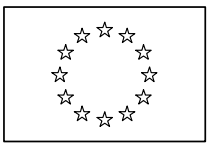

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COMMISSION STAFF WORKING DOCUMENT

Document accompanying the

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

on the mid term review of the Strategy on Life Sciences and Biotechnology

{COM(2007) 175 final}

This Working Paper has been prepared as support for the European Commission's Communication on the mid term review of the Strategy on Life Sciences and Biotechnology (hereinafter "the Communication").

1. BACKGROUND

In January 2002, the Commission adopted a Strategy for Europe on Life Sciences and Biotechnology[1]. This was in response to the importance attached to life sciences and biotechnology by the European Council. It proposes a comprehensive roadmap up to 2010 and puts the sector at the forefront of those leading technologies which are helping to take the European Union towards its long-term strategic goal established by the Lisbon European Council in March 2000.

The strategy set out by the Commission consists of two parts: policy orientations and a 30 point plan to transform policy into action. It sets out what was is needed from the Commission and the other European Institutions, but also recommends actions for other public and private stakeholders. The strategy therefore provides a framework and a reference point both for action undertaken by the many stakeholders concerned within their own responsibilities and for co-operation between these stakeholders.

The Commission has reported regularly on the progress made and adopted progress reports, supported by Staff Working papers in 2003, 2004 and 2005. The 2005 progress report[2] foresees that the Commission will:

– Carry out an independent study aimed at providing a comprehensive assessment and cost-benefit analysis of the consequences, opportunities and challenges that applications of modern biotechnology present for Europe in terms of economic, social and environmental aspects,

– Draw on both the study and an in-depth assessment of the progress achieved since 2002 to update the Community Strategy on Life Sciences and Biotechnology in good time for the 2007 Spring European Council.

The study referred to in the first bullet point has been finalised by the European Commission in April 2007. It is available online[3]. In order to take full account of this study, it was decided to slightly postpone the mid term review after the original deadline of the 2007 Spring Council.

2. OBJECTIVES

The main objective of the mid term review, as mentioned in the 2005 progress report, is to reflect on the role of Life Sciences and Biotechnology in relation to the main European policy goals. This implies in particular an understanding of how the adoption of modern biotechnology in the various production sectors can contribute to the objectives of the

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1 COM(2002)27 of 23/01/2002

2 COM(2005) 286 final of 29/06/2005 - http://ec.europa.eu/biotechnology/pdf/com2005286final_en.pdf

3 « BIO4EU » - http://bio4eu.jrc.es/index.html

European policy strategies on economic growth, sustainable development and environmental preservation.

It may already be understood that biotechnology goes far beyond the sole example of genetically modified organisms to be used in agro food, which actually represent only a tiny part of biotechnology. Modern biotechnology[4] plays an increasing role in the development of new treatments and preventions of diseases and the industrial landscape in Europe and elsewhere is steadily being transformed by the penetration of biotechnology into a large number of industries including food and feed, chemical, paper and pulp, textiles, and energy. New, eco-efficient and innovative industrial sectors (the "bio-economy") are emerging as biotechnology has introduced a new dimension to innovation in agriculture and other sectors, offering eco-efficient and cost effective means to produce a diverse array of novel value added products and tools. It has the potential to improve qualitative and quantitative aspects of food, feed, fibre and fuel production, reduce the dependency on chemicals and fossil fuels, diminish over-cultivation and erosion, and lower the cost of raw materials, all in an environmentally sustainable manner.

To reach the present objective, and following the request of the European Parliament, the Commission has undertaken the "BIO4EU" study to make an assessment of the economic, social and environmental impact of biotechnology and genetic engineering, including genetically modified organisms, in the light of major European policy goals formulated in the Lisbon strategy, Agenda 21, and sustainable development. Furthermore, the Commission has prepared a report[5] on the competitiveness of the European biotechnology industry and its possible contribution to growth and employment.

It appears from the analysis of the action plan that the Commission plays a major role in the development of biotechnology in Europe, in the field of research, education, regulation, finances, enforcement and international cooperation, this list being non-exhaustive. It is evident that, if all actions certainly have an interest, they do not all have the same priority in the current context, nor have they reached the same level of achievement (see Annex I for the refocused priorities).

In addition to this, the present Staff Working Paper presents a detailed overview of the progress made in implementing the action plan set out in the Strategy, the main achievements being highlighted in a chart annexed to this document (Annex II).

The present document, as well as the Communication describes how the Commission intends to pursue its involvement in the field of biotechnology, and the means it envisages to use. Nonetheless, the Commission is only one of the actors in the development of biotechnology in Europe, aside Member States and stakeholder who should also continue to implement the Strategy. The Commission intends to present the mid term review to other institutions and stakeholders, to explore how to maximise synergies and improve the implementation of the Strategy.

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[4] According to the latest OECD definition, modern biotechnology is defined as "*the application of science and technology to living organisms as well as parts, products and models thereof, to alter living or non-living materials for the production of knowledge, goods and services*" http://stats.oecd.org/glossary/index.htm

[5] http://ec.europa.eu/enterprise/phabiocom/comp_biotech_comp.htm

3. PROCEDURAL ISSUES AND CONSULTATION OF INTERESTED PARTIES

3.1. Procedure

The aim of the present Staff Working Paper is first to take stock of progress made on the actions contained in the original strategy from 2002, both from the legal/political perspective and on the basis of concrete facts, and assess what can be developed, improved, continued or simplified.

This report is based on contributions made by Commission services, as well as stakeholders and national authorities which were consulted in July-September 2006. It also builds on other Commission reports, on the implementation of specific sectoral legislation, such as for example Regulation 1829/2003[6], and on horizontal issues (such as horizontal policies in the field of innovation).

On the basis of those elements, the Staff Working Paper presents an exhaustive review of all actions for the 2002-2006 period and makes suggestions for a simplified and refocused Life Sciences and Biotechnology Strategy for the 2007-2010 period, which are further elaborated in the Communication. To this extent, the current exercise goes beyond a mere reporting exercise and defines clear and concrete political objectives, with deliverables, for the 2010 perspective.

The Strategy was purposely large in content and actions, aiming at an initial mapping of the situation which would allow for identification of relevant policy areas. The Strategy has been successful in achieving this and most of the actions contained in the Strategy have been or are currently being implemented.

The preliminary conclusion is that the achievements are consequential and call for a continuation of the Strategy, which nonetheless needs to be partially refocused in view of the changes undergone since it was designed.

The second conclusion is that most of the actions appear to be still pertinent. This is somehow not a surprise given the very broad scope and long term perspective of the Life Sciences and Biotechnology Strategy.

Nonetheless, the corollary of this is that some of the foreseen actions, such as in the field of education or regional policy, are actually so broad that they are difficult to evaluate, since the relevant corresponding EC policies are not life sciences and biotechnology-specific.

The analysis of the implementation of the action plan relies on a list of priorities, which envisage three categories of action, those needing to be reinforced, those which should be continued and finally those which have been achieved. This constitutes the backbone of the political orientations contained in the Communication

Concrete deliverables have also been assigned for priority actions, which will permit a more thorough monitoring and evaluation of the current Strategy for the years to come, and help with reflection upon possible post 2010 initiatives.

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[6] COM(206) 626 final of 25/10/2006

3.2. Consultation of interested parties

A public consultation was launched on 5 July 2006 and was open for comments until 30 September 2006. It was addressed to a very broad range of "institutional" stakeholders[7], identified on the basis of contact lists proposed by all Commission services, and put online on the Europa webpage for contribution by all citizens[8]. The consultation was based on the 2002 Life Sciences and Biotechnology Action plan, complemented by emerging issues identified in the 2004 and 2005 Progress Reports.

This consultation allows drawing upon a wide range of views with respect to both the positive potential and short-comings of the actions.

The Commission received over 30 responses from individuals and organisations in 16 countries representing a wide range of stakeholders (consumer and patient organisations, farmers, NGOs and other interest groups, research organisations, private companies and individual citizens). The overall number of responses may appear very limited, but some of the answers received originated from very large organisations, both from the industry and NGO side, representing a very substantial number of companies or associations established at international level. While some stakeholders chose to provide only general comments assessing the Strategy, others chose to also submit detailed suggestions for refining specific actions. In general, the responses provide a positive assessment of the Strategy.

Aside from this consultation on the Action Plan, discussions on the mid term review have also taken place with the contact network with Member States ministries with responsibility for competitiveness in biotechnology[9], the industry and NGOs within the framework of the "Bio4EU" study[10], the Commission's Competitiveness in Biotechnology Advisory Group and the newly established network of high level officials on the Knowledge-Based Bio-Economy (KBBE-NET). Both industry and NGOs were satisfied to be consulted.

The conclusions from these different consultations are that the contributions are largely in agreement with the preliminary assessment done by the Commission and they match the suggested way forward described in the current Staff Working Paper.

4. ANALYSIS OF THE IMPLEMENTATION OF THE LIFE SCIENCES AND BIOTECHNOLOGY ACTION PLAN

<u>Action 1 – Education and training</u>

Reference to ongoing EU education programs will need to be updated to reflect the evolution of education programs *"The Commission will, together with competent*

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7 Consulted stakeholders include representative from industry, environmental NGOs, consumer groups, ethics organisations/National Committees, Member State's competent authorities, national/regional Research institutes, academia, competent authorities from third countries, agricultural organisation, retail sector, international institutions, chambers of commerce and specialised consultants.

8 http://ec.europa.eu/biotechnology/index_en.htm

9 http://ec.europa.eu/enterprise/phabiocom/comp_biotech_commit.htm

10 http://bio4eu.jrc.es/stakeholders.html

authorities in Member States, identify the education needs in life sciences within the 'Ten-year objectives for learning in the knowledge society' the education and training contribution to the Lisbon strategy and the 10-year work programme on Education and Training 2010 – and from 2007 on under the integrated Lifelong Learning Programme". After carrying out thorough research in the Compendia of Centralised Comenius Actions (Comenius 2.1 projects and Comenius 3 Networks) for the whole period of Socrates II programme (2000 to 2006 included), it appears that there is no project or network in the area of Biosciences and Biotechnology. There are many projects concerning sciences in general but none on biosciences. Despite the high importance of education it may prove difficult to go beyond what is already contained in the Action Plan and a general political recommendation to develop and strengthen education in the field of life sciences, given the absence of more specific sectoral information.

Action successfully implemented and will be further pursued

Action 2a - Match a skilled workforce with job opportunities

This action aiming at matching a skilled workforce with job opportunities is particularly important in the context of the Lisbon strategy.

The Commission established in 1993 the EURES portal in order to facilitate the geographic mobility of workers as a means to match job opportunities with appropriate and well-skilled candidates, and to contribute thereby to the development of a genuine labour market at the European level. The occasion of the 2006 European Year of Workers' mobility has provided considerable impetus to the portal, by enabling all EU citizens to access directly, in their own language, all job opportunities published by the Public Employment Services, i.e. around 1 million jobs at any given time. In addition to the access to job vacancies, the EURES platform offers the possibility for jobseekers in all activity areas to post their CV and access comprehensive and up to date information on living and working conditions in 30 countries. Beyond information provision, the EURES portal is supported by a network of 750 advisors, located in all EU regions, with the aim of providing customised assistance to workers and their families in all matters relating to their mobility experience.

The EURES Job Mobility Portal[11] is a key Commission initiative in this respect.

Action successfully implemented and will be further pursued

Action 2b – Fight brain drain

The Commission foresees a new "skill and mobility action plan", which will contribute to fulfilling the objectives of this action aimed at attracting and retaining scientists. The European Charter for Researchers and a Code of Conduct for the recruitment of researchers are now being implemented and a number of specific actions have been supported under the 6th Framework Programme for Research 2002

[11] http://ec.europa.eu/eures/home.jsp?lang=en

– 2006 (hereinafter "FP6"). The implementation of Action 2b will need to be updated in light of FP7.

In the frame of the integrated strategy the Commission has set out to enhance the quality and quantity of researchers in Europe. In March 2005 the Commission adopted a Recommendation to Member States on the European Charter for Researchers and a Code of Conduct for the recruitment of researchers. Together with the formal launch and unfolding across Europe of the ERA-MORE network[12] of proximity assistance to mobile researchers in 2004, as well as the Directive on the entry and stay in the EU of third country researchers[13], these are highlights of key steps towards the creation of a real European researchers' labour market.

The European Charter for Researchers addresses the roles, responsibilities and entitlements of researchers as professionals and those of their employers or the funding organisations. It aims at ensuring that the relationship between these parties contributes to successful performance in the generation, transfer and sharing of knowledge, and to the career development of researchers. The Code of Conduct for the Recruitment of Researchers aims to improve recruitment, to make selection procedures fairer and more transparent and proposes appropriate means of judging merit, which should not be based just on traditional academic criteria, e.g. the number of publications, but on a wider range of evaluation criteria, including teaching, supervision, patents, spin-offs, other teamwork, knowledge transfer, research management and public awareness activities.

One year after its adoption various initiatives to raise awareness and support the implementation of the Recommendation have been undertaken at European as well as at national level. More than one hundred organisations all over Europe have already signed the Charter.

The Marie Curie actions in FP6 were conceived to give broad support for the development of abundant, dynamic and world class human resources in European Research systems. The actions comprise support for researchers at all stages of their careers from postgraduate researchers to senior professors with a number of aims: to facilitate movement between countries in Europe; to develop their careers outside Europe; and to attract the best researchers from around the world to come to Europe and undertake research. Support is on a bottom-up basis, across the entire range of scientific disciplines, with selection based on excellence. In all Marie Curie actions the life sciences are heavily represented and account for between a quarter and a third of the total budget.

To date in FP6, just over €500 million has been committed in the Marie Curie actions across the broad spectrum of life sciences and biotechnology in FP6. This support has taken various forms. It has enabled approximately 1000 experienced researchers to apply for individual postdoctoral support at the research institution of their choice in the public or private sector in Europe or in third countries. It has funded institutions to hire postdoctoral researchers to work on collaborative research

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12 http://ec.europa.eu/eracareers/index_en.cfm

13 Council Directive 2005/71/EC of 12 October 2005 on a specific procedure for admitting third-country nationals for the purposes of scientific research, OJ L 289, 3.11.2005, p. 15–22

projects. About 1000 full-time, three year PhD positions have been funded, allowing researchers at the beginning of their careers to access excellent foreign doctoral research programmes. Nearly €10 million has been used to fund conferences and dissemination activities. Funding for 45 teams has been provided (€70 million) to allow experienced researchers to set up their own research groups for the first time in industry or academia. Furthermore, 11 top-level "Chair" appointments have been made, attracting world-class researchers and encouraging them to resume their careers in Europe (€6.5 million).

The trans-national access activity of the Research Infrastructures programme has also provided opportunities for several thousand researchers to enjoy hands-on access to 35 life sciences research infrastructures, with tens of thousands also able to access some of these resources remotely.

Finally, a large number of the Network of Excellence implemented under FP6 include the programme "Integration and Strengthening of ERA", which incorporates training and mobility activities.

The following provide a comprehensive overview of the different actions implemented in FP6 contributing to training and mobility of researchers in the area of Life Sciences and Biotechnology.

– 47 Research Training networks (€130 million) funding 400 full-time, 3 year PhD positions alongside more than 500 years of postdoctoral support;

– 61 Early Stage Training contracts (€90 million) funding 600 full-time, 3 year PhD positions;

– 50 Transfer of Knowledge "Development" contracts (€26 million) aimed at skills transfer mainly to Convergence Regions;

– 17 contracts (€7 million) to stimulate exchange and partnership between industry and academia in all areas of life sciences with a heavy emphasis on biotechnology, supporting 60 years of experienced researchers to move sectors temporarily;

– Approximately 500 individual, postdoctoral fellowships of up to 2 years duration for mobility within Europe (€100 million);

– Approximately 100 individual, postdoctoral fellowships for excellent European researchers to carry out research in a third country for up to 2 years and subsequently return to Europe (€25 million);

– Approximately 160 individual, postdoctoral fellowships to bring in excellent third country researchers to carry out research in Europe (€25 million);

– Approximately 200 experienced European researchers have been given grants (€16 million in total) to enable them to reintegrate in Europe following a longer stay in a third country;

– In terms of dissemination and exploitation activities, Marie Curie actions have supported 4 large conferences (€ 400,000) and 18 linked conferences/workshops/ summer schools (€8 million);

– Trans-national access of researchers is supported under FP6 to 35 life sciences research infrastructures, such as animal repositories, synchrotron beam-lines for structural biology, NMR (Nuclear Magnetic Resonance) installations, sequence databases or natural history sample collections. A total of 3500 researchers will have "hands on" access and tens of thousands of researchers will use the infrastructures remotely. These trans-national access activities have a budget of €22 million devoted to the life sciences, plus some smaller scale funding for training the infrastructure users;

– Projects exploring the use of e-learning on sustainable development and land use.

The investment in human resources activities in People and Capacities programmes has maintained the same approximate percentage of total FP funding (10% for People) as in FP6, which reflects the continued importance of investing in human resource following the Lisbon Agenda. No major changes are needed, the main thrusts of the People programme show clear continuation from FP6.

The strategies developed in previous Framework Programmes to attract and retain scientists and avoid brain drain will be built upon and continued. The Seventh Framework Programme (2006-2013) has an entire programme "People" dedicated to attracting and retaining researchers in Europe, and ensuring life-long career development opportunities. Continued efforts will be undertaken to attract the best foreign researchers and support the return of EU researchers established in other parts of the world.

In synergy with the activities proposed under the Communication "A Mobility Strategy for the European Research Area", the Commission launched in 2002 the "Skills and Mobility Action Plan", as a contribution to achieving the Lisbon objectives of more and better jobs, greater social cohesion and a dynamic knowledge-based society. The Action Plan, which was adopted by the Commission in February 2002 and endorsed by the Barcelona European Council in March 2002, aims at expanding occupational mobility and skills development, by ensuring that education and training systems become more responsive to the labour market, that administrative and legal barriers to mobility are duly removed, and that information about existing opportunities for mobility and related support mechanisms are set up, covering all sectors of activity in the EU. The final report for the Action Plan will be presented by the Commission. A new Action Plan, involving all operational Commission services dealing with mobility, is foreseen as a follow up to the European Year of Workers' Mobility of 2006.

On a very practical level the Commission is working on better co-ordination of the social security schemes of EU Member States and with third countries[14]. This is a key issue for persons exercising their fundamental right to free movement. This concerns e.g. the portability of pension rights but also the right to free movement

[14] http://ec.europa.eu/employment_social/social_security_schemes/relations_en.htm

with third countries (e.g. agreement on free movement of persons with Switzerland which entered into force in 2002).

Action successfully implemented and will be further pursued under FP7

Action 3 - Research

Under FP6

FP6 has brought a strong impetus to Life Sciences and Biotechnology research in Europe, in particular in terms of critical mass of human and financial resources, sharing of knowledge and facilities, strengthening of scientific excellence, coordination of national activities and support to EU policies.

The activities undertaken in the context of FP6 illustrate the broad application of Life Sciences and Biotechnology research to a large number of industrial sectors (e.g. health, food, agriculture, chemical, energy) and its continuing evolution integrating new and emerging disciplines such as the "omics" technologies (genomics, proteomics, metabolomics, glycomics…) as well as its convergence with other technologies (nano, info, cognitive and social sciences). The importance of **Nanosciences and nanotechnology** for underpinning the advances in life sciences and biotechnology was stressed in the Commission's Communication "Towards a European Strategy for Nanotechnology"[15] adopted on 12 May 2004. The disciplines of synthetic and systems biology are gaining prominence at the embodiment of the future of biological sciences.[16].

Around €2512 million have been awarded for "**Life sciences, genomics and biotechnology for health"** research. These funds went to around 613 projects, involving more than 7600 participants. These projects ranged from fundamental genomics to applied genomics, poverty related diseases cancer, cardio-vascular diseases, diabetes, age and brain related diseases as well as rare diseases.

Another €756 million have been awarded under the thematic priority **"Food quality and safety research"**. These funds went to 186 projects, involving more than 3032 participants. These projects ranged from food processing and safety to nutrition and food related diseases as well as agriculture-related research topics including animal and plant production systems, forestry, plant and animal biotechnology.

A number of projects dedicated to renewable energy based on biomass e.g. energy crops and agrowastes, were funded (approx. €20 million awarded) under the thematic priority **"Sustainable development"** in the specific programme "Sustainable Energy Systems".

A number of projects on innovative bioprocesses for water, water-waste, sludge, sediments and soil treatment/remediation have been funded under the priority **"Global changes and ecosystems"**.

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15 Towards a European Strategy for Nanotechnology COM(2004) 338

16 http://ec.europa.eu/research/biotechnology/ec-us/index_en.html

Socio-economic research was among others funded under the priority "Citizen and governance" addressing issues such as the dynamics of institutions and markets in Europe, indicators for emerging technology sectors and regional models.

Industrial biotechnology was a research area which during the implementation of FP6 emerged as an important eco-efficient innovative industrial sector. Industrial biotechnology refers to its use in manufacturing (chemicals, pharmaceutical, food and drinks, pulp and paper, textile, energy) at every stage in the process, from supply of raw materials to end-of-pipe and clean-up. It is seen as a key technology for the sustainable development of societies worldwide. Biological processes offer the prospect of cheap and renewable resources, lower energy and less waste consumption, reduction of greenhouse gas emissions, reduced dependence on (imported) petroleum and new markets for European agriculture. Examples of products already on the market include one of the most widely used fibrous polymers for household applications such as carpeting, a biodegradable plastic or use of enzymes in the manufacture of chemicals. This is a field in which European companies take a world lead. Industrial biotechnology is expected to contribute to a smooth transition from a fossil-fuel-based economy to a bio-based economy. Recent reports predict annual growth rates of 5% for fermentation products and a 10% market share of bio-based products within the chemical industry (around €100 billion value)[17]. Although numbers may differ, all reports agree that industrial biotech will play a significant role the future.

Several Member States (e.g. UK, Belgium, Germany, The Netherlands, Sweden, France…) have launched their own initiatives and additional public–private partnerships on Industrial Biotechnology have been set up recently in the Netherlands and Belgium. Australia, USA, Canada, and Japan and many emerging countries such as China, India, Brazil, and South Africa are stepping up their financial and strategic efforts to remain in the scene. An international dialogue is also taking place at the level of the OECD[18].

The Commission, recognising Industrial Biotechnology as a key industrial technology with great potential for sustainability (in line with the Environmental Technology Action Plan[19]) and cost efficiency, integrating different fields of research from nano-scale to engineering and production and with many sectoral applications, has for its part:

– Supported research in the area of industrial biotechnology for a total of €61 million (under the thematic priority "Nanotechnologies and Materials";

– Supported the launch of the “Industrial Biotechnology Platform” as part of the wider Sustainable Chemistry Technology Platform in order to boost this area in Europe;

– Ensured that Industrial Biotechnology becomes one of the priorities in FP7 under the theme “Food, Agriculture, Fisheries, and Biotechnology” as well as under the

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17 http://ec.europa.eu/enterprise/phabiocom/docs/cbag_2006_final_version.pdf

18 http://www.oecd.org/topic/0,2686,en_2649_37437_1_1_1_1_37437,00.html

19 http://ec.europa.eu/environment/etap/index_en.htm

themes "Nanosciences, nanotechnologies, materials and new production technologies and "Energy". It will form an important pillar of the "Knowledge Based Bioeconomy".

