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

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INTRODUCTION

This Working Paper has been prepared as support for the European Commission's Communication to the European Parliament, the Council, the Committee of Regions and the Economic and Social Committee on Third Progress Report and Future Orientation on Life Sciences and Biotechnology.

It aims to provide a detailed overview of the progress made in implementing the action plan set out in the Strategy.

Actions are subdivided into four headings as follows:

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

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

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

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

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

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

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

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

1. HARVESTING THE POTENTIAL

1.1. THE RESOURCE BASE

1.1.1. *Investing in people*

1.1.1.1. *Identifying the education and training needs in Life Sciences*

Investment in human resources is at the heart of Education and Training policies for the knowledge based society.

In its Joint Interim Report of 2004 "Education and Training 2010"¹, the Council and the Commission emphasise the urgent need for reforms and to carry forward the Lisbon

¹ http://europa.eu.int/comm/education/policies/2010/doc/jir_council_final.pdf

strategy much more resolutely. The objectives set for education and training in the detailed work programme adopted in 2002² remain fully valid for the years ahead.

Three following levers of success should be acted upon simultaneously and without delay:

- **Focus reform and investment on the key areas:** a) mobilise the necessary resources effectively, and b) make the profession of teacher/trainer more attractive;
- **Make lifelong learning a concrete reality;**
- **Establish a Europe of Education and Training.**

Furthermore, the Education Council adopted in May 2003 five European benchmarks in the field of Education and Training to be achieved by 2010³.

1.1.1.2. Match a skilled workforce with job opportunities

Amongst the 24 actions of the **Action Plan for Skills and Mobility**⁴,

- action 2 seeks to promote maths, science and technology skills,
- action 4 seeks closer links between education, industry and careers guidance.
- Actions 23 and 24 address explicitly the issue of a one stop mobility and information/qualifications website, and the existing EURES website on the classification of professions

The 2004 mid-term review of the Action plan⁵ notes that with regard to actions 2 and 4 further progress will have to be made whereas the one stop mobility website has been successfully launched in September 2003 and it's now regularly attracting half a million visits each month.

With the aim to ensure that as far as possible, mobility for education and training purposes will be a positive experience both in the host country and after return to the country of origin, the Commission is preparing a proposal for a second Recommendation of the European Parliament and of the Council on transnational mobility within the Community.

The proposed Recommendation is a continuation to the Recommendation 2001/613/EC of the European Parliament and of the Council of 10 July 2001 on mobility within the Community for students, persons undergoing training, volunteers, teachers and trainers. It focuses on the quality aspects of mobility, and is entitled a "European Quality Charter for Mobility in Education and Training".

² http://europa.eu.int/eur-lex/pri/en/oj/dat/2002/c_142/c_14220020614en00010022.pdf

³ http://europa.eu.int/comm/education/policies/2010/doc/after-council-meeting_en.pdf

⁴ COM(2002) 72

⁵ COM(2004) 66

It is expected that the proposed Recommendation will contribute when adopted, to matching a skilled workforce with job opportunities.

1.1.1.3. Human resources in R&D: Researchers

One key prerequisite for the effective realisation of greater investments in Life Sciences and Biotechnology research and, in particular the activation of private investment, is the availability of numerous, well trained and motivated researchers. This presupposes targeted efforts for providing researchers with attractive long term career perspectives, by improving the employment and working conditions, by making the “professions” in research and development more attractive and by creating more favourable conditions for every form of mobility within a given research career path. These issues are crucial because the way in which research careers are structured and organised in Europe as well as their fragmentation at local (national, regional) level, does not allow the full exploitation of the European potential in this field.

In the frame of the integrated strategy the Commission has set into place to enhance the quality and quantity of researchers in Europe, and based on preparatory work including a wide consultation with stakeholders and Member States’ experts undertaken during 2004, the Commission has adopted in March 2005 a Recommendation to Member States on the **European Charter for Researchers and a Code of Conduct for the recruitment of researchers**⁶. Together with the formal launch and unfolding across Europe of the ERA-MORE network of proximity assistance to mobile researchers in 2004, as well as the forthcoming Directive on the entry and stay in the EU of third country researchers, these are highlights of key steps towards the creation of a real European researchers’ labour market. The Commission has also started to create a dynamic overview of researchers’ stocks, in- and outflows, career paths and geographical and inter-sectoral mobility flows, in both public and private sectors.

The Commission published on 11 March 2005 a staff working document "Women in Science: Excellence and Innovation – Gender Equality in Science"⁷ which outlines new and continuing priorities for future action both at Member State and European levels and suggests that, in terms of the participation of women in science, the objectives need now to be more narrowly focused, to concentrate essentially on women in decision-making positions and on certain disciplines or fields.

1.1.2. Generating and exploiting knowledge

1.1.2.1. Research

A) Life Sciences and Biotechnology in the Sixth Framework programme

The **6th Framework Programme for Research (FP6)** is continuing to bring 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

⁶ C(2005) 576
⁷ SEC(2005) 370

http://europa.eu.int/comm/research/science-society/pdf/documents_women_sec_en.pdf, annex:
http://europa.eu.int/comm/research/science-society/pdf/documents_women_sec2_en.pdf

facilities, strengthening of scientific excellence, coordination of national activities and support to EU policies.

Around €470 million have been awarded for "Life sciences, genomics and biotechnology for health" research in 2004. These funds will go to around 130 projects, involving more than 1500 participants. This will bring to **more than €100 million the EU contribution to research in this sector** over the first two years (2003 and 2004) of FP6. Pursuing its effort in this field, the EC has published the next call for proposals with research priorities and an indicative budget of €1080 million for the next two years

Another €198 million have been awarded for food quality and safety research in 2004. These funds will go to 44 projects, involving more than 850 participants. This will bring to **€402 million the EU contribution to research in this sector** over the first two years (2003 and 2004) of FP6. Pursuing its effort in this field, the EC has published the next call for proposals with research priorities and an indicative budget of €360 million for the next two years.

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...) and its continuing evolution integrating new and emerging disciplines such as the "omics" technologies (genomics, proteomics, metabolomics, glycomics...) as well as its converging with other technologies (nano, info, cognitive and social sciences). The "**PATHFINDER**" initiatives under the "New and Emerging Science and Technology" activities in FP6 identified "synthetic biology" as an emerging area in biotechnology expecting to be a standard approach in "biotechnology of the year 2030". These new challenges were also discussed at the workshop on "Future Challenges for Life Sciences Research" organised in September 2004 by the European Group on Life Sciences (EGLS)⁸. On December 2004, the European Commission organised the high-level conference: **Funding Basic Research in the life sciences: exploring opportunities for European synergies**. In this context, the participants proposed to establish a forum for the dialogue and coordination of funders, performers and decision makers, dedicated to setting future strategies in life science research.

The following examples of projects supported under FP6 clearly illustrate that modern life sciences and biotechnology goes far beyond the technology of genetic modification or genetic engineering.

- **Next generation toolbox for European genomic research**

The limitations of current technology – including cost and insufficient throughput and sensitivity – make it difficult to analyse genome variation between humans, or between different somatic cells within one individual. Such factors are vital in establishing the link between genetic profiles and diseases such as cancer. The new generation micro arrays will, for example, be able to monitor genomes in action by measuring gene expression levels and correlating the resulting molecular profiles to a given disease state.

⁸ http://europa.eu.int/comm/research/life-sciences/egls/index_en.html

A new technology-based research project “**MolTools: advanced molecular tools for array-based analyses of genomes, transcriptomes, proteomes and cells**”⁹ comprising 12 leading European academic groups, four biotech SMEs and one US laboratory, is expecting to produce a set of radically new array-based tools that will enable functional analyses of individual genomes and proteomes, right down to the level of single DNA, RNA and protein molecules within cells.

An ERA NET project has been implemented under FP6: **Trans European Cooperation and Coordination of Genome Sequencing and Functional Genomics of Human Pathogenic Microorganisms** (PATHOGENOMICS, 11 partners, 8 affiliated partners) with the main aim to harmonise the national pathogenomics programmes and to facilitate the research results exploitation.

The array-based technologies making up the new ‘genomic toolbox’, will have an important impact on the development of diagnostic tools for clinical use. For this reason, the Commission has proposed that biotechnology research topics such as high throughput research, large scale data gathering and systems biology will be included amongst of the priorities in FP7 under the theme Health.

- **Addressing the obesity epidemic and the burden of diet related diseases**

Research on obesity and nutrigenomics, the study of diet-gene interactions and their consequences for our health, is becoming an increasingly important area of research. The European Council of Ministers has expressed grave concern about the social and economic impact of the rise in the prevalence of obesity in Europe. In several countries, the cost of obesity is already representing 5% of total public health expenditure, largely due to the treatment of people suffering from high blood pressure, diabetes and high level of cholesterol in the blood. As a consequence of the rise in obesity, it is expected that by 2010, some 31 million Europeans will require treatment for diabetes¹⁰.

A number of EC funded projects under FP6 are bringing together a critical mass of complementary scientific competences in this area.

– Among others the projects “**Diet, genomics and the metabolic syndrome (LIPGENE)**”¹¹, “**Diet, obesity and genes**” (DIOGENES), **European Nutrigenomics Organisation (NUGO)**¹² aim to find out whether our genes modify the way diet affects our body. The project “**Novel molecular targets for obesity and type 2 diabetes (DIABESITY)**” brings together the leading researchers in Europe to find targets for intervening in the neuronal circuits that regulate body weight. Earlier research from project members has formed the basis for some of the most promising approaches for weight control currently in clinical trials.

- **Genomics to advance animal health**

Improving the health of farm animals is a pressing issue. Diseases, in particular infectious diseases, not only cause very high economic losses (for example, a total loss of €2.7 billion was recorded in several EU countries in 2001 as a result of the

⁹ http://europa.eu.int/comm/research/health/genomics/newsletter/issue3/newsletter1_en.htm

¹⁰ <http://www.idf.org/webdata/docs/CouncilConclusionsDiabetesMay2004.pdf>

¹¹ www.lipgene.tcd.ie

¹² www.nugo.org

foot and mouth epidemic, but are a source of great public health concern due to the emergence of diseases transmitted from animals to humans (zoonotic diseases) such as West Nile, SARS, avian flu, BSE etc. In addition, therapies are becoming less effective as pathogens continue to develop resistance to them and there is an increasing pressure to cut down the use of drugs in order to reduce the risk that they enter the food chain. So, new control methods must be found to keep animals healthy and prevent diseases. Genomics offers new opportunities for controlling disease- for example by breeding genetic resistance into animals, developing new vaccines, and for rapid diagnosis.

- A number of projects funded under the thematic priority “ Food Quality and Safety” are addressing these issues such as the projects “**European animal disease genomics network**” (EADGENE)¹³, “**Prevention, control and management of prion diseases**” (NeuroPrion)¹⁴, “**Network for the prevention and control of zoonoses**” (MED-VET-NET)¹⁵, “**Development of natural alternatives to anti-microbial for the control of pig health**” (FEED FOR PIG HEALTH), “**Control of the intestinal flora in poultry...**” (POULTRYFLORGUT).
- An **EC-US Workshop on “Emerging infectious diseases”** organised in the context of the EC-US Task Force on Biotechnology Research, took place in June 2004. Two main recommendations emerged from the workshop: (1) the need to increase the understanding of the complex interactions of disease agents with wildlife and the environment and (2) the need for interdisciplinary research on emerging diseases, specifically human and veterinary medicine, but also the need to include other disciplines such as ecology, meteorology, bioinformatics, remote sensing, sociology etc
- The recently launched “**European Technology Platform for Global Animal Health**” which aims to facilitate and accelerate the development and distribution of the most effective tools for controlling animal diseases of major importance to Europe and the rest of the world, is expected to help speed up knowledge and product delivery and increase the collaboration at global level in this important area of research

• **Plant genomics and biotechnology**

The Commission has continued its effort to promote research in **Plant Genomics and Biotechnology** at European level.

- In addition to the Integrated Project on improvement of grain legumes for food and feed (**GRAIN LEGUMES**)¹⁶ from 2003, a second Integrated Project entitled “**Exploitation of natural plant biodiversity for the pesticide-free production of food**” (**BIOEXPLOIT**) has been selected in 2004 for funding. This project will investigate the molecular components involved in durable disease resistance. It aims to develop, using genomics and post-genomics tools, efficient and rational marker–assisted breeding and genetic engineering strategies to create disease resistant varieties. The project expects in particular to make substantial improvements in conventional breeding. It will focus on potato and wheat, the two most important staple crops for EU consumers, for which pesticides are indispensable at the moment. The impact of genomics research on classical breeding is still relatively low because there are no strong traditional strong links between breeders and genomics-orientated researchers in the EU. The BIOEXPLOIT project will establish these links by bringing together breeders, geneticists, molecular biologists, plant pathologists, bio-informaticians, economic interest groups, biotech companies and breeding companies into single project.

¹³ www.eadgene.org
¹⁴ www.neuroprion.com
¹⁵ www.medvetnet.org
¹⁶ www.eugrainlegumes.org

- The Commission efforts in this area have been strengthened by the launching of the **Technology platform on Plants for the Future**¹⁷ in June 2004.

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- **Food and food safety**

The first generation of genetically modified crops focused primarily on improving agronomic traits for the benefit of the farmer, such as herbicide and pest resistance. The second generation is expected to try to improve food attributes such as nutritional value, colour, texture, flavour or processing properties. Foods, which might be genetically modified, in particular, are marketed by using claims of benefits to the consumers. Such claims can be broad, but the efficacy of the benefits and the inherent safety of the product must be demonstrated, in accordance with Community legislation.

