EJBDRT

Recommendations

Contributions from WP 5: Life Sciences & Biotechnology
(Joint Final Version, June 8, 2004)

INTRODUCTION

This is the first report of Working Party 5 on Life Sciences & Biotechnology, that was created in 2003. It is the result of a seminar held in Tokyo, December, 2003 and is thought to be comprehensive in order to form a sound basis for reports in the forthcoming years.

Economic growth depends on the development and use of new technologies and new products. Equitable access to new technologies will, therefore, be crucial. Biotechnology is an important new technology; both the EU and Japan have recognised this through development of Action Plans in this area. The enlargement of the EU will trigger additional investment opportunities, linked with growth, competitiveness and increased employment.

LS & BT for Health, also known as “Red Biotechnology” in the EU, has already made an impact on healthcare and will continue to contribute to improving human health and life expectancy.

Today, 20% of marketed medicines, 50% of those in clinical trials and 80% in early development, are Biotech-based products. 40% of these candidate medicines are for the treatment of cancer.

Industrial/Environmental Biotechnology (IEB), also known as “White Biotechnology” in the EU, is the application of Biotechnology to achieve sustainable production of Bio-chemicals, Bio-materials and Bio-fuels from renewable resources, using living cells and/or their enzymes. Undesired by-products are minimal and costly separation techniques may not be required. Economic and ecological benefits are achieved simultaneously, making IEB an important technology to generate sustainable production systems.

Plant Biotechnology, also known as “Green Biotechnology” in the EU, has the potential to make traditional food production more efficient; it is also leading to the creation and improvement of functional foods. With a growing worldwide population that is becoming increasingly aged the benefits of plant Biotechnology will be needed. It will be critical to improve public acceptance of Biotechnology through intensified scientific discussion among the many stakeholders in the EU and Japan.

Part I – General Recommendations

Key Points of Recommendations

5-EJ-1 Implement with urgency the Action Plans issued by the EU in 2002 and by Japan in 2002 through the strong initiatives by both Governments. Continuous review of these Action Plans is recommended to ensure that they keep pace with advances in LS&BT and the changes of society.

5-EJ-2 Maintain dialogue between Government and Industry in both the EU and Japan to discuss issues and implement the resulting Action Plans. Current important issues include:

- Reassessment and harmonisation of current regulations of the EU and Japan to facilitate commercialisation of products of LS&BT
- Cooperation to improve public understanding and acceptance of LS&BT, in particular taking into consideration EU enlargement
- Sharing of best practice regarding successful business concepts for start-up companies and Bio-ventures between the EU & Japan
- Support an annual LS&BT Workshop such as the BDRT WP5 Bioseminar that took place in December 2003 in Tokyo. Representatives from both the EU (in particular from Accession countries) and Japanese governments should be encouraged to participate.

5-E-1 Strengthen intellectual property protection for Biotechnology by :

- Ensuring all Member States implement Directive 98/44 on the protection of Biotechnological inventions without modification or further delay

- Establishing a coherent, centralised European-wide patent protection regime that restricts the original application to a maximum of three languages – English, German and French.

5-J-1 Strengthen the coordinating functions of the Government across the Ministries to implement more efficiently and effectively the Action Plans in the Biotechnology Guidelines. This needs additional resource in the form of both budget and manpower. It is recommended to have better interactions with industries on the governmental policies and measures from the planning to evaluation stages.

5-J-2 Encourage academics in particular scientists from prestigious public universities, to play a greater role in fostering public understanding of Biotechnology. Academics should be intensified and encouraged to spend part of their time fulfilling this role.

Explanatory Notes

Biotechnology is a key technology, which can contribute considerably to the Healthcare, Industrial and Agricultural sectors. Both Japan and the EU have prepared Action Plans to support and further develop Life Sciences and Biotechnology.

Greater focus and effective co-ordination by Governments are required to implement these Action Plans in an efficient and timely manner, in particular to ensure that the EU and Japan can again compete effectively with the United States.

Implementation of the EU Action Plan for LS & BT, is the responsibility of Member States, the EU Commission, the industry and other stakeholders. Co-ordination and communication is key.

Japan's Action Plan has more of a central co-ordination through the Council for Science & Technology Policy (CSTP), but still, stronger co-ordination is needed.

A continuous dialogue between the EU and Japan and also between the Governments and industry on a regular basis is very important to ensure effective implementation of the Action Plans and to resolve issues or barriers relating to LS&BT.