Industry, and in particular **Small & Medium Enterprises** (SME) have benefited from the FP6 .In the Health Research Priority 17% of all participating partners in projects funded are SMEs (representing around 14 % of the budget). As expected, the area "Application of knowledge and technologies in the field of genomics and biotechnology for health" attracted the highest number of industrial partners within Health Research Priority. The participation of SME's was in particular high in the diagnostic sector (42% of the proposals received in the specific SME call). Indeed the diagnostic sector is closer, its products are faster to the market and the risk is lower both financially and scientifically, compared to the drug and therapies sector. This situation is shared by investors and active owners of SMEs, such as venture capitalists.

Under the thematic priority "Food Quality and Safety" 19% of all participating partners in projects funded are SMEs (representing around 12 % of the budget).

In addition to the participation in the activities implemented under the priority thematic areas, two specific schemes for SMEs having a potential to innovate but with limited research capacity have been implemented. Within these schemes, SMEs or groupings dominated by SMEs may entrust research work to solve their particular problems to research performers (research institutes, universities etc.) About 23% of the budget allocated to these specific activities for SME's has been attributed to research in the field of Life Sciences and Biotechnology.

Three main actions supporting **Research Infrastructures** in Europe were taken under FP6, with some focus on the Life Sciences and Biotechnologies:

– 20 projects dedicated to Life Sciences have been awarded an EU contribution of €66 million. Life Sciences will also benefit indirectly from a number of large multidisciplinary infrastructure projects such as access to synchrotrons, to neutron sources or to natural history museum collections, as well as use of the GEANT high capacity academic network, of the DEISA distributed infrastructure for supercomputing applications, and of the network enabling grids for e-science in Europe;

– The European Commission services initiated an exercise for mapping existing Research Infrastructures in Europe, in collaboration with the European Science Foundation and the EUROHORCs. This will assist in the gaining of an up-to-date picture about the current pattern, and will go towards understanding the needs for future Research Infrastructures;

– The Council of Ministers in its meetings of 1-3 July and 25-26 November 2004 also proposed to develop a strategic roadmap for new Research Infrastructures in Europe over the next 10 to 20 years. The European Strategy Forum for Research Infrastructures (ESFRI) endorsed this work and is now preparing a roadmap that will in particular cover several major projects for the "Biological and Medical Sciences".

In addition to this, the Commission is in the process of developing core competences in **bioinformatics** (including bioinformatics infrastructure). It has been accepted as a member of the European Molecular Biology Network (EMBnet)[20] which is the only organisation world-wide bringing bioinformatics professionals to work together. The combined expertise of the nodes allows EMBnet to provide services to the European molecular biology community which encompasses more than can be provided by a single node.

Concrete progress has been made in **structuring the European Research Area** and the active participation of all Member States has been achieved. The coordination of national policies has been initiated in the context of the Standing Committee on Agriculture Research (SCAR) and of the Member States Network on the Knowledge Based Bio-Economy (KBBE-NET). As announced in the 3rd progress report on the implementation of the strategy on Life Sciences and Biotechnology[21], the KBBE-NET has been established, bringing together high level officials from Member States, acceding and candidate countries to support the European Commission and the Member States to achieve a coordinated effort in the development and implementation of a European research policy for a knowledge-based bio-economy. This involves:

– Strategic discussion and recommendations for establishing a European Research Agenda in the long term (FP7, and beyond) which should allow the building of a European Knowledge Based Bio-Economy. The work should also contribute to the midterm review of the EU Life Sciences and Biotechnology Strategy in 2006-2007;

– Enhancing exchange of information between Member States regarding national research policies and mapping of activities including international cooperation;

– Enhancing cooperation between Member States (joint research programmes, common infrastructures, training programmes, etc).

A number of projects have been funded through the **Specific measures in support of international co-operation - Developing countries** on "Bio-diverse, bio-safe and value added crops" and on “Health of livestock populations” largely focused on the livestock health protection through the development and use of diagnostic tools and vaccines. This research area of the 'food security' priority makes use of advanced biotechnological techniques.

Coordination of national and regional research programmes has been achieved through the ERA-NET scheme[22] in which programme owners and programme managers identify national and regional programmes they subsequently coordinate or open up mutually. 15 ERA-NET actions relating to Life Sciences biotechnology are now implemented:

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20 http://www.es.embnet.org/

21 http://ec.europa.eu/biotechnology/progress_reports_en.htm

22 http://cordis.europa.eu/coordination/era-net.htm

– Four ERA- NETS on Plant genomics, Biotech for SMEs, Pathogenomics and Systems Biology, have already launched joint calls for trans-national research projects using national funding. Together these projects have already committed some €80 million to these calls for 2007 and at least €50 million more for 2008.

– In the medical sector Era-Nets in the area of Organ transplantation, Health emergencies, and Health technology assessment have been implemented.

The establishment of **technology platforms**[23], an innovation in EU research policy, have continued to develop and foster public-private partnerships at European level. They represent a mobilising force by bringing together all relevant stakeholders in a given sector to develop a strategic, long-term research agenda and to implement the research agenda through public and private investments at European, national and regional level. They are expected to contribute to the effort to boost research and technological development in Europe and to leverage knowledge for economic growth and competitiveness. Industry's lead role in the platforms is crucial in this regard. The industrial leadership of platforms ensures that they are focussed on potential future markets for key technologies. This leadership can provide the necessary impulse to realise Europe's potential in leading-edge technologies and help to build the capacity to transform scientific excellence into commercial success and economic growth. It can also stimulate the emergence of first-mover markets in Europe. They provide a framework for industrial, scientific and financial worlds to come together and make viable projects that can only be conceived at European level. This in turn will boost research performance and investment.

So far **8 technology platforms in life sciences and biotechnology** have now been launched: Innovative Medicines Initiatives, Nanomedicine - Nanotechnologies for Medical Applications, Plant genomics and Biotechnology, Industrial biotechnology under the sustainable Chemistry technology platform, Food for Life, Sustainable animal breading and reproduction, global Animal Health, Forestry and Biofuels. The last 6 technology platforms have established a virtual KBBE- Net in order to ensure a coherent and coordinated approach to the implementation of a Knowledge-Based Bio-Economy. Close collaboration between technology platforms and the KBBE related ERA Nets has been initiated.

Under FP7

The **Seventh Framework Programme (2007-2013)** will continue to provide a strong impetus to Life Sciences and Biotechnology research in Europe.

Life Sciences and Biotechnology research for medical applications will remain an important priority in FP7 in particular under the "Health" theme in the "Cooperation Programme". This theme will promote research to improve the health of European citizens and increase the competitiveness of the European health related industries and businesses. It will support both basic and applied collaborative research. This includes discovery activities, translational research and early clinical trials (normally only phase I and II). Activities will be structured in 3 main areas:

[23] http://www.cordis.lu/technology-platforms/home.html

– Biotechnology, generic tools and technologies for human health;

– Translating research for human health;

– Optimising the delivery of healthcare.

The Health Theme emphasises the importance of innovation and the integration of SMEs in health research projects in order to reach the Lisbon goal, with special attention on the inclusion of 'high-tech' SMEs in projects. To that aim, in addition to appropriate work programme formulation of topics and calls, an articulated strategy is ongoing to improve visibility and awareness among the Healthcare SMEs community, through participation in international meetings relevant to SMEs including Trade Fairs, enhancing communication, supporting information multipliers and developing additional appropriate support structures.

As in FP6, and in addition to the activities implemented under the Themes of the Cooperation programme, a specific scheme is being developed to strengthen the competitiveness of SMEs, including Life Sciences SMEs, by enhancing their investment in RTD-activities (supporting SMEs or SME associations in need of outsourcing research to research services providers such as universities, research centres or research performing SMEs) and acquisition of intellectual property rights and knowledge.

The **Innovative Medicines Initiative (IMI)** [24] is expected to be established as a **Joint Technology Initiative under FP7**, forming a public-private partnership between the **European Commission** and the **European Federation of Pharmaceutical Industries Associations (EFPIA)**. IMI aims at increasing the competitiveness of the European biopharmaceutical industry and is therefore a direct answer to the objectives of the Lisbon's Strategy. Industry will invest in research by co-funding collaborative research projects taking place in Europe, together with academia, SMEs, and patients associations supported by public funds. IMI research objectives are to provide new tools for accelerating the development of safer and more effective medicines for patients, by overcoming four key pre-competitive research bottlenecks in the drug development process: **prediction of safety, prediction of efficacy, knowledge management, and education & training**.

"The **European Technology Platform on NanoMedicine**[25] aims at strengthening the competitive situation for nanomedicine at global level. Its strategic research agenda puts forward a sound basis for decision making processes for policy makers and funding agencies, providing an overview of needs and challenges, existing technologies and future opportunities in nanomedicine. It also takes into account education and training, ethical requirements, benefit/risk assessment, public acceptance, regulatory framework and intellectual property issues. The initiative concentrates on three key areas: Targeted drug delivery, nano-diagnostics and regenerative medicine. The Platform delivered a sound basis for the work programme of FP7 in this area. Industry is ready to invest considerable funds in

[24] www.europa.eu.int/comm/research/imi.html

[25] www.cordis.europa.eu/nanotechnology/nanomedicine.htm

European nanomedicine research projects together with the European Commission and other stakeholders."

FP7 is also expected to contribute to building a *European Knowledge-Based Bio-Economy,* by bringing together research, industry and relevant stakeholders under the theme *"Food, Agriculture and Fisheries, and Biotechnology"* to exploit the new opportunities that life sciences and biotechnology offer to create added value in society, to enhance sustainability through the optimal use of renewable biological resources, to mitigate the emission of greenhouse gases, to provide new eco-efficient and competitive products and to reduce the adverse impact on the environment of agriculture, industry and aquaculture.

Three main areas of research will be addressed:

– Sustainable production and management of biological resources from land, forest and aquatic environments;

– "Fork to Farm": Food, health and well being;

– Life Sciences and biotechnology for sustainable non-food products and processes.

This progress in science and research strongly contributes to the implementation of the objectives of the revised Lisbon strategy, as outlined in the "Kok report"[26]. Life Sciences and biotechnology will help to move towards a European Knowledge-Based Bio-Economy, where not only food and feed, but also other industrial goods are produced in a more sophisticated and sustainable manner by incorporating life sciences and biotechnology innovations. As an example, the chemical industries may undergo transformation at several levels: Firstly the industry may undergo raw material conversion from fossil feedstock to biological resources. Secondly, it may undergo process conversion from using chemical processes to using bioprocess.

These knowledge-intensive and eco-efficient bio-products include among others biofuels, bioplastics, green chemicals, lubricants, biopharmaceuticals, food and feed, as well as other bio-products.

The move towards a bio-based economy is not only taking place in Europe, but is emerging globally and our main competitors are now strongly investing in these areas of research.

As stressed in the recent "Aho report"[27], research, technology and innovation can only be powerful vectors of sustainable growth, if supply-side measures (public investment in research) are rebalanced with demand-side policies (public procurement, standards, regulation, ….) in order to stimulate private investment into research and product development. As expressed in the report, "simultaneous and synchronous efforts are needed at all levels in three areas":

– Creation of a market for innovative products and services;

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26 http://ec.europa.eu/growthandjobs/pdf/kok_report_en.pdf

27 http://ec.europa.eu/invest-in-research/action/2006_ahogroup_en.htm

– Providing sufficient resources for R&D and innovation and;

– Improving the structural mobility and adaptability of Europe.

A number of supply-side policies are already in place to support the emergence of a European bio-economy, in particular R&D support through national and Community research framework programmes. The KBBE-NET network was established in 2005 to exchange information on national research policies and programmes and to enhance cooperation between Member States (joint research programmes, common infrastructures, training programmes, etc) with a view to develop and implement a European Research Agenda for the knowledge-based bio-economy.

However, if Europe wants to explore the full potential of the "Knowledge Based Bioeconomy" it needs to engage in demand side policies to create dynamic market conditions. ("lead markets"). "Bio-based products" could be a prominent example of a European lead market given that Europe has some key strategic advances:

– A strong, world-class biotechnology R&D base;

– Key-enzymes producers being located in the EU;

– A strong chemical industry, which are leaders in the development and production of bio-specialities (food ingredients, pharmaceuticals and fine chemicals);

– The availability of renewable resources, in particular agricultural biomass through the recent EU enlargements;

– Strong political support for and more advanced concepts of sustainable development

– Strong public support for industrial biotechnology (according to the 2005 Eurobarometer on public perception of Biotechnology[28] 70% of the respondents supported bioplastic and biofuels and are willing to pay more for these products).

Such a **lead market initiative for eco-efficient bio-based products** should stimulate private investments and lead to more demanding and novelty-seeking customers, and potential higher returns on investment will act as a strong incentive to private research and innovation.

Several actions could be considered, both from the supply and the demand sides, to provide a push for eco-efficient biobased products. The list below takes into account the discussion at the Presidencies Biotech Policy Round Table in Helsinki in June 2006[29] and the work of the network with high level officials on the Knowledge Based bio Economy. The Commission will further reflect on these actions, in cooperation with the concerned stakeholder, bearing in mind that some proposals may need to be subject to an impact assessment, including an evaluation of possible administrative burden, and compatible with EC rules in the field of competition and internal market.

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28 http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf

29 http://www.ktm.fi/index.phtml?l=en&s=1741

(1) Providing sufficient resources for R&D and innovation

(a) Mobilise national research funding (e.g. re-enforcement of ERA-Nets) and reinforce the coordination of national research activities amongst others through the Member State network on KBBE. Special attention should be made to:

– Launching of demonstration projects/pilot plants at European/National/regional levels e.g. integrated diversified biorefinery;

– Implementation of the strategic research agendas developed by the Technology Platforms at European, national and regional levels.

(2) Creation of a market for eco-efficient bio-based products

(a) Establishment of standards/minimum requirements to claim a bio-based product is eco-efficient (bio-products that leads to less pollution, less resource-intensive production and more effective management of biological resources);

(b) Help convert conventional industrial processes into eco-efficient bio-based products by developing faster regulatory approval system for eco-efficient bio-based products;

(c) Secure affordable supply of biomass feedstock through supportive innovation programmes, agriculture policies and price incentives;

(d) Provide market incentives to stimulate the commercialisation of bio-based products:

– Include the issue of eco-efficient bio-based products in the EU green Public Procurement Policy in order to stimulate public procurement of eco-efficient bio-based products. The French Environment Agency Bioproducts guidebook for Greener Procurements may serve as a model;

– Establish EU labelling of eco-efficient bio-based products compatible with EC rules on eco-labelling.

– Temporary pricing measures.

(3) Improving the structural mobility and adaptability of Europe

(a) Enhance coordination and coherence of the various policy initiatives at EU level e.g. biomass action plan, ETAP, sustainable development strategy, implementation of the biofuel directive30 etc;

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30 Directive 2003/30/EC of the European Parliament and of the Council of 8 May 2003 on the promotion of the use of biofuels or other renewable fuels for transport, OJEU L 123, 17/05/2003, p. 42-46

(b) Enhance cooperation between the Commission and Member States among others through the Member States network on Knowledge Based Bio- Economy (KBBE-NET) in cooperation with Council Presidency;

(c) Continue to elaborate the KBBE concept, assess its potential impact and make practical steps to ensure its implementation. Developments inside and outside the EU should be monitored through, amongst other methods, the Member States network on Knowledge Based Bio-Economy (KBBE-NET) and interaction with the OECD;

(d) Enhance the collaboration with industry and other stakeholders through the technology platforms amongst other mechanisms.

(4) Create awareness amongst stakeholders

(a) Launch information campaign on eco-efficient bio-based products and the potential of the "Knowledge Based Bio-Economy" including interactions with civil society, NGOs, investors, policy makers etc;

(5) Promote interdisciplinary education and training programmes.

(6) Improve investment in eco-efficient bio-based SME's

(a) Attract new public and private investors

(b) Increase availability of seed funding for Eco-efficient bio-based start-ups by reassuring investors through the involvement of public funding bodies (EIF,EIB etc);

(c) Put incentives in place to motivate private individuals and foundations to invest in "green" investment funds.

(d) Better target the available funding at new technology projects.

Support for life sciences and biotechnology research under FP 7 clearly appears as a top priority. Hence the original "Action 3", which has already been achieved, needs to be revised to take into account the objective and structure of FP7. In addition to this, new sub-actions should be envisaged in order to provide a push for eco-efficient bio-based products and the implementation of the Knowledge based bio-economy. Such actions would certainly be relevant in a perspective of sustainable development. They may nonetheless require an impact assessment (i.e. as far as they foresee for example the establishment of standards to assess the eco-efficiency of bio-based products, of incentives for the marketing of such products or of specific eco-labelling).

The Commission will enhance its support for life sciences and biotechnology research, technological development, demonstration and training activities under the next Framework Programme 2007-2013 aimed at contributing to the creation of a knowledge society and to provide a more stable foundation for the European Research Area.

Life Sciences and Biotechnology research will mainly be supported under the "Health" and the "Food, agriculture and Fisheries, and biotechnology" thematic areas under the Cooperation programme. The following thematic areas under the Cooperation programme will also contribute to the implementation of the strategy:

(1) Information and Communication Technologies;

(2) Nanosciences, nanotechnologies, Materials and new Production Technologies;

(3) Energy;

(4) Environment;

(5) Socio-economic Sciences and Humanities;

(6) Security and Space, notably biosecurity.

Specific measures will be provided to encourage "investigator-driven research" in relation to the establishment of the European Research Council, mobility and training of researchers, coordination of national and regional programmes, SME participation, regional research driven clusters, research infrastructures, international cooperation and science and society issues.

In the course of the mid-term review of FP7 in 2009 an assessment will be carried out regarding the accomplishment of creating a "European Knowledge Based Bio-Economy". The contribution in terms of human and financial resources from, in particular theme 2 "Food, agriculture, fisheries and biotechnology", theme 4 "Nanosciences, Nanotechnologies, Materials and new Production Technologies", theme 5 "Energy" and theme 6 " Environment, as well as the need for new strategic research priorities. The contribution from Member States, industry and other stakeholders will also be assessed.

Action 3 remains of strategic importance, in particular in view of the emerging of industrial, environmental and marine biotechnologies as important sectors not only in Europe but globally. It needs to be refocused in light of the new FP7 and of emerging issues

Action 4 - Management and legal services

The two actions aiming at creating networks of biotechnology company managers and at developing specific legal competence in this field do not have triggered interest from the concerned audience. The two actions do not have any strategic importance at European level and do not need to be pursued further to the review.

The idea to create networks of biotechnology company managers has been probed but the Commission has found that there is no interest for this action at European level. The existing biotech clusters/regional organisations seem to fill the needs.

A reinforced collaboration between law schools, law firms and companies has not raised any interest at European level.

The needs to improve biotech companies' business models, acquire legal competence and recruit competent leaders are often cited in various reports. As the European biotech sector gradually matures, these needs will be more accentuated, and the existing clusters and networks (including the recently created CEBR; see action 9) can provide the demanded services and networking possibilities.

Action 4 does not need to be pursued as a specific action

Action 5 - Patenting of new research findings

Intellectual property rights (IPR) have a special role to play in the life sciences and biotechnology sector. Biotechnology requires huge levels of R&D investment and in many cases it takes a long time to obtain legal approval for products to enter the market. The patents registered by a biotech company constitute a large part of that company's value, being the company's main asset to generate future revenues. Intellectual property may even be the one and only collateral to obtain financing for the company's research and development activities. Therefore the acquisition of patents, a legal mechanism that ensures a return on investments is crucial to life sciences. IPR instruments such as trademarks, commercial names, domain names, know-how and licensing agreements secure the commercial interest of entrepreneurs in this sector.

While the patenting of new research findings in the field of biotechnology has economical and ethical implications, this action should be considered in the global context of research in general. Given its importance, which has been clearly confirmed by stakeholders, this action should be continued and remains a political priority. In particular, the economic consequences of not having a cost effective Community Patent should be studied. Ultimately, efforts should continue to agree and introduce a Community Patent, whilst it should be clear that this is not a biotechnology–specific issue and that only limited action can be taken for this purpose in the context of the Strategy.

Action 5 (a) has been achieved and all Member States have now implemented in their national laws Directive 98/44/EC[31] on the **legal protection of biotechnological**

[31] OJ L 213, 30.7.1998, p.13

inventions. The Directive aims to clarify certain principles of patent law applied to biotechnological inventions whilst ensuring that strict ethical rules are respected. Such clarifications have proved essential in order to fully exploit the medical, environmental and economic potential of biotechnology in line with high ethical standards.

For its part, the Commission has considered two questions identified in the annual report[32] of the Commission to the European Parliament and the Council on the development and implications of patent law in the field of biotechnology and genetic engineering provided for by Article 16(c) of Directive 98/44/EC. Namely the scope of **patents relating to sequences or part-sequences of genes isolated from the human body**, and the **patentability of human stem cells and cell lines obtained from them**. These two topics have been addressed in the last Commission report[33]. The Commission is financing two studies. One on the impact of human DNA patents in research and innovation[34] that is expected to provide an evidence-based analysis of the features and dynamics of patent applications. The second study, which has also been launched in the beginning of 2005, will analyse the EU patent system as applied to human embryonic stem cell related technologies[35]. Results of studies will be analysed by the Commission and discussed with Member States.

Regarding action 5(b), after receiving the opinion of the European Parliament, the Commission **proposal for a Regulation on the Community Patent**[36] has been discussed in the Council, where, on 3 March 2003, a common political approach was agreed on a number of issues. Following this, there was significant progress in the Council in incorporating the common political approach in the text of the Community Patent Regulation and the text was practically finalised in November 2003. However, since then the Council has repeatedly failed to reach final agreement. In the meantime, the Commission has on 23 December 2003 presented proposals for Council decisions on the setting up of the Community patent jurisdiction[37]. The Economic and Social Committee has issued its, overall, very positive opinion on 31 March 2004[38] and the European Court of Justice has delivered its opinion on these proposals on 29 October 2004[39].

In view of the difficulties to achieve progress in the field of patents in Europe, the Commission has in 2006 carried out a broad consultation of all interested parties on the future patent policy in Europe. The consultation focused on the structure of the patent system rather than on substantive patent law. One of the main issues in the consultation concerned the Community patent but it covered also issues such as basic principles of the patent system, the draft "European Patent Litigation Agreement"

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32 COM(2002)545 final, 7.10.2002

33 COM(2005)312 final, 14.07.2005

34 The Patenting of Human DNA: Global trends in commercial and public sector activity http://www.sussex.ac.uk/spru/1-4-14-1.html

35 Stem Cell Patents: European Patent Law and Ethics http://www.nottingham.ac.uk/law/StemCellProject/summary.htm

36 COM(2000)412

37 COM (2003) 827 and COM (2003) 828

38 OJ 2004, C 112/76 and C 112/81

39 Council document n° 14349/04

and approximation of Member States' national laws and mutual recognition of Member States' patents[40]. The consultation ended with a public hearing in July 2006. Following this consultation, the Commission is now preparing its position on the way forward.

Action 5(c) has been partially achieved from the Commission side. An expert group on technology transfer and legal specialists finalised in 2004 a report on **"Management of Intellectual Property in publicly funded research organisations – towards European Guidelines"**[41] .

A Commission study providing a detailed comparative analysis of the Intellectual Property Research (IPR) rules applicable to publicly-funded research, their evolution and their effects, in the "old" 15 EU Member States, in 2 "new" Member States, as well as in the US and Japan was launched in December 2005. The study focuses on legislative aspects and gives recommendations in order to improve the coherence of the IPR regimes applicable to publicly funded research in the European Union.

Regarding action 5(d), the Commission has encouraged research organisations in the life sciences and biotechnology area participating in the EU R&D Framework programmes to actively **protect, disseminate and exploit their research results**. It has supported the BioBIZ project, which provides entrepreneurship training, in particular in the New Member States, and has recently published a brochure with "100 Technology Offers"[42] collected from results of EU funded R&D projects.