- A STREP research project “**NOFORISK**” will develop new quantitative risk-benefit assessment methods in particular to assess the safety and claimed benefits of food
- In the area of food safety, the Commission is also supporting
- an ERA-NET “**SAFEFOODERA**” which will optimise and coordinate the funding of food safety research in Europe and strengthen the dialogue between consumers and producers.
- an IP “**SAFE FOODS**” where new safety assessment methods are developed for foods produced by different breeding approaches and production practices, using modern profiling techniques, and new qualitative and quantitative risk-benefit (e.g. nutritional, economic). The three divergent food production systems are: (i) traditional high input agriculture, (ii) low input systems, including organic production and (iii) cultivation of genetically modified (GM) crops.

- **Industrial Biotechnology**

Biotechnology’s best-known applications are currently in medicine and agriculture. However, it is already widely used in **efficient innovative industrial processes and products**, where its long-term impact may be greatest.

Industrial biotechnology refers to its use in manufacturing (chemicals, materials, 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 consumption and less waste products; zero 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 (du Pont’s SoronaTM is now produced from corn using engineered biocatalysis rather than petrochemicals, a biodegradable plastic (PLA) made from corn in large US bio refineries, use of enzymes in the manufacture of chemicals (this is a field in which European companies take a world lead), pulp and paper, food processing and mining and manufacture of some vitamins and antibiotics. Industrial biotechnology is

¹⁷ <http://www.epsoweb.org/Catalog/TP/index.htm>

¹⁸ <http://www.epsoweb.org/Catalog/TP/index.htm>

expected to provide a smooth transition from a fossil-fuel-based economy to a bio-based economy.

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. US, Canada, and Japan have announced strong government and industry support. An international dialogue is also taking place at the level of the OECD.

The recent report from the High Level Group headed by Wim Kok,¹⁹ which carried out an independent review of the Lisbon Strategy, stresses among others the importance of stimulating eco-innovation, building leadership in eco-industry and pursuing policies which lead to long term and sustained improvements in productivity through eco-efficiency.

The Commission recognising Industrial Biotechnology as an important eco-industry, has for its part,

- Supported the launch of the “**Industrial Biotechnology Platform**” as part of the a wider Sustainable Chemistry Technology Platform in order to boost this area in Europe;
- Proposed that Industrial Biotechnology becomes one of the priorities in FP7 under the theme “Food, Agriculture and Biotechnology”. It will form an important pillar of the “**Knowledge Based Bioeconomy**”.

- **EC-US cooperation on plant based bio-products**

The Commission has initiated collaboration with the US in the context of the EC-US Task Force on Biotechnology Research, which brings together experts from plant and industrial biotechnology to identify areas of collaboration with respect to plant based bio-products.

- **EC-US cooperation in plant based Bio- Products Research**
- An EC-US workshop on “**Applications of molecular biology to enhance plants for the purpose of producing bio based products and bio energy**”²⁰, supported by the EC-US Task Force on Biotechnology Research, took place in Albany, California, in April 2004. A joint working group²¹ was established to further facilitate and coordinate collaborative (EU-US) research in this field. The working group has developed a strategy paper “**Plant-Based Bioproducts: Creating value from renewable biological resources**”²² to underpin and direct a new vision for US-EU collaboration in agricultural and industrial biotechnology. In addition, the working group has initiated the development of two flagship projects²³: Plant cell walls: raw material quality and utility for biorefining²⁴ and Oilseed Engineering²⁵.

¹⁹ <http://europa.eu.int/growthandjobs/pdf/2004-1866-EN-complet.pdf>

²⁰ <http://www.pw.usda.gov/wrrcpagedoc/euus/US-%20EC%20Proceedings.pdf>

²¹ The steering committee is composed of representatives from the European Commission, University of York, National Hellenic Research Foundation and Agricultural Research Service of the U.S. Department of Agriculture. It is envisioned that a wider advisory network of specialists and stakeholders will support and take part in the committee

²² <http://www.pw.usda.gov/wrrcpagedoc/euus/Draft%20Strategic%20Vision%20pa%201.htm>

²³ Flagship projects address complex technological challenges and are to contribute to solving a major socio-economic problem. They require the demonstration of strong benefits, in particular for consumers and the

- **Nanotechnologies – Nano-biotechnology**

Nanosciences and nanotechnology are important for underpinning the advances in life sciences and biotechnology. The convergence of inorganic nanotechnology and biotechnology into nano-biotechnology has the potential to yield breakthrough advances in medical diagnosis, targeted drug delivery, regenerative medicine and chemicals screening.

An integrated and responsible approach to nanotechnology lies at the heart of the Commission's Communication "**Towards a European Strategy for Nanotechnology**"²⁶ adopted on 12 May 2004. Actions in a range of areas were highlighted: research and development; infrastructure; human resources; industrial innovation; societal issues, public health, safety and consumer protection; and international cooperation. It was also highlighted that synergy with the European Strategy on Life Sciences and Biotechnology may be beneficial.

The Communication was welcomed by the Council on 24 September 2004²⁷. The European Economic and Social Committee also issued a favourable opinion on the Communication on 10 November 2004²⁸. An open consultation then was conducted that received 750 responses from a wide range of stakeholders²⁹. Taking into account the outcome of that consultation, on 7th June 2005, the Commission adopted the Action Plan "**Nanosciences and nanotechnologies: An action plan for Europe 2005-2009**"³⁰. This Action Plan defines a series of articulated and interconnected actions for the immediate implementation of a safe, integrated and responsible strategy for nanosciences and nanotechnologies, based on the priority areas identified in the above-mentioned Communication.

- **NanoMedicine** is an emerging area with high potential for growth and employment with the ultimate target of improving quality of life. Already now not only large companies but a high number of SMEs are active in this field which nevertheless is quite fragmented. Therefore, stakeholders expressed the need for a **European Technology Platform** in this area to build a sound basis for competitiveness in NanoMedicine. A multidisciplinary and highly motivated group of stakeholders with many industrial companies in the area of NanoMedicine prepared a **vision document** that will be ready in summer 2005. The priority areas chosen by the stakeholders group are **1) nanodiagnostics including medical imaging 2) targeted drug delivery and release and 3) regenerative medicine**. The European Platform on NanoMedicine will be launched officially on 6th September 2005 with immediate creation of working groups to set up the **strategic research agenda**.
- A network of excellence "**NANO2LIFE**", already funded under FP6, provides an interface between nano- and biotechnology, between public and private sectors, and between academia, industry and hospitals. The intention is to build an EU community that shares

environment and should also be in line with other important policy priorities of both the EU and USA. They build on the respective strengths and complementarities of the European and US scientific and technological knowledge base and industries.

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<http://www.pw.usda.gov/wrrcpagedoc/euus/ANNEX%20I%201.htm>

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<http://www.pw.usda.gov/wrrcpagedoc/euus/OilseedFlagship%20I.htm>

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Conclusions of the Competitiveness Council, Brussels 24 September 2004 12487/04 p.24-26

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Opinion to be published on <http://www.esc.eu.int/>

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See <http://www.nanoforum.org/dateien/temp/nanosurvey6.pdf?20122004094532>

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research, training and tools as well as foresight analysis.

- In April 2004, the Commission organised a workshop to discuss the current situation and future developments and applications of **nanobiotechnology in the health sector**.
- The workshop served to design the prospective study “**Nanobiotechnology in the medical sector – drivers for development and possible impacts**”, which was launched January 2005. The study aims to draw a comprehensive picture of the R&D and commercial medical nanobiotechnology landscape in Europe in comparison to the US and Japan. Furthermore, the impact and likely development of nanobiotechnology applications in the medical sector will be investigated and the socio-economic aspects of this development analysed.

Nearly every European Member State has nanotechnology research funding initiatives, including activities covering medical applications.

- A recent study carried out for the **German Federal Ministry for Research and Education** in the context of a broad nanotechnology analysis³¹, investigates chances and challenges of nanotechnology applications in the medical sector. Within the next ten years major developments are expected. According to the study, highly selective diagnostics and therapeutics based on nanotechnology have the highest economic potential but also applications that support homecare and telemedicine
- In May 2004, the **French Senate** published a report on nanoscience and medical progress³². The report discusses the economic issues regarding nanobiotechnology both in France, other member states and non-European countries. It includes several recommendations on studies that should be carried out: one regarding possible nanotechnological impacts on the environment and health, one related to the toxicity of nanoparticles, and one study related to the cost of the growing use of nanobiotechnology. The report also proposes an interdepartmental programme (NanoTech or the French NNI) with the objective to integrate industry and academia to attract private funding for research
- In July 2004 The **UK Royal Society** published its report on “Nanoscience and nanotechnologies: opportunities and uncertainties”³³. It provides an overview of the state-of-the-art including nanobiotechnology and analyses potential risks and regulatory issues arising with the applications of nanotechnology. The main area of concern identified in the study related to production and use of nanoparticles. It is recommended to review regulation accordingly, including regulation on medicines and medical devices. The UK Government also issued a national agenda on nanotechnology earlier this year. The Government stresses the need for a precautionary approach and invites a public debate at an early stage. DEFRA has been given a co-ordinating role as regards the risk analysis and preventive measures.
- In October 2004, a call for the establishment of new “Laboratórios Associados” was launched in **Portugal**. The status of “Associated Laboratory” is attributed to

³¹ Farkas, R. et al., Nanotechnologie pro Gesundheit: Chancen und Risiken, 2003 . <http://www.bmbf.de/1324.php>
³² Lorrain J.M. and Raoul D., (2004), Rapport sur Nanosciences et progress medical, Bureau de l'Assemblée nationale and Bureau du Sénat, <http://www.senat.fr/rap/r03-293/r03-2931.pdf>
³³ The Royal Society: “Nanosciences and nanotechnologies: opportunities and uncertainties”, 2004, <http://www.royalsoc.ac.uk/landing.asp?id=1210>

institutions of high merit recognised from external assessments following application made by the institution and based on its capacity to cooperate in a stable, competent and efficient manner in the pursuit of specific national scientific and technological objectives. The call's priority areas include biotechnology and nanosciences-nanomaterials.

The **European Science Foundation (ESF)** recently carried out a foresight activity on nanomedicine ("Forward Look on Nanomedicine"). The initiative aimed at reviewing the state-of-the-art in Nanomedicine, and identifying future trends in the next decade. Points discussed were diagnostic tools, nanomaterials and nanodevices, and drug development and delivery. The preliminary version of the report is expected to be completed in 2005³⁴.

- **Small & Medium Enterprises (SME)**

The 6th Framework Programme for Research has also continued to attract industry and in particular SME's.

In the Health Research Priority 12% of all participating partners in projects funded in the first call are SMEs (representing around 10 % of the budget). 95% of the funded Integrated Projects in the first call includes one or more SMEs. More than 90 % of these are research intensive SMEs, and the remaining SMEs contributes with expertise in project management, communications, etc. 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. In this area, 23 % of the partners funded following the 1st call are from industry (of which 83 % are from SME) and 16.3 % of the budget was allocated to industry of which 90 % was attributed to SMEs. Further efforts have been made to increase the participation of SMEs. In the 2nd call around 14 % of participating organizations are SMEs (representing around 9 % of the budget). In the 3rd call 15.1% of the estimated budget (the projects are still under negotiation) was allocated to SMEs (for all types of proposals retained for funding) and 18.2% of partners being SMEs. In this call a high number of research topics of specific interest to SMEs were introduced, and in connection with the 4th call there will be a specific part dedicated to SME-STREPS (Science and Technology Research Projects) with an indicative budget €71 million.

Under the thematic priority " Food Quality and Safety " the ratio of SMEs participating in funded projects has increased significantly from 12.5% under the 1st call for proposals to 20.2% in the 2nd call and 12.6% of the budget was allocated to SME's

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.) So far 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. As an example, the co-

³⁴ <http://www.esf.org/publication/196/ESPB23.pdf>

operative research project MICROBEARRAY, which intends to carry out a genome scale analysis of the immune response against a variety of pathogenic micro-organisms thus filling the gap between genomic data and development of novel vaccines and diagnostic tools. Furthermore, an ERA-NET “**European network of transnational collaborative RTD for SMEs in the field of biotechnology**” (EUROTRANSBIO) was funded, to develop best practices and establish cross-border partnerships between SMEs and /or public research laboratories working in the field of biotechnology. A large number of initiatives have also been financed under FP6 to encourage and facilitate SMEs and SME groupings participation and exploitation of the research supported in FP6.

A number of projects funded under the thematic priority: *Life sciences, genomics and biotechnology for health* are addressing these issues, such as the projects **Training Programme for Future Bioentrepreneurs (BIOBIZ 4)**, **Biotech Venture Academy Coaching Programme for NAS Biotech Companies Seeking to Raise Investment (BIO VENTURE EAST)**.

Actions to support research for SMEs carried out by universities and research centres will be scaled up significantly in FP7.

The Research Framework Programme and the Competitiveness and Innovation Framework Programme (CIP) will operate side by side, and with considerable cross-over, in support of the Lisbon goals. The CIP programme will, for example, support networks that help SMEs to participate in the Research Framework Programme, and fund a Business Innovation Support Scheme as well as a new High Growth and Innovative SME facility aiming at reducing the equity market gap which prevents SMEs from exploiting research results.

