(Joint Recommendations FINAL – 26 May 2008

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

Tokyo, 3-4 July 208

Working Party 5
Life Sciences & Biotechnology

Life Sciences and Biotechnology (LS&BT) broadly cover healthcare, foods, industrial processes, environments, plants etc. They are fundamental requirements for society, both in terms of public welfare and economic activities, and are expected to be vital in realising the sustainability of the globe. Contrary to the considerable expectations that society holds 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 utilise these technologies for the future prosperity of human beings.

The EU Commission set forth a basic strategy in 2002 for promoting LS&BT-related fields and has carried out a mid-term review of the strategy based on an in-depth assessment of the progress made since 2002. The Commission is also carrying out the "Bio4EU" study which includes many concrete examples of how biotechnology is being used in health, food and the environment. Moreover, the EU is establishing a new funding scheme called “Joint Technology Initiatives” in order to promote innovation in several strategic fields under the 7th Framework Programme for Research and Technology Development. As the first scheme, the “Innovative Medicine Initiative (IMI)” was started to invigorate pharmaceutical R&D and better facilitate patient access to cutting-edge medical care. In Japan, BT Strategy Guidelines were issued by the government in 2002, and a new council for BT promotion was established in March

2008. The council, which consists of six Ministers as well as representatives of industry, academia and the public, reviews the progress of action plans in the BT strategy and revises or prioritises measures for BT promotion. Furthermore, a government-industry dialogue for innovative drug creation has been held four times since its start in January 2007, and a "Five-year strategy for innovative drug creation" has been developed as an overall policy for the promotion of the pharmaceutical/device industry. EUJBDRT members strongly welcome these movements and recommend similar approaches to address other LS&BT issues such as food, energy and GMOs, through the close relationship and cooperation of government and industry.

[LS/BT general]

5-EJ-1

Continue to promote, review and revise the BT strategies of both authorities.
Implement with a sense of urgency revised/prioritised measures for BT promotion through cooperative actions by governments and industry.

5-EJ-2

Significantly increase 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.

[Healthcare LS/BT]

5-EJ-3

Plan and implement measures to stimulate innovations in pharmaceuticals and other healthcare industries by addressing barriers throughout the whole value chain including R&D and product pricing systems. Establish priorities in order to focus on some specific innovation domains. The "Pharmaceutical Forum" in the EU and the "Government- Industry Dialogue for Innovative Drugs and Medical Devices" in Japan are expected to accelerate the progress of measures that are interrelated in complicated ways.

- Research on technologies to predict the efficacy and safety of drugs on an individual level by using bio- and genetic markers, and the establishment of an information platform that enables citizens around the world to utilise these results.

- Collaborative actions by the EU and Japan at international discussions, such as WHO intergovernmental working groups, to counter movements that aim to weaken the intellectual property rights for drugs.
- Realisation of new drug pricing systems that can evaluate the innovations of new drugs and give incentives for further efforts to improve patient QOL in Japan.
- Improvement of the infrastructures that support innovation in medical devices and promote the industry, and the urgent strengthening of the review function for approving medical devices in Japan.

[IEB and Plant BT]

5-EJ-4

Cooperation between the 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 in order to outline issues, study ways of cooperating in the area and exchange information about wider regional collaboration such as EU-Africa and Japan-Asia
- Unification of product standards through EU-Japan cooperation
- Collaborative development of technologies to produce bio-mass based products/ bio-fuels efficiently, consistently and economically by using non-edible plants in order to avoid impacting foods for human consumption
- Development and/or modification of materials by using plant biotechnologies.

5-E-1

Further 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 the 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 labelling 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.

5-J-1

Organise and lead a strong ALL-JAPAN collaboration consisting of the central and local governments, public and academic laboratories, and industry to develop GMO varieties that are useful for agriculture in Japan so that GMO crops will be commercially cultivated on a wide scale in Japan in the near future.

Production of GMO crops has been rapidly increasing, with GMO cultivation now exceeding 100 million hectares around the world. In addition to North and South America, GMO production has also been increasing in Asian countries. Although strong efforts are being made in Japan in the basic research of plant biotechnology, development of commercial GMO varieties has fallen far behind the leading countries. Unless effective measures are taken soon, Japan will lose its position as a leader in biotechnology and ultimately in the global economy as well.