The Commission has supported a number of support actions to raise awareness for and provide training on IPR issues, such as the "ScanBalt IP Knowledge Network" project[43], which aims to spread awareness and competence development in the field of strategic IP management in biosciences. The EPIPAGRI project, starting in September 2006, will bring together major EU research and technology transfer organisations to collectively manage public intellectual property in Agricultural Biotechnologies, both to support better access to IP for developing countries and SMEs.

Regarding action 5(e), Member States and the Commission took part actively in an OECD exercise to **develop licensing guidelines for genetic inventions**. On 23 February 2006, the OECD Council adopted the Recommendation[44] , which presents Guidelines for the Licensing of Genetic Inventions. These set out principles and best practices for the licensing of genetic inventions used for purposes of human healthcare.

As a conclusion, the Commission, the Council and the Member States should continue to support the objective of the action.

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40 The public consultation was closed on 12 April 2006. See: http://europa.eu.int/comm/internal_market/indprop/patent/consultation_en.htm

41 http://europa.eu.int/comm/research/era/pdf/iprmanagementguidelines-report.pdf

42 Brochure can be downloaded from http://www.cordis.europa.eu.int/lifescihealth/src/leaflet.htm

43 http://www.scanbaltipkn.org/

44 C(2005)149/Rev1
http://www.oecd.org/document/26/0,2340,en_2649_34537_34317658_1_1_1_1,00.html

In the biotechnology sector, patenting of new research findings needs to be done at an early stage to secure further investments and to realise its full economic value. Economic consequences of not having a cost-effective Community Patent should be studied, in particular for the realisation of European inventions originating from academia and young innovative companies

Developments in biotechnology may raise important ethical and legal questions with respect to their protection through patents, in particular in the area of human embryonic stem cells or the newly emerging area of synthetic biotechnology. Therefore special consideration needs to be given to the development of best practices for IPR taking into account ethical and societal concerns while encouraging patenting, licensing and spin-off creation.

With the increasing number of biotech patents, held both by the public and private sector, transaction costs will likely rise. To maintain the competitiveness of the EU industry, issues such as **patent pools, research exemption and new models for the use of IP in public-private research partnerships** are becoming important. The Commission, in cooperation with Members States and relevant stakeholders, should take a proactive role in initiating discussions on these important issues. In a first step the Commission is preparing **guidelines on knowledge transfer** between the public research base and industry across Europe (with an emphasis on the trans-national dimension) The guidelines which are expected to be adopted in 2007 will be addressed to public authorities and stakeholders.

Action 5 remains of strategic importance and needs to be continued in the appropriate fora. Biotech-specific aspects of this action also need to be refocused

Action 6 – Capital base

Regarding action 6a, the EIB's Innovation 2010 Initiative (i2i) aims to help increasing the spending on research, development & innovation in Europe by providing €10 billion in loans until 2010. More than €750 million in loans has been granted to the biotech & pharmaceutical sector.

The EIB loan facility has been strengthened by the introduction under FP7 of a new financing instrument, the **"risk-sharing finance facility"**, which will provide loans for larger research and infrastructure projects. It also aims to fund projects with higher risks. This facility, a joint loan instrument between the European Commission and the EIB, is managed by the EIB, and can provide finance for research in high technology areas by private companies and institutions, for which the risk cannot properly be assessed by classical banks and are therefore considered too risky.

FP7 funds will be used in addition to EIB and as a reserve to cover the risk associated with the EIB lending operation, thereby providing a leverage effect (factor of 3-4). This instrument can in particular be useful for financing high-risk biotech R&D drug development projects, large scale collaborative research projects (technology initiatives, Eureka projects) or new research infrastructures.

The Commission also supports the AFIBIO project ("Access to FInance in the BIOtech sector), a network of financing experts, including the EIF, to develop novel

and innovate ideas related to innovation financing and providing policy recommendations.

Regarding Action 6b, the **venture capital (VC) instruments** of the European Investment Fund (EIF) consist of equity investments in venture capital funds that support SMEs, particularly those that are in their early stages of development and those that are technology-oriented. The EIF's venture capital activity is backed by two sources of funding: (a) capital from the EIB Group (EIB and EIF) that forms the bulk of the EIF's investments, and (b) capital from the European Commission that is allocated under three different programmes:

– The ETF Start-up Facility is intended to adopt a higher risk profile than the EIB Group operations. It aims to invest in venture capital funds such as seed capital funds, business incubators, smaller or newly established funds, funds focused on specific industries or technologies and funds financing the exploitation of R&D results (i.e. funds linked to research centres and science parks);

– The EIF-ERP "Dachfonds" was started jointly by Germany and the EIF to encourage venture capital providers to invest in German high-technology firms, but also elsewhere in the EU. The €500 million fund is expected to raise an additional €1,7 billion through commercial VC investments;

– A new Commission framework programme called the Competitiveness and Innovation Programme (CIP) will operate from 2007. It brings together several separate programmes and aims to strengthen the funding available to stimulate investments in research and technological innovation, especially in SMEs. An increase of €1 billion of the EIB reserves from CIP has been decided;

– Fully achieved. A "Technology Transfer Accelerator" (TTA) was launched in 2006 after the Commission and the European Investment Fund (EIF) had carried out a feasibility study on a new type of risk capital and technology transfer investment vehicle. It aims to link different centres of excellence and universities in European countries. The TTA should bridge the finance gap between university/spin-off research and early stage investment, a sector currently not favoured by VC investors. The Commission is also financing entrepreneurship training courses with particular focus on scientists in the New Member States.

Regarding action 6d, the EIB commissioned an external study in 2005 to find out how many European biotechnology companies are creditworthy, i.e. actually able to take debt for their product development. The study estimates that only very few European biotech companies qualify for debt financing (according to the strictest criteria). The main factors for debt financing are the maturity of the company and a steady flow of revenues.

In September 2005, the Commission produced a report on "Best practices of public support for early-stage equity finance"[45]. This document analyses the demand and supply-side of early-stage finance, gives examples of funds operating in Member States, and provides recommendations for improvement of early-stage finance.

[45] http://ec.europa.eu/enterprise/entrepreneurship/financing/docs/report_early-stage_equity_finance.pdf

An analysis of the European biotechnology industry's competitiveness stance[46] was performed by the Commission early 2007. Europe's biotech companies are mostly SMEs with limited resources and they often depend on external investment capital to be able to follow through with their research and development projects. It is evident that in terms of research expenditure and number of employees European companies grow at a slower rate than their American counterparts. This can be attributed to three main constraints: Europe's fragmented patent system, the insufficient supply of risk capital and the not yet fully developed scientific and business cooperation. To remedy the under-funding problem a combination of demand and supply side measures are recommended.

Action 6 needs to be continued and highlighted as a political priority

Action 7: Biotechnology and Finance Forum

The Biotech and Finance Forum Advisory Board has been renewed and strengthened in 2002 to include all relevant stakeholders in Europe in the field of biotechnology and finance (EuropaBio, EFB, EVCA, EIB, EIF, etc.), as well as representatives of major bio-clusters, venture capital firms, consultants, etc. in the biotech sector. It has made important recommendations and initiated activities to improve access to finance, in particular for later stage companies and for the emerging sector of industrial biotechnology. Roundtable and investment conferences are organised twice a year (in December and May), bringing together industry, small companies, investors and policy makers. Recommendations of the Biotech and Finance Forum working group delivered in 2002 on "Financing of biotech companies" have led the EIB to provide an additional €500 million to the EIF to provide further venture capital to innovative SMEs, including for later stage biotech investments.

The European biotechnology industry has seen considerable growth during the late 1990s, in part due to strong policy initiatives to support university spin-offs, bio-cluster development, etc. While Europe has many biotech start-ups, there are still problems with getting adequate funding and making the European companies grow (US companies are on average better staffed and funded). Further growth seems to be hampered; possible reasons being the lack of access to early- and late-stage finance, and/or the small size of national markets and actual access to markets. An in-depth study of the factors hampering the growth of EU biotech companies is necessary in order to develop appropriate policy measures that could counteract a possible "value drain", i.e. an increased relocation of mid-stage EU companies to the US.

The biotechnology and finance forum to be established under this action is now established and operational, action 7 is thus achieved

[46] http://ec.europa.eu/enterprise/phabiocom/comp_biotech_comp.htm

Action 8a - Creation of a commercial biotechnology web portal

The creation of a commercial biotechnology web portal for Europe is near completion. An evaluation of the setup and the long term sustainability of the web portal should be made and the potential stakeholders should be mapped.

Action is near completion. An assessment of sustainability is required

Action 8b - Commission's central biotech web site

The Commission's central biotech web site is operational[47]. It will be regularly updated and provide necessary links to the Commission's different Directorate Generals' specific biotechnology related web pages.

The website is now established and operational, action 8b is thus achieved

Action 9a - Networking activities between biotechnology regions

The funding of a number of networking activities between biotechnology regions has facilitated the liaison between scientists and business, improving competitiveness.

The Commission has offered funding for a number of networking activities, either through the R&D Framework Programme (specific support actions through the Specific Programmes, and the Regions of Knowledge and INNOVA schemes) or through EU cohesion policy's INTERREG programmes. The Commission has recently launched a project, aimed at establishing a Council of European Bio Regions (CEBR). The aim of CEBR is to establish a long lasting network of bio-clusters and regional associations at the European level, thus facilitating better networking between scientists and business in the biotechnology area and improving competitiveness of the EU biotech industry. The inaugural meeting took place in June 2006

The INTERREG III cooperation programmes which are part of EU cohesion policy have supported projects to network biotechnology/life science regions in the framework of cross-border and trans-national co-operation programmes (INTERREG III A and B). Examples are set out below.

– Scanbalt Campus: This project, developed in the framework of IIIB Baltic Sea Region programme and in cooperation with the ScanBalt Bioregion umbrella initiative of the Nordic Innovation Centre, was founded with the aim of creating a model for trans-national and trans-sectoral institution-building in education, research and development. It includes 31 partners, most of them universities from the countries surrounding the Baltic Sea. The scope of this pilot project includes formulating the concept and structure of a virtual academy, establishing knowledge networks, identifying examples of shared curricula and creation of media services and visibility. The lead partner is the Chalmers/Göteborgs universitet, Centre for environment and sustainability (SE). The contribution of the European Regional Development Fund (ERDF) amounted to €462 405;

[47] http://ec.europa.eu/biotechnology/index_en.htm

– Reducing the environmental impact of aquaculture: This cross-border co-operation project developed in the FYN-K.E.R.N programme between Denmark and Germany aims at supporting the sustainable development of maricultures and to increase the market share of edible fish in refined fish production. The project combines German expertise in land-based fish breeding with Danish knowledge of the management of algae growth to reduce the harmful effects of nitrogen in fish production. The lead partnersare Leibniz-Institut für Meereskunde an der Christian-Albrechts-Universität, Kiel (DE) and the Institute for biochemistry and molecular biology at the University of Southern Denmark, Odense (DK). The contribution of the ERDF is €298,561;

– Creation of a university cross-border study course on biological oceanography: Bio-Ocean is a joint study programme in the FYN-K.E.R.N programme between Denmark and Germany in the sector of Biological Oceanography offering an interdisciplinary combination of lectures, seminars, practices. The programme covers Physical Oceanography, Chemical Oceanography, Biological Oceanography, Marine Geology, Experimental Design and Data Reporting and Cost-Benefit Analysis. During the first term students follow courses covering the basics of physical, chemical, biological and geological oceanography. In addition students follow elective courses relevant to biological oceanography. During the second term, at the University of Southern Denmark, the focus is on advanced biological oceanography and the management of natural resources and environmental economics. In the third and fourth terms students carry out independent project work in biological oceanography under the supervision of an academic advisor from Kiel and/or Odense. At the University of Southern Denmark in Odense, the students will attain a M.Sc. degree in Biology, specialized in Biological Oceanography. At the University of Kiel, this programme will lead to a Diploma degree. The lead partners are the Christian-Albrechts-Universität, Kiel (DE) and the Institute for biology at the University of Southern Denmark, Odense (DK). The contribution of the ERDF is €728,760.

– Harmonisation and upgrading of diagnostic and therapeutic strategies on osteoporosis. This project is developed in the framework of the cross-border co-operation programme between Denmark and Germany INTERREG IIIA Fyn-K.E.R.N. and comprises population-based patient studies and development and validation of a diagnosis instrument. The lead partners are Kiel Polytechnic (DE) and University Hospital of Odense (DK). The contribution of the ERDF is €267,056.

– Helsinki-Tallinn Science Twin City. Developed in the context of the cross-border co-operation programme between Finland and Estonia, the core concept of this project is to foster co-operation between players in the science park environment in the Helsinki (Uusimaa) and Tallinn (Harju) regions. Activities of the programme can be divided into three categories: 1) common curricula, graduate schools and research facilities; 2) exchange/mobility of undergraduate and graduate students and scientists; and 3) high-tech business development (e.g. networking, infrastructural development, start-up, growth and internationalisation phase programmes and other support measures, spin-off mechanisms, incubators, licensing and commercialisation of scientific research results etc.). In order to implement the 3rd item, an INTERREG IIIA Finland-Estonia project was run in 2002-2005. Three fields of science were addressed in the project. These were:

biomedicine and biotechnology; ICT; and material sciences and new technologies. The scope of the programme can be expanded later as new relevant fields of science and the need to foster cooperation within these fields arise. Interest has already been shown in including areas such as environmental, ecological and social sciences and urban studies in the project. The part of the project financed by Interreg IIIA was coordinated by Culminatum Ltd Oy (FI). The contribution of the ERDF was €81,400.

– RETSA. The objective of the project developed in the context of the cross-border co-operation programme between France and Spain is the creation of a food safety network. This network will answer needs and questions at scientific, technical and industrial level in the field of food safety. It will enable the development, the testing and the evaluation of new methods, as well as the exchange and transfer of experience and know-how between participants. This will permit to maintain a level of monitoring and information on food safety which can answer the needs of interested parties, in particular public administrations and enterprises from the food sector. Another objective of this network is to create a virtual centre of competence on food safety: competences of all participants will gather in a single place, decentralised geographically but unified from the point of view of the potential user. This centre will have a sufficient critical mass to launch cooperative research programmes between the different partners within already existing European Programmes (FP6, Eureka, bilateral programmes,…) The lead partner is the Centro Tecnico de Conservas Vegetales - Laboratorio del Ebro (E). The contribution of the ERDF is €537.844,80.

– Utilisation of adult stem cells in cardiologic diseases by regenerative cell therapy. The underlying idea of this project, developed within the framework of the cross-border programme between France and Spain, is based on the following hypothesis: mother cells taken on adult tissues (muscle, marrow and fat) have the capacity to regenerate cardiac muscular tissue damaged by an Acute Myocardial Infarction and can also contribute to the heart's contractile function. Stem cells have to be differentiated in vivo or in vitro from cells having the same characteristics as cardiac tissues. The demonstration of the functional capacity of the mother cells requires the use of an adequate animal model. The lead partner is the University of Navarra (E). The contribution of the ERDF is €974.396.

– Repartir – "REseau de Prospective et d'Animation visant à Renforcer les pôles Technologiques, d'Innovation et de Recherche et organiser leur complémentarité dans le Sud-Ouest Européen". The objective of this project developed within the framework of the trans-national programme "South West Europe (SUDOE)" is to lead a future-orientated reflection enabling coherent and complementary policies in the field of research and innovation, taking into account regional specificities. As a first step, a mapping of excellence in research and technology transfer will be done for the "SUDOE" region. This will permit the partners to present perspectives for each regional scientific and technological centre as part of the European Research Area and to propose a strategy for each region, and for the "SUDOE" as a whole, on areas of emerging new competences. A pilot action will be developed in the field of biotechnology. This action will lead partners to elaborate and draft research programmes for each network and to answer European calls for tender. Partners of REPARTIR + will contribute to ensuring the follow-up of collaboration and set up a research and development observatory

in the SUDOE region. The lead partner is the Réseau universitaire Toulouse Midi-Pyrénées (F).The contribution of the ERDF is €468.458,97.The network will be composed of the following participating regions:

(a) Cataluña : Biotechnology networks;

(b) País Vasco: Nano-materials networks;

(c) Midi-Pyrénées : Aeronautic network;

(d) Galicia and Aquitaine: Economical and societal working group aeronautics, nano-material and biotechnology.

– BioValley: Bio Valley is a tri-national project located between Alsace in France, South Baden in Germany and north-west Switzerland. It already received support during the INTERREG II programme (1997-1999), when support was used to identify the region's principal competences in biotechnology. The new project, supported through INTERREG III, has the objective of developing, on the basis of work undertaken during the INTERREG II period, a real profile as "biotech region" by determining areas of excellence and putting in place appropriate measures. Areas of activity include:

(a) Establishment of the BioValley profile (determination upper-Rhine areas of excellence in the field of biotechnology);

(b) Economic measures (creation of a network of biotech parks, transfer of technology between universities and enterprises);

(c) Communication activities towards scientists, business operators and the general public;

(d) Call for tenders programmes.

The aim is to reach, at the end of the INTERREG III project, self funding via a private structure. The lead partner is the Association Alsace Bio Valley (Illkirch). The contribution of the ERDF is €858.750[48].

The European Territorial Co-operation Objective replaces the INTERREG III initiative for the period 2007-2013. It will continue to provide support for cross-border, trans-national and inter-regional co-operation, including in the area of biotechnology.

Action to be continued as such: the funding of a number of networking activities has facilitated the liaison between scientists and business, improving competitiveness

[48] The project's website is at www.biovalley.com.

Action 9b - Biotechnology clusters

The implementation of action 9b should be refocused in order to identify and exploit the added value of specific cooperation actions between company clusters and bio-regions. Such actions could be supported through FP7 or the Competitiveness and Innovation framework Programme (CIP)[49]. While previous networks have largely focused on the exchange of best practise on regional development (i.e. of cluster management, incubator development, factors for attracting investment, etc), only a few strategic initiatives (such as the "ScanBalt Competence Region"[50], a project aimed at mapping competences within the ScanBalt region[51], identifying strengths and weaknesses, and developing a common strategy for improving overall competitiveness and attractiveness of the ScanBalt Network) exist which develop common strategies and activities within a network of bioregions/clusters with the objective of increasing overall competitiveness of the network. Another interesting initiative has been the creation by the BioValley region[52], supported by the cohesion policy's INTERREG II and III programmes (described further under action 9a above), of a One-Stop portal for the region which provides access to a large pool of Life Science-related jobs that range from research, marketing, management or communications[53]. The need for networking "people" such as young biotechnologists has also been recognised as important for ensuring the future competitiveness of Europe's biotech sector.

The role of biotechnology clusters remains important but action 9b should be re-focused to identify and exploit cooperation between bio-regions to increase competitiveness

Action 10 – Competitiveness monitoring

A contact network with Member States ministries and an Advisory Board in Competitiveness in Biotechnology Group have been created and are fully operational.

Action 10a has been fully achieved. The contact network with Member States ministries with responsibility for competitiveness in biotechnology was set up in 2003. The network has representatives from 20 Member States and meetings are organised at least twice per year. In 2006 the co-operation has intensified and four meetings have been held during the first semester. In preparation of the mid-term review of the Strategy on Life Sciences and Biotechnology and its Action Plan, the network has produced a set of concrete recommendations in four thematic fields: regulation, access to finance, plant science and the knowledge-based bio-economy, and communication with the public[54]: A summary of these recommendations is found in Annex III.

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49 http://ec.europa.eu/enterprise/enterprise_policy/cip/index_en.htm

50 http://www.scanbalt.org/sw225.asp

51 http://www.scanbalt.org/

52 http://www.biovalley.com/

53 http://www.biovalley.com/job_exchange/

54 http://ec.europa.eu/enterprise/phabiocom/comp_biotech_commit.htm

The contact network with Member States will continue to monitor the implementation of biotechnology regulation, the level of harmonisation at national level, and the effects of possible deficiencies.

Action 10b has been fully achieved. The Competitiveness in Biotechnology Advisory Group (CBAG) with industry and academia[55] was set up in 2003. It has delivered three reports in 2004, 2005 and 2006 with relevant policy advice on competitiveness issues that have served as input for the mid term review. The advisory group's reports were prepared for the use of the European Commission, but do not necessarily represent the Commission's official position. The 2006 report of the CBAG and its summary can be downloaded[56].

Action 10 has been fully achieved

Action 11 - Transparency in the administrative process for applicants

With the 2005 reform of the European Medicines Agency (EMEA), the drug development process has been simplified, facilitating the role of SMEs. Together with the recently published User Guide to European Regulation in Biotechnology, transparency in the way this area is regulated has been improved.

In the field of pharmaceuticals, action 11a has been fully achieved. The reform of EMEA (Regulation (EC) No 726/2004 and Regulation (EC) No 2049/2005) has meant a number of improvements:

- reinforced scientific advice as early as possible in the drug development process;
- an SME office to help SME applicants find their way more easily, and to provide administrative assistance such as translations;
- SMEs may also benefit from fee waivers and deferrals.
- In other fields of biotechnology, the Commission is in close contact with operators to help them with the notification procedures.

Action 11b has been fully achieved. The Commission has in collaboration with a consultant developed a User Guide to European Regulation in Biotechnology, which was finalised and published in 2006[57]. It has been conceived to help companies identify routes to regulatory compliance for their products and processes. At the same time, it will help all EU citizens to improve their understanding of the way regulation balances the benefits, risks and ethical issues arising from biotechnology.

Action 11 has been fully achieved

55 http://ec.europa.eu/enterprise/phabiocom/comp_biotech_commit.htm

56 http://ec.europa.eu/enterprise/phabiocom/docs/cbag_2006_final_version.pdf

57 http://ec.europa.eu/enterprise/phabiocom/docs/user_guide_biotech.pdf

Action 12 - Benchmarking of clusters and business incubators

Benchmarking clusters and business incubators have not met the interest that would make it worthwhile to go further with this action.

By contrast, a programme for benchmarking biotechnology policies has been started by the Commission. A first round of benchmarking of national policies took place in 2004 in close collaboration between the Commission and MS governments and was published in 2005. A second round is planned at a later stage to evaluate how far policies have evolved and what impact it has had on the biotech community.

Since 2002, new studies on the role and development of clusters have been made and improved our understanding of their importance. The action does not need to be pursued at the current time.

The benchmarking of clusters and business incubators in view of the current understanding and available studies does not seem necessary. Action 12 does not need to be pursued further

Action 13 - Societal scrutiny and dialogue

In the 2005 Eurobarometer survey on biotechnology[58], 52% of those polled indicated a belief that biotechnology will improve their quality of life. The Eurobarometer "Europeans and biotechnology in 2005" shows that most Europeans are in favour of medical applications of biotechnology when there are clear benefits for human health. They are also in favour of industrial applications, but they are still generally sceptical about agricultural biotech, and will continue to be so unless new crops and products are seen to have societal benefits. Confidence has increased in the European Union's regulation of biotechnology but there is no evidence that this has influenced the public's reported purchasing intentions, especially for GM foods. Overall, optimism about biotechnology's contribution to improving society has grown significantly since 1999. There is also support for research using stem cells, provided this is tightly regulated.

