EUROPEAN COMMISSION

ADDENDUM

to the Commission Services Progress Report

issued in April 2005 on the

EU-Japan Business Dialogue Round Table 2004 Recommendations

LIFE SCIENCES AND BIOTECHNOLOGY

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The following addendum outlines progress made in considering or implementing the recommendations put forward in 2004 by the European Union – Japan Business Dialogue Round Table (BDRT) on **Life Sciences and Biotechnology** (Working Party 5).

The recommendations of the Life Sciences and Biotechnology Working Party (WP) were structured in a general part and in the three major areas of biotechnology applications.

1. GENERAL

The WP called for urgent implementation of the European biotechnology strategy and action plan, a continuous dialogue between Commission, Member States and industry, and for reinforced intellectual property protection.

The European Commission publishes a regular Report on progress with implementation of the strategy, setting out the achievements, the delays in implementation and newly upcoming issues. This report takes into account the suggestions made by the Commissions advisory group with industry (Competitiveness in Biotechnology Advisory Group, CBAG). Both sources are major input into the permanent dialogue between Commission and member states (e.g. through the Commission's network with officials of member states) and industry. At two occasions (November 2004 in Maastricht and April 2005 in Lyon), a new formula of triangular discussions has been put into practise (Commission, Member States, industry) that has proven to be fruitful and that should be further developed.

Concerning intellectual property protection, until now, nineteen Member States have transposed Directive 98/44/EC 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 their national legislation. Among those, five infraction procedures are still in hand. In December 2004, two other infraction procedures were launched against Latvia and Lithuania.

The Community Patent still awaits adoption.

The establishment of **technology platforms**[1], an innovation in EU research policy, have continued to develop in 2004/ 2005 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.

On 6 April the Commission adopted a proposal for the **EU Seventh Research Framework Programme 2007-2013 (FP7)**[2]. 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.

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1 http://www.cordis.lu/technology-platforms/home.html

2 COM(2005) 119 final

Life Sciences and biotechnology research for medical applications will remain an important priority under the theme **"Health"** 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***[3]**,** 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 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.***

FP7 is also opening up for new perspectives for international cooperation including:

- Opening of all activities carried out in the thematic areas to researchers and institutes from all third countries;
- Specific co-operation in each thematic area dedicated to third countries in case of mutual interest in co-operating on particular topics;
- International out going and incoming fellowship, international cooperation scheme.

The European Parliament requested the Commission in late 2004 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.

A number of cost-benefit analyses limited to certain commercial applications of biotechnology and related risks/benefits are already available to the Commission or are on-going (specifically in Industrial Processes and in GM crops). However, 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).

The Commission is currently defining the content and structure of the activity. It is expected that the whole activity (comprising studies and a final conference) will take 18 to 24 months.

[3] The term "bio-economy" should be understood 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.

2. HEALTH

The WP called for efforts to support innovation (e.g. to ensure the recognition of innovation values in pricing), support to clinical research and to international regulatory harmonisation, for clear evaluation mechanisms for medicines and further improvements in the EU regulatory framework, such as enhanced dialogue between industry and regulators.

Pharmaceutical innovation is at the centre of several initiatives. There were a number of measures to encourage innovation in the recent review of pharmaceutical legislation including the strengthening of intellectual property through the harmonisation of data exclusivity at 10 years across the EU. 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 (EMEA) including:

– waivers 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 EMEA.

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.

The Commission would like to see this change in the regulatory structure matched by national action to improve the climate for innovation. Although many of the recommendations from the "G10 Medicines" process[4] could be implemented through existing Commission projects, others concerned national competence and required action by Member States. During 2004 some progress was made in these areas as well. In particular, with the update of the competitiveness indicators first published in the G10 Communication and in the examination of possible common approaches to relative effectiveness. However, there will be further work in 2005 to make progress in the remaining areas of information to patients and pricing. The Commission will be working with Member States to explore ways of improving pricing structures with a view to speed up access to the market for new medicines which will be to the benefit of European patients as well as industry. Also will be explored ways of lifting the remaining price controls on medicines neither purchased nor reimbursed by the state. There is no public health or budgetary reason for maintaining these controls and, indeed, many countries do not have them. The Member States have agreed to look at both areas in the Council conclusions in response to the Commission's Communication on the G10 process.

[4] 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.

The **European Platform on Innovative Medicines for Europe**[5] 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.

The Commission proposal for a **7th Framework Program Research** should substantially increase the funds available for research in the area of health. A Joint Technology Initiative for Innovative medicines is also expected to be launched with the aim to provide the long-term financial support for pre-competitive research that are critical to the pharmaceutical R&D.

3. INDUSTRIAL BIOTECHNOLOGY

The WP called for providing incentives for the development and up-take of white biotechnology processes such as research, demonstration projects, the analysis of the impact of regulation on innovation and sustainable development, and for setting up a European multi-stakeholder platform.

The recent report from the High Level Group headed by Wim Kok,[6] 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,

1) Supported the launch of the "**Industrial Biotechnology Platform"** [7] as part of a wider Sustainable Chemistry Technology Platform in order to boost this area in Europe. A vision paper has been finalised in April 2005 following discussion with relevant industrial sectors, consumers and NGOs. A working group has been set up to develop the Strategic Research Agenda.

2) 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**".

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

6 http://europa.eu.int/growthandjobs/pdf/2004-1866-EN-complet.pdf

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

4. PLANT BIOTECHNOLOGY

The WP called for action plans to promote public understanding, long-term perspectives for risk assessment and provisions for regulatory approval process, to re-start the approval process and a new public opinion survey.

Since the completion of the regulatory framework for biotechnology products the Commission has run all authorisation procedures normally: applications are being examined under the relevant authorisation procedures, on a case by case basis and on their own individual merits.

The Commission has played an active role in re-launching product approvals in the EU. In its orientation debate in January 2004, the College endorsed the approach that pending decisions concerning the placing on the market of new GM products and the lifting of national safeguard measures (bans) should be progressed through the relevant comitology procedures without any further delay, in accordance with the provisions of relevant EU legislation. Through 2004, the Commission has implemented the above approach.

Further draft decisions continue to progress through the administrative procedures, but, in spite of improvements in the new regulatory framework, public and political concerns with GMOs continue.

In its orientation debate in March 2005, the Commission concluded that it would continue to comply fully with its legal obligations and proceed with the approval of pending authorisations as appropriate, following scientific evaluation on a case by case basis. Further, the Commission declared to fulfil its responsibilities in the establishment of labelling thresholds, and, on the implementation of co-existence measures, to reflect on possible further steps on the basis of a report to be finalised by the end of this year, concerning the experience gained in the Member States.

The Commission will launch a Eurobarometer survey specifically focussed on biotechnology including plant biotechnology in the latter part of 2005 as the next in a series, which was started in 1991.

The Commission has continued its effort to promote research in **Plant Genomics and Biotechnology** at European level under 6th Framework Programme for research. These projects bring together bringing together breeders, geneticists, molecular biologists, plant pathologists, bio-informaticians, economic interest groups, biotech companies and breeding companies. The Commission efforts in this area have been strengthened by the launching of the **Technology platform on Plants for the Future**[8] in June 2004. This **Platform** is among others expected to add a new dimension of dynamism to societal dialogue by bringing together all interested stakeholders. – research organisations, industry, regulators, user groups, etc. – around key technologies, in order to devise and implement a common strategy for the development, deployment and use of these technologies in Europe.

[8] http://www.epsoweb.org/Catalog/TP/index.htm