EUJBDRT WP5 plans to organise, either in the EU or Japan an annual Bioseminar similar to the one held in Tokyo in December 2003 to share updated information and discuss recommendations for the Governments in the following year. The enlargement of the EU will create business opportunities as well as new challenges for EU and Japanese industries thus momentum needs to be maintained.

Part II – Recommendations by Topics

a) Biotechnology for Health

Key Points of Recommendations

5-EJ-3 Work together to ensure that the value of innovation is recognised in the pricing of medicines in EU Member States and Japan.

5-EJ-4 Support clinical research by addressing regulatory barriers, public involvement in clinical trials and facilitating development of an improved infrastructure for clinical research. The government should make clinical research a priority area for funding in Government research programmes.

5-EJ-5 Facilitate regulatory harmonisation where possible and practical by supporting international regulatory harmonisation through the International Conference on Harmonisation (ICH).

5-E-2 Ensure that in all Member States, mechanisms in place for the evaluation of medicines are based on clear, transparent and objective criteria, and are

subject to appeal. Encourage Member States to allow free pricing for medicines that are neither purchased nor reimbursed by the statutory healthcare system.

5-E-3 Work with industry to make further improvements to the EU regulatory framework for medicines, such as enhancing the dialogue between industry and regulators during early development and improving the appeal mechanism. Ensure consistency in regulatory practice for medicines between European Union Member States, particularly following the enlargement of the EU.

5-J-3 Work with industry to make changes to the current pricing system including revision of the 'repricing rule' to ensure that a price high enough to reward innovation is granted and maintained for all innovative medicines, rather than just a few.

5-J-4 Ensure the development of a fast, efficient and transparent process under the new regulatory organization (PMDA) in Japan. In particular – attention needs to be focused on international regulatory harmonisation for ethnic bridging clinical studies, application of new technologies and Bio-risks and harmonisation of specifications and testing methodologies.

Explanatory Notes

The Biotechnology and pharmaceutical sectors involved in research and development of new medicines make a significant contribution to both the health and wealth of European and Japanese people. As our population ages, we will rely increasingly on innovative new medicines that prolong and enhance the lives of our citizens. An environment that values and encourages innovation is critical if industry is to deliver innovative new medicines and vaccines that meet the needs of our populations.

It is important to encourage public understanding of Biomedical research and ensure that intellectual property issues are addressed effectively. Genetic research and should be supported and encouraged. Large collections of human tissues and DNA samples should be developed and readily be accessible to industry.

Cost containment mechanisms in both the EU and Japan are putting significant pressures on revenues generated for industry and delays to market access are resulting in patients' being denied access to new medicines.

To improve the competitiveness of the EU and Japan and to be able to compete more effectively with the US, industry believes that significant improvements need to be made to the environment in the EU and Japan for the research, development and commercialisation of healthcare products.

Our recommendations focus on a number of areas including rewarding innovation through appropriate pricing mechanisms for new medicines, encouraging clinical research and ensuring that effective regulatory review of new innovations is in place. Our objectives will be achieved only by industry and Government working together to address the barriers to innovation.

b) White Biotechnology / Industrial uses

Key Points of Recommendations

5-EJ-6 Provide incentives to enable industries to switch to more sustainable production processes.

- Make research for Industrial/Environmental Biotechnology (IEB) a priority in public research funding schemes (e.g. Framework Programme 7 in the EU)

- Consider tax abatements and investment tax credits to incentivise and speed up the implementation of sustainable production technologies.

- Provide financial support for highly promising Bio-based technologies at the proof-of-concept stage.

5-EJ-7 Support setting up a few demonstration projects, either in the area of Bio-chemicals, Bio-materials and/or Bio-fuels, using the US Bio-refineries as a model.

5-E-4 Utilisation of Biomass as a sustainable resource.

- Conduct feasibility studies on Biomass as a resource, including looking at availability in the EU and taking into account broader issues, for example the CAP reform, reform of the EU sugar regime and the effects of EU enlargement including the increasing availability of farm land.

- Fund R&D programmes to develop an efficient route of ligno-cellulose conversion into low-priced sugars.

5-E-5 Existing regulatory hurdles against GM technology are not evaluated in accordance to their broader potential benefits. The impact of new and existing regulations on innovation and industrial sustainability should be analysed, enabling the EU to reconsider regulation intensive policies.