A structured framework for the dialogue with stakeholders to make the regulatory oversight of biotechnology more open and transparent is still only partially achieved. Ongoing efforts to reassure rigour of the scientific risk assessment in the protection of human health and the environment should continue as a high priority. More efforts are also needed to assess and demonstrate how biotechnology can contribute to addressing global challenges. Nonetheless, a substantial number of actions have been implemented by Commission services to achieve the objectives of action 13. There exists a recognised need for the establishment of international quantitative impact indicators for all aspects of life sciences and biotechnology and to conduct a systematic impact analysis on the benefits and risks of biotechnology in order to support a structured and evidence based societal dialogue and policy making process. A close collaboration between the Commission, Eurostat, Industry, Member States and the OECD is needed.

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58 http://www.ec.europa.eu/research/press/2006/pdf/pr1906_eb_64_3_final_report-may2006_en.pdf

The Commission has set up the **Pharmaceutical Forum**, a senior platform which is designed to provide a broad political mandate to discuss and agree ways forward on key non-legislative issues that have an impact on European competitiveness and related health policies. Working groups set up under the Forum will treat three major, controversial and long-standing issues, namely pricing and reimbursement, relative effectiveness assessments and information to patients. The Pharmaceutical Forum is of strategic importance and the activity will continue. Depending on the outcome it may become possible to achieve common understanding at European level on several of the topics discussed.

The Commission has organised various **scientific meetings and workshops**[59] to raise awareness for the state of the art and existing challenges regarding measurements in life sciences and biotechnology. Particular topics such as reliability and comparability of bioanalytical measurement data, the evaluation of measurement uncertainties and their consideration for decision making processes as well as the full range of standardization and metrology for bioanalysis have been addressed. Measurements of biological molecules and other entities can still impose considerable challenges and international harmonisation is ongoing. The activities have to be continued at the various levels of the international technical measurement infrastructure and between scientists, industry and regulators.

In December 2003 the Commission organised the first stakeholder conference with the objective of exploring the effect of human perception on **risk assessment** and its significance and implications in promoting key scientific paradigms underlying regulatory oversight and governance. In particular, the conference addressed the issue of risk assessment and risk analysis, and how these processed could be improved.

Ever since, the European Commission has continued to take action to reassure the general public, stakeholders and Member States that Community decisions on GMOs are based on rigorous scientific assessments which deliver a high level of protection of both human health and the environment. To this end, the Commission has adopted a series of actions in its orientation debate of 12 April 2006. The Commission presented these actions to the Environment Council in June 2006 and Member States welcomed the Commission's proposal. The Commission will continue to work together with Member States EFSA, and stakeholders in the coming months with the objective of building greater consensus and transparency in this area of Community policy. Some steps have already been taken to ensure greater transparency in the risk assessment procedures, such as the recent public consultation organised by EFSA on GMO feeding trials[60]. However, more actions probably need to be undertaken to assess the current as well as the potential future benefits of agriculture biotechnology and therefore enhance society acceptance and confidence.

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[59] International Reference Material Conferences BERM-9, Berlin (DE), 2003 and BERM-10, Charleston (US), 2006; Brainstorming Workshop of the Joint Committee on Traceability in Laboratory Medicine (JCTLM), 2003; Conference "Confidence in measurements", Geel (BE), October 2005; Int. Symposium on Reference Materials for Genetic Testing, Geel (BE), 2005

[60] http://www.efsa.europa.eu/en/press_room/press_release/pr_gmo_feeding.html

By Commission Decision 2004/613/EC of 6 August 2004, the Commission has created an **advisory group on the food chain and animal and plant health**. The advisory group comprises 36 members representing different economic sectors, consumers and animal welfare organisations. These stakeholder representatives are consulted on health and consumer protection work programmes and measures in the areas of food safety, labelling, human nutrition, animal health and welfare and plants and pesticides. If there was need, a focus group on biotechnology could be set up within this advisory group

In the field of Community **research and development policies**, the Commission has developed a number of activities in the field of governance, notably regarding the participation of civil society in decision making processes, the collection and use of expertise and scientific advice.

At programme level, Civil Society Organizations and NGOs are increasingly becoming members of the advisory groups for the implementation of the various thematic priorities under Research Framework Programmes. Actions have been taken to launch public consultations in relation to the preparation of the research priorities including under the thematic priority on Sustainable development[61].

At project level, initiatives have been taken to involve for **example consumer and patient organisations** in research projects from the very beginning of a new project, rather than at the final stage, for instance, in relation to the acceptance of new food products. Behavioural studies and food choice aspects have been incorporated particularly in Integrated Projects. Examples of this approach are those projects aimed at developing new food products for reducing the prevalence of chronic diseases or networks that started under the initiative of patient associations[62]. Furthermore, in drawing up the work programme for the final Food Quality and Safety Programme Call for Proposals, specific efforts have been made to include consumer interests in research projects by making consumer aspects a requirement in specified programme areas.

Specific projects regarding the process of governance were supported, addressing issues of scientific advice, risk governance and the participation of civil society, notably in the field of GMOs, stem cells and so forth[63].

As a conclusion, a continuation of the effort made by the European Union – and its Member States – in recent years to draw together the "innovation triangle" (science, society and the economy) remains a priority.

One of the main conclusions which can be drawn from current experience is the need to involve Civil Society Organisations early in the research process and on a permanent basis and not only launching individual actions in relation to the implementation of programmes or projects. The experience gained may also contribute to the development of a framework for dialogue as proposed under action 13a.

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61 http://europa.eu/press_room/presspacks/sustdev/index_en.htm

62 Integrated Project LIPGENE www.lipgene.tcd.ie

63 http://ec.europa.eu/research/science-society/page_en.cfm?id=3132

This could imply a more systematic involvement of Civil Society Organizations, NGO's and other interest groups, such as networks of young biotechnologists, in the implementation of the strategy and should be encouraged. This could include:

– The establishment of a Civil Society Organization forum to assist the Commission in the implementation of the strategy. Initial steps have already been taken through announcement of the creation of this new forum on the revised Biosociety and KBBE Website and the invitation to Civil Society Organization and others, including individuals, to register for further information and to become involved in the broad based debate on the future of life sciences (particularly in food, agriculture and biotechnology);

– A more systematic involvement of Civil Society Organization and NGOs in, for example, technology platforms, research projects or conferences at community as well as at national level to discuss amongst other things research agendas, to assess research findings and to make the regulatory oversights of biotechnology more open and transparent. For example Civil Society Organizations were co-organising a EC conference on Stem Cells and their Therapeutic Applications in 2005 and CSOs will be invited to take part in the forthcoming foresight conference to be held early 2007 to consider the future of food and the food industry in 2030;

– Promote initiatives lead by Civil Society Organisations e.g. organisation of conferences or support the outsourcing of research in relation to the activities of this typt of organisations, including the dissemination of results to the public. FP7 will support such activities along with other mechanisms;

– Encourage research institutions to support innovative governance experiences.

The need to undertake impact assessment studies as one of the tools to inform the public and structure the debate should be highlighted. The inclusion of sustainable consumption and production among the priorities of the Sustainable Development Strategy will require enhancing the consideration of impact assessment in relation to policy dialogue. There is a need to develop new and better assessment tools regarding the economic, social and environmental impact of biotechnology. These aspects will be addressed in FP7.

The Commission as well as many Member States have called for an engagement of scientists with the public, at different levels. However scientists and in particular young scientists are faced with a paradigm, since going out of the laboratory and the need to communicate more actively with society in the early stage of a scientific career is not being emphasised. If we do not target directly early stage researchers, it will be impossible to develop a future scientific community integrating public engagement and interaction within its structural values and public duties. There is a need to take into account non-scientific experiences, in particular communication and engagement with public.

Action 13 should continue to encourage societal debates on the benefits and risk of life sciences and biotechnology

Action 14 - Better integration of socio-economic and ethical issues

This action aiming at better integration of socio-economic and ethical issues has been successfully implemented in FP6 and it is the Commission intention to continue to apply these tools for governance of research under FP7 (2007-2013). This action should be refocused to better reflect the intention of the Commission to define and apply ethical framework and standards for FP7, so as to reinforce the ethical review as well as encourage the participation of ethicists, lawyers, patient organisations, farmers, animal welfare organizations, and other stakeholders in research projects thereby active engagement in public dialogue could be envisaged.

In order to ensure that fundamental ethical principles are respected and the ethical, legal, social and wider cultural aspects are taken into account at the earliest possible stage of Community–funded research in Life Sciences and Biotechnology, involving the general public to the greatest extent possible, the Commission has taken a number of actions, under FP6 including:

– Defining an ethical framework and ethical standards for FP6[64];

– Reinforcement of the ethical review of project proposals that raise sensitive ethical issues or where ethical issues have not been properly addressed as part of the funding evaluation process, which is carried out by independent external experts. This additional assessment aims to make sure that the EU is not supporting research which might violate fundamental ethical principles;

– Encouraging the participation of social scientists and ethicists in research projects as well as integration of the analyses of the ethical, legal and social aspects into research projects funded under Priority 1 "Life sciences, genomics and biotechnology for health" and Priority 5 " Food quality and safety";

– Encouraging participation of stakeholders, including NGOs, in research projects and dialogue with the wider public in the research strategy;

– Supporting specific actions to promote the debate on ethical, legal, social and wider cultural aspects of Life Sciences and Biotechnology, as well as monitoring and evaluating consequences[65].

In summary, this action remains of strategic importance and it is the Commission's intention to continue to apply these tools for governance of research funded under FP7. Governance of research, in particular at project level, should also be encouraged at national level.

Action 14 should continue to promote the integration of socio-economic and ethical issues

[64] http://ec.europa.eu/research/science-society/page_en.cfm?id=3199

[65] http://ec.europa.eu/research/science-society/page_en.cfm?id=3120

Action 15 - European Group on Ethics –EGE and related activities

The European Group on Ethics (EGE)[66] is an independent, pluralist and multidisciplinary body which has the institutional role of advising the European Commission on ethical aspects of science and new technologies.

Following the Communication from the Commission (COM(2005) 243 final), and a request from the President, the EGE issued in January 2007, an Opinion on the Ethics of nanomedicine[67]. During 2006, the EGE has had hearings with relevant experts on a bi-monthly basis, met the Austrian National Ethics Council (NEC) in May 2006 -under the Austrian Presidency-, met both the FI NEC under the Finnish Presidency and, also on that occasion, the National Ethics Councils Forum (EU 25 NEC) in September 2006. The EGE also organised a public round table on ethics and nanomedicine in March 2006.

The Global dimension of science and technology and the intention of the Commission to take an active role in discussions on ethical, legal and social implications of biotechnology are not news but the main challenge is the relevance the Commission is attributing to it by promoting and actively participating in debates on ethics in the EU and beyond. Therefore, actions focusing on international dimensions will be carried out (networking between relevant ethics bodies and the creation of an International discussion platforms on ethics and science) as well as actions to reinforce the role of the EGE in current debates on ethics of science and new technologies.

An International Platform clustering National Ethics Councils of several non-European Countries will be established by the EGE Secretariat, and a platform between the Commission services dealing with ethics and bioethics has been established in the second half of 2006. The platform will be chaired by the Bureau of the European Policy Advisors (BEPA) to the President and will discuss the European Union's actions in the fields of ethics and European policies.

Networking of ethical bodies will remain an important task of the Commission. Some examples of networking activities promoted and supported by the Commission include: a) A Forum of National Ethics Councils (NEC Forum) established in 2003 now involving all 27 Member States[68]. It consists of the chairpersons and the secretaries of the national ethics councils; b) a European Network of Research Ethics Committees (EUREC) which will consist of almost all national associations of research ethics committees in Europe.

Action 15 should continue

66 http://ec.europa.eu/european_group_ethics/index_en.htm

67 http://ec.europa.eu/european_group_ethics/activities/docs/opinion_21_nano_en.pdf

68 http://ec.europa.eu/research/science-society/page_en.cfm?id=3161

Action 16 - Ethical guidance for best practice in the context of EC funded research projects

The need for the development of ethical guidance for best practice in the context of EC funded research projects has been highlighted in the area of Life Sciences and Biotechnology during FP6 and should be pursued. Many emerging issues (cloning of animals, use of non human primates for non-medical research…) and the high importance of ethical issues for public acceptance of biotechnology justify a particular priority being given to action in the field of ethics.

The Commission is closely following the regulatory developments in Member States regarding biobanks, stem cell research and genetic testing[69].

The development of guidelines on ethics which go beyond guidance for EC funded research is not likely to be achievable. However the experience from the ethical review and the implementation of research projects in the areas of Life Sciences and Biotechnology under FP6 have underlined the need to develop guidance for EC funded projects and an educational package is currently being prepared and should be available in early 2007. This will be the core curriculum to enable the research community to address ethical issues throughout an EC funded project lifecycle.

Action 16 should continue under FP7

Action 17 – Coexistence of GM crop with conventional and organic farming

Coexistence remains a key issue for the development of green biotechnology in the EU. The adoption of legislation on co-existence is under the competence of Member States. In 2003 the Commission adopted Recommendation 2003/556/EC on guidelines for the development of national strategies and best practices to ensure the co-existence of genetically modified crops with conventional and organic farming, which is intended to help Member States develop national legislative or other strategies for coexistence.

Actions will continue to be undertaken by the Commission in this field, in particular further to the conclusions of the April 2006 co-existence conference in Vienna and the May 2006 Agriculture Council conclusions. The emerging non-food/feed uses of GM crops (biofuel, industrial raw materials and pharmaceuticals) will require further action. These new types of GMOs provide challenges with respect to the risk assessment, but also with respect to co-existence, given the possible need for specific thresholds. There is currently much interest in non-food GMOs, so this emerging issue needs to be tackled.

Significant progress has been made in the field of co-existence. The Commission continued to assess national co-existence measures that were notified to the

[69] http://ec.europa.eu/research/biosociety/bioethics/documents_en.htm

Commission under the procedure of Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations[70].

New case studies on the co-existence of GM and non-GM crops in European agriculture were published by the Commission in January 2006[71].

On 9 March 2006 the Commission adopted a report on the implementation of national measures on the co-existence of genetically modified crops with conventional and organic farming[72]. This provides an overview of national co-existence measures adopted or being discussed in the Member States. In the report the Commission proposes a number of future actions to be taken in relation to co-existence.

In March 2006 the Commission also launched a study on liability in cases of damage resulting from the presence of GMOs in non-GM crops, which is aimed at providing an overview of the present legal situation in the Member States on this issue.

On 4-6 April 2006 the Commission jointly organised with the Austrian Presidency of the Council the conference "Co-existence of genetically modified, conventional and organic crops – freedom of choice"[73], which took place in Vienna. This conference allowed an exchange of information and positions on co-existence among policy makers, scientists, and a broad range of stakeholders, such as farmers and consumers' associations, NGOs, seed producers, importers, food and feed processors, etc.

On 9 May 2006 the Council adopted conclusions on co-existence, which include general considerations on this issue as well as proposals for future actions by the Commission.

The coordination network on co-existence, COEX-NET, has continued its activities, which are aimed at enhancing the exchange of information among Member States on regulatory approaches and practical experiences of co-existence. Future activities of this network group will be of particular importance to further the exchange of information among Member States on co-existence.

The increased use of stacked GM events poses new challenges to the development of quality assurance tools for the measurement of individual and combined GM events in crops.

The Commission has developed 9 new sets of certified reference materials for the identification and quantification of genetically modified crops. This supports also the reliable differentiation between conventional/organic farming and GM crops. Further research activities in relation to co-existence are funded under FP6, notably the large research projects SIGMEA, CO-EXTRA and TRANSCONTAINER with a total joint budget of €17 million in which the Commission also participates. Following the two

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70 Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations, OJEU L 204, 21.7.1998, p. 37–48

71 http://www.jrc.es/home/pages/detail.cfm?prs=1345

72 COM(2006)104 final

73 http://ec.europa.eu/agriculture/events/vienna2006/index_en.htm

calls for proposals, 17 actions were selected for co-funding, and the corresponding grant agreements, involving 17 coordinators and 162 partners in 25 Member States and 12 countries outside the EU have been signed.

Concerning the conservation of genetic resources in agriculture, the Commission put forward a proposal for the establishment of a new Community Programme, which was adopted by Council on 24 April 2004 (Council Regulation (EC) No 870/2004). The Community Programme, which covers the period 2004-2006, has a total budget of €10 million. It applies to the conservation, characterisation, collection and utilisation of plant, animal and microbial genetic resources that are or could be of use in agriculture. A corresponding work programme was adopted by the Commission on 28 December 2004[74]. The first call for proposals was launched on 26 July 2005[75] and a second call on 28 April 2006[76].

The actions that will be co-funded have a maximum duration of 4 years. The implementation of the Community Programme will cover the period until 2010.

The stated objective of launching a new action programme for the conservation, characterisation, collection and utilisation of genetic resources in agriculture in the Community has thus been fully achieved.

Scientific support for the implementation of co-existence, as well as the agricultural, environmental and economic assessment of policies remains important. FP7 will continue to support this area of research including the development of new assessment tools.

As a conclusion, co-existence will remain an important issue to be addressed in the future. Only a few Member States have already adopted national co-existence measures. Many Member States have not yet developed a legislative framework for coexistence or good farming practices for technical field measures in relation to crop segregation. Practical experience with commercial GM crop cultivation is still limited in most Member States. Amongst other measures, a need for guidelines with crop specific segregation measures, guidance in relation to cross-border issues, and sustainable solutions in cases, where co-existence is difficult to establish at local level, have been identified. In this context, research will continue to play an important role. Furthermore, the Council invited the Commission to explore whether further steps towards common principles regarding co-existence should be taken and to adopt labelling thresholds for the adventitious presence of GMOs in conventional seed lots. Based on an impact assessment which will be carried out in 2007, the Commission will consider whether it is necessary to establish these thresholds and for which products.

The Commission will continue its activities in relation to co-existence. It will carry on to assess national co-existence measures and to support research activities under the Framework Programme as well as via direct research conducted by the Joint Research Centre (JRC) in relation to co-existence. It will continue work on suitable

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74 C 5355/2004

75 OJEU C183 of 26 July 2005

76 OJUE C102 of 28 April 2006

approaches to implement the mandate for further work on co-existence provided by the Commission's co-existence report and the Council conclusions. In particular, the Commission will establish a Bureau for the elaboration of crop-specific guidance documents for co-existence measures, including, where appropriate, measures aimed at preventing cross-border problems and recommendations for regions, where farming conditions make farm-level co-existence difficult to achieve.

Concerning the conservation, characterisation, collection and utilisation of genetic resources in agriculture, Council Regulation (EC) No 870/2004 foresees an evaluation of the Community Programme by independent experts at the end of the Programme. The evaluation report shall assess the results of the Programme and make appropriate recommendations, and it shall be submitted to the European Parliament, the Council and the European Economic and Social Committee. The discussion on the need for revising the current policy, considering also new and emerging challenges, will take place in this context.

The objective stated in Action 17 regarding co-existence was met, but further activities in this area are required

Action 18 – Legislative development in the field of pharmaceuticals

The aim of this action was to speed up the adoption of three legislative proposals in the field of pharmaceutical.

Regarding action 18a, scientific advice has been reinforced and made easier in the 2004 revision of the Pharmaceutical legislation. Each committee of the EMEA has now established a standing working party with the sole remit of providing scientific advice to undertakings. The EMEA has also put in place a 'New Framework for Scientific Advice & Protocol Assistance'[77], which introduces significant changes to the way the Agency provides scientific advice on the research and development of new medicines. The main aspects of the new framework include:

– earlier and greater systematic involvement of internal and external experts from the pre-submission phase to the final adoption of scientific advice;

– faster delivery of the advice to sponsors to allow finalisation within 40 to a maximum of 70 days;

– increased transparency and communication with stakeholders.

Regarding action 18b, an accelerated procedure has been introduced in the 2005 revision of the Pharmaceutical legislation. When an application is submitted for a medicinal product that is of major public health interest and in particular from the viewpoint of therapeutic innovation, the assessment time may be reduced from 210 to 150 days.

[77] http://www.emea.eu.int/pdfs/human/press/pr/16597406en.pdf

Regarding action 18c, a Regulation on the conditional marketing authorisation for medicinal products for human use falling within the scope of the 'centralised procedure' (e.g. biotech products) has been adopted in March 2006[78].

The action can now be considered as achieved with objectives completed

Action 19 - New legislation on GM food and feed, and on the labelling and traceability of GMOs

The aim of this action was the adoption of new legislation on GM food and feed, and on the labelling and traceability of GMOs.

On 10 May 2006 the Commission issued to the Council and the European Parliament a report on the implementation of Regulation(EC) No. 1830/2003, based on the input from all involved stakeholders[79]. The majority of stakeholders have pointed to the fact that the Regulation has only been operational for a limited period of time and that experience in terms of its implementation is extremely limited. Therefore the Commission will draw up a second report, following a further period of 24 months to enable a more complete picture of implementation to be obtained.

Furthermore, on 25 October 2006, the Commission adopted a report to the Council and the European Parliament on the implementation of Regulation (EC) No 1829/2003 of the European Parliament and of the Council on genetically modified food and feed[80].

The objective has been fulfilled and action 19 can now be considered as achieved

Action 20 - GM plant propagating material, environmental liability and the implementation of the Biosafety Protocol

This action can be considered as achieved, since the Biosafety Protocol[81] has been ratified and implemented by the EC, the final piece of legislation adopted to this extent being Regulation 1946/2003[82]. Directive 2004/35/EC on environmental liability[83] has also been adopted, and there is no planned legislation on GM plant propagating material on top of GMO legislation.

The objective has been fulfilled and action 20 can now be considered as achieved

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78 http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_507/reg_2006_507_en.pdf

79 Report from the Commission to the Council and the European Parliament on the implementation of Regulation (EC) No 1830/2003 concerning the traceability and labelling of genetically modified organisms and the traceability of food and feed products produced from genetically modified organisms and amending Directive 2001/18/EC, COM/2006/0197 final

80 COM/2006/0626 final

81 http://www.biodiv.org/biosafety/default.aspx

82 Regulation (EC) No 1946/2003 of the European Parliament and of the Council of 15 July 2003 on transboundary movements of genetically modified organisms (Text with EEA relevance), OJEU L 287, 5.11.2003, p. 1–10

83 Directive 2004/35/CE of the European Parliament and of the Council of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage, OJEU L 143, 30.4.2004, p. 56–75

Action 21 - Implementation and enforcement activities

As far as the adoption of implementing measures under Regulation 1829/2003 and Directive 2001/18/EC are concerned this action should be considered as achieved. An updated list of the implementing measure of Directive 2001/18/EC and Regulation (EC) No. 1830/2003 can be found on the Europa webpage[84]. Reports on the implementation of the above mentioned legislation are published on a regular basis. Complementing this strictly regulatory approach, detailed information and further guidance is provided by the Commission on reference materials, validation processes and activities of the Community Reference Laboratory for GM Food and Feed[85]. Given the huge importance of reference material and detection methods for the enforcement of EC legislation, and in light of the recent Bt10, LL601 and Chine rice scandals, this action needs to be refocused and continued.

As far as the legal framework on GMOs is concerned, all Member States apart from France have notified the Commission of their transposition acts of Directive 2001/18/EC. The conformity check on these acts is currently ongoing. Two infringement procedures are currently open: one against France for non transposition of Directive 2001/18/EC and one against Poland for a general ban of GM seeds. Furthermore, there is one pending case at the ECJ regarding the imposition of a general ban on GMOs in the region of Upper Austria.

The Commission is also checking the legality of the co-existence measures of Member States as notified under the procedure of Directive 98/34/EC.

In addition to the regulatory work on GM Food and Feed (Regulation 1829/2003) and on traceability and labelling (Regulation 1830/2003), the Commission has issued Commission Recommendation 2004/787/EC on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation 1830/2003[86]. These guidelines also provide principles for expressing percentages of GMOs. Moreover, Commission Regulation 65/2004, establishing a system for the development and assignment of unique identifiers for GMOs, was adopted as implementing measure of Regulation 1830/2003 on traceability and labelling.