The Commission has proposed a substantial simplification and rationalisation of the way the 7th Framework Programme will work and it is hoped that these measures will facilitate the participation of SMEs in the programme.

- **Infrastructures**

Six new projects for Research Infrastructures in Life Sciences and Biotechnology have been awarded an EU contribution of €10.3 million in 2004. The projects will participate in structuring the European Research Area, by supporting European access to a technology infrastructure on neural computation, by coordinating European infrastructures in the domain of protein crystallography, by designing European databases in the fields of glycomics and human development and by supporting the construction of new European infrastructures in the fields of structural biology and highly contagious diseases.

The Council of Ministers in its meetings of 1-3 July and 25-26 November 2004 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) is now preparing a roadmap that will in particular cover "Biological and Medical Sciences". A first list is expected to be presented to the Commission in 2005.

The Commission has started an exercise for **mapping existing Research Infrastructures in Europe**. This will provide an up-to-date picture about the current pattern, and will help in understanding the needs for future Research Infrastructures. The whole range of scientific and technological fields is covered by the survey, including Life Sciences and Biotechnology. The results of the survey will be made public in the second half of 2005.

- **Technology Platforms**

The establishment of technology platforms³⁵, 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 industry, 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 investments.

A number of technology platforms in life sciences and biotechnology have now been launched.

- The **Technology platform on Plants for the Future**³⁶ was officially launched in June 2004 and a vision paper was made public at the same time. A broader stakeholder involvement to is foreseen for the development and deployment of the strategic research agenda, which is expected to be available for discussion and consultation in 2005. The platform focus is on improving the sustainable use of plants to produce healthy, affordable and diverse food and feed, biomaterials and bioenergy, making use of modern biotechnology
- The European Platform on Innovative Medicines for Europe³⁷ was established during 2004. A vision paper was prepared in December 2004. The objective is to remove bottlenecks hampering the efficiency of the development of new medicines, and where research is the key to resolve current obstacles for the European pharma/biotechnology industry to become world leaders. The strategic research agenda identifying critical scientific gaps in which more pre-competitive research is urgently required is developed together with relevant stakeholders. Specific areas to be addressed by the platform are the improvement of methods for prediction of safety and efficacy of new drugs, improved knowledge management across disciplines involved in the drug development process, improved mobility of researchers between disciplines as well as education and training aspects.
- **Industrial Biotechnology Platform**³⁸ is one of the three pillars of the Sustainable Chemistry Technology Platform, which was set up in June 2004. It has organised two stakeholder events. A vision paper has been finalised in April 2005 following discussion with relevant

³⁵ <http://www.cordis.lu/technology-platforms/home.html>

³⁶ <http://www.epsoweb.org/Catalog/TP/index.htm>

³⁷ http://europa.eu.int:8082/comm/research/fp6/p1/innovative-medicines/index_en.html

³⁸ http://www.europabio.org/sustainable_chemistry_platform.htm

industrial sectors, consumers and NGOs. A working group has been set up to develop the Strategic Research Agenda. The focus is on the application of biotechnology for sustainable and eco-efficient production of chemicals, materials and bioenergy. Industrial biotechnology use living cells and/ or their enzymes to transform renewable feedstock (e.g. starch) into such products.

- The **European Technology Platform for Global Animal Health**³⁹ was launched on 16 December 2004. The objective is to facilitate and accelerate the development and distribution of the most effective tools (vaccines, diagnostics...) for controlling animal diseases of major importance to Europe and to the rest of the world. An interim vision paper was prepared by a high level group.

Other technology platforms are under preparation and are expected to be launched in 2005 including European Technology Platforms on NanoMedicine⁴⁰, Food for Life⁴¹, Forestry- based sector⁴² and Farm animal breeding⁴³.

The technology platforms are expected to play an important role in the transition from FP6 to FP7. In fact, it is proposed that FP7 should have more focus than in the past on developing research that responds to the needs of European industry, through the work of Technology Platforms and the new “Joint Technology Initiatives”. The definition of work programmes should draw on the strategic research agendas developed by the industry-led technology platforms. The new “Joint Technology Initiatives” will be projects in fields of major European public interest on subjects identified through dialogue with industry, in particular in the European Technology Platforms.

B) The Seventh Framework Programme

On 6 April the Commission adopted a proposal for the **EU Seventh Research Framework Programme 2007-2013 (FP7)**⁴⁴. Subtitled “Building the European research area of knowledge for growth”, FP7 is designed to provide new impetus to increase Europe’s growth and competitiveness, recognising that knowledge is Europe’s greatest resource. The Commission proposes in particular to double the FP7 budget compared with FP6.

Life Sciences and biotechnology research for medical applications will remain an important priority under the theme “**Health**” (including healthcare technologies, medical technology and pharmaceutical industries). But FP7 is also expected to give a major impetus to food, agriculture, marine, industrial and environmental biotechnology under the theme “**Agriculture, food and Biotechnology**”. It is the intention of the Commission to bring together the relevant technologies and sectors to develop a European **Knowledge Based Bio-Economy**⁴⁵, which will provide the necessary critical mass, synergies, and outputs to meet social and economic demands for the sustainable and eco-efficient production and utilisation of renewable biological resources and their transformation into health, food, energy and other

³⁹ http://europa.eu.int/comm/research/agriculture/pdf/etpgah_vision2015_paper-final_en.pdf

⁴⁰ www.cordis.lu/nanotechnology/src/nanomedicine.htm

⁴¹ <http://www.ciaa.be>

⁴² <http://www.forestplatform>

⁴³ <http://www.faip.info/>

⁴⁴ COM(2005) 119 final

⁴⁵ We understand the term “bio-economy” as including all industries and economic sectors that produce, manage and otherwise exploit biological resources (such as ,agriculture, food, forestry, fisheries, health) and related services, supply or consumer industries.

industrial products which can provide an incentive for increased growth and employment. A conference “**Towards a knowledge based bio- economy in Europe**”, addressing these aspects, will take place 15-16 September 2005. The conference will bring together policy makers and civil servants (research policy makers at EU and national level), representatives from research funding bodies, industrial managers, civil society representative groups, learned societies etc. It is hoped that this conference will be the start of a European debate on the challenges of a **Knowledge Based Bio-Economy**.

As a follow-up of this conference the Commission intends to establish a network of officials from across Europe in order to stimulate a coordinated effort in the development and implementation of a research and innovation policy for a **knowledge based bio-economy**. This work will be carried out in coordination with the Standing Committee on Agricultural Research (SCAR) and other existing Biotechnology Networks. The Commission will report on the outcome of this coordination.

FP7 will establish for the first time a “**European Research Council**” (ERC), funding the best of European science, as assessed by peer review of European scientists. This will be the first time that a body like this has existed at European level, identifying the very best of European research wherever and however it is carried out. As the ERC will be open to any scientific discipline it will also provide the opportunity to identify new scientific ideas and areas in the field of Life Sciences, which could be taken up elsewhere for further action and promotion.

Another new element will be the development of “**regions of knowledge**”, bringing together research partners – such as universities, research centres, enterprises and regional authorities - in a region to strengthen their research potential.

1.1.2.2. *Exploitation of intellectual property*

A) Intellectual property protection

After receiving the opinion of the European Parliament, the Commission proposal for a Regulation on the Community Patent⁴⁶ is being 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 meanwhile, the Commission has on 23 December 2003 presented **proposals for Council decisions on the setting up of the Community patent jurisdiction**⁴⁷. The Economic and Social Committee has issued its overall very positive opinion on 31 March 2004⁴⁸ and the European Court of Justice has delivered its opinion on these proposals on 29 October 2004⁴⁹.

⁴⁶ COM(2000)412

⁴⁷ COM (2003) 827 and COM (2003) 828

⁴⁸ OJ 2004, C 112/76 and C 112/81

⁴⁹ Council document n° 14349/04

To date, twenty Member States⁵⁰ have transposed Directive 98/44/EC⁵¹ on the legal protection of biotechnological inventions into their national legal systems while the other Member States are currently at varying stages of progress.

On 9 July 2003, the Commission referred eight Member States to the European Court of Justice for their failure to transpose the Directive into national legislation. Among those, three infringement procedures are still pending⁵². In December 2004, two other infraction procedures were launched against Latvia and Lithuania.

For its part, in its second report pursuant to Article 16c of the Directive, the Commission has considered two questions identified in the Annual Report of the Commission to the European Parliament and the Council on the development and implications of patent law in the field of biotechnology and genetic engineering provided for by Article 16(c) of Directive 98/44/EC⁵³, 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. The Commission analysis takes into account the contribution made by its informal group of independent experts set up for advising the Commission on the preparation of 16c reports.

The Commission is also working on the first report provided for in Article 16a on any problems encountered with regard to the relationship between the directive and international agreements on the protection of human rights to which the Member States have acceded. Its adoption is scheduled for October 2005.

B) Improve understanding within academic community on how to turn applied research into innovative products

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”⁵⁴ and a "*Handbook on responsible partnering*" developed by four European associations (with Commission support), in order to facilitate university-industry R&D collaborations and technology transfer has been published⁵⁵. CREST made a number of recommendations in October 2004⁵⁶, which also relate to university-industry relations and technology transfer.

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 15 EU Member States, in 2 accession countries, as well as in the US and Japan will be launched by **end of 2005**. The study will focus 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.

The Commission is also financing under FP6, the following projects

⁵⁰ Denmark, Finland, Ireland, United Kingdom, Greece, Spain, Portugal, Sweden, the Netherlands, France, Germany, Belgium, Estonia, Czech Republic, Slovakia, Cyprus, Poland, Hungary, Malta and Slovenia.

⁵¹ OJ L 213, 30.7.1998, p.13.

⁵² Luxembourg, Austria and Italy.

⁵³ COM(2002)545

⁵⁴ <http://europa.eu.int/comm/research/era/pdf/iprmanagementguidelines-report.pdf>

⁵⁵ see http://www.eirma.asso.fr/f3/local_links.php?action=jump&id=796

⁵⁶ see http://europa.eu.int/comm/research/era/3pct/pdf/crest-conclusions_en.pdf, in particular recommendations 11-18

- **The patenting of human DNA: Global trends in commercial and public sector activity (PATGEN)** which will provide an evidence-based analysis of the dynamics of patent applications and grants claiming human DNA sequences and will analyse the data for determination of patent grants rate made to the EPO, the fate of patents not granted and the ways in which granted DNA patent are being exploited. This information will be reviewed and interpreted in light of current national and EU policies for IP in biotechnology. The results will be available end 2005/beginning 2006;
- **Stem Cell Patents: European Patent Law and Ethics (Stem Cell Patents)** –launched in 2005, aims to provide an analysis of the EU patent system, as applied to biotechnological invention in general and to embryonic stem cell related technology in particular, with a view to ascertaining the legal effect of ethical or legal divergence on European patent laws.

Member States and the Commission are actively participating in an **OECD exercise to develop licensing guidelines for genetic inventions**, in particular as regards access for research purposes and genetic testing in public health care. Draft guidelines will be available early 2005.

In Denmark, a national network for technology transfer has been established with the aim of promoting professionalism in the management of IP and commercialisation of inventions from public research by training of tech trans officers and R&D-managers. The Danish Tech Trans Network also activated a web-site⁵⁷ offering an overview of IPRs and access to tech trans contact-points and policies from all public research institutions. The network was assigned a government grant of €2 million for the period 2005-2008.

C) Capital base

The Commission has adopted a proposal for a Competitiveness and Innovation Program⁵⁸ with a total budget of 4.2 billion € for 2007-2013. It is designed to provide instruments to develop and sustain a supportive environment for innovative firms, encouraging clusters, and strengthening access to finance by new elements (e.g. a risk capital instrument for High Growth and Innovative Companies and securitisation” of banks’ SME loan portfolios).

Providing access to capital seems to be particularly relevant at this stage since the global economic slowdown and the burst of the high-tech bubble in equity markets have hit the biotech industry particularly hard. The drop in price/earnings ratios and the fall in high-tech indices like the NASDAQ Biotech Index provide a clear indicator for the increased difficulties biotech SMEs and even established companies have in this sector to get access to capital.

The Commission has in collaboration with European Investment funds (EIF) launched a feasibility study in June 2004 on a new type of risk capital and technology transfer investment vehicle, the “**Technology Transfer Accelerator**”, which aims to link different centres of excellence and universities in European countries. This instrument should bridge the finance gap between university/spin-off research and early stage investment, a sector currently not favoured by VC investors. The result of the study on a possible “Technology Transfer Accelerator” instrument

⁵⁷
⁵⁸

www.techtrans.dk
COM(2005)121

should be available by mid 2005. The Commission is also financing **entrepreneurship training courses** with particular focus on scientists in the New Member States.

The **Biotech and Finance Forum (BFF) Advisory Board**, including all relevant biotech stakeholders in Europe, as well as representatives of major bio-clusters, venture capital firms, consultants, etc. in the biotech sector, will among others address the creation of a better investment climate for industrial and plant biotechnology. A first round table bringing together industry, small companies and investors in the area of industrial biotechnology was organised just following the BFF conference in Barcelona in November 2004.

The Commission, within its proposal for the 7th R&D Framework Programme (FP7), has outlined a new financing instrument, the “**risk-sharing finance facility**”, which could provide loans for larger research and infrastructure projects. This instrument, relying on an existing facility of the EIB and managed by the EIB, could 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 be in particular useful for financing high-risk biotech R&D drug development projects, large scale collaborative research projects (technology initiatives, Eureka projects) or for new research infrastructures.