5-E-6 Set up a fully integrated European multi-stakeholder platforms for IEB.

5-J-5 Work with industry to establish standards for Bio-materials such as biodegradable polymers in order to facilitate commercialization of products from the Bio-materials.

Explanatory Notes

Industrial/Environmental Biotechnology (IEB), also known as “White Biotechnology” in the EU, is the application of Biotechnology for sustainable production of Bio-chemicals, Bio-materials and Bio-fuels from renewable resources using living cells and/or their enzymes. This normally results in environmentally friendly processes with

a minimum of waste generation and energy use. Bio-materials include polymers such as polylactic acid and polyhydroxyalkonoates. Typical Bio-fuels are ethanol and hydrogen.

Other industrial sectors with the potential to apply IEB are the textile- and leather-, the paper & pulp and the food & feed industries.

IEB is still in its infancy in Europe and elsewhere in the world. This technology needs to be nurtured with the creation of effective support measures to remove existing obstacles for the implementation of this sustainable production technology.

Renewable agricultural-based feedstocks, like sugars and vegetable oils, are currently in use for Bio-production routes under contained use conditions in the chemical industry. Regulated markets in Europe and generally high feedstock prices are one of the major obstacles blocking further progress of the use of this production technology.

The way forward should include:

- A feasibility study for the development of a non-food sector for Bio-materials using US activities as a model. An option for the development of new agricultural-based activities in the accession countries of Eastern Europe.

- Demonstration project, using the US Bio-refineries as a model, including however, diversification into Bio-chemicals.

- The development of enzyme systems, which can cleave cellulosic agricultural waste into low-priced sugars – a route, which is currently investigated in the US, which will also be the key for further progress in Europe.

The Japanese Strategic Guidelines for Biotechnology states that IEB is the most important environmental or sustainable technology; IEB makes it possible to utilise agricultural and fishery wastes, food wastes and Biodegradable plastics to create new energy or products and replace the use of fossil resources. In addition, bio-remediation will play an important role in improving the environment. Bioprocesses using microorganisms produce useful materials and products with lower cost and less burden to the environment.

c) Plant Biotechnology

Key Points of Recommendations

5-EJ-8 Formulate and implement joint Action Plans to promote public understanding of Biotechnology, including the use of GM-technology in the EU and Japan.

5-EJ-9 Provide long-term perspectives for risk assessment procedures and general provisions for the regulatory approval process for new types of Biotech traits, such as improved nutritional value and high-valued

pharmaceutical precursors or other functional agents produced in plants.

5-E-7 Re-commence the process for market approvals of GM-technology products without any further delay.

5-E-8 Conduct a new Eurobarometer-based survey, to look at the shift in public opinion to GM-technology, following EU enlargement.

5-J-6 Make a public announcement about the central government's position on utilisation of GM technology, including measures to help the public understand the benefits of the technology, and show strong leadership to harmonise the actions of central and local Governments.

Explanatory Notes

Limited public acceptance for Biotechnology in the EU and Japan will delay market access for Biotech based products. It will also lead to trade issues in the food sector and delay the development and use of environmental friendly, sustainable agricultural production.

Legislation for genetically modified plants has now been finalised in the EU. It comprises directives/regulations on the deliberate release of seeds/plants, the Novel Food/Feed regulation and a regulation on Labelling & Traceability. It demands a sound safety assessment, prior to market authorisation, and provides consumers with a choice by labelling and traceability requirements for all genetically modified organisms and products derived from them.

The de facto five-year Moratorium associated with the political debate in the US has caused great trade-related disharmonies with other agricultural trading partners.

Therefore, Working Group 5 of the EUJBDRT calls for application of this legislation, without any further delay and a resumption of the authorisation process for new GMOs on a case-by-case basis according to the legislation.

In the current and future accession countries of the EU agriculture is an important factor in their economies. Access to new technologies with the potential to enhance productivity will play a major role in integrating these countries economically within the European Union.

A feasibility study could reveal, to what extent the development of a non-food agricultural sector could facilitate economic progress in accession countries.

Local Governments in certain areas in Japan have recently announced actions to substantially prohibit cultivation of GM crops, although the concerned traits had been authorised by the central Government based upon a thorough safety assessment. These uncoordinated Government activities will ultimately confuse the general public and cause significant delays in public acceptance.