The uniform implementation and monitoring of the EU legislation on GMOs has been supported by the development, production and distribution of new generations of matrix reference materials. Since 2002, the following GMO Certified Reference Materials, each consisting of sets of different GMO concentrations, have been released: RoundupReady®soybean, Bt-176 maize, Bt-11 maize, GA21 maize, NK603 maize, MON 863 maize, MON 863 x MON 810 maize, 1507 maize, and MIR604 maize. These reference materials are widely used by Member State

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84 http://ec.europa.eu/environment/biotechnology/index_en.htm

85 http://gmo-crl.jrc.it/

86 Commission Recommendation of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation (EC) No 1830/2003Text with EEA relevance, OJEU L 348 , 24/11/2004 P. 0018 - 0026

laboratories and worldwide for calibration and quality assurance to fulfil regulations EC 1829/2003 and EC 1830/2003.

A Regulation on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 as regards the CRL for GMOs, settling the issue of the contribution of applicants to the costs of the CRL and defining tasks and duties of CRL and of the European Network of GMO Laboratories has been adopted by the Commission on 22 December 2006[87].

The development of independent calibration standards for the quantification of a wide range of GM products in the frame of the labelling regulation represents a considerable scientific challenge. Moreover, the creation of quality assurance tools which mimic closely the status of various commercial food products with respect to their analytical measurement behaviour poses additional challenges to reference material developers.

As far as the adoption of implementing measures under Regulation 1829/2003 and Directive 2001/18/EC are concerned, this action should be considered as achieved. Nonetheless, activities on reference materials and validation processes of detection methods are of key importance and need to be pursued

Action 22 – Further improve the consistency of the legal framework on GMOs

The action to improve the consistency and efficiency of the regulatory framework for the deliberate release of GMOs into the environment has been partially implemented with the entry into force of the so called "one door one key" procedure under Regulation 1829/2003. The Commission has issued its report on the implementation of Directive 2001/18/EC on 5 March 2007[88]. As shown by the April 2006 College orientation debate, work to improve the consistency and the efficiency of the regulatory framework is still needed.

Action 22 needs to be continued

Action 23 – Long term environmental impact of GMOs

How to assess the potential long term positive and negative effects of GMOs on the environment and health remains a key issue, both scientifically, technically and politically, in particular with the arrival of so-called second and third generation of GMOs Currently commercially available GM crops (first generation) concern agronomic input (production) traits and emerging GM crops (second and third generation) include more complex traits and the production of novel products through molecular farming. There is clearly a need for further improvement in risk assessment practices as regards long term effects on the environment and

87 Commission Regulation (EC) No 1981/2006 of 22 December 2006 on detailed rules for the implementation of Article 32 of Regulation (EC) No 1829/2003 of the European Parliament and of the Council as regards the Community reference laboratory for genetically modified organisms (Text with EEA relevance), OJ L 368, 23.12.2006, p. 99–109

88 Second report from the Commission to the Council and the European Parliament on the experience of Member States with GMOs placed on the market under Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms. COM/2007/0081 final

biodiversity for reasons of substance (experience with import and cultivation of GMOs in Europe somewhat limited) and in order to increase confidence in the scientific basis of the decision-making process on GMOs. This action should be given high priority given its key role in restoring confidence in the regulatory process and in preparing methods to address forthcoming challenges. In particular it is important to further address the potential contributions of GMOs to address global challenges. European agriculture faces major challenges related to climate change, for instance regarding water management. Biotechnology could contribute towards helping EU agriculture to address some of these challenges while maintaining its competitiveness.

New and emerging issues on GM crops for non-food uses, such as in agricultural production of biofuels, biomass, industrial raw materials and pharmaceuticals will require further attention. The development of molecular farming raises new opportunities but poses also new challenges and makes the development of quality assurance tools a high priority. Consideration should be given to regarding how future GMOs for non-food applications (e.g. for producing vaccines or monoclonal antibodies) could be produced in a way which does not compromise the safety of food production and biodiversity. There may therefore be a need to adapt existing guidance on the environmental risk assessment and monitoring of potential adverse effects on the environment, including the long-term effects, of particular types of GMOs, like animals, or for particular uses of GMOs, such as non-food applications.

Under FP6 several research projects have started on GM traceability and safety of which the most important ones are SAFEFOODS and NOFORISK. On a regular base EFSA and Commission services are informed about the progress of these projects.

How to assess long term effects on the environment and health of GMOs at the pre- and post-market assessment stage remains a scientific challenge that will be addressed under FP7.

EFSA has established a self-tasking working group to study requirements for Post Market Environmental Monitoring (PMEM WG) in order to produce guidance for both applicants and regulatory authorities. Based on its mandate, the PMEM WG initiated a series of consultation workshops with different stakeholders (applicants, environmental NGOs and scientific institutes, experts from Member States) to establish a rationale and general framework for General Surveillance as a component of Post Market Environmental Monitoring[89]. EFSA's PMEM Working Group intends to publish a new version for the chapter 11.4 "General Surveillance of the Impacts of the GM Plants" of the "Guidance Document for the Risk Assessment of GM Plants and Derived Food and Feed".

The Commission has also established a Working Group with the Competent Authorities designated under Directive 2001/18/EC, to examine these issues. It is expected to finalise its work in 2007.

The Commission and EFSA will endeavour to define how monitoring plans should be tailored to address potential long-term effects taking into account the work of the

[89] http://www.efsa.europa.eu/en/science/gmo/gmo_consultations/483.html

Member State Monitoring Working Group which has been established under Directive 2001/18/EC (c.f. Annex VII) and the implementing measure adopted under Directive 2001/18/EC which addresses the objective, general principles and design of the monitoring plan[90]. Moreover, in view of the outcome of the risk assessment, further consideration will be given as to the extent of risk management measures required to address potential long-term effects. Further consideration is also needed on whether and how relevant representative geographical areas in relation to the release of the GMO in question could be taken into account in the context of the above exercise.

Action 23 should be given a high priority as further assessment of the long term positive/negative effects of GMOs on the environment and health is key to the implementation of the relevant legislation

Action 24 – Development of international standards in the field of biotechnology

The recent incidents with the transboundary movement of unapproved GMOs demonstrate that there is an urgent need to further develop the framework for the international governance of GMOs. The EU should continue to play a leading role in developing international guidelines, standards and recommendations, in particular regarding the implementation of the Cartagena Protocol on Biosafety and activities in standards bodies and Codex (including the discussions on adventitious presence), where the Commission continues to play a key role.

The Commission actively participates in the meetings of the Codex Task Force on Biotechnology. This Task Force has produced guidelines for the food safety assessment of plants and micro-organisms derived from modern biotechnology. Work is ongoing in order to develop a similar guidance document for the food safety assessment of recombinant DNA animals and plants modified for nutritional or health benefit. The Task Force has agreed in its 6th session to commence work on the low level presence of recombinant-DNA plant material in food resulting from asynchronous authorisation. The focus of this work will be two-fold; on developing guidelines on the risk assessment of this low-level presence and on the data and information mechanisms necessary to facilitate this assessment.

The Commission plays a lead technical role in a number of international bodies that are responsible for setting the standards such as:

– CEN: the European Committee for Standardisation[91];

– ISO: the International Organization for Standardization[92];

– Codex Alimentarius[93].

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90 Council Decision 2002/811/EC of 3 October 2002 establishing guidance notes supplementing Annex VII to Directive 2001/18/EC of the European Parliament and of the Council on the deliberate release into the environment of genetically modified organisms and repealing Council Directive 90/220/EEC, OJ L 280 , 18.10.2002 p. 27 – 36.

91 http://www.cenorm.be/cenorm/index.htm

92 http://www.iso.org/iso/en/ISOOnline.frontpage

The Commission has contributed significantly to the development of international guidelines and standards for bioanalysis. For instance, the revision of ISO Standards (such as 15193 'reference measurement procedures for in vitro diagnostics' and 15194 'reference materials for in vitro diagnostic measurements') and ISO Guides (such as Guide 35 'certification of reference materials') and the development of new standards for GMO analysis (such as EN ISO 21570 'quantitative DNA-based detection standard', EN ISO 24276 'general document', EN ISO 21571 'DNA extraction standard', EN ISO 21572 'protein based method standard', EN ISO 21569 'qualitative DNA-based standard') were performed with the support of the Commission's Joint Research Centre.

Scientific advice, recommendations and measurement standards are regularly provided to international metrology, standardization and accreditation bodies such as CIPM/CCQM, CEN, ISO, AOAC, EA and ILAC. By that the international measurement system and infrastructure is further developed and supported to allow the obtaining of reliable and harmonised measurement results in life sciences and biotechnology. The Commission is also involved in the Joint Committee for Traceability in Laboratory Medicine (JCTLM). It co-chairs the WG 'Reference materials and reference methods' for the evaluation of corresponding applications for inclusion in the JCTLM/BIPM database of materials and methods of higher order for in vitro diagnostics.

The Commission chairs the European Network of GMO Laboratories, which is a consortium of all 25 EU enforcement laboratories (plus Norway, Switzerland). In addition to providing support to the Community Reference Laboratory for GM Food and Feed, this network contributes to the harmonisation and standardisation of GMO detection protocols. In this context the Commission is developing a guidance document on the evaluation of the measurement uncertainty during GM quantification. In 2004 The Commission's DG JRC/IRMM pioneered to become worldwide the first institution to be accredited for the production of GM reference materials.

In the context of nanobiotechnology, the Commission contributes to the planning and performance of research for new testing methodologies for risk assessment of engineered nanomaterials and the development of new biosensors. The Commission participates in CEN and ISO Technical Committees for the development of international standards in the field of nanotechnologies. A strategy for the Commission's activities with regard to nanotechnology, in particular nanobiotechnology, is currently being prepared on the basis of a Commission action plan from 2005[94].

The further development of international guidelines and standards, including measurement standards, for harmonised and reliable measurements of a large range of parameters relevant to life sciences and biotechnology continues to make necessary major scientific challenges.

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[93] http://www.codexalimentarius.net/web/index_en.jsp

[94] http://cordis.europa.eu/nanotechnology/actionplan.htm

Information on recent developments under the Cartagena Protocol on Biosafety is available online[95]. The Cartagena Protocol has now been ratified by 138 countries. For 2007, work is continuing in particular on liability and redress (Article 27 of the Protocol), identification of living modified organisms (Article 18.2(a) of the Protocol) as well as on capacity building, the Biosafety Clearing House, risk assessment and further development of the Roster of Biosafety Experts.

Action 24 needs to be continued

Action 25 - Cooperation with the developing world in the field of agricultural biotechnology

Biotechnology has also a potential to contribute to the objective of the EU's Development Cooperation Policy Framework, which emphasises that the EU will promote the integration of development objectives into its R&D and innovation policies, and that the EU will continue to assist developing countries in enhancing their domestic capacities in the area of Sciences and Technology. Indeed, the EU already supports global, regional and national efforts in research and development to address the special needs of developing countries in the areas of health, including prevention and treatment of HIV/AIDS, agriculture, natural resource, environmental management, energy, and climate.

The Strategy is highly relevant to three of the 12 of the Policy Coherence for Development[96] thematic priorities (Environment, Agriculture, and Science and Innovation), and development issues should continue to be taken into account, special attention being given to:

– Engaging in scientific partnerships with developing countries so that they benefit from technological development, amongst others, in the field of agricultural and environmental research;

– Addressing specific problems that third countries face or that have a global character, and where biotechnology can contribute to finding solutions;

– Pursuing the EU commitment to a strengthening and implementation of the Cartagena Protocol on Biosafety[97], of the Bonn Guidelines on Access and Benefit Sharing and of the FAO International Treaty on Plant Genetic Resources for Food and Agriculture.

Thus, this action aiming at enhancing cooperation with the developing world in the field of agricultural biotechnology still remains important and should possibly be reviewed in the context of the UN Millennium Development Goals[98].

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95 http://www.biodiv.org/biosafety/default.aspx

96 Joint Development Policy Statement or "European Consensus on Development" (JDPS), adopted by the Council, the European Parliament and the Commission in 2005

97 http://www.biodiv.org/biosafety/default.aspx

98 http://www.undp.org/mdg/

The Commission has played a key role in the elaboration and entry into force of the Cartagena Protocol on Biosafety[99], and continues to be one of the driving forces in its further development (for example in the field of identification of GMOs or in reflection on possible liability regimes). The Cartagena Protocol is a key element of cooperation with the developing world in the field of agricultural biotechnology.

The INCO programme has launched two calls aiming at promoting international research with the Developing Countries on "Bio-diverse, bio-safe and value added crops" which is a research area of the 'food security' priority. The area deals with research to increase the sustainable use and productivity of annual and perennial under-utilised tropical and sub-tropical crops and species important for the livelihoods of local populations. This means crops with a potential for wider use contributing to food security, agricultural diversification and income generation. The calls emphasized the need for innovative tools and techniques for the characterisation, development and use of crops with enhanced tolerance to abiotic stress, particularly 'Tolerance to drought, salinity, heat, cold'; 'Enhanced nutrient uptake' and 'Enhanced tolerance to heavy metals and acid soil'. INCO teams are set up on the principle of equitable partnership building (3+3). Calls were also launched on “Health of livestock populations” largely focused on livestock health protection through the development and use of diagnostic tools and vaccines.

The Commission is also engaged in the selection of research proposals from the CGIAR[100] and in particular of co-funding the Generation Challenge Programme (GCP). This programme aims to unlock the genetic diversity of crops for the resource-poor. The activities of the GCP are centred on identifying genetic diversity of the genetic resource collections of the CGIAR, comparative genomics, improving plant traits, bio-informatics and capacity building.

A number of projects involving partners from developing and "emerging" countries have been implemented under the thematic priority "Food quality and safety". These projects cover a large range of issues including:

– Adaptation to European food quality and safety standards of food products in exporting countries, including food traceability and food-chain approach;

– Establishment of scientific fora fostering bilateral dialogues in the area of food, agriculture and biotechnology research (including trade-related issues) between the EU and other regions in the world;

– Global issues interesting Europe and different regions in the world like sustainable use of water in agriculture, mycotoxins in food products, food allergies, food born diseases, the use of microbial resources, agricultural biodiversity, food processing wastes, diet and health, epizootics and zoonotic diseases.

As a conclusion, this action remains important and should be reviewed in the context of the UN Millenium Development Goals.

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99 http://www.biodiv.org/biosafety/default.aspx

100 http://www.cgiar.org/

International cooperation will be addressed in all programs under FP7 and priorities will be defined according to the principle of mutual benefits and shared interests between the EU and the targeted region, taking into account local needs and socio-economic contexts. Special attention will be given to the achievement of the UN Millenium Development Goals in the case of "Specific International Co-operation Actions" dealing with the poorest countries.

Any research agenda on biotech should take into account the negotiations/outcomes of various inter-governmental fora in this domain.

The EC Strategy on Agricultural Research for Development (ARD) has been updated in 2004 in cooperation with Member States, through the European Initiative for Agricultural Research for Development (EIARD). The updated strategy includes giving support to the global, continental and regional ARD multi-stakeholders networks and platforms in order to:

– actively include farmers and other stakeholders in the development and setting of ARD priorities;

– Develop a more integrated approach to ARD, including the integration of new and traditional techniques.

The Commission has supported the development of research partnerships at national, sub-regional, regional and at global level through the implementation of Competitive Regional Research Programmes and through the CGIAR Global Challenge Programmes, in collaboration with Member States through EIARD.

Capacity building and physical infrastructure have been supported through various financial instruments.

The Commission has launched the European Technology Platforms with Strategic Research Agenda adopted in 2006. Main stakeholders contribute to the promotion of the European knowledge dissemination, through Private Public Partnership.

The EC support to sub-regional, regional and international research organisations has been provided in consultation with Member States through EIARD.

EC provides support to ARD at regional level through EDF regional envelopes. Examples include the support given to sub regional organisations (SRO) such as ASARECA for East and Central Africa, CORAF for Western and Central Africa and SADC for Southern Africa.

The EC support to the International Agricultural Research Centres of the CGIAR for the period 2002-2006 has been provided, for an average amount of €22 million per year. Member States through EIARD regularly collaborate in the allocation and monitoring process.

For the future, the new Thematic Programme on Food Security 2007-210 (FSTP) is being finalised and will become operational in 2007. The FSTP will support the delivery of international public goods contributing to food security: research and technology. The FSTP aims at contributing to the delivery of scientific, technological

innovations and policies responding to beneficiaries' needs and the enhancing of the active role of low-income smallholder farmers in research programmes.

The FSTP will include support for continental, regional and sub-regional programmes and institutions, which coordinate and support national agricultural research systems.

Research Partnerships will be further supported through the incoming FSTP. The FSTP will support the exchange of information, experience and knowledge, through scientific networks and (multi)stakeholder platforms to strengthen Institutions and capacities of developing countries.

Funds from FP7 will be allocated to support SRA activities.

The EC support for the sub-regional, regional and international organisations and to the International Agricultural Research Centres of the CGIAR for the period 2007-2010 will be included in the Multi-Annual Indicative Programme of the new FSTP.

The EC ARD strategy will be updated in early 2007, in collaboration with Member States through EIARD, taking into account the new EC/EU development policies, the evolution of the international ARD actors, the state of attainment of MDGs, the global drivers for ARD (e.g. trade liberalization, climate change, emerging economies, decentralization processes), the emerging of new ARD paradigms (rural innovation systems, knowledge systems), the evolution of Science and Technology, trends in ARD financing (public and private).

Action 25 needs to be continued

Action 26 - Cooperation with the developing world in the field of genetic resources

This action aiming at enhancing cooperation with the developing world in the field of genetic resources should be pursued and Commission and Member States should continue their active engagement in the relevant international fora.

The Commission and the Member States have been actively engaged in the relevant different international fora (TRIPs[101], CBD[102], WIPO[103] and FAO[104]).

At the WTO, the Commission actively participated in the review of Article 27.3.b of the TRIPs and examination of the relationship between the TRIPS Agreement and the CBD. In 2002 the Commission presented a submission that was well received by developing countries. The Commission continues its active participation in the debate on TRIPS and Biodiversity.

[101] http://www.wto.org/english/tratop_e/trips_e/trips_e.htm

[102] http://www.biodiv.org/default.shtml

[103] http://www.wipo.int/portal/index.html.en

[104] http://www.fao.org/

In the CBD, the Commission and the Member States were active negotiators of the Bonn Guidelines on Access and Benefit Sharing adopted in 2002. The Commission is actively engaged in negotiations of an International Regime on Access and Benefit-sharing. The negotiations are supposed to be completed at the latest in 2010.

At WIPO, in 2004 the EU submitted a proposal that if accepted would introduce a mandatory requirement to disclose the country of origin or source of genetic resources in patent applications.

At the FAO, the European Community and 22 Member States ratified the International Treaty on Plant Genetic Resources. The Commission and the Member States have been active negotiators in its implementation, including the recently adopted standard Material Transfer Agreement

International discussions on the issues within the different relevant forum continue. The Commission and the Member States should continue to support the objective of the action.

There is no need to revise the policy or actions. But, the Commission and the Member States should continue their active engagement in international discussions/ negotiations in the appropriate fora for the development or the enforcement of effective measures to provide access to genetic resources and to share equitably the benefits arising from the utilization of genetic resources and associated traditional knowledge. This implies the following actions:

- Continue to support mandatory disclosure of the country of origin or source of genetic resources and associated traditional knowledge in patent applications in WIPO;

- Continue to actively participate in the debate on TRIPS and CBD in the WTO/TRIPS;

- Completion of the negotiations of an International Regime on Access and Benefit-sharing in the CBD framework;

- Implementation of the International Treaty on Plant Genetic Resources for Food and Agriculture.

Furthermore, in 2007, the Commission will support part of an international conference about Animal Genetic resources. A deep inventory of indigenous resources has been carried out worldwide under the FAO coordination. Main results and next steps will be presented during the Conference in Switzerland.

Action 26 needs to be continued

Action 27 – Combat poverty related diseases

The EU's commitment to research to combat HIV, Malaria, TB and other poverty related diseases has been concretised under FP6 and shall be pursued. Issues such as food, health, malnutrition and the influence of global environmental changes should also be added.

Under FP6 poverty related diseases section, numerous projects focused on developing promising and innovative interventions (vaccines, drugs and microbicides) against HIV/AIDS, TB and malaria have been funded. The total budget allocated for this area in FP6 under the thematic priority 1 is estimated at €221.5 million (1st call: €73 million, 2nd call €27.5million, 3rd call: €54 million, 4th call: €67 million). Most of the projects are based on the collaboration with developing countries. Further support under FP6 was provided during 2004 by means of a special call for high risk and innovative projects (STREP/SSA) in drug and vaccine development for HIV/AIDS, TB and malaria. The total budget was €27.5 million. There were 16 STREPs selected (€14.2 million: for 7 projects in the field of HIV/AIDS, 5 in the field of malaria, 4 in the field of TB) and 5 SSAs (€1.3 million: for 2 projects in the field of HIV/AIDS and 3 in the field of TB).

A project looking at the redistribution and spread of malaria in Europe and North Africa as a result of global environmental changes was supported under the thematic priority "Sustainable development".

The European and Developing Countries Clinical Trials Partnership (EDCTP) initiative[105], with its Head Office located in The Hague (The Netherlands) was officially launched at the beginning of 2004 and an African Office of the EDCTP was opened in Cape-Town (South Africa) in July 2004. A balanced North/South partnership and the networking/coordination of participating European States' national programmes have been widely considered in the setting-up of the structure of this pilot EU initiative which now operates within its own implementation structures, calls for proposals, evaluation and selection procedures.

In the first EDCTP call, 9 projects on phase II /phase III clinical trials in the field of HIV/AIDS, tuberculosis and malaria drugs have been selected for funding and 6 senior fellowships were granted to African scientists. A total volume of about €20 million is committed and 31 partners are concerned from African institutions representing 16 sub-Saharan African countries.

Following the second EDCTP call, final negotiations with the selected proposals should start shortly. It is worth noting that for the first time participating European States co-fund EDCTP projects in through contributing to a total budget of €25 million (to be equally funded/devoted by the EC budget and by the participating European States). The projects cover research on microbicides against sexual transmission of HIV, capacity building and site development for TB vaccines as well as combination therapies against double-infected HIV/TB patients.

Referring to the third EDCTP call, clinical trials for the three diseases and capacity building activities will be considered. The call is expected to be launched during the second half of 2006.

The South African Cochran database (A Clinical Trial Registry) has also been selected.

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105 http://www.edctp.org/

In 2004, the operational basis for the networking and coordination of National Programmes was set up through the establishment of the European Network of National Programmes (ENNP)

In the annual "Work Programme 2005" for grants issued by the Commission in April 2005, a restrain call in support of clinical trials sites in Africa, selected by the EDCTP programme was earmarked. The implementation of the three projects selected, following this call (for a total of € 15 million) is expected during the second half of 2006.

Under the same conditions and funding scheme, the Commission's support to EDCTP has been recently renewed, according to the "Work Programme 2006" for grants.

A project supporting the construction of new infrastructures of bio-safety level 3 and 4 laboratories for studying highly contagious diseases ("EUTRICOD") including viral hemorrhagic fevers was initiated involving the Republic of Ghana and Uganda. During 2004, additional funds were also made available to support North/South collaborative research projects on further "neglected tropical diseases", on child survival, on reproductive health and on "health systems research".