1.2. NETWORKING EUROPE’S BIOTECHNOLOGY COMMUNITIES

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

In consequence, networking is vital for the effective further development of biotechnology in Europe.

Several initiatives supporting networks in Europe are on-going.

- The Commission is supporting the creation of a **commercial biotechnology web portal for Europe** that will help free access to information and networking available Internet platforms. The tender process was completed and the contract awarded in 2003. However, subsequent delays related to co-funding have led to the project now being some two years behind the originally-envisaged schedule. Work was held up due to a delay in the availability of expected co-funding. The co-funding issue has been addressed by putting the project on hold until the required funding from the French authorities becomes available. Work is expected to resume in spring/summer 2005 with completion likely in late-2005.
- Stronger cross-border and interregional co-operation in the life sciences and biotechnology area is developing in a number of European regions. These

activities, such as interregional networks, can be considered eligible for financing under the **INTERREG III** initiative. The INTERREG III ber programs (strands A, B and C) are operational in all 25 Member States. In particular the INTERREG III C program launched two calls for proposal projects in 2004⁵⁹.

- The Commission, through the 6th Research Framework Programme, has funded a number of specific support actions aiming at increasing networking between European bioregions and clusters. An example is the project “**ScanBalt Competence Region**”, a model case to enhance European competitiveness in life sciences, genomics and biotechnology for health on a global scale”. It aims to map the competence in the member regions of the ScanBalt network and jointly design a development strategy for this region and the ScanBalt IP knowledge network is a project aiming at developing a sustainable intellectual infrastructure that can increase the creation of value from bioscience research.
- A larger workshop bringing together about 100 representatives of European bioregions took place in the Bio-Vision 2005 conference in April in Lyon. At a workshop of the Bio-Vision 2005 conference a new meta-region network “**EuroBioClusterSouth**” was launched, bringing together bioregions from Spain, France, Germany, Switzerland and Italy.
- The Commission has also organised a workshop in Basel in March 2004 bringing together over 40 representatives of bioregions, clusters and incubators to discuss the way forward to increased networking of bioregions in Europe. In a follow-up meeting in June 2004, a proposal for establishing a **formal network of bioregions** from across Europe was made, for which start-up financing is currently being sought. This pan-European network of bioregions should identify a joint strategy, including structures for supporting research collaboration, networking and joint actions, to strengthen the economic development of European Biotechnology. A second preparatory meeting is planned for mid 2005.

1.3. A PROACTIVE ROLE FOR PUBLIC AUTHORITIES

1.3.1. *The Contact network*

In 2004, all Member States from EU15 except for Greece were part of the **contact network with national ministries with responsibilities for competitiveness in biotechnology** set up by the Commission. New Member States - Lithuania and Slovakia - have also joined. Contact points in almost all other Member States have been established. For these, official appointments should take place in 2005. The network has met regularly in 2004. Relevant contributions to the study on benchmarking of public biotechnology policy have been made.

1.3.2. *The Competitiveness in Biotechnology Advisory Group*

In accordance with Action 10b of the Strategy, in 2003 the Commission appointed a **Competitiveness in Biotechnology Advisory Group** with Industry and Academia (**CBAG**). It gathers representatives from all the various industry segments and from companies at every stage of company development together with entrepreneurial

⁵⁹ All relevant information about this program can be found at: www.interreg3c.net

academics and has the role of issuing recommendations to the Commission and contributing to this annual report.

The CBAG's 2004 Report provided 10 "key recommendations", which were in effect policy statements regarding various aspects of biotechnology strategy⁶⁰. It also specified a larger number of detailed actions, focusing on the policy areas of Financial Opportunities, Issues & Obstacles and Regulatory Issues & Requirements.

1.3.3. *The guide to Community regulation*

The contract for a guide to Community regulation for users and for entrepreneurs has been awarded in 2004 and drafting of the guide will be finalised by end 2005. It will then be published on the Commission's biotechnology web-pages and regularly updated.

1.3.4. *The benchmarking study*

The **study on benchmarking of public biotech policy** aimed primarily at providing European policy-makers with a set of tools that will assist them in their policy-making regarding biotechnology. The contents of the benchmarking study of public biotechnology policy were agreed beginning 2004. The project-team directed most efforts at putting in place the right methodology. Analysis of the first round of benchmarking has allowed identifying the benefits as well as the limitations⁶¹ of the tool-box. For this, suitability of the methodology should be verified in future exercises. The general objective of the project is to identify public policies that affect the development of biotech in Europe and assess their effectiveness against a background of verifiable data. Final report was delivered in mid-March 2005⁶².

The report will be published, and its results be used for policy discussion with member states and industry. Commission and Member States will proceed to a new round of benchmarking in 2006/7.

2. GOVERNING LIFE SCIENCES AND BIOTECHNOLOGY

2.1. SOCIAL SCRUTINY AND DIALOGUE

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. **The Science in Society Forum 2005**⁶³ organised by the Commission on 9-11 March 2005 reviewed these efforts and helped to plot a new course forward in the field of Science in Society. The conference reviewed a number of national and EU experience on citizens' participation in science deliberations and public debated on issues linked to life sciences and biotechnology. A series of national mirror events helped setting the tone and agenda for the Forum.

⁶⁰ the full text of the Group's report is available at http://europa.eu.int/comm/dgs/enterprise/index_en.htm

⁶¹ Mostly related to lack of comparable data and insufficient time lag between input and output indicators.

⁶² http://europa.eu.int/comm/dgs/enterprise/index_en.htm

⁶³ Science in Society Forum 2005: <http://europa.eu.int/comm/research/society2005.html>

Biotechnology, in particular in agriculture and food, is still not well-received by the general public. Recent public perceptions analysis clearly suggests that consumers' reluctance towards GMOs is caused not so much by perceived risks rather than lack of perceived benefits⁶⁴. 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:

- The project "**Impact of Scientific Advice on Risk Communication**" is examining the issue of risk communication with the general public through the printed media and will analyse the flow of risk related scientific advice between the main actors involved (scientists, policy makers and civil society). This will be illustrated by two case studies on GMOs and SARS. The final report will be available in 2005.
- The European Risk Communication Network project will develop a reference book, guidelines and training material that can guide in the communication among the various actors and reinforce the links between them including presentation and discussion of basic risk concepts and EU policies in schools, science museums and settings fostering public participation and involvement
- The project "**Participatory Approaches in Science and Technology**" (PATH) will form a network bringing together academics, practitioners, policy-makers and stakeholders to exchange knowledge and develop future directions for the involvement of society in the deliberation of science-based policy issues. The two cross-cutting themes of representation and scale will be explored at a generic level, and via three case study areas: genetically modified organisms (GMOs) in agriculture, biodiversity conservation and nanotechnology
- The **Deliberative Citizens' Debates in European Centres and Museums project (DECIDE)** aims to raise awareness and understanding of deliberative democracy methods, produce a tool to conduct and facilitate face-to-face and on-line deliberative consultations and monitor the change of attitudes among the European public on Life Sciences. DECIDE will produce a "kit" to facilitate structured debates on controversial issues (notably stem cells, cloning, GMO, genetic and property rights etc.) in many science centres and museums across Europe
- A **European Multimedia Repository on Life Sciences** will produce short films on topical life science issues. The films will be made available through TV, internet and by VHS/DVD/CD ROM. In addition the proposal will also provide a rapid response science network where scientists will answer questions related to topics addressed in the films

The Commission has also supported a number of conferences in 2004. In particular, the **3rd Science Generation Symposium "Biotechnologies: possibilities, risks, ethics and society"** took place in Stockholm in August 2004, as a satellite of the EuroScience Forum. It gathered hundreds of EU students, teachers and parents to discuss with science experts and policy makers on genetically modified crops and genetic integrity. The Encounter "**Modern Biology and Visions of Humanity**", organised under the aegis of the European Group on Life Sciences (EGLS) in Genoa in March 2004, gathered scientists and thinkers from the humanities and the arts to reflect on the impact of life sciences on our representations of humanity and nature⁶⁵. The Commission will launch a Eurobarometer survey specifically focussed on biotechnology in the latter part of 2005 as the next in a series, which was started in 1991. Interestingly, the April 2005 Special Eurobarometer on "The Attitudes of European Citizens towards Environment"⁶⁶ showed that the use of genetically

⁶⁴ Gaskell, G., Allum, N., Wagner, W., Kronberger, N., Torgensen, H., and Bardes, J. (2004). GM foods and the misperception of risk perception. *Risk analysis*, 24. (1). 183 - 192.

⁶⁵ EGLS http://europa.eu.int/comm/research/life-sciences/egls/index_en.html

⁶⁶ http://europa.eu.int/comm/public_opinion/archives/ebs/ebs_217_en.pdf

modified organisms in farming is not among the environmental issues that worry the Europeans most. 24% of the respondents mentioned it as an issue of concern, the topic being the 10th most mentioned topic out of 15. However, the topic stands out as the 2nd most often mentioned issue for which Europeans feel they lack information, environmental protection associations and scientist being the most trusted sources of information.

2.2. DEVELOPING LIFE SCIENCES AND BIOTECHNOLOGY IN HARMONY WITH ETHICAL VALUES AND SOCIETAL GOALS

2.2.1. *Community support for research into socio-economic and ethical issues*

Several specific actions have been undertaken in the context of implementation of the **Science and society action plan**⁶⁷. In particular,

- A **High Level Strata Group on Ethical Values and Science** has been set up to discuss methodologies to analyze underlying ethical values in the ERA. The Group will present its final report in 2005.
- **The Forum of National Ethics Councils (NEC Forum) consists of the chairpersons and the secretaries of the national ethics councils. The President of the European Group on Ethics (EGE) and the President of the Bureau of COMETH (Council of Europe) are invited to the meetings. Established in 2003 involves now has representatives from all 25 EU Member States. It is an independent informal platform for exchange of information, experience and best practices on issues of common interest in the field of ethics and science. The forum has in 2004 exchanged view on working methods of the committees and addressed the specific issue of creation of human animal hybrids.**
- A Conference "Research Ethics committees in Europe: facing the future together" took place in Brussels on 27-28 January 2005. This event was the first of its kind and gathered together around 450 representatives of European research ethics committees (RECs), which evaluate, at local or regional level, any type of research protocols involving human beings. It was the first Conference on REC working activities⁶⁸.
- A feasibility study for setting up an information and documentation system on ethics in research was conducted in 2004.
- The Global Forum on Bioethics in Research provides a venue for delegates from developing and developed countries to debate the ethical issues surrounding international collaborative research carried out in developing countries. The next Forum took place in Malawi on 16-18 March 2005. It focused on what happens once the research is over, examining ethical debates on post-trial access to drugs, devices, or vaccines
- Capacity building on ethics committees in developing countries: the European and Developing Countries Clinical Trials Partnership (EDCTP) is conducting research (clinical trials) in developing countries that often have no local ethics committees to approve the research conducted on human beings. Cooperation has been established with the US National Institute of Health (NIH), the Magnus Warren Centre for clinical trials to jointly organize training workshops in developing countries that are of particular interest for EDCTP. Further actions are foreseen in 2005 to facilitate the networking of those EU centres that have specific activities on capacity building and training on ethics in developing countries.
- Dialogue with China: China has achieved the first fusion of an animal cell and a human cell in summer this year. China is strong in stem cell research and is certainly a global player. Several SARS trials are taking place in China. It is intended to create a network of focal point in the different MS and candidate countries to discuss the relation to China in ethics. A network of institutes of Asian studies, ethicists etc. may be created, twining single partners

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COM(2001)714 final

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http://europa.eu.int/comm/research/conferences/2005/recs/index_en.htm

with partners in China. A workshop will take place in the second half of 2005

- Several projects are under negotiation from last call for proposals related to “Research into ethics”. Topics covered in the proposals include: nanotechnology, human-animal chimera, robotics, pre-implantation genetic diagnosis, capacity building in ethics in dev. Countries, education on bioethics for PhD students (biotechnology), training for members of research Ethics Committees etc.
- Several projects are under negotiation from last call for proposals in life sciences and health communication for promoting the awareness of scientific topics among different actors from Europe with a strong international dimension

2.2.2. *Governing EC funded research in Life Science and Biotechnology*

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, including:

- Establishment of ethical rules for FP6,
- Reinforcement of the ethical review,
- Integration of the analysis of the ethical, legal and social and wider cultural aspects (ELSA) into research projects under Priority 1 "Life sciences, genomics and biotechnology for health" and Priority 5 “ Food quality and safety” by encouraging both the participation of social scientists and civil society (e.g. NGO) in the project and the engagement of scientist in public dialogue,
- Supporting specific actions to promote the debate on ethical, legal, social and wider cultural aspects of Life Sciences and Biotechnology have been launched.

2.2.3. *Ethical review in Community supported-research*

The number of research proposals undergoing ethical review in 2004 was almost double the number reviewed in 2003 (see Table 1).

