

Recommendations 2006
WP 5: Life Sciences & Biotechnology

INTRODUCTION

This is the third report of Working Party 5 on Life Sciences & Biotechnology (LS&BT), which 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 life science 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 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. Proper allocation of resources has to be carried out by the strengthened function of pre- and post-evaluation of projects in cooperation with industries. Further, governments and industries should work together to consider ways to increase the mobility of human resources within/between the regions, especially of post-doctoral fellows.
- 5-EJ-2** No recognizable progress has been seen in the promotion of LS&BT public understanding, both in the EU and Japan, regarding recommendation 5-EJ-2 in 2005.
Governments should urgently establish “National LS&BT Understanding Promotion Plans” through a strong governmental initiative in cooperation with industrial and academic sectors, and establish a cross-ministerial head office for the accelerated and efficient promotion of public understanding of biotechnology. Information exchange between the EU and Japan will be valuable during the process. For example, mutual introduction of experiences such as best practices will elucidate critical issues on this matter and be helpful for the promotion. Also, academic research through the social scientific approach should be encouraged to evaluate the risks and benefits of cutting-edge technologies.
- 5-EJ-3** Make research for LS&BT a priority in public research funding schemes.
- Adoption of the final EU FP7 programme should confirm the importance of research in biotechnology as outlined in the initial Commission proposal of April 2005.
 - The Japanese government should invest continuously in the LS&BT fields according to the 3rd Science and Technology Basic Plan adopted in 2006.
 - Continuous funding in basic research of LS&BT is important because its R&D usually takes a long period of time before launch. Also, much more funding in the social/regulatory science field is essential to promote public acceptance of LS&BT stagnating in the EU and Japan.

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 authorities 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 are keys.

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 authorities 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.

In 2003 and 2005, we held joint seminars comprised of representatives from the Japanese government, EU Commission, and industry to establish a valuable means of exchanging views.

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 eighth meeting was held on January 26th this year and the progress of the action plans was evaluated. Although the council members appreciated the assurance of progress, especially in basic research fields, they pointed out that several issues still remain to be addressed 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.

In 2004, the Japan Association of Bioindustries Executives (JABEX) proposed that the Japanese government establish a "National LS&BT Understanding Promotion Plan" for a nation-wide and strategic approach to the issue. In the EUJ BDRT Recommendations 2005, BDRT members strongly supported this and recommend a similar way for promoting public understanding of LS&BT in the EU. However, as no concrete progress has been seen, BDRT members urge prompt action to establish those plans as well as a head office to promote measures through the strong initiatives of authorities.

Japan's 3rd Science and Technology Basic Plan started in April 2006. In the plan, the LS&BT area is set as one of the four focus areas where intensive funding will be made. BDRT members appreciate efforts to finalize this basic plan and call for continuous and consistent measures which will lead to industry advancements.

2. LS&BT for Health

- 5-EJ-4** Ensure the communication mechanisms between industry and government regarding the pricing system of medicines in order to address the barrier to innovation. Consistency between industry promotion measures and pricing policy is the key to the increased competitiveness of the healthcare industry.
- Encourage the Pharmaceutical Forum starting in 2006 and establish similar high level councils in member states in the EU
 - Establish in Japan an official committee for dialogue between government and industry in order to discuss consistent promotion measures for the industry.
 - Enhance dialogues to realize "pricing systems reflecting innovation of medicines" which is believed to be essential for medical advancements.
- 5-EJ-5** Enhance funding to clinical research and facilitate development of infrastructures for clinical trials/research. The government should make clinical research a priority area for funding in research programmes. Intensive support to translational research is also important for practical application of basic findings.
- 5-EJ-6** Continue to facilitate regulatory harmonization with respect to increasing demand for simultaneous global development of medicines. International common rules on the handling of clinical data should be applied, especially on the handling of adverse event data. Regarding the approval review of biosimilars, authorities must be careful to ensure patient safety as the first priority. The Japanese government should encourage PMDA to strengthen its capabilities in terms of both quality and quantity.

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 that meet the needs of our populations.

Cost containment mechanisms in both the EU and Japan are putting significant pressures on revenues generated by industry, and delays to market access are resulting in patients being denied access to new medicines. Policy makers have to recognize the industry's contributions to not only public health but also the economy, such as improving medical efficiency, increasing social productivity, generating employment, and so on, when it provides 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.

BDRT recommendations in LS/BT 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.

