Recommendations
of the
EU-Japan Business Dialogue Round Table
to the Leaders of the EU and Japan

Berlin, 3 - 4 June 2007

Working Party 5
"Life Sciences and Biotechnology"

Life sciences and biotechnology (LS&BT) broadly cover healthcare, foods, industrial processes, environments, plants etc. They are socially fundamental requirements both for the public welfare and economic activities, and are expected to be vital in order to realize sustainability of the globe. Contrary to the considerable expectations held by society for them, some issues are not being addressed in a straightforward, scientific and logical fashion. Because LS&BT are so closely interconnected with how we live, their rapid changes may tremendously affect our day-to-day lives, directly or indirectly, where many stakeholders are related to each other from different points of view. To conquer this situation, national and/or worldwide discussions involving governments, industries, academia and citizens are necessary to confirm the principles of how to utilize these technologies for the future prosperity of human beings.

The EU Commission has set some basic strategies promoting LS&BT related fields and has started "the Pharmaceutical Forum" for discussions between the pharmaceutical industry and ministers of member states. In Japan, the Prime Minister is establishing "Innovation 25", a basic and long-term strategy creating innovation towards year 2025, and a "dialogue between industry and governments for innovative drug discovery" has also started since January 31st this year. EUJBDRT members strongly welcome these movements and recommend similar approaches to address other issues regarding LS&BT such as environments and genetically modified crops matters.

1. General Recommendations

5-EJ-1: Continue to implement the Biotechnology Action Plans set by both governments in 2002 and intensively allocate government resources, including budgets and legislative/administrative supports, on prioritized measures. Proper revision of the strategies must be done according to advancements of science and technology. Establish a promotion body in Japan for implementation.

5-EJ-2: Significantly increase budget for promotion of public understanding of LS&BT.

Establish third-party institution(s) to lead scientific approach to evaluate social risks/benefits of new technologies in LS&BT. Governments should urgently establish "National LS/BT Understanding Promotion Plans" through a strong governmental initiative in cooperation with industrial and academic sectors for the accelerated and efficient promotion of public understanding of biotechnology. More information exchange on this matter between EU and Japan is strongly recommended.

5-EJ-3: Enhance international communication between EU and Japan in LS&BT areas, such as bio-ventures/bio-clusters, by supporting international conferences and industrial exchange activities.

2. LS&BT for Health

5-EJ-4: Plan and implement measures to activate innovations in pharmaceuticals and other healthcare industries, addressing barriers throughout the whole value chain including R&D and product pricing systems. Identify priorities in order to focus on some specific innovation domains. Establish mechanisms to develop concrete measures in response to the Pharmaceutical Forum in the EU and the Government-Pharmaceutical Industry Dialogue in Japan.

5-EJ-5: Improve infrastructures supporting innovation in medical devices and promote the industry. Urgently strengthen the review function for approval of medical devices in Japan.

3. LS&BT for Industrial/Environmental Uses

5-EJ-6: Cooperation between EU and Japan to increase global competitiveness in bio-mass based and bio-fuel products:

- Communications such as a joint forum on bio-mass based products/bio-fuels to outline issues, study ways of cooperating in the area, and exchange information about wider regional collaboration such as EU-Africa and Japan-Asia
- Collaborative development of technologies to avoid confliction with food issues
- Development and/or modification of materials by use of plant biotechnologies.

4. LS&BT for Plants

5-EJ-7: 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, established by co-decision between the European Parliament, the European Commission and member states), 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 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 are concerned about the continuous tendency that prefectural governments implement local laws and/or guidelines to tightly regulate the cultivation and use of the GMO crops that are approved by the central government for cultivation and use in Japan based on scientific safety evaluation. We urge the Japanese central government to take a strong leadership and effective actions to encourage local governments to promote the cultivation and use of the GMO crops.
- We would like the Japanese government to keep organizing nationwide discussion of importance of GMO crops in sustainable growth of economy in the near future and inviting every stakeholder to actively participate in the discussion.