which are a vital part of the biotechnology community. For them, requirements and procedures which are manageable by larger companies may represent a major obstacle or even a dissuasion to engage in certain activities.

1. Healthcare Biotechnology

Healthcare biotech products generally enjoy better acceptance than other biotech sectors. They are centrally assessed by the European Agency for the Evaluation of Medicinal Products (EMEA), and covered by legislations such as the pharmaceutical legislation, which has recently undergone a major review, or the Orphan Drug Regulation. As a result, biopharmaceuticals account today for about 20% of all marketed medicines and for over 50% of all medicines in the pipeline[2]. Up to November 2003, twelve orphan drugs have obtained

[2] Commission communication – "A stronger based pharmaceutical industry for the benefit of the patients – A call for action"

EU approval. However, in this field too, Europe keeps lagging behind the US[3], and applications for biotech medicinal products at the EMEA have kept decreasing since 2001[4].

To reap the benefits of biotechnology, Europe must not only address public health challenges[5] and seize economic opportunities; it must above all show **coherence and continuity in policy** through an enabling regulatory environment and consideration for both the European and the global regulatory scene. Healthcare biotech has a 20 year life-cycle of innovation and investment. Therefore, incomplete and cumbersome legislation, lack of implementation or frequent changes in Member State policy will undermine investment which requires a predictable environment, particularly in relation to intellectual property rights and timely market authorisation. Marketing delays not only create financial problems for the SMEs themselves but, as importantly, they also delay patient access to innovative medicine.

EU assessment and approval should be adapted to facilitate global development programs for biotech products, recognising the highly specific scientific and technical nature of these products. Likewise, it should take account of the specificity of the companies (SMEs in particular) that are sponsoring them.

Recommendation
CBAG calls for an adaptation of the regulatory framework according to: • Scientific and technological advances; e.g. through a CPMP/industry joint working group to develop guidance on criteria for new biomarkers/surrogate clinical end-points which could streamline and accelerate product development. • Novel biotechnology-based healthcare applications that do not fit existing definitions; e.g. through a separate marketing authorization legislation for human cell and tissue based products that are neither medicines nor devices. • The specificity of SMEs e.g. through specific regulatory support measures and adaptation of EMEA fees for SMEs.

Because of the scientific and technical nature of biological medicinal products, companies developing them need a **continuous dialogue** with the EMEA to obtain **timely and relevant scientific advice** and to get **appropriate protocol assistance**.

Recommendation
The CBAG call for an enhanced communication and expertise: • The EMEA should keep a standing communication with the FDA to avoid assessment discrepancies between both systems. • Because of the technical nature of biological medicinal products, internationally recognized scientific and medical experts from industry and academia should be

[3] The US has three times more revenues and public companies, ten times the amount of market capitalisation, twice the number of jobs even though the US has almost 30% less biotech companies. And the US spends almost three times as much as the EU on healthcare biotech R & D – Source: Ernst & Young (2002)

[4] The number of applications at the EMEA, by biotech medicinal products or active substances, dropped by *ca.* 40% between 2001 and 2002 with the exception of orphan medicines. Source: EMEA annual report 2002

[5] Most of biotech medicines in the pipeline are focusing on treating cancer (ca. 40%) - Source: PhRMA Survey (2002)

even more involved in the review process, from scientific advice down to application procedure, and in the preparation of EU regulatory documents and guidelines.
- EMEA expertise should be extended so as to make the agency capable of assessing and authorising non-medicinal human cell and tissue-based products.

Appropriate and consistent **intellectual property** protection of registration data are needed to ensure continued investment and innovation to meet the needs of patients and society.

Recommendation

- The CBAG calls for the maintenance of the centralized procedure which is necessary to ensure a uniform treatment of biological medicinal products in Europe, including biosimilars.
- To ensure patient safety, biosimilars should be clearly differentiated from conventional generics, and appropriate pre-clinical and clinical data requirements put in place.

Finally, European Member States must work on a system for **equitable and timely access** to medicines after EU approval. Access and reimbursement is important for patients, and are a key condition for SMEs to attract capital and funding.

Recommendation

- The CBAG calls for the authorisation process to remain based on scientific assessment only (quality, safety and efficacy), without any economic considerations, so that faster access to medicines can be achieved.
- The CBAG calls for unambiguous and explicit reference in pharmaceutical legislation to therapies for severe unmet medical needs and for which fast track and exceptional circumstances provisions will grant faster patient access. In this regard, Member States should avail themselves of electronic patient information technology, to remain informed on the unmet medical needs of European citizens.

2. Agriculture and Food Biotechnology

European agri-food biotechnology, both in academia and in industry, is lagging behind the US, Canada, Argentina, Brazil and other parts of the world[6] in the use of modern biotechnology-derived crop plants, offering both socioeconomic and environmental benefits. The reasons for this include a European population of which the majority is wary of the use of genetic modification in agriculture. Another reason is the failure of the EU to have in place a sound science based regulatory procedure for GMOs that is enabling, rather than disabling; non-discriminatory, rather than discriminatory; consistent, rather than inconsistent in its application, and transparent, rather than opaque in its implementation.

