EU-J BRT Recommendations 2009 from WPB
~Life sciences and Biotechnology~

Introduction

During this century, our world is expected to face numerous issues for the first time, including human-caused global climate change, fast-aging societies and explosive population growth in developing countries. Life sciences and biotechnology may possess the potential to overcome difficult issues in various areas.

The Japanese government established the Government-Industry Council for Biotechnology Strategy Promotion in March 2008 and published a new strategy, “Dream BT Japan”, to promote and realize the “Biotechnology Strategy Guidelines” issued in 2002.

The strategy identifies public understanding of biotechnology as the most serious and crucial issue for BT promotion, and the “Committee for Promotion of BT Public Understanding” was established under the Council to implement concrete measures.

[LS/BT General]

- B-EJ-1 Continue to intensively promote biotechnology related R&D according to the revised BT strategies (EU in 2007 and Japan in 2008) by both governments.

- B-EJ-2 Significantly increase the budget for promotion of public understanding of LS/BT. Establish “National LS/BT Understanding Promotion Plans” through a strong governmental initiative in cooperation with industry and academic sectors for the accelerated and efficient promotion of public understanding of biotechnology, particularly its contribution to broader issues of sustainability such as the food crisis, the breakdown of the environment and global warming.

[LS/BT Healthcare]

The business environment surrounding the healthcare industry, especially the pharmaceutical industry, has been changing drastically. The success rate of new drug creation is decreasing despite sharply increasing R&D costs, and the regulations for ensuring drug safety are becoming ever stricter.

On the other hand, governments have implemented drug cost containment measures and probably will strengthen their containment policies. There are concerns that this approach of taking separate and uncoordinated measures to deal with the different parts of the value chain may hinder new drug creation and interfere with appropriate access to innovative drugs by patients.

Governments and the industries should jointly plan and implement measures to stimulate innovations in pharmaceuticals and other healthcare industries by addressing barriers that exist throughout the whole value chain, from basic research to commercialization including

drug pricing and reimbursement systems.

- B-J-3 The Japanese drug pricing system, where drug prices go down continuously even during patent protected period, increases the time required to recover R&D investments and lowers the priority of new drug development in Japan. BRT members strongly support the realization of a more attractive and internationally competitive new drug pricing system in Japan (industry proposal), which is now under discussion at the Central Social Insurance Medical Council.

- B-E-4 In the European Union, innovation policy is stated by the Lisbon declaration and the G10 group report indicating the importance of innovation in pharmaceuticals. However, each state operates its own healthcare system in different ways, resulting in gaps in survival rates and the QOL of citizens. BRT members calls on the European Union to clarify its healthcare policy and to discuss and totally improve healthcare situations in member states by securing appropriate healthcare budgets, preventing interference with patient access to new medicines, and considering the proper utilization of healthcare technology assessment.

- B-E-5 BRT members also argue for urgent responses by EU governments to the danger of counterfeit drugs that enter the market due to the repackaging of pharmaceuticals, and also to the confusion of medication caused when prescriptions for original (brand) and similar biopharmaceuticals use the same generic drug names as WHO INN rules. These issues have a very serious impact on patient safety, and prompt actions are needed.

[Plant biotechnology]

Over the next decades, global agriculture will be faced with considerable challenges such as an increase in human population, a rise in per capita food consumption as well as environmental issues such as climate change and water shortage. At the same time only very limited additional land for agriculture will be available. A substantial increase in food production will be required to meet the needs of this population.

These challenges from agricultural requirements and competing land use claims can only be met if we use all options available for increasing productivity and safeguarding harvests. We need a “Second Green Revolution” focusing on substantial investment in research and development.

In order to produce sufficient, diversified and affordable high-quality agricultural products innovation is needed to reduce loss of yields due to weeds, pathogens and pests. A combination of innovative crop protection and modern plant biotechnology under the frame of integrated crop management has a key role to play in the quest to increase yields and quality in a sustainable way. An efficient use of agricultural resources is decisive for

improving productivity with a lower environmental impact. Thus, further options of efficiency increases have to be investigated by plant biotechnology e.g. reducing fertilization and water requirements.

Innovations for plant tolerance towards non-biotic factors are necessary due to climatic changes: improved tolerance to water limitation and drought, improved tolerance to cold temperatures as well as improved salt tolerance through molecular breeding and/or transgenic techniques. In addition, research improving plant physiology such as photosynthesis and metabolic efficiency or architecture of crops could develop fundamentally new approaches.

- B-EJ-6 The BRT members urge EU and Japan to increase spending for research in plant biotechnology and enhance international cooperation to advance the development of plants with new beneficial traits to the advantage of developed and developing countries.

- B-E-7 It is furthermore important to implement and enforce existing regulatory frameworks of EU government on GMO crops.

  - 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 not be questioned.
  - 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.
  - We urge the Commission to change its zero tolerance policy for the low level presence of EU-unapproved GM plant materials found in imported commodities which have been approved by other Regulatory Agencies. It is disproportionate to any potential risk.

[Industrial Biotechnology & Biofuels]

- B-EJ-8 To increase the cooperation between the EU and Japan to enhance global

competitiveness of the biobased economy, we suggest a number of actions that would strengthen activities in the area of industrial biotechnology:

- Develop and implement common R&D programmes and strategies to encourage the use of agro-food by-products and wastes. These are representing huge amounts of biomass already available and at low costs. Using such matrices as feedstock for biobased products would bring a two-fold benefit: the sustainable disposal of impacting wastes, and the generation of added value bioproducts with remarkable improvements of the sustainability of the agro-food industry.
- Support collaborative development of technologies to produce biomass based products and sustainable biofuels efficiently, consistently and economically, for example through improved biorefining technologies to ‘make more out of the biomass’ and development of biorefinery infrastructure.
- Develop joint programmes to stimulate and enhance technological innovation and to accelerate the transformation of knowledge into commercial products at a scale that can prove economic feasibility via public-private partnerships.
- Advance the unification of product standards (such as determination of biobased content, environmental footprint, etc.) through EU-Japan cooperation
- Benchmark the EU and Japanese policy strategies and legislation/regulations in order to stimulate the market introduction of biobased products coming from innovative technologies and to use the positive aspects and advantages of both policies.
- Set up a common task force to analyse which global incentives could be worked out to stimulate or support the reconversion towards a biobased economy.