Developed countries will be faced with highly aging populations and low-rate economic growth. There has been discussion in both the EU and Japan about the strategic approaches that authorities can take to focus on new economic growth leveraged by "Innovation" and the control of healthcare costs in order to ensure the continuity of social security systems. Simultaneous pursuit of the issues may be hard, but BDRT members believe that they are not incompatible, and that a pricing policy for healthcare products, especially for medicines, that encourages innovation would contribute to healthcare cost efficiency as well as the improvement of public QOL. BDRT members encourage forums for dialogue between high-level authority and industry representatives to discuss at one table ways to achieve a balance between industry promotion and pricing policy. In the EU, the pharmaceutical forum is starting this year for this purpose and a similar forum must be urgently established in Japan also. Stakeholders have to be aware that the viewpoint on "healthcare expenditures" should be changed from a "Cost" to an "Investment".

3. LS&BT for Industrial/Environmental Uses

5-E-7 Encourage the European Commission and Member State governments to permanently keep the present interpretation of EU Regulation 1829/2003 on Genetically Modified Food and Feed that "Food and feed (including food and feed ingredients 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-8 Provide more incentives to enable industries to switch to more sustainable production processes utilizing biotechnologies.**
- Consider tax abatements and investment tax credits as incentives and speed up the implementation of sustainable production technologies.
 - Provide financial support to improve infrastructures for the utilization of biomass and production of bioethanol fuels.
- 5-EJ-9 Some progress has been made in Japan to promote such biotechnology demonstration projects as biorefinery, bioethanol and bioplastics. Encourage these activities and provide further support to promote the commercialisation of these projects.**

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 polyhydroxyalkanoates. Typical Bio-fuels are ethanol and hydrogen. They are of growing importance due to recent spikes in oil prices and concern for the depletion of oil resources in the future.

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

4. LS&BT for Plants

- 5-EJ-10 Further implement and enforce existing regulatory frameworks of EU and Japanese central government on GMO crops.**

In the EU:

- 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 without undue delay. (and are not subject to an internal de facto moratorium in the European Commission.)

- The role of EFSA (established by co-decision between the European Parliament, the European Commission and member states) as scientific body should be strengthened.
- 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 do not support linking European-wide legislation for coexistence (as a precondition) with GMO approvals for cultivation in the EU. Guidelines for Coexistence as proposed by the Commission in July 2003 reflect the different geographic and climatic conditions. Further unnecessary and burdensome legislation (that is directive or regulation) has to be avoided.
- We urge the Commission to come up with a proposal to establish practical and workable labeling thresholds for trace amounts of EU approved GM seed in conventional seed.

In Japan:

- We urge the Japanese central government to take effective actions to discourage local governments from delaying and/or restricting by local laws and/or guidelines 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 the Japanese government to organize nationwide discussion of importance of GMO crops in sustainable growth of economy in the near future, and to encourage every stakeholder to actively participate in the discussion.

Explanatory Notes

There is no question that GMO crops will play a central role in the production of not only food and feed but also energy and industrial materials to support the rapidly growing world population. Oil prices have been rising quite rapidly, generating concerns for instability in the supply of energy and materials in the near future. Proper control of greenhouse gases to prevent global warming has been a key issue in sustainable growth. Plants are able to provide carbon neutral supplies of energy and materials, and products like bio-ethanol and bio-diesel are considered as very important alternative fuels. Biotechnology will enable us to take full advantage of the capability of plants, and the study, application and commercialisation of GMO crops are core activities. Nevertheless, limited public acceptance for biotechnology in the EU and Japan has been delaying 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.

In the EU and Japan, the level of public understanding of GMO technology seems to have been driven backward in recent years, and if this tendency is not changed, there is a big risk that the EU

and Japan will be left behind in the area of plant biotechnology, leading to a rapid weakening of their position and competitiveness in the global economy.

Several prefectural governments in Japan have been further tightening regulation of cultivation of GMO crops by their own local laws and/or guidelines. A byelaw that was adopted by Hokkaido prefecture 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.

Governments and authorities must stop this tendency, and must lead and pave the way for progress and wide application of plant biotechnology. Policy coherence at the central and local governments must be ensured. Public funding to research in plant biotechnology needs to be strengthened and market approvals need to be granted for these innovative and competitive products without any delay. Policy inconsistency from governments and authorities can only confuse the public and further delay acceptance of plant biotechnology.