Applying the EU Legislation

The EU has a completed set of interlinked GM legislation that should be fully operational by mid April 2004, with the Deliberate Release Directive 2001/18/EC, the GM Food and Feed Regulation (EC) 1829/2003 and the GM Traceability and Labelling Regulation (EC)

6 See ISAAA brief 29/2003 "GLOBAL REVIEW OF Commercialized Transgenic Crops: 2002"

1830/2003. This set of legislation achieves two major objectives: (a) a thorough safety based assessment of all GMOs on a case by case basis prior to approval for cultivation, for use as human food and for use as animal feed; and (b) so as to provide consumers with choice, traceability and labelling requirements for all GMOs and food or feed derived from them, irrespective of whether they contain novel DNA or protein or whether in fact they are identical in every way to their non-GM counterparts.

Recommendation
For the CBAG, • EU Member States must now implement this legislation in an enabling, non-discriminatory, consistent and transparent way. • the Commission, as the guardian of the Treaty, has a key role to play in ensuring that the legislation is: • properly transposed into MS National law. • properly and consistently enforced in a timely manner. • products assessed as safe by the scientific committees must be approved so that they may be offered to the market. • the large backlog of submissions resulting from 5 years of a *de facto* moratorium on approvals must be dealt with quickly so as not to further distort the trade difficulties already experienced with other agricultural trading nations. • prohibitions by Member States on already approved specific GMOs, made purportedly because of "new" information indicating possibility of risk, must, where the Scientific Committees have indicated that there is no new information relating to risk, be immediately withdrawn.

Coexistence of GM crops with conventional and organic agriculture

Directive 2001/18/EC, under Article 95 of the Treaty, sets in place the EU procedure for safety assessment and approval of GM products prior to their being placed on the market. A key "choice-permitting" component of regulation ((EC)1829/2003 and (EC) 1830/2003) was to set a threshold of 0.9% above which GM material, adventitiously present in non-GM produce, would require GM labelling. This fixed threshold is a key concept in the provision of choice, and consequently in the Commission's Guidelines on Coexistence (COM 2003/556/EC).

Recommendation
For the CBAG, • the Commission must ensure that Article 95 of the Treaty, under which 2001/18/EC operates, is applied so that EU approved products are not arbitrarily prohibited by National or Regional law from being offered to the market in certain Member States or Regions of Member States. • it is crucial that the Commission follow through with obligations on the coexistence of the different farming methods. In working to establish guidelines for coexistence, the institutions must recognise the 0.9% labelling threshold as the guiding baseline in establishing coexistence. • those wishing to offer produce guaranteed to be lower than this legally binding threshold must themselves be responsible for the additional measures required

to achieve their chosen threshold.

Seed – adventitious presence of GM in non-GM seed

For the past four years, the European seed industry has operated in an environment without consistent EU approach of adventitious presence of GM seed in non-GM seed. It has operated in a business environment without legal certainty and in which different Member States have managed the issue in very disparate ways. The failure to act on this crucial issue over the past four years has resulted in chaos for the conventional non-GM seed industry across the different Member States.

Recommendation
The CBAG requests: • legal certainty for the seed industry and, in particular, the urgent completion by the Commission of legislation that sets in place practicable thresholds for the adventitious presence of EU approved GM seed in non-GM seed.

3. Industrial and Environmental Biotechnology

Europe is still a frontrunner in Industrial Biotechnology (IB) research and innovation, a key technology to make industrial production more sustainable environmentally and economically. But its global competitive position is eroding quickly, due to the long term strategic investments in the new technology by the United States and East Asia, as well as to Europe's structural weaknesses. Europe's academic research and industry suffer from fragmentation and from a lack of incentives for innovation in sustainable industrial production and for its adoption by companies.

Recommendation
To keep its competitive position, the CBAG asks Europe to • create a common platform to overcome fragmentation of research and innovation in Europe, • enhance co-operation between academy and industry in public-private partnerships, • develop a common vision, political strategy and action plan with the relevant stakeholders.

Sustainable industrial production and consumption is one of the focus areas of the Gothenburg summit strategy for a more sustainable Europe and of the Environmental Technologies Action Plan (ETAP). Industrial Biotechnology will contribute significantly to reduce the environmental footprint in a number of industry sectors, like chemicals, pharmaceuticals or textiles. However, policy makers, entrepreneurs and the general public lack awareness about Industrial Biotechnology's potential to enhance sustainable industrial production by reducing energy and raw material use, waste, as well as costs.

Recommendation
To enhance industrial sustainability, the CBAG asks Europe to: • encourage the use of industrial biotechnological processes for improving environmental and economic sustainability, • develop incentives to facilitate adoption of these processes by industry, • support the use of renewable materials for bio-materials that are more eco-efficient than comparable non-renewable materials, • reduce biological feedstock prices, needed to enhance biological production, by taking appropriate legislative measures and furthering research in more efficient forms of biomass conversion.

Concerning the food enzyme legislation under preparation (draft proposal WGA/003/03), industry expects a clear and simple approval system, while keeping the present definitions of processing aids based on "non-functionality" in the final food. Industry also needs clarification of the scope of the GM-Food/Feed regulation as to products produced with GM microorganisms no longer present in the final product, as well as clear Commission guidance as to whether to consider self-cloned organisms as GMOs when implementing Regulation 90/219.

Recommendations
The CBAG calls for • introduction of a transparent approval system, • clarification of the scope of regulation on GM Food/Feed concerning GM microorganisms no longer present in the final product, • a clear implementation guide from the Commission on regulation 90/219 considering self-cloned organisms as GMOs.