Table 1
Number of proposals received for Ethical Review

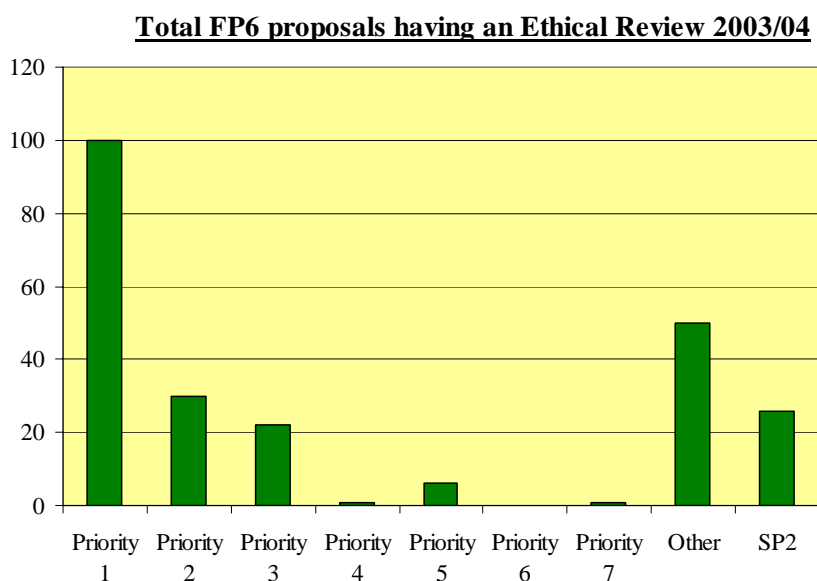
January – December 2003	
Number of Ethical Reviews exercises carried out	Number of Proposals
5	83
January – December 2004	
Number of Ethical Reviews carried out	Number of Proposals
5	153

One reason for this sharp increase is greater awareness amongst project officers of the ethical review process, resulting in better briefing of scientific evaluators on identification of proposals involving sensitive ethical issues.

2.2.3.1. Overview 2003-2004

Ethical review took place on 5 occasions during 2004. The main “customers” for ethical review remain Priorities 1, 2 and 3 but 2004 has seen a significant increase in the numbers of proposals relating to Policy Support and NEST research calls. (See Table 2)

Table 2



2.2.3.2. Ethical review in 2005

Current indications are that the number of proposals submitted for ethical review in 2005 will show another significant increase over those submitted in 2004. The ethical review in April 2005 had around 90 proposals to be reviewed in comparison with the 69 proposals reviewed in March 2004 (where the largest number of proposals was reviewed).

2.2.3.3. Issues of major significance on ethics emerging from the ethical review

When considering the issue of ethics in the Framework Programme, it is clear that the issue of research involving hES cells is of importance. However, it is also worth noting that figures of December 2004 show that out of the 236 proposals submitted to the ethical review process, only 3 involved the use of hES cell (existing hES cell lines) (i.e. 1,3%). Across the whole of the FP6 research agenda, many other significant and important ethical issues have been identified and addressed through the Commission’s ethical review process such as persons unable to give consent, use of non –human primates, use of genetic information etc .

2.2.4. Stem cells research

Stem cell research is one of the promising areas of biotechnology that is currently receiving important investments in terms of financial and human resources in both private and public sectors. However, when this research involves the use of human embryos it raises the question of ethical values at stake and of the limits and conditions for such research. An intense public and political debate continues in many countries concerning the future of stem cell research and therapy. In the last 3 years, Europe has seen a boom of new national legislation in this area. 9 EU Member States have passed specific legislation regarding human embryonic stem (hES) cell research between 2001 and mid- 2004. The recent scientific breakthrough regarding the technique of therapeutic cloning, published by research team in South Korea in May 2005, has reopened the debate worldwide

– REGULATION OF HUMAN EMBRYONIC STEM CELL RESEARCH IN EU MEMBER STATES⁶⁹

- 9 Member States (**Belgium, Denmark, Finland, France, Greece, Spain, the Netherlands, Sweden, and United Kingdom**) have a law allowing the procurement of human embryonic stem cells from supernumerary embryos. 2 MS (Belgium and United Kingdom) also allow the creation of human embryos for research purposes or for the procurement of stem cells. Somatic cell nuclear transfer (the so-call therapeutic cloning) is also allowed in these countries as well as recently in Sweden. Finland is discussing this last issue.
- 4 Member States (**Estonia, Hungary, Latvia, Slovenia**) have a law on medically assisted reproduction that does not exclude some research activities on supernumerary embryos but without specific reference to hES cell research.
- 2 Member States (**Germany, Italy**) prohibit the procurement hES cells from human embryos by law but not the importation of hES cell lines. Germany has established by law the conditions for the importation of these cell lines.
- 3 Member States (**Austria, Lithuania, Poland**) prohibit the procurement of embryonic stem cells from human embryos by law.
- 5 Member States (**Czech Republic, Luxembourg, Ireland, Malta, Portugal, The Republic of Cyprus, Slovak Republic**), have no specific legislation.

For its part, following the FP6 1st call for proposals, the Commission is supporting 25 research projects, with a total EC contribution of around €160 millions, that involve at least one component of stem cell research. More than 90% of these projects involve the use of human stem cells from adult origin. **Only 2 of these projects involving components of human embryonic stem cell (the use of existing hES cell lines)**. These 25 projects aims to develop new stem cell based therapies (often called regenerative medicine or cell based therapies), to use stem cells lines in drug development at pre-clinical stage and in toxicology, to understand human development and the basic mechanisms of cell differentiation and proliferation.

Figures from the FP6 2nd call for proposals, show that the Commission is expected to support around 17 projects with at least 1 component of stem cell research. This represents an EC contribution of around €110 million. As in the 1st call, more than

⁶⁹ http://europa.eu.int/comm/research/biosociety/bioethics/documents_en.htm

90% of these projects involve the use of human stem cells from adult origin. Only 1 of these projects involves a component of hES cell research (use of existing hES lines).

A number of Member States including UK, Sweden and Spain are engaging in the establishment of **public stem cell banks**. The stem cell bank intends not only to provide high quality starting materials to facilitate the development of stem cell research, but, in providing a centralised resource for researchers, it will optimise the use of existing human embryonic stem cell lines and may reduce the use of human embryos for the development of new stem cell lines by individual teams.

In the context of the decision-making process of FP6, the Commission has committed itself to support the establishment of a European registry of hES cell lines, similar to the National Institute of Health (NIH) registry in the USA. Support for such a registry, which would allow an ethical tracking of existing hES cell lines in Europe and their optimal use, has been the subject of the 2nd and 3rd calls for proposals in Priority 1. In both cases, the proposals received were found by the evaluators to be of insufficient quality to be funded. Because the Commission attaches great importance to this subject, it will be reopened for proposals in the 4th call for proposals in the course of 2005.

2.2.5. *The European Group on Ethics in Science and New Technologies*

The European Group on Ethics in Sciences and New Technologies (EGE) is a neutral, independent, pluralist and multidisciplinary body. It advises the Commission on all ethical questions related to Science and New Technologies in connection with the preparation and implementation of Community legislation or policies, acting either at the direct request of the European Commission or other Commissioners. The Parliament and the Council may also draw the Commission's attention to the need for ethical advice in these fields.

The EGE has issued Opinions on a wide range of ethical issues in the life sciences, from labelling food derived from modern biotechnology (N°5) to stem cell research (N°15). These Opinions are all available on the EGE Website⁷⁰.

The current mandate expired at the end of March 2005 and a Commission decision on a revised mandate for the EGE for the next 4 years will be adopted beginning of May 2005. The end of the current mandate provided the opportunity to strengthen the status and role of the EGE. The new mandate extends the EGE membership from 12 to 15 in order to include members from the new Member States and to bring in new competences. Another major improvement envisages the production of shorter Opinions or Statements that respond to scientific and technological developments in a more timely manner. In order to rationalise the functioning of the EGE and to facilitate meeting participation for the members, two-day meetings will be organised. Finally, in order to formalize and increase the transparency of the nomination procedure of the EGE members a call for expressions of interest was launched on the Internet.

⁷⁰ http://europa.eu.int/comm/european_group_ethics/index_en.htm

2.3. CONFIDENCE IN SCIENCE-BASED REGULATORY OVERSIGHT

2.3.1. *Review of the pharmaceutical legislation*

Following the adoption of the new Community Pharmaceutical legislative framework and its publication on 30 March 2004, the focus of work has been on its implementation and the introduction of implementing measures and guidelines. These measures include a **Commission Regulation on incentives for Small and Medium-sized Enterprises (SMEs) in their dealings with the European Medicines Agency (EMA)** including

- reductions and deferrals for a number of fees;
- easier access to scientific advice from the Agency;
- special incentives for companies developing orphan medicinal products;
- taking-over of certain administrative services (e.g. translations);
- tailored administrative support with the establishment of a new “SME office” within the EMA;
- publication of a User Guide, providing an overview of relevant Community legislation and incentives for SMEs in the pharmaceutical sector.

Public consultation, including a workshop with industry, on the proposal was concluded on 26 November 2004. Once adopted, the Regulation should apply with the full entering into force of the new pharmaceutical legislation, i.e. by the end of November 2005.

In addition, the Commission adopted a **proposal for a Regulation on paediatric medicines** on 29 September 2004⁷¹. This will provide a number of incentives to industry to develop medicines specifically for use in children, including enhanced intellectual property rights.

Finally, although the formal **G10 Medicines process**⁷² came to an end with the last meeting of the High Level Group of 3rd June 2004, a number of recommendations, primarily concerning national competence, remain to be implemented. These are being taken forward in a new Commission industrial strategy for the pharmaceutical sector⁷³.

⁷¹ COM(2004) 599

⁷² The G10 Medicines process was launched in 2001 to look at ways of improving the competitiveness of the European-based pharmaceutical sector in line with our public health objectives. The G10 Medicines High Level Group produced a report in 2002 which was followed by a Commission Communication and supportive Council recommendations in 2003.

⁷³ <http://europa.eu.int/rapid/pressReleasesAction.do?reference=IP/05/641&format=HTML&aged=0&language=EN&guiLanguage=fr>

2.3.2. *Genetically Modified Organisms (GMOs) legislation*

2.3.2.1. *Implementation of the new regulatory framework on GMOs*

The new legal framework on GMO has entered into application, namely:

- **Directive 2001/18/EC on the deliberate release into the environment of genetically modified organisms**, governing the placing on the market of GMOs for cultivation, import or processing into industrial products, as well as deliberate release for research purposes. It has replaced Directive 90/220/EC and applies since October 2002.

With the exception of Greece, to date all Member States have fully communicated their implementation measures for Directive 2001/18/EC. These are currently being assessed by the Commission for their conformity.

- **Regulation (EC) No 1829/2003 on genetically modified (GM) food and feed**, governing the placing on the market of GMOs intended for food or feed and of food or feed products containing, consisting of or produced from GMOs⁷⁴. Where a food or feed product contains or consists of GMOs, the applicant has a choice: (1) either the application in its entirety is uniquely subject to this Regulation, applying the "**one door, one key**" principle, in order to obtain authorisation for the deliberate release of a GMO into the environment - in accordance with the criteria laid down by Directive 2001/18/EC - and for the use of this GMO in food or feed products - in accordance with the criteria laid down by Regulation (EC) No 1829/2003⁷⁵; or (2) the application is split, one part being submitted under Directive 2001/18/EC and the other part Regulation (EC) 1829/2003.

Regulation (EC) No 1829/2003 on GM food and feed is fully applicable since 18 April 2004. Detailed rules on the implementation of this Regulation were adopted on 6 April 2004 with Commission Regulation (EC) No 641/2004. These rules refer to new applications for authorisation of GM food and feed, the notification of existing products and adventitious or technically unavoidable presence of GM material. Detailed guidance for the applicant concerning the data to be submitted for the risk assessment of GM plants and derived food and feed has been adopted by the European Food Safety Authority on 24 September 2004.

- In addition, GMOs and food and feed products produced from GMOs placed on the market must also comply with labelling and traceability requirements. These requirements are found in Regulation No (EC) 1829/2003 on GM food and feed and in **Regulation (EC) 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. Regulation (EC) No 1830/2003 was adopted on 22 September 2003 and entered into force on 7 November 2003. Its subsequent application was

⁷⁴ Article 46(1) of the Regulation on GM Food and Feed provides that applications made under the **Novel Foods Regulation** (i.e. Regulation 258/97) which have received a final scientific assessment before the coming into application of the new Regulation are still to be processed under the Novel Foods Regulation

⁷⁵ So far, operators have not made use of the possibility of requesting cultivation under GMO Food and Feed legislation, however, this cannot be excluded for the future

dependent upon the publication of an implementing measure, following its adoption via comitology, establishing a system for the development and assignment of unique identifiers to GMOs. This system was laid down in **Commission Regulation (EC) No 65/2004**, which was published on 16 January 2004. Regulation (EC) No 1830/2003 was fully applicable 90 days later (15 April 2004) in accordance with its Article 13(b). A **Commission Recommendation (2004/787/EC)** establishing guidance on sampling and testing was adopted on 4 October 2004 and published on 24 November 2004 completing the necessary implementing measures under the Regulation.

- In enforcement of the above Community legislation on GMOs, the Commission has adopted a decision aimed to avoid that maize products produced from the non authorised GM Bt10 maize are placed on the Community market⁷⁶. The decision applies to corn gluten feed and to brewers grains containing or produced from GM maize. Member States shall allow the first placing on the market of the above products only where accompanied by an original analytical report based on a suitable and validated method for the event-specific detection of GM Bt10 maize, issued by an accredited laboratory and demonstrating that the product does not contain Bt10 maize or feed produced from Bt10 maize. The decision also provides that Member States have to take all the appropriate measures to verify the absence of Bt10 maize in products already on the market.
- Finally, **Directive 2002/53/EC and Directive 2002/55/EC** governing the marketing, and - as a consequence - the commercial cultivation, of seeds of GM plant varieties throughout the Community. According to these Directives, the Commission is required to inscribe in the Common Catalogue any such varieties which have been added to national catalogues. The GM seed varieties shall only be accepted for inclusion in a national catalogue after having been authorised in accordance with the above Community legislation.

