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Recommendations 2005
WP 5: Life Sciences & Biotechnology

INTRODUCTION

This is the second report of Working Party 5 on Life Sciences & Biotechnology (LS&BT), that was created in 2003.

LS & BT broadly cover healthcare, foods, industrial processes, environments, plants etc. They are social fundamental requirements for economic activities and are expected to be vital in order to realize sustainability of the globe.

Economic growth depends on the development and use of new technologies and new products. Equitable access to new technologies will, therefore, be crucial. LS&BT are important new technologies; both the EU and Japan have recognised this through development of Action Plans in LS & BT strategies. The enlargement of the EU has triggered 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. Market share of biotech medicines has reached around 10% worldwide and is steeply increasing into the future, especially in crucial disease areas such as cancer. Historically, biotech medicine meant a product which produced by biotechnology such as a protein drug. However, recently, biotechnologies are utilized widely in pharmaceutical development even for traditional synthetic chemicals through target identification, drug discovery, clinical development, and also post-marketing evaluations. Advancement of lifescience and utilization of biotechnology are essential to overcome diseases and no one can assume the appearance of an innovative medicine without these.

LS&BT for Industrial/Environmental Uses (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.

LS&BT for Plants, 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.

1. General Recommendations

5-EJ-1 Continue to 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. Further, project evaluation functions and inter-minister/ inter-states coordination should be strengthened.

5-EJ-2 Encourage Governments to establish "National LS/BT Understanding Promotion Plans" by a strong governmental initiative in cooperation with industrial and academic sectors for promoting public understanding of biotechnology in the form of a strengthened education in biotechnology and in the form of more direct Communication programs. Encourage the academic society to help by playing a greater role in fostering understanding in biotechnology.

- Cooperation to improve public understanding and acceptance of LS&BT
- Reassessment and harmonisation of current regulations of the EU and Japan to facilitate commercialisation of products of LS&BT

5-EJ-3 Make research for LS & BT a priority in public research funding schemes (e.g.; Framework Programme 7 in the EU and the 3rd term S&T Basic Plan in Japan)

- Adoption of the final EU FP7 programme should confirm the importance of research in biotechnology that was outlined in the initial Commission proposal of April 2005.
- The Japanese government should position the LS/ BT fields in top priority in the 3rd term Science and Technology Basic Plan starting in 2006.

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.

With our joint EU-Japan seminar of the Japanese government and Commission officials, and industry representatives we established a valuable means of exchanging views.

With respect to the implementation of the EU-Biotechnology strategy the Competitiveness Advisory Group stressed in its report (January 2005) that implementation has been patchy and there remain some serious concerns, in particular:

- R&D framework programs as presently designed do too little to encourage innovation.
- Entrepreneurship in biotechnology needs to be encouraged
- The complex and expensive system of patenting in Europe requires urgent attention
- The regulatory framework for all areas of biotechnology must not be over-stringent and should ensure that requirements remain rational and science-based.
- EU rules should encourage rapid patient access to important new medicines.
- Of great concern is the continued politicisation by certain EU Member States concerning decision making for approval of biotechnology research and development
- Another point of concern is the lack of progress towards a clear harmonized regulation for human cell and tissue-based. Europe is currently not taking advantage f its innovative potential by letting this field linger on without harmonized regulations and therefore without a clear basis for reimbursement.
- The actions of some Member States and regions within Member States to establish disproportional and discriminatory "coexistence" rules that would act to discourage or prohibit farmers from choosing to grow GM crops is contrary to both established EU law, and to the Lisbon Strategy.

In addition, some inconsistencies are apparent in the implementation of the strategy recommendations, both between units of the Commission and within and between Member States. Discussion of the progress reports at the level of ministerial Councils (competitiveness, trade, industry, environment, internal market) would help to ensure that their contents were properly Considered and acted upon by Member States.

Implementation of action plans in Japan's Biotechnology Strategy Guidelines has been reviewed at least once a year by the Biotechnology Strategy Council chaired by the Prime Minister. The seventh

meeting was held on March 15th this year and the progresses of the action plans were evaluated. Although the council members appreciated the assurance of progress, especially in basic research fields, it was pointed out that there still remained several issues to be considered or solved. During the discussion, it was commonly recognized that "public understanding" on LS & BT is very important and will be crucial for future development in this area. However, progress in the promotion of public understanding has been quite insufficient due to the lack of detailed actions to be effective towards the real goal.

Japan Association of Bioindustries Executives (JABEX) proposed that the Japanese government establish "National LS/BT Understanding Promotion Plan" for a nation-wide and strategic approach to the issue. The WP5 members definitely support this and also recommend a similar way for promotion for public understanding in this field in the EU.