A number of initiatives on capacity building on ethics in developing and emerging countries are being supported by the Commission. Four African institutions together with two European organizations and the World Health Organization have come together to foster the networking of medical research ethics committees in Africa: Networking for Ethics on Biomedical Research in Africa (NEBRA). As a first step, the project will identify existing ethics review capacity and needs in 15 African countries. A series of training and capacity building workshops on ethical review of clinical trials has been launched in several developing countries through the project "European and Developing Countries Ethics Partnership".

The European Group on Ethics issued Opinion (N°17) on the ethics of clinical research in developing countries which has been published and is available online[106].

The Forum of National Ethics Councils discussed capacity building for ethics committees in developing countries during its March 2006 meeting in Vienna, Austria. A presentation was made by the NEBRA project. Plans for an upcoming conference on this subject were welcomed.

A project has been launched addressing the issue of genomics and benefit sharing with developing countries.

From the above it is advisable that, in the future, the cooperation and exchange of information between projects like EUTRICOD or Committees like NEBRA with the EDCTP programme on clinical trials in Africa should be encouraged.

As a conclusion, action 27 remains an important action. The issue of food, health and malnutrition should be addressed as well. These issues are important in the combat

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106 http://ec.europa.eu/european_group_ethics/docs/avis17_en.pdf

against these diseases as the general health status and nutrition of the patients affect the outcome of treatments and prevention of diseases as well as mothers' nutrition during pregnancy and infancy.

Consideration should also be given to the influence of global environmental changes[107], and the action should include food, health and malnutrition issues as policy actions as well as the influence of global environmental changes.

There are also new and emerging challenges. Although the EDCTP is now operating, major issues still need to be addressed such as the necessity to attract further funds not earmarked for research (e.g. the private sector, in particular the pharma sector and biotech companies), the need to consolidate the global dimension of the EDCTP (e.g. through international partnerships with the New Partnership for Africa's Development (NEPAD), the International AIDS Vaccine Initiative (IAVI), the World Health Organisation (WHO), Glaxo Smith & Kline (GSK), Medicines for Malaria Venture (MMV) or the recently founded Global HIV Vaccine Enterprise (GVE)), the African participation and ownership within the EDCTP and finally the questions related to participating Member States' medium and long term commitments vis-à vis EDCTP. It should do the same for more impact and visibility of the EDCTP at the global level, in particular through the G8, where the EC is holding an observer position and participates/may contribute to the various preparatory documents as well to the final statement. Significant efforts are currently being put in by the Commission to that end.

The strong implication of the Commission and member states into the Global partnership to fight against Avian Flu and prevent an Influenza Pandemic includes support to developing countries and their Integrated Action Plan focused on strengthening sanitary services.

Action 27 needs to be continued

Action 28: Promote a responsible and careful use of biotechnology in developing countries

This action aiming at promoting a responsible and careful use of biotechnology in developing countries should be continued. This includes, amongst other measures, continuous involvement in projects in relation to the implementation of the Cartagena Protocol on Biosafety, such as those from UNEP-GEF[108].

The Commission launched in March 2005 a study: "Guidelines for Green, White, Blue and Red Biotechnologies", on the potential future of "biotechnologies" in the Developing Countries. As a follow up to this study, the Commission is working on a Biotech policy document for the Developing Countries in mid 2007 the Commission will propose a Strategic Paper about its support for developing countries on biotechnologies. In response to the beneficiaries' request, the paper will highlight the great need for capacity building.

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107 http://ec.europa.eu/environment/health/action_plan.htm

108 http://www.unep.ch/biosafety/

With support from the international community, West African countries and Regional Economic Communities (ECOWAS, WAEMU) have identified their needs and gaps in dealing with biotechnologies/challenges and appreciate the opportunities these technologies afford. The Commission will co-finance WAEMU programme with the World Bank, the Global Environment Fund and Member States.

Action 28 needs to be continued

Action 29: Policy coordination and emerging issues

Foresight, monitoring and coordination activities have been a key element of the Commission's activities in the field of Life Sciences and Biotechnology and need to be pursued. Forward looking coordination on emerging technologies, both between services and with Member States and/or stakeholders has to be enhanced. A reflection could possibly take place on the pertinence of a cross sector co-ordinated interface for a dialogue with Member States on biotechnology, as suggested in Action 29c.

Regarding action 29a, the Commission has clearly put an emphasis on the identification and assessment of newly emerging issues. Foresight actions are being planned by the Standing Committee on Agriculture (SCAR) which has established a working Group to prepare inputs for a European agricultural research agenda with a 20 year perspective, based on national and EU-wide foresight initiatives. In addition major foresight conferences on food and on agriculture are currently being planned for the first half of 2007.

Close coordination amongst Commission services and with Member States also enables the mapping of emerging issues (such as the possible placing on the market of GM fish, application of cloning technology in animals, and in particular the introduction of products obtained from cloned livestock into the food chain.) and the early development of policy responses. Two complementary initiatives have been launched by the Commission in this area, at the end of 2004. A project aiming at stimulating an informed, public debate across Europe on farm animal cloning and to ensure public participation in the forming of policies has been launched under the thematic priority "Food quality and Safety". The project will provide conclusions and possible options for policy actions covering research on farm animal cloning and its subsequent applications[109]. A stakeholder conference has taken place in Brussels 5-6 October 2006.

A number of research projects funded under FP6 are developing tools for assessing the impact of adoption of biotechnology on land use, agriculture and forestry as well as tools for assessing the macro-economic impact.

The Commission has used a number of focused expert groups both to review and to determine future research needs in preparations FP7. In addition major foresight conferences e.g. on food and on agriculture are currently being planned for the first half of 2007.

[109] http://www.sl.kvl.dk/cloninginpublic/

In addition the Commission, in response to a request by the Parliament, has carried out a study on the actual and potential impact of biotechnology on the economy and on European society: "Consequences, opportunities and challenges of modern biotechnology for Europe" (Bio4EU Study)[110]. The study evaluates the consequences, opportunities and challenges of modern biotechnology for Europe, in terms of economic, social and environmental impacts, in particular their contribution to the achievement of major European policy goals. It will help to increase public awareness and understanding of life sciences and biotechnology. The study focuses on major modern biotechnologies in three main application areas: human and animal health, primary production and agro-food and industrial processes, energy and environment. Results are available since April 2007.

Furthermore, the work of an EC interservice group on **genetic testing** has allowed the identification of a number of emerging issues and has put forward actions in order to ensure the highest quality of genetic testing in the EU including closer collaboration with Member States on quality assurance and networking for rare diseases, a review of Directive 98/79/EC[111] on in vitro diagnostic medical devices, and the launching of a network on public health aspects of genetic testing. The emerging issues of genetic testing, pharmacogenetics and biobanks, identified in the Life Sciences and Biotechnology progress reports, have been subject to specific actions by the Commission within this interservice group.

(1) Genetic testing

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

The need for policy actions regarding the use of genetic testing both for medical and non-medical purposes have been stressed in the European Parliament Report on the Commission communication on Life Sciences and Biotechnology- A Strategy for Europe – adopted in November 2002. This calls on the Commission to draft a legislative regulation for the introduction of a standard for genetic tests, since these services lie outside the scope of Council Regulation (EEC) N° 2309/93 laying down Community procedures for the authorisation and supervision of medicinal products for human and veterinary use[112] and Directive 98/79/EC on in-vitro diagnostic medical devices, which applies only to products to be marketed. In the draft report from Temporary Committee on Human Genetics from November 2001 the EP: *"Notes that genetic testing will in many cases be used for predictive purposes and that any discussion on the enormous medical, ethical, psychological and legal implications of inaccurate findings raises the need to determine a legal and*

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110 http://bio4eu.jrc.es/

111 Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on in vitro diagnostic medical devices, OJEU L 331, 7.12.1998, p. 1–37

112 Council Regulation (EEC) No 2309/93 of 22 July 1993 laying down Community procedures for the authorization and supervision of medicinal products for human and veterinary use and establishing a European Agency for the Evaluation of Medicinal Products, OJEU L 214, 24.8.1993, p. 1–21

regulatory framework at European and national level to: guarantee the quality […] of genetic testing in Europe […].”

A growing number of laboratories in Europe and the world are offering a wide and varied array of genetic testing and analysis services. These practices are becoming increasingly frequent, highly variable in quality, and available across national boundaries and some genetic tests are becoming the subject of uncontrolled “mass marketing”, including via the Internet. In a statement, the European Group on Ethics in Science and New Technologies (EGE) warned against the risks of advertising genetic testing via the Internet, in particular due to the serious concerns raised from the perspective of fundamental rights and the private life of the person. The Group also addressed the ethical and legal issues of genetic testing in the workplace and adopted an Opinion on this subject on 28 July, 2003 (Opinion nr 18 on "the ethical aspects of genetic testing in the workplace "[113]).

The ETAN-STRATA high level group composed of representatives from pharmaceutical companies, NGOs including patients' organisations, scientists and ethicists and legal experts set up by the Commission in 2003 called for actions at EU level and gave 25 recommendations[114]. These recommendations were also discussed at a public conference organised in Brussels on May 6-7, 2004[115].

In the specific case of rare diseases, the majority of which having a genetic origin, no EU Member State is as yet self-sufficient in testing for these, and there remains room for improvement in cross-border co-operation. This highlights the need to encourage a broader exchange of information and samples though trans-national networking, which is essential for ensuring the development of tests as well as for accessibility to genetic testing.

Although genetics specialists and professional organisations have made many moves to promote quality assessment, genetic testing services are provided under widely varying conditions and regulatory frameworks in different countries, as well as in the EU. The 2003 prospective study from the Commission’s JRC[116] identifies shortcomings and measures to ensure the highest quality of such services, including:

- Harmonised quality control of genetic tests and the counselling that accompanies them;
- Development of a common range of certified reference materials;
- Better cross-border co-operation including the establishment of a network for genetic testing of rare diseases, and;
- The establishment of a European database of genetic testing centres.

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113 http://ec.europa.eu/european_group_ethics/docs/avis18_en.pdf

114 http://europa.eu.int/comm/research/conferences/2004/genetic/recommendations_en.htm#top

115 ("Human genetic testing, what implications?" http://ec.europa.eu/research/conferences/2004/genetic/index_en.htm

116 "Towards quality assurance and harmonisation of genetic testing services in the EU" (EUR 20977 EN; 2003 http://www.jrc.es/home/pages/detail.cfm?prs=1124

Genetic testing and the use of genetic information need to be seen in the non-exhaustive context of:

- Quality assurance of genetic tests (kits) and testing services;
- Use of genetic testing and genetic information in health care including for diagnosis, screening of newborns and adults, predictive/ pre-symptomatic testing, pharmacogenetics, selection of donors;
- Collection, storage transmission and analysis of personal genetic information for the purpose of public health and/or medical research including applications like medical registers and bio-banks;
- Use of genetic testing and genetic information in employment and obligatory public health insurance;
- Use of genetic testing and genetic information in private life and/or health insurance;
- Forensic use of genetic testing in criminal investigation (including parental…) and public security (including fights against terrorism)

The Commission identified genetic testing in its second and third progress reports on the implementation of the Life Sciences and Biotech strategy as an emerging issue with important scientific, ethical, legal and social implications.

In the second progress report on the Life Sciences and Biotechnology Strategy (2004) the priorities identified for future actions by Commission and Member States were as follows:

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

The third progress report (June 2005) identified the following priorities:

- To enhance an EU-wide exchange of information on best practice and cooperation on the development and use of genetic testing through the open method of coordination. In particular, an evaluation of the clinical validity/utility of genetic tests and the establishment of a referral system at EU level for genetic testing of rare and complex diseases will be addressed in 2005- 2006;
- To take whatever action appropriate or required, as arising from the coordination;
- To launch an initiative on the protection of workers' personal data in the employment context, taking account of the European Group on Ethics in Science and New Technologies Opinion No 18 “Ethical Aspects of Genetic Testing in the Workplace”. The initiative will also address the processing of genetic data;
- To analyse the possibility of setting standards on genetic testing under Article 152 or 153 of the Treaty and the appropriate legal instrument;
- To analyse the Directive 98/79/EC on in vitro diagnostic medical devices in the context of genetic testing and in particular regarding quality and performance assurance of genetic test devices;
- To launch a mapping and networking exercise on public health aspects of genetic testing.

The Commission will pursue the work on the action proposed in 3rd progress report: "Analyse the possibility of setting standards on genetic testing under Article 152 or 153 of the EC Treaty and the appropriate legal instrument taking into account the result of the analyses of the Directive 98/79/EC in the context of genetic testing". Since these recommendations were made, the main achievements have been:

– Establishment of informal network on genetic testing with experts and officials from EU Member States in 2004, which meets each year to exchange information about national activities and discuss the way forward to ensure the highest quality of genetic testing in the EU

– Based on the work of the informal network a survey on national legislation and activities regarding genetic testing was prepared in 2005 and is now being updated[117].

On 17 March 2004, the advisory committee, "Article 29 Working Party" (National Data Protection Authorities), adopted a working document on the processing of genetic data. One of this opinion's main conclusions is that any use of genetic data for purposes other than directly safeguarding the data subject's health and pursuing scientific research should require national rules to be implemented, in accordance with the data protection principles provided for in Directive 95/46/EC[118]. The processing of genetic data should be authorized in the employment and insurance fields only in very exceptional cases provided for by law, so as to protect individuals from being discriminated against on the basis of their genetic profile. The Working Party may revisit the working document in the light of experience acquired by National Data Protection Authorities and may decide to focus in detail on specific areas at a later stage, in order to keep in line with the technological developments linked to the processing of genetic data. This opinion will be considered by the relevant Commission services for consistency with the current "acquis".

The IVD, in vitro diagnostic, technical group under the Directive 98/79/EC on in vitro diagnostic medical devices has analysed the directive in the context of genetic testing and in particular regarding quality and performance assurance of genetic test devices. The Conclusions were endorsed by the Competent Authorities representatives of the Medical Devices Expert Group in spring 2006. The conclusions can be summarized as follows:

– The current requirements for the quality and performance assurance of genetic tests are assured by the Directive 98/79/EC on in vitro diagnostic medical devices;
– But, genetic tests that do not have a medical purpose, e.g. genetic tests for forensic or predictive purposes, are not covered by the Directive;
– Also, it is recognised that a number of genetic tests are "manufactured and used only within the same health institution", so-called "in-house" products, and are thus excluded from the scope of the current Directive;

117 http://ec.europa.eu/research/biosociety/pdf/bioethics-survey-test2106.pdf

118 Directive 95/46/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data, OJEU L 281, 23.11.1995, p. 31–50

- Hence, they are covered by national rather than harmonised community legislation;
- Member States are encouraged to apply national controls equivalent to the community controls in such instances and to collaborate in the field of quality assurance programs for laboratories;
- The term 'health institution' needs elaboration or definition to clarify that commercial laboratories are covered by the Directive; many commercial test laboratories claim to be 'health institutions' and thus claim to be excluded from the Directive. Such a laboratory must use in vitro diagnostic tests bearing CE marking in accordance with the Directive, even where the tests has been manufactured and used within the same laboratory;
- Where considered necessary by Member States, there is already the possibility, under Article 14 (Comitology), to introduce certain or all genetic tests currently covered by the Directive, into Annex II (List A or B), or, by derogation to the normal rules, to prescribe specific conformity assessment routes;
- As 'New Products' have to be notified under Article 10(4), guidance on this could be given for those New Genetic Tests, particularly as regards to clinical evaluation.

A large network of excellence, EUROGENTEST, for test development, harmonization, validation and standardization of services across Europe has been launched under FP6, thematic priority "Life sciences, genomics and biotechnology for health". Amongst other measures, an International Symposium on Reference Materials for Genetic Testing was organised jointly with the Commission's Joint Research Centre (IRMM) in 2005. Proceedings of the symposium will be available on the EuroGentest website[119].

The Commission's Joint Research Centre (IRMM) has produced three Certified Reference Materials (CRMs) for the analysis of the human Factor II (prothrombin) gene G20210A mutation. Moreover, IRMM has launched a large EQA study among European laboratories using these reference materials in order to identify the problems related to molecular genetic testing.

The Commission has contributed to the work of the OECD on guidelines on Quality Assurance of Molecular Genetic Testing (currently under adoption process)[120] and is participating in the work of the Council of Europe regarding a protocol on Genetic Testing issued by the Steering Committee on Bioethics (CDBI), still under internal consultation[121].

Forensic use of genetic testing and genetic data in criminal investigation and public security (including measures taken to prevent terrorism) and the establishment of databases raise issues related to individual rights (including rights to privacy) and public interest (including antiterrorism and security measures). Current legal initiatives, such as the proposal for a Council Framework Decision on the protection of personal data processes in the framework of police and judicial co-operation in criminal matters will lay down a legal framework that will be applied to these activities.

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119 www.eurogentest.org/

120 http://www.oecd.org/sti/biotechnology

121 http://www.coe.int

(2) Public Health Genomics (including genetic testing) and the integration of genome-based knowledge and technologies into practice

The great success of current genomic research already lead to exponential growth of genome based information and technologies. The genome based information and technologies comprise all aspects of genetic testing. The advances in genomics and the underlying technologies create new challenges for researchers, policy makers and other stakeholders. To complement the Community research actions in genomics and more narrowly in genetic testing as described above, a Public Health Genomics European Network (PHGEN)[122] was launched on 1 January 2006 co-funded by the Community under the EU Public Health Programme. PHGEN conjuncts public health and genomics aiming at a responsible and effective translation of genome-based knowledge and technologies into public policy and health services for the benefit of population health. Genetic testing is subsumed under public health genomics as a more narrow focus resulting from genetic research prior to the Genomics era. Translation in this area requires stakeholder involvement together with the recognition and integration of related projects in genetics, Health Technology Assessment, orphan diseases and cross border health services.

Public Health must be seen as the starting point of this enterprise as it ensures the development of a coherent, socially balanced and ethically responsible policy framework. This is reflected by the integral role of ethics and legal experts in the PHGEN network. Thus, Public Health Genomics can be seen as the tool which guarantees societal benefits from genetics / genomics and not an erratic progress which neglects the health needs of the people of Europe. The Community competences in biotechnology and Public Health call for continuing the holistic approach for a coherent and integrating policy strategy. With the emerging field of Public Health Genomics, genome-based knowledge no longer solely belongs to the sphere of national health care systems, additionally Fundamental Rights, Market Freedom, Consumer Rights and Consumer Protection need to be integrated.

Consequently, a communication process with stakeholders and Member States should be started and facilitated as Public Health requires a gearing of competences and regulatory frameworks. The Community competences, e.g. in the single market, the freedom of service providers, employment, data protection, access to information, marketing authorisation, intellectual property rights, cross border health services, pharmaceuticals and research supervision must be explored in relation to the translation of genome based information and technologies for population as well as individual health. Examples are Art 3 (p), 95 par. 3 and 152 par. 1 of the Treaty, which oblige the Community to achieve a high level of health protection in all its regulatory actions.

It becomes more and more apparent that genomics requires a coherent health strategy which assesses potential interdependences and unwanted consequences. Public Health Genomics is an umbrella enterprise which offers the capabilities needed by the Community and the Member States. With the translation from basic sciences into health care, the framing of ethically and legally acceptable standards and the

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[122] http://www.phgen.nrw.de

empowerment of professionals and lay people Public Health Genomics supports implementation and transcription of relevant Community competences into practice.

In conclusion, these actions remain important. One should have in mind that the European Parliament called on the Commission to draft legislation for the introduction of a standard for genetic tests in its report on the strategy.

(3) Biobanks

Biobanks (storage of genetic material linked to lifestyle, medical and other information of the individual for research and biomedical purposes) were also identified as emerging issues in the context of the progress reports on the Life Sciences and Biotech strategy.

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

Priorities for future actions for Commission and Member States are the following:

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

– For the Commission to consider the need for an opinion from the European Group on Ethics regarding the ethical implications, some of which were covered in their Opinion No 19 "Ethical aspects of umbilical cord blood banking"[123].

The main achievements were:

– The Commission has launched a study on Biobanks in Europe - Prospects for Coordination and Networking (a comprehensive picture of biobanks in the EU (and non-EU regions) - and will explore the possibilities of networking among European biobanks, with the results expected in September 2007,

– A European initiative "EUHEALTHGEN" has been launched in 2004 to promote the translation of the outputs from research on population genetics into direct health benefits for European citizens. It is jointly funded by the European Commission, and the Wellcome Trust;

[123] http://ec.europa.eu/european_group_ethics/docs/avis19_en.pdf

– An international conference entitled 'From Biobanks to Biomarkers – Translating the potential of human population genetics research to improve the quality of health of the EU citizen' was held on 20–22 September 2005 to promote the aims of this initiative[124];

– The Commission recently held a high-level expert workshop on unifying databases of human genetic variation[125].

(4) Pharmacogenetics

Pharmacogenetics (genetic variability to drug response) is still at the research and development stage, but its application in drug development and evaluation is expected soon, and appropriate measures should be prepared in time for this evolution. The potential impact of pharmacogenetics on health care and its ethical, legal and socio-economic implications are still uncertain. The European Medicines Evaluation Agency (EMEA)[126] organised an expert meeting in November 2004, which stressed that no legislative provisions should be made before a wide-ranging consultation process with all the relevant stakeholders has taken place, and highlighted the importance of ensuring high quality and validation methods for pharmacogenetic tests. The research projects funded under FP7 and the newly established Technology Platform for Innovative Medicines are expected to provide incentives in this field and enhance cooperation between all the stakeholders concerned.

In the third progress report (June 2005) the priorities for future actions were for the Commission to launch initiatives on the potential benefits, risks and possible new policy issues associated with the application of pharmacogenetics, including a prospective study, and consider the need for an opinion from the European Group on Ethics on the ethical implications.

In response to this, the Commission has recently completed a study on pharmacogenetics and pharmacogenomics in the EU. The study maps the current R&D status in the field, assesses its potential socio-economic impact, and finally provides a comparison of regulatory and quality assurance frameworks in the EU and the US[127].

As outlined in the above mentioned study, gathering and analysis of pharmacogenetics data is more and more common in the conducting of clinical trials of medicines. In the future, use of pharmacogenetics could affect critical elements of an increasing number of drugs, such as dosage or target population. The strategic importance of pharmacogenetics has therefore increased. It is now reaching a critical stage where it may justify the need for policy action, in order to better regulate the use of pharmacogenetics in the development and monitoring of medicines.

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124 http://www.wellcome.ac.uk/doc_WTX032108.html

125 ftp://ftp.cordis.europa.eu/pub/lifescihealth/docs/geneticvariationworkshopfinalreport_200604.pdf

126 http://www.emea.europa.eu/

127 "Pharmacogenetics and Pharmacogenomics: State-of-the-art and potential socio-economic impacts in the EU" (EUR 22214; 2006 http://www.jrc.es/home/pages/detail.cfm?prs=1387

The European Medicines Evaluation Agency (EMEA) is in the process of drafting new harmonised guideline on the terminology used in Pharmacogenomics[128]. The goal of this initiative is to harmonise at international level definitions for Pharmacogenomics, Pharmacogenetics, genomic biomarkers, and relevant sample and data coding. Standardised terminology will be proposed for incorporation in future regulatory documents related to pharmacogenetics and pharmacogenomics.

The Commission considers the issue of personalised medicine and use of pharmacogenetics in drug development of strategic importance, justifying policy action in the coming years through an appropriate revision of the existing Community regulatory framework on pharmaceuticals.