2.3.2.2. *State of play on GMO authorisations*

A) Applications under Directive 2001/18/EC

Directive 2001/18/EC covers the approval of GMOs for import and industrial processing as well as cultivation. The Directive also covered approval for use in feed but under the new regulatory framework, this has subsequently been transferred to Regulation (EC) No 1829/2003 on GM food and feed from its date of application (18 April 2004). However, certain applications for GMOs including their use in feed that were submitted under Directive 2001/18/EC prior to this date will continue to be approved under the Directive during a transition period according to the transitional measures laid down in Article 46(3) of Regulation (EC) No 1829/2003 on GM food and feed.

Eleven applications out of the 25 submitted under Directive 2001/18/EC included requested uses as feed and were to be transformed into applications under Regulation (EC) No 1829/2003 on GM food and feed in accordance with its Article 46(3) given that the assessment reports required under Article 14(3) of the Directive had not been received by the Commission before the date of application of the Regulation.

⁷⁶ Commission Decision 2005/317/EC of 18 April 2005 (OJ L 101)

One product (NK603) has been approved in 2004 and two others (GT73 and MON863) are at an advanced stage of the approval procedure. Other applications are at different stages of the approval processes and some of them are currently being considered by the European Food Safety Authority (EFSA).

B) Application under Regulation (EC) No. 258/97 on novel foods and Regulation (EC) No 1829/2003 on GM food and feed

In 2004, two products (Bt 11 sweet maize and NK603 maize) were approved under the normal authorisation procedure of Regulation (EC) N° 258/97 on novel food. The authorisation process is on-going for the remaining applications for authorisation of GMOs pending under Regulation 258/97 (i.e. GA 21 maize and MON863 maize). All of these authorisations are upgraded to the standards of the new regulatory framework, in particular concerning the labelling and traceability requirements.

In accordance with Article 46(1) of Regulation (EC) No 1829/2003 on GM food and feed, applications under Regulation (EC) N° 258/97 on novel food for which the assessment report provided for under Article 6(3) of this Regulation had not been forwarded to the Commission before 18 April 2004, were transformed into applications under Regulation 1829/2003 on GM food and feed.

In addition, a series of new applications for authorisation of GM food and feed have been submitted under Regulation (EC) No 1829/2003 on GM food and feed since it became applicable on 18 April 2004. EFSA has given a positive opinion on one of these applications on the 3 of March 2005 (1507 maize) and is currently conducting the risk assessment of the remaining applications.

The new regulatory framework has also contributed by a notification procedure to further clarify which GM food and feed could already be legally placed on the market in the EU before the entry into force of Regulation (EC) No 1829/2003 on GM food and feed. Following this notification procedure, 26 GM products were entered in the **Community Register on GM food and feed** on 18 April 2005. With the entry into the Register, these products may stay legally on the Community market for a time period between 3 and 9 years, after which a renewal of the application for authorisation is necessary. The publication of the Register also allows withdrawing formally the authorisation of products for which no notification has been submitted.

C) Directive 2002/53/EC on the common catalogue of varieties of agricultural plant species

On 8 September 2004, the Commission has approved the inscription of 17 GM varieties derived from MON 810 maize in the Common Catalogue of agricultural plant species. The GM maize varieties will be the subject to the labelling and traceability requirements as established in Regulation 1830/2003 and in the seed legislation.

2.3.2.3. The Community Reference Laboratory for GM Food and Feed

By the implementation date of Regulation (EC) No 1829/03 on GM food and feed the Joint Research Centre was ready to operate the “Community Reference Laboratory” (CRL) in the context of the GM Food and Feed Regulation. The CRL in the meanwhile has established a key reference position within the EU regulatory

framework and has been instrumental in building up consumer confidence, particularly with respect to labelling and traceability.

"Community Reference Laboratories" (CRLs) have been designated in different Community Decisions, Directives and Regulations. Whereas normally the task of CRL is assigned to a (consortium of) National Laboratory (-ies), the Joint Research Centre has been nominated "CRL" because Council and Parliament wished to benefit from the JRC's expertise in the area of Genetically Modified Organisms (GMOs). The Community Reference Laboratory for GM Food and Feed was established by European Regulation (EC) No 1829/2003 on genetically modified (GM) food and feed, and started its operations on 19th April 2004.

The CRL is assisted by a consortium of 75 national GMO enforcement control laboratories, from each of the 25 Member States of the EU, established in the existing European Network of GMO Laboratories (ENGL).

Its main task is the testing and validation of the methods for detection and identification of the transformation events but it is also responsible for the distribution of control samples. At the end of the validation process, evaluation reports are submitted to the European Food Safety Authority. Regulation (EC) No 641/2004 defines the implementing measures to comply with the GM Food and Feed regulation.

During 2004 a total of thirty-five dossiers have been submitted to the CRL. These concern applications and notification of GMOs of various nature (superior plants, fermentation products) and species (maize, soybean, rice, sugar beet, oilseed rape, cotton). The validation of a quantitative event-specific method of detection was completed for the following GMO maize lines: NK603, GA21, MON 863 and TC-1507. For these studies, a full validation report together with a detailed validated protocol was compiled⁷⁷.

All updated versions of the documents are published in the CRL website⁷⁸.

The expertise of the CRL has also been demonstrated in the alert reaction of the European Commission in the case of advertent release of unapproved maize of the BT10 event in the EU. It was responsible for the in-house validation and subsequent approval of a method that detects small traces of BT10. This method is the only one approved in the Community for certifying that maize commodities are free of BT10.

2.3.2.4. *National 'safeguard clauses'*

During the late 1990s, a number of Member States (Austria, Luxembourg, Germany, France and Greece) invoked the 'safeguard clause' under Article 16 of Directive 90/220/EEC to provisionally ban the placing on the market of certain GMOs (maize and oilseed rape) in their territories (Annex II).

In December 2003, the Commission requested the above Member States to reconsider their pending safeguard clauses in view of the new regulatory framework

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<http://gmo-crl.jrc.it>

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<http://gmo-crl.jrc.it/guidancedocs.htm>

and if necessary, to re-submit them under Article 23 of Directive 2001/18/EC (which replaced Directive 90/220/EEC). In view of this request, Greece and Austria submitted, in January 2004, further information in support of their bans. This additional information potentially impacted on all eight cases and was submitted to EFSA for opinion. EFSA concluded, on 8 July 2004, that the additional information did not invalidate the original risk assessments for the products in question.

Following the opinions of EFSA, aligned with the new regulatory framework draft decisions requesting Member States to withdraw their national measures were submitted to the Regulatory Committee for opinion. The Regulatory Committee, on 29 November 2004, failed to reach qualified majority either in favour or against any of the draft decisions. Subsequently, in April 2005, the Commission adopted proposals for Council Decisions relating the measures taken. The Council has three months to act.

In January 2005, Hungary invoked Article 23 (safeguard clause) of Directive 2001/18/EC to provisionally prohibit the production, use and distribution of sowing seeds of in-bred lines and hybrids originating from the MON 810 maize line⁷⁹, along with its importation into the territory of the Republic of Hungary. The ban extends to plants originating from cross-breeding with any traditionally improved maize varieties and lines. It does not apply to the use of MON 810 maize in the food/feed production chains, nor does it apply to transportation across Hungary without packaging and any further treatment if it is guaranteed that such maize is not released into the environment. The Commission has requested an opinion to EFSA, following which a decision will be taken in accordance with the regulatory procedure.

With respect to the national safeguard clause (Article 12) invoked by Italy under Regulation N° 258/97, further to the ruling of the European Court of Justice (case C-236/01) the regional Court of Justice of Lazio has cancelled the Italian decree of August 2000.

Poland has submitted on 31 March 2005 an application for the introduction of a temporary two year ban on the use and placing on the market of seed material from genetically modified varieties of corn line MON 810 (inscribed in the Common Catalogue of agricultural plant species on 17 September 2004). This application is based on article 16(2) of Directive 2002/53/EC on the common catalogue of agricultural plant species. The application shall be dealt with under the regulatory committee procedure which is foreseen for seeds of genetically modified varieties. In the meantime the marketing of seeds of the varieties concerned is still permitted in Poland.

Greece prohibited for a period of two years the marketing of seeds of 17 varieties from genetically modified hybrids of maize included in the common catalogue on 17 September 2004. The measure is taken on the basis of article 18 of Directive 2002/53/EC and was notified to the Commission on 4 April 2005. The national prohibition applied by Greece will be dealt with under the regulatory committee procedure which is foreseen for seeds of genetically modified varieties. According to the Directive, a decision shall be taken within a period of 3 months. In the meantime, marketing of the seeds of the varieties concerned is prohibited in Greece.

⁷⁹ Reference C/F/95/12-02

2.3.2.5. Co-existence of GM crops with conventional and organic crops

In 2003, the European Parliament and the Council adopted a new article to Directive 2001/18/EC (Article 26a) endorsing the Commission position that co-existence would be best managed at national or regional level. Several Member States and Regions are now developing their own co-existence measures.

Under these circumstances, when the measures in question consists of technical regulations in the sense specified by Directive 98/34/EC laying down a procedure for the provision of information in the field of technical standards and regulations, and by the case-law of the Court of Justice in the area, these measures must be notified to the Commission at the draft stage.

Since late 2003, the Commission has received a number of these co-existence measures. In most cases, the Commission issued a detailed opinion (Article 9(2) of Directive 98/34/EC) according to which the draft measures presented aspects that could possibly create barriers to the free movement of goods within the internal market. A dialogue between the Member States in question and the Commission was initiated in these cases; the Commission encouraged those Member States to take better account of its Recommendation on coexistence (Recommendation 2003/556/EC). This exchange provided the opportunity to clarify certain points.

– **Coexistence measures notified to the Commission to date under Directive 98/34/EC (on provision of information on technical standards and regulations):**

- **Notification 2003/200/Autriche – Carinthie** : Le texte adopté a été reçu le 01/02/05. La procédure de notification est terminée.
- **Notification 2003/236/Italie (semences importées des pays tiers)** : Après une réunion, le 12/11/04, entre les autorités italiennes et les services de la Commission, l'Italie a confirmé son intention de modifier le texte du projet dans le sens demandé.
- **Notification 2003/475/Autriche – Salzbourg** : Salzbourg a transmis sa réponse à l'avis circonstancié mais a adopté le texte avant de recevoir la réaction de la Commission sur cette réponse.
- **Notification 2004/133 et 241/Allemagne** : La procédure de notification terminée
- **Notification 2004/311/Autriche – Tyrol** : La réponse de l'Autriche à l'avis circonstancié a été jugée satisfaisante. Communication à l'Autriche le 8 mars 2005
- **Notification 2004/393/Danemark**: Il s'agit d'une loi cadre qui ne contient pas de règles techniques. Le premier règlement d'application a été notifié sous la référence 2005/546/DK
- **Notification 2004/426/Luxembourg**: Un avis circonstancié a été envoyé le 25/01/05. En attente de la réponse
- **2004/459/Autriche – Burgenland**: Un avis circonstancié a été envoyé le 31/01/05. En attente de la réponse
- **2004/538/Autriche – Vienne** : Un avis circonstancié a été envoyé le 21/03/05. En attente de la réponse
- **2004/546/Danemark** : Observations ont été envoyées le 21/03/05

- **2005/005/Autriche – Basse-Autriche** : procédure interne de consultation en cours
- **2005/012/Autriche – semences** : n'est pas en infraction avec le droit communautaire

Notification under Article 95 of the Treaty

- **Upper Austria draft act** prohibiting the cultivation of GM seeds and the used of GM animals and their releases: rejected by Commission Decision 2003/653/EC of 2.9.2003. The regional Parliament of Upper Austria and the Austrian Federal government have appealed against the Commission decision to the Court of Justice

In addition, the Commission is aware of a number of municipalities and regions in different Member States that have declared themselves “GMO-free”. As long as these declarations are a mere declaration of intent, a description of the status quo, or are based on voluntary agreements of all stakeholders concerned and do not imply a prohibition of the use of authorised products, they do not require notification by the Member State to the Commission. However, if those decisions are aimed at producing legal effects and result in a ban on the placing on the market of authorised GMOs, such measures might be in contradiction with Directive 2001/18/EC.

– **European Regional and local authorities taking part in (GMO-free zones) and regions movement**

– *(Last update: 10 February 2005; Source “Assembly of the European Regions”)*

An Europeans regions' network to prevent risks of genetic contamination in agriculture

In a joint declaration of 4 November 2003, **10 European regions** have asked the European Union to accept that European regions define their own territory or part of it as GM-free areas. These Regions are Toscana (I), Upper-Austria (A), Aquitaine (F), Basque Country (E), Bolzano (I), Limousin (F), Marche (I), Thrace (EL), Salzburg (A), Schleswig-Holstein (D), Wales (UK). **Ten other regions** – Highlands (UK), Burgenland (A), Lazio (I), Bretagne (F), Poitou Charentes (F), Emilia-Romania (I), Ile de France (F), Drama-Kavala-Xanthi (G), Sardegna (I) - have then joined the network

On **4th February 2005**, the above twenty regions and local representative, signed a **charter** in Florence aiming to lay the foundations for their action plan to defend the right and the ability of EU farmers freely to choose between conventional, organic or transgenic farming. Since then, some additional regions have signed the charter

With the exception of Upper Austria, the Commission has not yet received any formal notification of regional measures prohibiting the use of GMOs under the appropriate notification procedures.