2. LS&BT for Health

5-EJ-4 Ensure the communication mechanisms between industry and Government regarding pricing and evaluation system of medicines to address the barrier to the innovation

- Work together to ensure that the value of innovation is recognised in the pricing of medicines in EU Member States and Japan.
- Ensure that mechanisms in place for the evaluation of medicines are based on clear, transparent and objective criteria, and are subject to appeal.

5-EJ-5 Enhance funding to the clinical research and facilitate regulatory harmonization to enhance the integrity as well as the practicability of meaningful pre- and post approval review

- 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 research programmes and through establishment of study programmes for clinical practitioners.
- Continue to facilitate regulatory harmonisation where possible and practical by supporting international regulatory harmonization. Review the regulatory requirements for vaccines between EU & Japan
- Work with industry to make further improvements to the regulatory framework for medicines, such as supporting the development in biomakers, surrogates, and predictive technologies to ensure development of regulatory competence and acceptance

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. Policy makers have to recognize contributions of the industry not only for public health and also for economy such as improving medial efficiency, increasing social productivity, generating employment, and so on, through providing innovative 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.

3. LS&BT for Industrial/Environmental Uses

5-EJ-6 Encourage Governments to work towards harmonisation of regulatory requirements for biotechnology products and processes.

- In particular encourage the European Commission and Member States governments to keep the present interpretation of EU Regulation 1829/2003 on Genetically modified Food and Feed that "Food and feed (including food and feed ingredients such as additives, flavourings and vitamins) produced by fermentation using a genetically modified microorganism (GMM) which is kept under contained conditions and is not present in the final product are not included in the scope of Regulation 1829/2003"

5-EJ-7 Provide incentives to enable industries to switch to more sustainable production processes.

- 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-8 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.

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.

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.

Full support should be provided to the first EU-Japan IEB Summit that will be organized between EuropaBio and the Japan Bioindustry Association (JBA) in the beginning of September, 2005.

4. LS&BT for Plants

5-EJ-9 Further implement and enforce existing regulatory frameworks on GMOs, both in the EU and in Japan.

<u>In the EU:</u>

- We urge the Commission to ensure that all applications made in accordance with the EU legislation and that have received a positive safety assessment from the European Food Safety Authority (EFSA), receive a timely approval.

- We would also like to see the Commission ensuring that Member States that have invoked bans based on "safeguard clauses" and that have failed to provide the required scientific justification to support these bans, withdraw these illegal bans immediately.
- We are against linking European-wide legislation for coexistence (as a precondition) with GMO approvals for cultivation in the EU.

In Japan:

- We urge the Japanese government to ensure that the central and local governments take the same position that GMO technology is essential in innovation of agriculture in Japan and the governments take unified actions toward wide applications of the advanced technology.
- We urge the Japanese government to prevent regulation, delay and/or restriction by laws and/or guidelines of local governments in the cultivation and use of the GMO crops that are approved by the central government for cultivation and use in Japan based on safety evaluation.
- We would like Japanese government to make and implement comprehensive, nationwide action plans for public understanding/acceptance of GMO crops to provide the public with accurate and sufficient information in order to remove apprehension for GMO crops among consumers and farmers.

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.

Industry keeps funding individual programmes to promote public understanding of plant biotechnology in the EU and in Japan respectively. However there is still no public-funded Joint Action Plan to promote jointly, both in the EU and Japan, public understanding of plant biotechnology.

In addition governments and authorities also have a key role to play in public acceptance and consumers' confidence in plant biotechnology by ensuring policy coherence on plant biotechnology. For instance on one hand public funding is rightly allocated to research in plant biotechnology but on the other hand market approvals are not granted for these innovative and competitive products. This policy inconsistency from governments and authorities can only confuse the public and further delay acceptance of plant biotechnology. In this frame proper implementation of the existing regulatory frameworks of GMOs (including experimental and commercial approvals for GM plants) is now a top priority both in the EU and in Japan.

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

Several prefectural governments in Japan are tightening regulation of cultivation of GMO crops by their own local laws and/or guidelines. A byelaw that was adopted by Hokkaido prefecture this year is especially strict because criminal penalties could be imposed on ones who cultivate GMO crops without permission from the prefecture even if the safety of the GMO crops have already been approved by the central government. These local governments are claiming that such legislation is necessary to avoid confusions resulted from cultivation of GMO crops, considering apprehension for GMO crops among consumers and farmers. On the contrary, it is clear that such over regulation is a key factor inciting apprehension and creating a negative cycle to drive public understanding backward.