Pharmacogenetics raises a number of scientific, ethical, legal and economic challenges. On the regulatory side, the main challenges for the Commission are related to: the use of pharmacogenetics data in the evaluation of medicines, licensing decisions and post-marketing monitoring; the harmonisation of requirements for the conduct of pharmacogenetics studies, in particular at clinical level; the co-evaluation of medicines in combination with pharmacogenetics tests (drug-test application); and the labelling of medicines based on pharmacogenetics data. Because of the specific features of pharmacogenetics it is necessary that its impact on fundamental rights and in particular protection of personal data shall also be carefully examined and integrated in any study/policy that will be carried out. The Forum of National Ethics Councils will address the implementation of ethical frameworks for pharmacogenetics.

(5) Other prospective studies on biotechnology

Other prospective studies carried out by the Commission on biotechnology as early identification activities are:

– "Human tissue-engineered products - Today's markets and future prospects" (EUR 21000; 2003[129]). The study provides data on products on the market and in the pipeline and the structure of the tissue engineering sector, as well as the challenges the sector is facing.

– "Human tissue-engineered products: Potential socio-economic impacts of a new European regulatory framework for authorisation, supervision and vigilance" (EUR 21838; 2005[130]). The study analyses the potential economic, social and environmental impacts that a future European level regulation on human tissue-engineered products could have.

– "Nanobiotechnology in the medical sector – drivers for development and possible impacts". The study aims to draw a comprehensive picture of the R&D and commercial medical nanobiotechnology landscape in Europe in comparison with the US and Japan. Furthermore, the impact and likely development of nanobiotechnology applications in the medical sector will be investigated and the

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128 http://www.emea.europa.eu/htms/human/humanguidelines/multidiscipline.htm

129 http://www.jrc.es/home/publications/publication.cfm?pub=1127

130 http://www.jrc.es/home/pages/detail.cfm?prs=1338

socio-economic aspects of this development analysed. Publication of results is expected for the second half of 2007.

– "Animal Cloning and Genetic Modification and derived products" The study aims to provide a comprehensive picture of research and commercial activities involving animal cloning and/or genetic modification, to identify the potential benefits, risks and socio-economic impacts, as well as to assess policy implications of the developments of these technologies and of the commercialization of their products in the EU. Publication of results is expected for the second half of 2007.

– "Review of GMOs under Research and Development and in the Pipeline in Europe" (EUR20680 EN; 2003[131]). The report describes which agricultural GM plants are most likely to be developed up to the market level in the next decade. The results are based on an original survey on the situation of European R&D projects and a statistical analysis of the database of experimental GM releases in Europe.

Regarding Action 29b, the Commission has already published three progress reports on the Life Sciences and Biotechnology Strategy[132], which have reported thoroughly on the implementation of the Strategy. Furthermore, several relevant reports from the Commission are providing regular updates on the implementation of the relevant Community legislation (such as the reports on Directive 2001/18/EC or Regulation 1829/2003). In addition to this, the College is holding regular orientation debates on Biotechnology, which are an opportunity to reassess the pertinence of the legislation and policy orientations, which have so far always been confirmed, sometimes including some fine tuning.

With regards to societal and economical aspects, the Commission is supporting assessments on the use of biotechnology and pays the highest attention to the positions expressed by all stakeholders, whether they represent the industry, the environmental organisations, the consumers or any other part of civil society. The Commission has developed a culture of transparency and is generally involving stakeholders closely. Nonetheless, there are limits to this involvement, which quite often relate to the protection of the Commission's right of initiative, or of confidential business information or personal data. On some occasions concerns were voiced by stakeholders about restrictions to their access to information or participation in the decision making process, but such restrictions are always related to a legal obligation by which the Commission is bound. In conclusion, there is certainly an adequate follow-up to policies and legislation in the field of biotechnology and proper synergies with Member States, stakeholders, but also third countries and international organisations. Nonetheless, it has to be pointed out that the implementation of the legislation in the field of biotechnology, mostly in the field of GMO, has proven to be quite cumbersome and that several implementation and enforcement problems have been encountered. This is in particular linked to the ambivalence of European societies towards food biotechnology. According to the Eurobarometer 2005 58% of the respondents oppose GM food while 42% do not.

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131 http://www.jrc.es/home/pages/detail.cfm?prs=1091

132 http://ec.europa.eu/biotechnology/progress_reports_en.htm

The Eurobarometer confirmed also that there were major differences in acceptance between the societies of different Member States.

Overall, all fields of biotechnology generally enjoy a high level of public support with the exception of GM food. It should be noted that 50% or more say they would buy GM food if it is healthier, if it contains less pesticide residues, or if it is more environmentally friendly. Moreover, the supporters outnumber the opponents on this issue. This indicates that public support would rise if the benefits are demonstrated to the consumers, but also that public awareness of GMOs currently is linked to negative perceptions.

Regarding action 29c, biotechnology is a policy area under particularly thorough scrutiny and solid coordination between all involved Commission services exists, at an informal level and through the Biotechnology Steering Committee, a Commission internal coordination group composed of concerned cabinets and services. In addition to this, all involved Commission services have organised specific technical groups with Member States' competent authorities and/or relevant stakeholders, which enable efficient information sharing and rapid response in case of problems (for example, the cooperation between Commission and Member States enabled swift reaction further to the Bt10 maize and LL601 rice cases, for which emergency safeguard measures had to be taken).

As a conclusion, Biotechnology is a fast evolving and complex policy area, both from a scientific and legal point of view and the Commission should further enhance its foresight functions to be able to anticipate the possible future introduction of new applications and ensure that they can benefit the European economy, whilst respecting the highest quality and safety standards. Forward looking coordination on emerging technologies, both between services and with Member States and/or stakeholders has to be enhanced. A reflection exercise could possibly take place on the pertinence of a cross sector co-ordinated interface for a dialogue with Member States on biotechnology, as suggested in Action 29c.

Furthermore, biotechnology is emerging as an eco-efficient technology (as evidenced in the Kok report[133]) which can contribute to economic growth and at the same time contribute to enhanced sustainability through the optimal use of renewable biological resources including for example production of bioproducts, to mitigate the emissions of greenhouse gases and reduce the adverse impact on the environment of agriculture, industry and aquaculture. A better coordination and coherence of the various policy initiatives at EU level e.g. biomass action plan, implementation of biofuel directive, ETAP, sustainable Development Strategy etc will be required in order to fully benefit from this emerging potential of life sciences and biotechnology. The Commission has initiated a closer collaboration with Member States on this issue in the context of the network of high level officials on the Knowledge based Bio-Economy. Discussions with industry are taking place in, amongst other fora, the context of the Technology platforms and an interaction exercise with civil society is under development.

[133] http://ec.europa.eu/growthandjobs/pdf/kok_report_en.pdf

In addition to this, efforts have to be pursued to reinforce Member State's support in the GMO decision making process, in order to improve the implementation and enforcement of relevant legislation. In particular, the actions agreed by the College at its 12 April 2006 orientation debate have to be implemented.

Action 29 should be given high priority as foresight, monitoring and coordination activities in the field of biotechnology should continue

Action 30 - Progress reports

Progress reports have so far been produced on a yearly basis. In the elaboration of the 2005 Progress Report, it appeared that they were no sufficient developments to produce a progress report in 2006. It was therefore decided to merge the 2006 progress report with the 2007 mid term review. The frequency of Life Sciences reports should therefore be from now on every two years.

The next report will be published in 2009

5. CONCLUSIONS AND WAY FORWARD FOR THE CONTINUATION OF THE STRATEGY

The main conclusions of this review exercise are that:

- The Strategy has been successful and is still relevant. The list of achievements for the period of reference, for example, research activities, or regional integration of "poles of excellences", clearly highlights the role that the Strategy played to integrate the "biotech dimension" in other policy areas. Furthermore, the Strategy has always been and still is supported by the relevant stakeholders, which also contributes to demonstrating its pertinence;

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

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

- A majority of actions need to be continued, in a way which is coherent with other horizontal initiatives (e.g. education, IPR,…) or in accordance with the EU's international commitments (e.g. contribution to Multilateral Environmental Agreements);

- Some actions need to be refocused and given a special priority for the coming years, given their importance and biotechnology-specific character.

The original design of the Strategy was purposely large in content and actions, so as to aim for an initial mapping of the situation which would allow for identification of relevant policy areas. It has been successful in achieving this. The mid term review is nonetheless the occasion to reflect on how to maximise the aforementioned benefits of potential uses of biotechnology. This implies pursuing actions which are still

relevant according to their original design and following the deliverables foreseen, reinforcing synergies with other pertinent horizontal policies and reviewing priorities which are specific to the sector of biotechnologies to improve the efficiency of the Strategy for its implementation until 2010.

These biotech-specific priorities can be regrouped under five main themes, which are interdependent:

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

(2) *Foster competitiveness, knowledge transfer and innovation from the science base to industry.* Europe's biotech companies are mostly SMEs with limited resources whose growth and economic sustainability are held back by three main constraints: Europe's fragmented patent system, the insufficient supply of risk capital and the not yet fully developed scientific and business cooperation. As evidenced in the Communication "An innovation-friendly modern Europe"[134], Europe urgently needs a clear and coherent legal framework for IPR protection. The Commission will propose concrete steps toward a modern and affordable framework. In addition to this, the refocusing of part of the Action Plan can contribute to addressing some framework conditions relating to competitiveness which are specific to the biotech sector.

(3) *Encourage informed societal debates on the benefits and risks of life sciences and biotechnology.* The uptake of biotechnology is also conditioned to its societal and market acceptance. Ethical concerns are also more prevalent than in other forefront technologies. Thus, there is a clear prerequisite for actions aiming at associating the public and stakeholders as closely as possible to the decision making process and to follow a cost-benefit approach to regulation, based on harmonised data and statistics and including ethical considerations.

(4) *Ensure a sustainable contribution of modern biotechnology to agriculture*. Biotechnology in the field of primary production and agro/food has by all means a huge potential for development, in particular for the replacement of chemical processes and fossil fuels. Nonetheless, some of the technologies involved need close scrutiny. This is why the legal framework which regulates the uptake of GM technology takes into account possible long-term effects on the environment and health, the safety of the food chain, when crops are used for example for the production of pharmaceutical substances, and respect other modes of agricultural production;

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134 COM(2006) 589 final, 12.10.2006

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

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

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Annex I: Refocused Life Sciences and Biotechnology Action Plan

(1) Promote research and market development for life sciences and biotechnology applications and the Knowledge Based Bio-Economy (KBBE).

(a) Research (supply–side measures) (action 3[135]). Deliverables:

– Generation of new knowledge under FP7 in particular under the themes "Health", "Food, Agriculture and Fisheries, and Biotechnology", "Nanosciences", "Energy" and "Environment". **Implementer:** Commission.

– Mobilise national and regional public and private research funding and reinforce the coordination of research in the field of life sciences and biotechnology **Implementer:** Commission, Industry and Member States and other funding bodies.

– Implementation of the Joint Technology Initiative on Innovative Medicine under FP7 with a specific focus on biotechnology. **Implementer:** Public-private partnership between the Commission and the European Federation of Pharmaceutical Industries Associations (EFPIA).

(b) Promotion, demonstration and facilitation of the uptake of eco-efficient bio-based products and processes. (Demand-side measures.) Deliverables:

– Engage schemes to finance/promote the establishment of multi-functional pilot plants to demonstrate the potential of bio-based applications and facilitate their market penetration. **Implementer**: Member States, Industry and Commission through the network of high level officials on the KBBE as well as with relevant European Technology Platforms and the EIB.

– Explore in cooperation with stakeholders lead market initiatives in the areas of eco-efficient bio-based products, by facilitating the development of markets in these areas through public policy actions such as, standards, labelling, regulation and financial incentives, subject to impact assessment and compatibility with EC rules in the field of competition and internal market. **Implementer:** Commission.

(2) Foster competitiveness, knowledge transfer and innovation from the science base to industry

(a) Patenting of new research findings in the field of biotechnology (action 5). Deliverables:

– Development of best practices in the responsible licensing of genetic inventions taking into account ethical and societal concerns while

[135] Action numbers in brackets refer to the original Action Plan

encouraging patenting, licensing and spin-off creation. **Implementer:** Commission, Member States.

– Promote knowledge transfer by improving links between research organisations and industry (e.g. conferences, publications, funding, and promotion of best practice). Incentives to innovation should be improved by facilitating patent pools, research exemption and promoting new models for IPR in public-private partnerships. **Implementer:** Commission, Member States.

– Monitor the implementation of Directive 98/44/EC on the legal protection of biotechnological inventions, particularly in terms of the economic consequences of possible divergences between Member States. **Implementer:** Commission.

(b) Access to finance (action 6)

– Encourage Member States to include biotechnology in national schemes, specific rules and/or incentives for Young Innovative Companies, taking into account the European framework for state aid in research and innovation **Implementer:** Commission, Member States.

– Promote the use of EIF/EIB instruments and the Competitiveness and Innovation Framework Programme to facilitate access to finance for biotechnology companies **Implementer:** Commission.

– Implementation of Risk–Sharing Finance Facilities for actors in the biotech sector (including SME's, research organisations etc) which will be co-funded by FP7 and the EIB. **Implementer:** Commission, EIB.

(c) Regions and clusters (action 9)

– Support a better integration between clusters of European companies into "mega clusters", the cooperation between bio-clusters and regional networks and the development, across Europe, of regional "research–driven clusters" associating universities, research centres, enterprises and regional authorities, through the "Capacity Programme" under FP7. **Implementer:** Commission.

(3) Encourage societal debates on the benefits and risk of life sciences and biotechnology

(a) Structured framework for the dialogue with stakeholders to make the regulatory oversight of biotechnology more open and transparent (action 13). Deliverables:

– Stimulate the possible establishment of a Civil Society Organization Forum, which would be an institutionalised interface with different stakeholders on benefits and risk of life sciences and biotechnology. A first step could be a call for expression of interest of CSO groups. **Implementer:** Commission.

– Set up proposals on how to improve the cooperation with all relevant stakeholders to ensure input in Commission's activities. **Implementer:** Commission.

(b) Improve the indicators that are needed to monitor the impacts of life sciences and biotechnology

– Set up a proposal for establishment of international quantitative impact indicators (including social and economic) and structured collection of data for all aspects of life sciences and biotechnology. **Implementer:** Commission in collaboration with Eurostat, Industry, Member States, OECD.

(c) Continue the effort to promote the integration of socio-economic and ethical issues (actions 14 and 16). Deliverables:

– Adapt the action to the new FP7, and produce guidance for EC funded research projects to enable the research community to address ethical issues during the entire project lifecycle. **Implementer:** Commission

– Anticipate the possible ethical and socio-economic impact of emerging scientific issues by launching foresight studies and by encouraging experts in ethics, social sciences and economy to participate in EC funded research projects in life sciences and biotechnology. **Implementer:** Commission.

(4) Ensure a sustainable contribution of modern biotechnology to agriculture

(a) Coexistence between GM, conventional and organic crops (action 17). Deliverables:

– Assessment of notified national and regional co-existence measures and study of the national civil liability systems with regard to co-existence, including specific compensation and insurance schemes developed in the Member States. **Implementer:** Commission.

– In line with the Council conclusions on co-existence of May 2006, re-evaluation by 2008 of the possible need for further guidance at EU level, on the basis of practical experiences gathered with the cultivation of GM crops in the Member States and result from research. **Implementer:** Commission.

– Development of guidelines for crop-specific co-existence measures through the activity of a technical European Co-existence Bureau (ECoB) at the European Commission's Joint Research Centre. Exchange of information on best practices among Member States, through the co-ordination network on co-existence (COEX-NET"). **Implementer:** Commission, Member States.

– Adoption of crop-specific labelling thresholds for seeds. **Implementer:** Commission.

(b) Assessment of the long term positive/negative effects of GMOs on the environment and health (action 23). Deliverables:

– Conduct studies and support related research activities on potential positive and negative long term environmental effects of commercially available GMOs. **Implementer:** Commission.

– Explore benefits and risks of GM crops used for industrial transformation or molecular farming. **Implementer:** Commission

(5) Improve the implementation of the legislation and its impact on competitiveness

(a) Foresight, monitoring and coordination activities in the field of biotechnology (action 29).

– Reinforce the existing networks with Member States (e.g. KBBE-NET, Biotech Competitiveness Network) to monitor the implementation of the Strategy, with a special emphasis on addressing regulatory obstacles to competitiveness **Implementer:** Commission

– Pursue foresight activities and the evaluation of the regulatory coverage on emerging issues (genetic testing, biobanks, cloning, GM animals, nano-biotechnology, non-food use of biological resources, adventitious presence of GMO traces in food and feed, GMOs for non-food applications …). **Implementer:** Commission.

– Improve policy coordination and on cross cutting issues, with a particular focus on newly emerging issues (biofuel, nano – biotechnology, innovative therapies…) and develop a coherent policy agenda for the Knowledge Based Bioeconomy (improve the collection of data, develop indicators, evaluate regulatory needs, ensure policy coherence). **Implementer:** Commission.

Annex II: State of implementation of the Life Sciences and Biotechnology Action Plan – Summary chart of main achievements

N°	DESCRIPTION	ACHIEVEMENTS
1	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, - 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 program - 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 upport discussion for specialist scientists, with the objective of nulating **an exchange across disciplines**. Community support be provided under the Erasmus program	Funding of projects concerning sciences in general under Socrates II program (no breakdown available for biotech specific projects).
2a	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.	The EURES Job Mobility Portal (*http://ec.europa.eu/eures/home.jsp?lang=en*) The 2006 European Year of Workers' mobility has provided considerable impetus to the portal, by enabling all EU citizens to access directly, in their own language, all job opportunities published by the Public Employment Services, i.e. around 1 million jobs at any given time.
2b	The Commission will explore with Member States possible measures to **attract and retain scientists** and avoid brain drain.	- in 2004, the ERA-MORE network of proximity assistance to mobile researchers was launched - the Directive on the entry and stay in the EU of third country researchers -in March 2005 the Commission adopted a Recommendation to Member States on the European Charter for Researchers and a Code of Conduct for the recruitment of researchers. -in all Marie Curie actions in FP6 the life sciences are heavily represented and account for over €500 million (postdoctoral positions, PhD, funding to allow experienced researchers to set up their own research groups for the first time and "Chair" appointments to attract world-class researchers and encouraging them to resume their careers in Europe.

N°	DESCRIPTION	ACHIEVEMENTS
3	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. - encouraging **SME participation, international cooperation and mobility and training of researchers**.	The FP6 has brought a strong impetus to Life Sciences and Biotechnology research in Europe, in particular in terms of critical mass of human and financial resources, sharing of knowledge and facilities, strengthening of scientific excellence, coordination of national activities and support to EU policies. -Concrete progress has been made in **structuring the European Research Area** and an active participation of all Member States has been achieved. -Support under thematic priorities. **-Coordination of national and regional research programmes** has been achieved through the ERA-NET scheme (*http://cordis.europa.eu/coordination/era-net.htm*). - Industry, and in particular **Small & Medium Enterprises** (SME) have benefited from the FP6. - Establishment of technology platforms.
4	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.	This action has not triggered interest from the concerned audience.
5a	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.	All Member States have now implemented in their national laws Directive 98/44/EC

N°	DESCRIPTION	ACHIEVEMENTS
5b	Council adopting the **Community Patent Regulation**.	The Commission has launched on 16 January 2006 a broad consultation of all interested parties on the future patent policy in Europe. One of the main issues in the consultation concerns the Community patent but the consultation covers also issues such as basic principles of the patent system, the draft "European Patent Litigation Agreement" and approximation of Member States' national laws and mutual recognition of Member States' patents. The Commission has embarked on a wide-ranging review of IPR policy as a whole and will propose concrete steps toward a modern and affordable framework in 2007. *http://europa.eu.int/comm/internal_market/indprop/patent/consultation_en.htm*
5c	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.	- An expert group of technology transfer and legal specialists has finalised in 2004 a report on **"Management of Intellectual Property in publicly funded research organisations – towards European Guidelines"** (*http://europa.eu.int/comm/research/era/pdf/iprmanagementguidelines-report.pdf*) A Commission study providing a detailed comparative analysis of the Intellectual Property Research (IPR) rules applicable to publicly-funded research has been launched in December 2005.
5d	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.	- the BioBIZ project - entrepreneurship training, in particular in the New Member States and a brochure with "100 Technology Offers" collected from results of EU funded R&D project (*http://www.cordis.europa.eu.int/lifescihealth/src/leaflet.htm*) - a number of support actions to raise awareness for and provide training on IPR issue, such as the "ScanBalt IP Knowledge Network" project (*http://www.scanbaltipkn.org/*) -The EPIPAGRI project brings together major EU research and technology transfer organisations to collectively manage public intellectual property in Agricultural Biotechnologies
5e	. 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.	Member States and the Commission took an active part in an OECD exercise to **develop licensing guidelines for genetic inventions**. On 23 February 2006, the OECD Council adopted the Recommendation, which presents Guidelines for the Licensing of Genetic Inventions. (C(2005)149/Rev1 *http://www.oecd.org/document/26/0,2340,en_2649_34537_34317658_1_1_1_1,00.html*)
6a	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	the EIB's Innovation 2010 Initiative (i2i) aims to help increase the spending on research, development & innovation in Europe by providing 10 bn € in loans until 2010. More than 750 mn € in loans has been granted to the biotech & pharmaceutical sector.

N°	DESCRIPTION	ACHIEVEMENTS
6b	Seeking to stimulate investments in business incubators through the **EIF Start Up Facility**	Capital from the European Commission that is allocated to the European Investment Fund (EIF) under 3 different programmes: – The ETF Start-up Facility which aims to invest in venture capital funds such as seed capital funds, business incubators, smaller or newly established funds, funds focused on specific industries or technologies and funds financing the exploitation of R&D results (i.e. funds linked to research centres and science parks); – The EIF-ERP Dachfonds was started jointly by Germany and the EIF to encourage venture capital providers to invest in German high-technology firms, but also elsewhere in the EU. The 500 mn € fund is expected to raise an additional 1,7 bn € through commercial VC investments; – A new Commission framework programme called the Competitiveness and Innovation Programme (CIP) will operate from 2007. It brings together several separate programmes and aims at strengthening the funding available to stimulate investments in research and technological innovation, especially in SMEs.
6c	Studying measures to support technology transfer mechanisms, such as financing of patent pools or other methods for patent exploitation.	A "Technology Transfer Accelerator" was launched in 2006 after the Commission and the European Investment Fund (EIF) had carried out a feasibility study on a new type of risk capital and technology transfer investment vehicle. It aims to link different centres of excellence and universities in European countries. The Commission is also financing entrepreneurship training courses with particular focus on scientists in the New Member States.
6d	Studying measures to encourage commercial financing of companies based on a medium-term investment perspective.	The EIB commissioned an external study in 2005 to find out how many European biotechnology companies are creditworthy, i.e. actually able to take debt for their product development. In September 2005, Commission produced "Best practices of public support for early-stage equity finance". (*http://ec.europa.eu/enterprise/entrepreneurship/financing/docs/report_early-stage_equity_finance.pdf*) An analysis of the European biotechnology industry's competitiveness and access to finance has been made early 2007.
7	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 Biotech and Finance Forum Advisory Board has been renewed and strengthened in 2002 to include all relevant biotech stakeholders in Europe (EuropaBio, EFB, EVCA, EIB, EIF, etc.), as well as representatives of major bio-clusters, venture capital firms, consultants, etc. in the biotech sector. Recommendations of the Biotech and Finance Forum working group delivered in 2002 on "Financing of biotech companies" have led the EIB to provide an additional €500 million to the EIF to provide further venture capital to innovative SMEs, including for later stage biotech investments.
8a	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.	The creation of a commercial biotechnology web portal for Europe is near completion

N°	DESCRIPTION	ACHIEVEMENTS
8b	The Commission will develop its **newly created Commission web site** to provide a broad entry platform into the Commission's work on biotechnology.	The Commission's central biotech web site is operational *http://ec.europa.eu/biotechnology/index_en.htm*
9a	Member States, their regions, the Commission and the EIB will support **stronger interregional cooperation**, 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).	The funding of a number of networking activities between biotechnology regions under has facilitated the liaison between scientists and business, improving competitiveness: In particular, EU regional policy's INTERREG III Community Initiative has facilitated co-operation across regional and national borders on a variety of biotechnology projects, thus fostering the development of European biotechnology regions. The INTERREG III website provides both information on INTERREG and links to the websites of individual programmes. See http://ec.europa.eu/regional_policy/interreg3/index_en.htm
9b	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 have largely focused on the exchange of best practise on regional development (i.e. of cluster management, incubator development, factors for attracting investment, etc). A few strategic initiatives (such as the "ScanBalt Competence Region") aim at developing common strategies and activities within a network of bioregions/clusters with the objective of increasing overall competitiveness of the network
10a	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 with Member States ministries with responsibility for competitiveness in biotechnology was set up in 2003.
10b	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 with industry and academia was set up in 2003. It has delivered three reports in 2004, 2005 and 2006 with relevant policy advice on competitiveness issues that have served as input for the Commission's annual progress reports on the biotechnology strategy and action plan.