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

On 16 December 2004 the **Economic and Social Committee** adopted an own-initiative opinion on coexistence calling for rules on good professional practice to be set or harmonised at a high (i.e. Community) level, whilst remaining flexible enough to take account of the various conditions of cultivation and processing.

The Member States are split with respect to their preference for Community legislation versus a continuation of the subsidiarity approach towards coexistence. Some Member States have repeatedly asked for harmonisation, while others have consistently opposed this.

- **Co-ordination network on co-existence**

Directive 2001/18/EC and Commission Recommendation 2003/556/EC provide for a coordination role of the Commission in the field of co-existence. In order to implement these obligations and commitments, and in line with conclusions of the Commission debate of 28 January 2004, the Commission is working on the setting up of a network group on co-existence as a forum in which Member States may present and discuss national or regional approaches to co-existence. The network will become operational within 2005.

At the “Agriculture and Fisheries” Council of 18 October 2004, a number of Member States requested the Commission to set up a European Task Force on co-existence.

- **Study on the implementation of co-existence legislation in the Member States**

In 2004, the Commission launched a study that should support the Commission in preparing the report on the experience gained in the Member States concerning the implementation of measures to address co-existence, which shall be presented in 2005 to the Council and the European Parliament. The study should provide an overview and analysis of all relevant legislative and other approaches developed by the Member States, on national and regional level, with respect to co-existence. On the basis of the above report, the Commission will reflect on possible further steps to take on co-existence policy.

- **Follow-up study on co-existence in crop and seed production**

In the JRC-IPTS study “*New case studies on the co-existence of GM and non-GM crops in European agriculture*” the seed and crop production of maize, sugar beet and cotton is investigated regarding co-existence in the same region. The feasibility (technical and economical) of producing crops and seeds with different thresholds for the adventitious presence of GM crops is considered, with particular emphasis on the seed production sector in order to support the Commission decision on establishing labelling thresholds for seed production. The scope of the study covers the production up to the farm gate. Technical and economic consequences of threshold introduction beyond this stage are not included.

The study identifies and maps geographical areas in several Member States where the adoption of GM maize, GM sugar beet, GM cotton is most probable (based on agronomical considerations). This will help to anticipate coexistence hotspots. The study also reviews the existing quantitative models on gene flow and will provide information on the level of validation of these models, in particular for the two models used in the JRC-IPTS co-existence study, namely MAPOD® and GeneSys®.

- **Research Projects of Relevance under FP6**

Research regarding co-existence between conventional, organic and GM crop production is being addressed under the 6th Framework Programme for Research. So far 2 projects have been funded with a total EC contribution of 17.5 M Euro under Priority 5 “Food quality and safety” and Priority 8 “Research for policy support”:

“Sustainable introduction of GMOs into European Agriculture” (SIGMEA project): This project aims to set up a science-based framework, strategies, methods and a practical toolbox for assessing ecological and economic impacts of GM crops and for effective managing of their development within European farming systems. It brings together the principal programmes and experts from UK, France, Italy, Denmark, Germany, Belgium, Slovenia, Switzerland, Spain, The Netherlands, Czech Republic, Poland and the Joint Research Centre. In the context of SIGMEA, JRC-IPTS will conduct in 2005 a specific study on the socioeconomic dimension of the *Bt maize* adoption by Spanish farmers (the only case so far in the EU of GM crops adoption). One of the objectives of this study is the evaluation of the economic performance of *Bt maize* versus its conventional counterpart. It will be the first study world-wide on the economic balance of a GM crop that considers potential costs derived from adopting measures to ensure co-existence

- **“GM and non-GM supply chains: their co-existence and traceability” (Co-Extra):** This project will study and validate biological containment methods and models for food and feed supply chain organisations. It will develop mathematic models for pollen emission and its impact on long distance dissemination as well as assess innovative detection methods for unknown GMOs and stacked GMOs. All methods and tools will be assessed from the technical as well as from the economic and legal points of view.

3. EUROPE IN THE WORLD - RESPONDING TO GLOBAL CHALLENGES

3.1. A EUROPEAN AGENDA FOR INTERNATIONAL COOPERATION

3.1.1. *WTO dispute*

Following the establishment of the WTO panel in August 2003, the panellists have been appointed in March 2004 by the Director General of the WTO. Each party has filed three written submissions and one meeting of the parties with the Panel took place in June. The dispute will expand in 2005; the report of the Panel is expected in June 2005. In its written submissions as well as during the meeting with the Panel, the Commission, on behalf of the European Communities, has firmly rejected any concept of moratorium or undue delay in the processing of applications for authorisation. Rather, the Commission has explained the technical and scientific complexity of GMO issues, taking account in particular of the technical and scientific knowledge at the time of the occurrence of the alleged delays. From the Commission point of view, such complexity provides sound justification for the evolution of EU policy and regulation since the mid-nineties. The Commission has made it clear to the panel that in the EU, applications for authorisations are dealt with on a case by case basis and only products that fulfil the criteria laid down in the Community legislation can be approved. The Commission considers that the approvals granted under Directive 2001/18 or under Regulation (EC) N° 258/97 are irrefutable proofs that the case brought by the complaining parties is moot.

3.1.2. *Cartagena Protocol on Biosafety.*

The Conference of the Party serving as the first Meeting of the Party took place in February 2004. The meeting has been a major success for the EU who has supported the Protocol since its birth.

- **Main outcomes of the meeting**
- adoption of a compliance procedure and mechanism
- launch of negotiations on rules and procedure on liability and redress

- adoption of interim measures on documentation requirements for GMO shipments
- adoption of guidance to parties in their dealing with non-parties
- adoption of rules for the functioning of the Biosafety Clearing House
- adoption of an action plan for capacity building
- adoption of Guidance to the Financial Mechanism on support for the Protocol,
- adoption of a Medium-term programme of work for the next four meetings of the parties,
- adoption of a separate budget for the distinct costs of the Protocol.

The EU participated to the 2nd Meeting of the Parties that took place in Montreal from 30 May to 3 June 2005.

3.1.3. *Agriculture and Genetic Resources*

The Commission together with Member states, representatives of Civil Society organisations and the private sector, has completed a study to design an EU a pro-poor strategy for green, red, white and blue biotechnologies in Developing countries. The final report was submitted by the consultants and the EU will finalise this proposal during 2005. The report identifies a number of choices for EU support to different clusters of developing countries, and crucial areas for EU interventions with respect to promoting pro-poor biotechnology.

3.1.4. *Health*

Under FP6 poverty related diseases section has been funded projects focused on developing promising candidate interventions (vaccines, therapies and microbicides) against HIV, TB and malaria. The total budget allocated for this area, in FP6 is estimated at 221.5 million euro (1st call: 73million €, 2nd call 27.5million €, 3rd call: 54 million €, 4th call: 67 million €).

Most of the projects are based on the collaboration with developing countries. In the 1st call of thematic priority 1 –under the poverty related diseases section, are participating as partners, in NoE and IP projects, the groups from: Ethiopia, Gabon, Guinea, Mali, South Africa, Sudan, Senegal, Uganda.

Further support under FP6 was provided during 2004 for 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 selected 16 STREPs (14.2 million euro: for 7 projects in the field of HIV/AIDS, 5 in the field of malaria, 4 in the field of tuberculosis) and 5SSAs (1.3 million € for 2 projects in the field of HIV/AIDS and 3 in the field of TB).

For the final call for poverty related diseases research, a budget of 67 million € will be provided.

The *European and Developing Countries Clinical Trials Partnership (EDCTP)* initiative, 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 in July 2004. A balanced North/South partnership and the networking/coordination of participating European national programmes have been widely considered in the setting-up of the structure of this European pilot initiative which now operates within its own implementation structures, calls for proposals, evaluation and selection procedures.

- **European and Developing Countries Clinical Trials Partnership (EDCTP)**
- 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.
- **The South African Cochran database (A Clinical Trial Registry) has also been selected.**
- **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 DG AIDCO in April 2005, a specific call for supporting clinical trials sites selected by the EDCTP programme was earmarked**

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. from the European Development Fund specific budget lines and the private sector), 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

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 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 which has been published and is available online⁸⁰.

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

3.1.5. *Food safety*

A “**food quality and safety platform**” promoting science and technology dialogue between EU and Latin America (in the context of the ALCUE bi-regional dialogue) has been initialled with the support of the Commission. It aims at a) facilitating information development and knowledge sharing on factors influencing food quality and safety with the objective of stimulating enhanced regulations and practises, b) promoting a greater convergence in RTD and elaboration of food quality and safety policies, c) synergizing technology transfer and trade and d) optimising the utilization of cooperation resources.

4. **IMPLEMENTATION AND COHERENCE ACROSS POLICIES, SECTORS AND ACTORS**

4.1. **FORESIGHT ACTIVITIES**

4.1.1. *Study on biotechnology*

The European Parliament requested the Commission in late 2004 to “assess and conduct a cost-benefit analysis of biotechnology and genetic engineering, including GMOs. The aim of the study is to conduct a comprehensive assessment and cost-benefit analysis of the opportunities afforded by, and the risks of, biotechnology and genetic engineering, including the medical and agricultural spheres, account being taken of the Lisbon strategy, the Copenhagen environment criteria and Agenda 21 sustainable development”⁸¹.

Modern biotechnology is generally regarded as a key enabling technology with a potentially wide range of applications. However, recent studies suggest that the actual adoption and use of modern biotechnology across industrial sectors may be lower than expected three decades after the key scientific discoveries took place⁸². The use of biotechnology in industrial processing is still largely limited to a few examples, genetically modified crops are hardly grown in Europe and promising applications such as stem cells are still in R&D phases⁸³. Modern biotechnology seems to have succeeded mostly in niche applications where it does not compete with alternative technologies (a clear example is protein or antibody-based pharmaceuticals).

⁸⁰ http://europa.eu.int/comm/european_group_ethics/avis3_en.htm

⁸¹ Document 12 – Parliament 2nd reading – Amendments adopted by the Committee on Budgets.

http://www.europarl.eu.int/comparl/budg/budg2005/procedure/default_en.htm

⁸² A. Arundel (2003) Biotechnology indicators and public policy. OECD STI working papers 2003/5

⁸³ JRC-IPTS studies on GM crops (EUR 20680), tissue engineering (EUR 21000), genetic testing (EUR 20977), biocatalysis (EUR 20407) and bio-based polymer production (publication pending), OECD report “The application of biotechnology to industrial sustainability” (2001)

Yet, the same studies acknowledge that data on the actual adoption of biotechnology and related economic, social and environmental consequences is very scarce and hampered by the lack of appropriate and updated statistics. This is why a profound analysis of the current state, and the opportunities and challenges of modern biotechnology for Europe is not available and cannot be performed without undertaking significant previous work.

Evaluating the consequences, opportunities and challenges of modern biotechnology for Europe is important both for policy makers and industry. European policy strategies on economic growth, sustainable development and environmental preservation have been outlined in the past years. Understanding how the adoption of modern biotechnology in the various production sectors could contribute to the objectives of these strategies is a recognized need.

The Commission recognises the potential value of carrying out a comprehensive study on biotechnology. The study will be executed by the Institute for Prospective Technological Studies of the Commission Joint Research Centre (JRC-IPTS) in close collaboration with the other services of the Commission.

The Commission is currently defining the content and structure of the activity. The objective will be to provide a comprehensive assessment of the consequences, opportunities and challenges that applications of modern biotechnology present for Europe in terms of economic, social, and environmental aspects, having in mind major European policy goals, i.e. to become the most competitive and dynamic knowledge-based economy in the world capable of sustainable economic growth with more and better jobs and greater social cohesion and respect for the environment.

It is expected that the whole activity, including a final symposium, will take up to 24 months.

4.2. EMERGING ISSUES

4.2.1. Tissue engineering

Human tissue engineering is an emerging, multidisciplinary biotechnology sector focusing on the regeneration of diseased human tissues. The development of this novel biotechnology promises to change medical practice profoundly and heralds new treatment possibilities for European patients. The hope is that human tissue engineered products will deliver superior treatments by improving the speed, extent and duration of healing compared to conventional treatments. However, legislation currently varies from one Member State to another. The lack of a clear and uniform regulatory framework leads to legal uncertainty and to a fragmentation of this emerging market. The European Commission has therefore announced that it would propose new legislation harmonising the authorisation procedures for human tissue engineered products.

In April 2004, the Commission services published a consultation paper on the future proposal for a harmonised regulatory framework on human tissue engineered

products⁸⁴. This document outlined key issues to be addressed in future legislation and invited written comments from interested parties. Regulatory orientations were also discussed during a stakeholders' conference.

In addition, following a first report on human tissue-engineered products (hTEPs) published December 2003⁸⁵, JRC-IPTS finalised in 2004 a study analysing the potential economic, social and environmental impacts a future European level regulation on hTEPs could have⁸⁶. The study showed that Member States currently approach authorisation of hTEPs in very diverse ways, ranging from hTEPs not being regulated at all to being regulated as medicinal products. This situation results in differing safety, quality and efficacy standards and a fragmentation of the European market, which presents a hurdle to the competitive development of the sector. The tissue-engineering sector is a young and still developing sector, and thus has the opportunity to adapt to a changed regulatory environment. As the sector is characterised by fairly small manufacturers, including hospitals and tissue banks, specific support measures might be considered to avoid overly burdensome authorisation processes. The planned regulation could help to build trust in this new technology, thereby encouraging its acceptance in medical practice and reimbursement policies. It would thus indirectly target another major hurdle for the further development of tissue engineering.