N°	DESCRIPTION	ACHIEVEMENTS
11	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. Tthe 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.	With the 2005 reform of EMEA, the drug development process has been simplified, facilitating the role of SMEs. Together with the recently published User Guide to European Regulation in Biotechnology, transparency in the way this area is regulated has been improved. -The 2005 reform (Regulation (EC) No 726/2004 and Regulation (EC) No 2049/2005) of the European Medicines Agency (EMEA) has meant a number of improvements including reinforced scientific advice in the drug development process; the creation of an SME office to help SME applicants and new fee waivers and deferrals. -The Commission has in collaboration with a consultant developed a User Guide to European Regulation in Biotechnology, which was finalised and published in 2006. (*http://ec.europa.eu/enterprise/phabiocom/docs/user_guide_biotech.pdf*)
12	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 programme for benchmarking of biotechnology policies has been started by the Commission. A first round of benchmarking of national policies took place in 2004 in close collaboration between the Commission and MS governments and was published in 2005.
13a	The Commission will propose a framework for a process of **dialogue and follow-up with stakeholders** as a result of the European strategy for life sciences and biotechnology. The framework will notably include a broadly based **Stakeholders'** **Forum**.	The Commission has organised various **scientific meetings and workshops** to raise awareness for the state of the art and existing challenges regarding measurements in life sciences and biotechnology
13b	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 Commission has adopted a series of actions in its orientation debate of 12 April 2006. The Commission will discuss its proposals with the Member States in the Council, and with EFSA, in the coming months with the objective of building greater consensus and transparency in this area of Community policy. The Commission has created an **advisory group on the food chain and animal and plant health**. (Commission Decision 2004/613/EC of 6 August 2004) that ix consulted on health and consumer's protection work programmes and measures in the areas of food safety, labelling, human nutrition, animal health and welfare and plants and pesticides.

N°	DESCRIPTION	ACHIEVEMENTS
13c	the Commission encourage **public debates on biotechnology** between scientists, industry and civil society	In the field of Community **research and development policies**, the Commission has developed a number of activities in the field of governance, notably regarding the participation of civil society to decision making processes, the collection and use of expertise and scientific advice: -Civil Society Organization and NGOs increasing participation in the advisory groups for the implementation of the various thematic priorities under Research FPs. (*http://europa.eu/press_room/presspacks/sustdev/index_en.htm*) -In order to communicate developments in Life Sciences and biotechnology more widely, the Biosociety web site was created on the Europa website: http://ec.europa.eu/research/biosociety/index_en.htm -**Gender equality** in the communication of research policy objectives and results is a key objective of EU's research policy. -initiatives have been taken to involve for **example consumer and patient organisations** in research projects from the very beginning -Specific projects regarding the process of governance were supported, addressing issues of scientific advice, risk governance and participation of civil society, notably in the field of GMOs, stem cells, etc. *http://ec.europa.eu/research/science-society/page_en.cfm?id=3132*
14	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 agrifood production, to facilitate future reporting and to provide a good basis for societal decisions on the application of biotechnology and life sciences. program research support to a more systematic **Mapping of benefits and disadvantages/risks** which should include a strong component for dissemination of information and debate. -Ensure that ethical, legal and social implications are taken into account at the earliest possible stages of Community supported research by means of Funding bioethics research and of providing an ethical review of research proposals received.	the Commission has taken a number of actions, under FP6 including: – Defining an ethical framework and ethical standards for FP6 *http://ec.europa.eu/research/science-society/page_en.cfm?id=3199* – Reinforcement of the ethical review of project proposals that raise sensitive ethical issues or where ethical issues have not been properly addressed as part of the funding evaluation process, which is carried out by independent external experts. – Encouraging the participation of social scientists and ethicists in research projects as well as integration of the analyses of the ethical, legal and social aspects into research projects funded under Priority 1 and 5 – Encouraging participation of stakeholders including NGOs in research projects and dialogue with the wider public communication in the research strategy; – Supporting specific actions to promote the debate on ethical, legal, social and wider cultural aspects of Life Sciences and Biotechnology, as well as monitoring and evaluating consequences *http://ec.europa.eu/research/science-society/page_en.cfm?id=3120*

N°	DESCRIPTION	ACHIEVEMENTS
15	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 promote collaboration between Community, national and local levels by promoting networking of national and local ethical bodies and elected representatives organize a network of academic and professional experts for ad-hoc advice on specific socioeconomic aspects.	A Forum of National Ethics Councils (NEC Forum) established in 2003 involves now all 25 Member States. It consists of the chairpersons and the secretaries of the national ethics councils. (*http://ec.europa.eu/research/science-society/page_en.cfm?id=3161*)
16	The Commission -Will develop, jointly with the European Parliament, outreach **measures to inform about the analysis ethical issues** at the EU level. -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 is closely following the regulatory developments in Member States regarding biobanks, stem cell research and genetic testing (*http://ec.europa.eu/research/biosociety/bioethics/documents_en.htm*).

N°	DESCRIPTION	ACHIEVEMENTS
17	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. To launch a new action program for the conservation, characterization, collection and utilization of genetic resources in agriculture in the Community.	The Commission continued to assess national co-existence measures that were notified to the Commission under the procedure of Directive 98/34/EC of the European Parliament and of the Council of 22 June 1998 laying down a procedure for the provision of information in the field of technical standards and regulations In March 2006 the Commission adopted a report on the implementation of national measures on the co-existence of genetically modified crops with conventional and organic farming (COM(2006)104 final). the Commission has organised jointly with the Austrian Presidency of the Council the conference "Co-existence of genetically modified, conventional and organic crops – freedom of choice" that allowed an exchange of information and positions on co-existence among policy makers, scientists, and a broad range of stakeholders, such as farmers and consumers associations, NGOs, seed producers, importers, food and feed processors, etc. (*http://ec.europa.eu/agriculture/events/vienna2006/index_en.htm*) In 2006 the Council adopted conclusions on co-existence, which include general considerations on this issue as well as proposals for future actions by the Commission. The coordination network on co-existence, COEX-NET, has been created to enhance the exchange of information among Member States on regulatory approaches and practical experiences with co-existence. New case studies on the co-existence of GM and non-GM crops in European agriculture were published by the Commission in January 2006 (*http://www.jrc.es/home/pages/detail.cfm?prs=1345*) The Commission has developed 9 new sets of certified reference materials for the identification and quantification of genetically modified crops. Concerning the conservation of genetic resources in agriculture, two calls for proposals were launched on 26 July 2005 and on 28 April 2006. Following the two calls for proposals, 17 actions were selected for co-funding, and the corresponding grant agreements, involving 17 coordinators and 162 partners in 25 Member States and 12 countries outside the EU have been signed.
18	To speed up the adoption of the **three legislative proposals**, revising the Community **pharmaceutical legislation**	EMEA has reinforced and made easier scientific advice in the 2004 revision of the Pharmaceutical legislation. The EMEA has also put in place a 'New Framework for Scientific Advice & Protocol Assistance', which introduces significant changes to the way the Agency provides scientific advice on the research and development of new medicines .*http://www.emea.eu.int/pdfs/human/press/pr/16597406en.pdf* An accelerated procedure has been introduced in the 2005 revision of the Pharmaceutical legislation. When an application is submitted for a medicinal product that is of major public health interest and in particular from the viewpoint of therapeutic innovation, the assessment time may be reduced from 210 to 150 days. a Regulation on the conditional marketing authorisation for medicinal products for human use falling within the scope of the 'centralised procedure' (e.g. biotech products) has been adopted in March 2006 *http://ec.europa.eu/enterprise/pharmaceuticals/eudralex/vol-1/reg_2006_507/reg_2006_507_en.pdf*

N°	DESCRIPTION	ACHIEVEMENTS
19	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 Organism** - Proposal for a European Parliament and Council Regulation on **Genetically Modified Food and Feed**.	In 2006 the Commission issued to the Council and the European Parliament reports on the implementation of Regulations (EC) No. 1829/2003, 1830/2003 and Directive 2001/18/EC.
20	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 Biosafety Protocol has been ratified and implemented (http://www.biodiv.org/biosafety/default.aspx), lastly through Regulation (EC) No 1946/2003 of 15 July 2003 on transboundary movements of genetically modified organisms. Directive 2004/35/CE of 21 April 2004 on environmental liability with regard to the prevention and remedying of environmental damage has also been adopted. There is no planned legislation on GM plant propagating material on top of GMO legislation.
21	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 To establish a **molecular register** that is accessible to the public, containing information on events of genetic modification.	An updated list of the implementing measure of Directive 2001/18/EC and Regulation (EC) No. 1830/2003 has been published (*http://ec.europa.eu/environment/biotechnology/index_en.htm*). Reports on the implementation of the above mentioned legislation are published on a regular basis. Aside from this strictly regulatory approach, detailed information has been provided by the JRC on reference material and activities of the Community Reference Laboratory (*http://gmo-crl.jrc.it/*). All Member States apart from France have notified to the Commission their transposition acts of Directive 2001/18/EC. The conformity check on these acts is currently ongoing. The Commission is also checking the legality of the co-existence measures of Member States as notified under the procedure of Directive 98/34/EC. In addition to the regulatory work on GM Food and Feed (Regulation 1829/2003) and on traceability and labelling (Regulation 1830/2003), the Commission has issued Commission Recommendation 2004/787/EC of 4 October 2004 on technical guidance for sampling and detection of genetically modified organisms and material produced from genetically modified organisms as or in products in the context of Regulation 1830/2003 The uniform implementation and monitoring of the EU legislation on GMOs has been supported by the development, production and distribution of new generations of matrix reference materials which are widely used by Member State laboratories and worldwide for the calibration and quality assurance to fulfil regulations EC 1829/2003 and EC 1830/2003. Commission Regulation 378/2005 on detailed rules for the implementation of Regulation (EC) No 1831/2003 as regards the duties and tasks of the Community Reference Laboratory concerning applications for authorisations of feed additives, provides guidance on the operational procedures of the Community Reference Laboratory (CRL) operated by DG JRC (*http://gmo-crl.jrc.it/*).

N°	DESCRIPTION	ACHIEVEMENTS
22	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.	The so called "one door one key" procedure under Regulation 1829/2003 has entered into force. The Commission will issue a report on the implementation of Directive 2001/18/EC in 2007, where it will make reference to the prospects of a centralised Community authorisation procedure.
23	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.	Under FP6 several research projects have started on GM traceability and safety of which the most important ones are SAFEFOODS and NOFORISK. On a regular base EFSA and Commission services are informed about the progress of these projects. EFSA has established a self-tasking working group to study requirements for Post Market Environmental Monitoring (PMEM WG) in order to produce guidance for both applicants and regulatory authorities. Based on its mandate, the PMEM WG initiated a series of consultation workshops with different stakeholders (applicants, environmental NGOs and scientific institutes, experts from Member States) to establish a rationale and general framework for General Surveillance as a component of Post Market Environmental Monitoring.
24	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 actively participates in the meetings of the Codex Task Force on Biotechnology. , which has produced guidelines for the food safety assessment of plants and micro-organisms derived from modern biotechnology. Work is ongoing in order to develop a similar guidance document for the food safety assessment of recombinant DNA animals and plants modified for nutritional or health benefit. The Commission has contributed significantly to the development of international guidelines and standards for bioanalysis with a lead technical role in a number of international bodies that are responsible for setting the standards such as CEN, the European Committee for Standardisation; ISO, the International Organization for Standardization and Codex Alimentarius. The Commission chairs the European Network of GMO Laboratories, which is a consortium of all 25 EU enforcement laboratories (plus Norway, Switzerland). In addition to providing support to the Community Reference Laboratory for GM Food and Feed, this network contributes to the harmonisation and standardisation of GMO detection protocols.
25a	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.	The Commission has played a key role in the elaboration and entry into force of the Cartagena Protocol on Biosafety (*http://www.biodiv.org/biosafety/default.aspx*), and continues to be one of the driving forces in its further development (for example in the field of identification of GMOs or in reflection on possible liability regimes).

N°	DESCRIPTION	ACHIEVEMENTS
25b	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.	The INCO programme has launched two calls aiming at promoting international research with the Developing Countries on "Bio-diverse, bio-safe and value added crops" which is a research area of the 'food security' priority. Calls were also launched on "Health of livestock populations" largely focused on the livestock health protection through the development and use of diagnostic tools and vaccines. The Commission is also engaged in the selection of research proposals from the CGIAR and in particular of co-funding the Generation Challenge Programme. This programme aims at unlocking the genetic diversity of crops for the resource-poor (http://www.cgiar.org/). A number of projects involving partners from developing and "emerging" countries have been implemented under the thematic priority "Food quality and safety".
25c	The Commission will in cooperation with Member States support **sub-regional, regional and international organizations**, in particular the International Agricultural Research Centers.	The Commission has supported the development of research partnerships at national, sub-regional, regional and at global level through the implementation of Competitive Regional Research Programmes and through the CGIAR Global Challenge Programmes, in collaboration with Member States through EIARD. EC provides support to ARD at regional level, through EDF regional envelopes. Examples include the support given to sub regional organisations (SRO) such as ASARECA for East and Central Africa, CORAF for Western and Central Africa and SADC for Southern Africa.
26 (a),(b), (c)	The Commission and the Member States will support the **conservation and sustainable use of genetic resources** in developing countries and their equitablesharing 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**. -. supporting the **participation of delegates from developing countries in the negotiations of relevant International Conventions**. -. 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.	At the WTO, the Commission actively participated in the review of Article 27.3.b of the TRIPs and examination of the relationship between the TRIPS Agreement and the CBD. In 2002 the Commission presented a submission that was well received by developing countries (*http://www.wto.org/english/tratop_e/trips_e/trips_e.htm*). In the CBD, the Commission and the Member States were active negotiators of the Bonn Guidelines on Access and Benefit Sharing adopted in 2002. The Commission is actively engaged in negotiations of an International Regime on Access and Benefit-sharing. The negotiations are supposed to be completed at the latest in 2010. (*http://www.biodiv.org/default.shtml*). At WIPO, in 2004 the EU submitted a proposal that if accepted would introduce a mandatory requirement to disclose the country of origin or source of genetic resources in patent applications. (*http://www.wipo.int/portal/index.html.en*). At the FAO, the European Community and 22 Member States have ratified the International Treaty on Plant Genetic Resources. The Commission and the Member States have been active negotiators in its implementation, including the recently adopted standard Material Transfer Agreement (*http://www.fao.org/*).

N°	DESCRIPTION	ACHIEVEMENTS
27	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.	Under FP6, poverty related diseases section, numerous projects focused on developing promising and innovative interventions (vaccines, drugs and microbicides) against HIV/AIDS, TB and malaria have been funded. The European and Developing Countries Clinical Trials Partnership (EDCTP) initiative was officially launched at the beginning of 2004 and an African Office of the EDCTP was opened in Cape-Town (South Africa) in July 2004. (*http://www.edctp.org/*). In 2004, the operational basis for the networking and coordination of National Programmes was set up through the establishment of the European Network of National programmes (ENNP). A project supporting the construction of new infrastructures for studying highly contagious diseases ("EUTRICOD") including viral hemorrhagic fevers was initiated involving the Republic of Ghana and Uganda. During 2004, additional funds were also made available to support North/South collaborative research projects on further "neglected tropical diseases", on child survival, on reproductive health and on "health systems research". A number of initiatives on capacity building on ethics in developing and emerging countries are being supported by the Commission. Four African institutions together with two European organizations and the World Health Organization have come together to foster networking of medical research ethics committees in Africa: Networking for Ethics on Biomedical Research in Africa (NEBRA). As a first step, the project will identify existing ethics review capacity and needs in 15 African countries. A series of training and capacity building workshops on ethical review of clinical trials have been launched in several developing countries through the project "European and Developing Countries Ethics Partnership". The European Group on Ethics issued Opinion (N°17) on the ethics of clinical research in developing countries (*http://ec.europa.eu/european_group_ethics/docs/avis17_en.pdf*).
28 **(a),(b), (c), (d),(e)**	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 assess and manage risk** for man and the environment, und conditions prevailing in the country. The development of appropriate administrative, legislative a regulatory measures in the developing countries, for the **prop implementation of the Cartagena Protocol**. 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. That the **international regulatory requirements** rem manageable by developing countries, so as not to impede th trade and production prospects.	The Commission has published in March 2005 "Guidelines for Green, White, Blue and Red Biotechnologies", on the potential future of "biotechnologies" in the Developing Countries. As a follow up of this study, Commission is working on a Biotech policy document for the Developing Countries. With support from international Community, West African countries and Regional Economic Communities (ECOWAS, WAEMU) have identified their needs and gaps to deal with biotechnologies / challenges and appreciate opportunities. The Commission will co finance WAEMU programme with World Bank, Global Environment Fund and Member States.

N°	DESCRIPTION	ACHIEVEMENTS
29a	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 has adopted the "Bio4EU" study *http://bio4eu.jrc.es/* The Commission has engaged in substantial prospective work on: - Genetic testing; - Biobanks; - Pharmacogenetics; - Other emerging issues such as human tissues or nano-biotechnology.
29b	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 has already published three progress reports on the Life Sciences and Biotechnology Strategy, which have provided for a thorough reporting on the implementation of the Strategy. Furthermore, several relevant reports from the Commission are providing a regular update on the implementation of the relevant Community legislation (such as the reports on Directive 2001/18/EC or Regulation 1829/2003). In addition to this, the College is holding regular orientation debates on Biotechnology, which are an opportunity to reassess the pertinence of the legislation and policy orientations, which have so far always been confirmed. (*http://ec.europa.eu/biotechnology/progress_reports_en.htm*)
29c	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.	Establishment in 2003 of the "Biotechnology Steering Committee", an internal coordination group involving Commission's cabinets and services involved in the field of Life Sciences and Biotechnology.
30	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.	Progress reports have so far been produced on a yearly basis. (*http://ec.europa.eu/biotechnology/progress_reports_en.htm*)

Annex III: Summary of recommendations from the contact network with Member States' ministries with responsibility for competitiveness in biotechnology 2006

The network's report was prepared for the use of the European Commission, but do not necessarily represent the Commission's official position.

The network has developed concrete recommendations in four thematic fields:

- Regulation;
- Access to finance;
- Plant science and the knowledge-based bio economy;
- Communication with the public.

(1) Regulation

- Study ways to improve the harmonisation of the implementation of EU legislation;
- Identify areas of inconsistent national implementation of EU legislation;
- Identify best practices in national follow-up of the effects and correct implementation of legislation, e.g. a monitoring body for the national impact of Directive 98/44/EC on the legal protection of biotechnological inventions;
- Compare the stringency of legislation in the EU and in other countries (benchmark impact and costs);
- Consider using Regulation instead of Directive (where the benefits of harmonization are greater than the advantages of subsidiarity; for future legislation);
- Identify what legislation could be considered under a regulatory simplification agenda. Competitiveness Network to draw up a list of proposals;
- Consider setting up a Task Force on Regulatory Simplification, to enable a discussion between Member States, industry and the Commission;

(2) Access to finance

(a) Making companies more attractive to investors:

- Fiscal incentives may increase R&D expenditure and encourage employment by reducing the tax wedge;
- Promote the Young Innovative Company scheme across Europe;

– Explain and promote the possibilities offered by the new EC framework for state aid to R&D&I;

– Study the possibility of introducing advantages for SMEs at the European Patent Office;

– Argue for an EU agreement on an effective Community Patent;

– Increase critical mass of early-stage companies (e.g. business plan, funding, product pipeline, management skills) by:

- improving support services and advice from seed capital schemes;
- encouraging the creation of technological incubators for launching high-tech enterprises;
- Identifying best practices in national business assistance, e.g. a one-stop-shop for start-ups which provides business advice, co-financing, and an interface with other investors.

(b) Increasing the investment capital available for European biotech companies:

– Increase public funding and leverage private funding through public funding;

– Increase spending of institutional investors in the biotech companies;

– Encourage the creation of a pan-European seed fund;

– Encourage the creation of a European Incubator Capital Fund;

– Propose fiscal incentives for risk capital investments.

(3) Plant science and the knowledge-based bio economy

– Strive for coherence of all policies impacting on the knowledge-based bio economy (KBBE); integration and coordination of activities;

– A limiting factor is the absence of scientifically validated measurement techniques for the impact of bio-based products. Support to the development of measurement techniques is necessary;

– Support the development of a harmonised statistical approach, e.g. by OECD, to measure e.g. R&D investments, employment, innovation, products, and the value of the KBBE;

– Support innovation in plant and industrial biotechnology; coordinate national and EU finance instruments;

– Support the setting up of demonstration/pilot projects and integrated bio-refineries, which are flexible installations at pilot or industrial scale

for the production of biofuels and other biomaterials, based on a variety of feedstock. Giving support to demonstration projects is important since SMEs active in this area do not have the resources to set up a real proof-of-concept. It would also help to test logistical solutions and form value chain coalitions between actors;

– Support of the entire KBBE value chain: increase and ensure the supply raw materials at a competitive price, stimulate users to switch to sustainable bio-processes, stimulate the demand for bio-based products by considering specific labelling of bio-based products and by adapting procurement practices, and consider a fast-track regulatory procedures for eco-friendly products;

– Ensure access to finance for industrial biotechnology and particularly for SMEs (industrial biotech are not working under the same conditions as healthcare biotech);

– Develop a communication strategy; raise political and public awareness about the KBBE.

(4) Communication with the public

Communication may offer valuable support in order to:

– create transparency;

– open or continue a dialogue with the public;

– open or continue an inter-institutional dialogue;

– accompany the mid-term review of the biotechnology strategy;

– Contribute to policy coherence.

Further observations of the role of communication, which:

– is a necessary element of successful policy making, is vital for marketing and must be science-based;

– should be carefully tailored to meet specific goals and target groups;

– should use all pathways (TV, web sites, publications, competitions, events etc);

– should make adequate use of multipliers such as journalists, teachers, scientists, members of political parties or parliament, NGOs etc;

– needs a clear strategy to support future biotech products and markets;

– Is a common, but shared responsibility of every stakeholder, where the scientific community and industry should contribute to a balanced debate by demonstrating the benefits of scientific discoveries and

innovation, and where policy makers should explain the regulatory framework at both national, EU and international level.