In light of this preparatory work, the principles and main elements of the legislative proposal have now been agreed upon. The key objectives are the following:

- To guarantee a high level of health protection for European patients treated with advanced therapies (gene therapy, somatic cell therapy, tissue engineering);
- To facilitate market access for advanced therapies, in particular tissue engineered products, by establishing a harmonised and tailored regulatory framework for their authorisation, supervision and post-authorisation vigilance;
- To foster the competitiveness of European undertakings operating in this field;
- To provide overall legal certainty, while allowing for sufficient flexibility at technical level, in order to keep the pace with the evolution of science and technology.

Stakeholders will be consulted on the draft Regulation in May-June 2005. Adoption of the Commission proposal is foreseen for the last quarter of 2005.

⁸⁴ DG Enterprise Consultation Paper "Proposal for a harmonised regulatory framework on human tissue engineered products. April 2004.
http://pharmacos.eudra.org/F3/humantissue/Consultation_document.pdf.

⁸⁵ Bock, A.K., Ibarreta, D., Rodriguez-Cerezo, E.: "Human tissue-engineered products - Today's markets and future prospects", Joint Research Centre - Institute for Prospective Technological Studies (European Commission) 2003, EUR 21000 EN
<http://www.jrc.es/home/publications/publication.cfm?pub=1127>.

⁸⁶ Bock, A.K., Rodriguez-Cerezo, E., Hüsing, B., Bühlren, B., and Nusser, M.: "Human tissue-engineered products: Potential socio-economic impacts of a new European regulatory framework for authorisation, supervision and vigilance", Joint Research Centre - Institute for Prospective Technological Studies (European Commission), publication pending.

Under the 1st call of Life sciences genomics and biotechnology for health programme 8 projects has been funded in tissue engineering field.

Adult mesenchymal stem cells engineering for connective tissue disorders, from the bench to the bed side (Genostem). This IP (23 partners) launched in 2004, brings together experts from Molecular Biology, Cellular Biology, Biomechanics, Genomics, Proteomics, Bioinformatics and Molecular Medicine, for establishing an European international scientific leadership in stem cell regenerative medicine focus on connective tissue engineering based on autologous adult mesenchymal stem cells(MSCs). The project will: a) develop new technologies to generate biodegradable matrices, scaffolds and microcarriers; b) improve methods for gene transfer using original lentivirus or non viral delivery systems; c) develop a number of transplantation models of MSCs mimicking human pathological processes.

4.2.2. Genetic testing and related issues

Genetic testing, its scientific, ethical, legal and social implications, have continued to be subject to debate both internationally and nationally. New legislation is underway in several EU Member States. Sweden is expected to adopt a new law in summer 2005, which will address the use of genetic testing in employment, insurance and health care. The need for a bill has also been addressed by the German Minister for Health.

For its part, the Commission, in response to the priority action stated in the second progress report on the Strategy for Europe on Life Sciences and Biotechnology, has

- has established an **informal working group involving officials and experts from Member States** to ensure exchange of information and to identify actions which should be addressed at EU level in order to assure the highest quality of genetic testing. The need for collaboration and exchange of information at EU level was confirmed at the two meetings organised so far in May 2004 and March 2005. A survey on national legislations and activities regarding genetic testing has been prepared. Discussion is continuing on the basis of an "open issues paper" summarizing the questions that should be tackled by the Commission and Member States.
- has started 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. The results are expected early 2006;
- has implemented, under FP6, a Network of Excellence "**EUROGENTEST**"⁸⁷ addressing the issue of harmonisation, validation and standardisation of genetic tests. A public database including all laboratories in the EU that provide genetic testing (molecular, biochemical, cytogenetics) will be available early 2006;
- is supporting the a series of activities to improve information and to network concerned parties in the field of rare diseases in the **EU Public Health Programme**⁸⁸. A number of research projects on genetic testing of rare diseases are funded under FP5 and FP6. So far the need for a referral system for rare and complex genetic diseases has been identified as an issue which need special attention

An initiative **on the protection of worker's personal data in the employment** context is expected to be launched in 2005. The initiative will also address the

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www.eurogentest.org

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http://europa.eu.int/comm/health/ph_threats/non_com/rare_diseases_en.htm

http://europa.eu.int/comm/health/ph_projects/rarediseases_project_en.htm

http://europa.eu.int/comm/health/ph_projects/action1_en.htm

processing of genetic data. The European Group on Ethics issued Opinion (N°18) on the ethics of genetic testing in the work place which has been published and is available online⁸⁹.

On 17 March 2004, the **Article 29 Working Party (National Data Protection Authorities-DPAs)** adopted a working document on the processing of genetic data⁹⁰. One of its 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. 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 DPAs 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.

The recommendation from the high level expert group “**ETAN-STRATA**”⁹¹, addressing the ethical, social and legal aspects of human genetic testing in research and healthcare applications, has been published in 19 EU languages⁹².

4.2.2.1. *Interface between in vitro fertilization techniques and pre-implantation genetic diagnosis (PGD).*

JRC-IPTS, together with the European Society of Human Genetics and the European Society for Human Reproduction and Embryology, organized a workshop in March 2005 on the interface between *in vitro* fertilization techniques and pre-implantation genetic diagnosis (PGD), a new application of genetic testing that is taking off very quickly and with potential large impacts of many kinds. Different regulations, practices and lack of professional recommendations and guidelines may still lead to large differences across Member States. There seems to be many questions around the genetic services involved in assisted reproduction that could benefit from a European coordination effort, including the quality of these services.

A key issue is the scientific claim that by genetic screening, the routine procedure of implantation of several embryos per woman can be reduced to implanting a single embryo, with potential large economic savings (by increasing efficiency) and reduction of multiple births. While not all scientists agree yet with this claim, the technology is likely to become routine in some clinics. Another key issue is the apparent generalisation of genetic testing of donors of sperm with very little control since most activities occur in the private sphere. It seems a fact that a few genetic profiles may be being used massively as donors.

Pre-implantation genetic diagnosis is affected by Directive 2004/23/EC of the European Parliament and of the Council of 31 March 2004 on setting standards of quality and safety for the donation, procurement, testing, processing, preservation,

⁸⁹ http://europa.eu.int/comm/european_group_ethics/avis3_en.htm

⁹⁰ http://europa.eu.int/comm/internal_market/privacy/docs/wpdocs/2004/wp91_en.pdf

⁹¹ http://europa.eu.int/comm/research/conferences/2004/genetic/recommendations_en.htm#top

⁹² Translations in Chinese, Russian, Arabic and Japanese are foreseen in 2005.

storage and distribution of human tissues and cells. The donation of eggs, sperm and embryo fall within its scope and so do the type of genetic screening performed, amount of clinical history of donors included, amount of genetic information and so forth. The European Society of Human Genetics (ESHG) and the European Society of Human Reproduction are currently providing input to a Commission's guidelines document for implementation of the directive. The background document being prepared and the discussion at the workshop will tackle these issues.

JRC-IPTS will launch an assessment of the current practices of pre-implantation genetic diagnosis in EU to define the needs in the area and assess potential options to solve them. Results will be available by mid 2006.

4.2.2.2. *Pharmacogenetics*

Pharmacogenetics is the study of inter-individual specific genetic variation related to response to medicines. It is often said that pharmacogenetics (PG) might enable the pharmaceutical industry to significantly enhance the productivity of drug discovery and development, allowing also the re-evaluation of drugs that have failed because of low response rates in the general population. In health care, PG could help reduce the overall cost of disease management, minimizing adverse effects and improving therapeutic efficacy. As the applications of PG are relatively recent (although the term itself is some 50 years old), a comprehensive picture of the state-of-the-art in the EU in terms of research activities, commercial applications in drug development, PG-related market and industry structure and probable future developments has yet to emerge.

JRC-IPTS, together with the European Society of Human Genetics, organized a workshop in 2004 with experts from different disciplines to review the field. The workshop concluded that the clinical application of PG has so far been overestimated and expectations have not yet been fulfilled. It has not moved yet to practical applications, except for very limited drug examples. There is uncertainty when estimating the possible impacts that a large development of PG applications could have on health care in Europe. There are multiple ways in which PG will influence health systems and various pressures which will in turn affect the successful implementation of PG. A paper including a detailed background document and conclusions of the workshop is under preparation for publication (*available in September 2005*).

The workshop served to define the scope of an on-going JRC-IPTS study mapping the R&D situation of PG in Europe, identifying upcoming socio-economic issues and potential barriers to development and implementation of PG applications in clinical practice. The study includes the detailed cost-benefit analysis of two case studies of existing PG applications. The final report will be available by *July 2005*, and is expected to be presented in an OECD-organised meeting addressing challenges to health systems from pharmacogenetics, that will take place in October 2005 in Rome,.

The European Medicines Evaluation Agency (EMEA), currently addressing these issues, organised in November 2004 an expert meeting to discuss regulatory needs. It was stressed that no legislative provisions should be made before a wide-ranging consultation process with all relevant stakeholders has taken place. The importance

of ensuring high quality and validation methods for pharmacogenetic tests was also stressed.

A number of research projects promoting the development of pharmacogenetics in Europe are funded under FP6, such as the “**Genome based therapeutic drugs for depression(GENDEP)**”, an integrated project with 18 partners launched in 2004 and if successful will lead to validated pharmacogenomic methods for symptom improvement in depression, the prediction of response to psychiatric drug treatment and the reduction of adverse effects.

4.2.2.3. *Bio-banks*

The establishment of human bio-banks⁹³ and access to information contained in them are important infrastructures for the development of genetic tests. A number of bio-banks have been established worldwide⁹⁴. At the same time it has led to new ethical dilemmas which among others are under discussion in ethics committees at national and international levels. New specific legislations regarding bio-banks have been implemented in a few countries (Denmark, Norway, Iceland, Estonia and Sweden) and other countries are discussing legislative proposals or the need for specific regulation⁹⁵.

The ability to optimise the use of bio-banks across Europe is an important foundation to ensure progress of European biomedical science including for 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 bio banks differ between countries.

4.2.3. *Animal biotechnology*

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 recommendations for regulation and guidelines covering research on farm animal cloning and its subsequent applications. Secondly, a prospective study on Animal Cloning and Genetic Modification and derived products has been launched by the Institute for Prospective Technological Studies (JRC-

⁹³ biological material from one or several human beings collected and stored indefinitely or for a specified time and whose origin can be traced to the human or humans from whom it originates

⁹⁴ UK Biobank <http://www.ukbiobank.ac.uk/>
CARTaGENE <http://www.cartagene.qc.ca/en/>
GenomEUtwin <http://www.genomeutwin.helsinki.fi/>
Swedish Twin Registry http://www.mep.ki.se/twinreg/index_en/
Estonian Genome Foundation <http://www.geenivaramu.ee/index.php?sho=main&lang=eng/>
ecode Genetics <http://www.decode.com/>
Umea University Medical Biobank <http://www.biobanks.se/medical%20biobank.html/>
Danish Twin Registry <http://www.dtr.sdu.dk/?dideid=index&sprog=eng/>
Genomics Collaborative, Inc., <http://www.genomidsinc.com/>
European Prospective Investigation into Cancer and Nutrition (EPIC) <http://www.iarc.fr/epic/>
MRC/Cancer Research UK/BHF Clinical Trial Service Unit & Epidemiological Studies Unit <http://www.ctsu.ox.ac.uk>
Neocodex <http://neocodex.es>
Oxagen <http://www.oxagen.co.uk>

⁹⁵ <http://europa.eu.int/comm/research/biosociety/bioethics/>

IPTS). The study aims to provide a comprehensive picture of research and commercial activities involving animal cloning and/or genetic modification and current and future products obtained from these animals world wide; to identify the potential benefits, risks and socio-economic impacts; to compare the regulatory frameworks world-wide and to assess new policy implications of the developments of these technologies and of the commercialization of their products in the EU.

4.2.4. *Converging sciences and technologies*

A high level expert group on Converging Technologies (the convergence of nanotechnology, biotechnology, information technology and cognitive science) was set up by the Commission at the end of 2003. The report of the EU expert group, entitled “Converging Technologies – Shaping the Future of European Societies”⁹⁶, was discussed during a conference organised by the Commission in September 2004. The group and the participants to the conference have insisted on the new scientific paradigms and new scientific production modes relying on inter- and trans-disciplinarity. The European expert group stressed the importance of specific societal needs that must be identified in order to take advantage of and preserve Europe’s cultural diversity and to create economic opportunity. Social sciences and humanities should provide orientation where Converging Technologies could disrupt traditional ways of life and should serve as intermediaries between political actors, researchers and society, and help to assess risks. The expert group suggested that research programmes at national and EU levels should include activities focusing on cross cutting and converging issues. A number of national conferences or events are already foreseen in the first quarter of 2005 and the Commission is reflecting on future actions in the context of the preparation of FP7.

The European Group on Ethics has adopted Opinion (N°20) on the ethics of information and communication technology (ICT) implants in the human body. This Opinion is published and is available online⁹⁷. The ethical analysis addresses convergent technologies (ICT and life sciences) and responds to a number of human rights issues in this interdisciplinary field.

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http://europa.eu.int/comm/research/conferences/2004/ntw/index_en.html

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http://europa.eu.int/comm/european_group_ethics/avis3_en.htm