

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

Brussels, 7-8 July 2005

*“A Continued Innovative Approach  
to Address New Common Challenges”*

**Part I  
Summary of Recommendations**

**I. A. Introduction**

The EU-Japan Business Dialogue Round Table (BDRT) held its annual meeting in Brussels on 7 and 8 July 2005 under the co-chairmanship of Viscount Davignon and Mr. Kobayashi, and in the presence of Mr. Verheugen, Vice-President of the European Commission and Commissioner for Enterprise & Industry, Mrs. Reding, Commissioner for Information Society & Media, and Mr. Lamoureux, Director-General of Energy & Transport DG; and from the Japanese Government: Mr. Onodera, Parliamentary Secretary for Foreign Affairs (MOFA), Mr. Yamamoto, Parliamentary Secretary for Economy, Trade and Industry (METI) and Mr. Matsui, Vice-Minister for Policy Coordination, International Affairs (MIC).

The participants were informed of the decisions of the last EU-Japan Summit held in Luxembourg on 2 May 2005. They appreciated the call for “a continued innovative approach to the Action Plan to address new common challenges”. Among others, issues on international accounting standards, regulatory reforms, REACH regulations, intellectual property rights, etc. are subjects on which the BDRT has been focusing. It was with those elements in mind that they drew up their new Recommendations to the Authorities.

The BDRT is pleased with the deepening relationship between the enlarged European Union and Japan and welcomes the positive business environment created to foster growth in two-way direct investment. Having noted some positive response to last year’s Recommendations, the BDRT requests that further efforts be made by both the EU and Japanese Authorities to implement pending or new Recommendations.

At this year’s annual meeting the work undertaken by the working parties was reviewed by the BDRT Members, and the general discussions focused on six major areas:

- *Competitiveness*: Europe and Japan share a lot of common concerns. They need in particular to tackle the issue of a growing ageing population and to answer two fundamental questions: how to sustain economic efficiency with a high level of environmental and social protection, and how to deal with the trends of delocalisation and the rise of new competitors. The BDRT participants called for close cooperation between the EU and Japanese Authorities on competitiveness issues and underlined the need to deliver on economic reform in order to speed up growth.

- *WTO*: The BDRT made a plea in favour of a successful completion of the Doha Development Agenda negotiations and urged the EU and Japan to reinforce their common views in the run-up to the Hong Kong WTO Ministerial Conference in December 2005.
- *Investment*: Even if the investment environment is improving, overseas capital still faces barriers. A continuous pressure from Industry is needed to make Europe and Japan more attractive places to invest, for the benefit of growth and employment. It is expected that the Government of Japan, the European Commission and the Governments of the Member States will pay particular attention to this issue. In that context, the BDRT noted the progress made since last year in implementing the recently set-up Investment Framework, as stressed by both Leaders at the last Summit meeting. However, further action is still needed to remove remaining barriers to trade and investment, particularly those identified by the BDRT “Trade & Investment” Working Party.
- *Importance of a harmonised market*: The EU as a single market, under which unified rules are valid throughout the Union, will benefit both European and third-country companies equally. However, there are quite a few fields in which rules remain independent and vary from Member State to Member State due to the nature of the Union. The BDRT Members take this opportunity to request that the EU Authorities pay prioritised attention to finding solutions for these shortcomings.
- *Energy issues*: Recognising the close relationship between energy and economic growth as well as the present volatility of the international energy markets, the BDRT underlined the need to forcefully address current energy challenges, including those related to security of supply, sustainability and competitiveness. The BDRT especially noted that a more rational use of energy should be pursued, as well as the need to develop close international cooperation, in particular between the EU and Japan, on energy efficiency and the role of each energy source.

In the present energy situation, BDRT Members consider that the International Energy Agency should play an active and important role. In this regard, the IEA should select as a priority the promotion of energy efficiency and the increase of cooperation between its members on these topics.

BDRT Members suggest cooperation between the EU and Japan in order to promote the use of clean technology, particularly in the coal sector. This cooperation could be implemented through a partnership between public and private sectors. The use of this technology should be utilised in the first instance in China and in India.

The BDRT considers that great effort should be made in the development of renewable energies, including in the need for the required incentives.

- *China*: BDRT Members noted with satisfaction the progress made by China’s economy. Indeed, such an evolution, provided it occurs at a steady pace, is a source of new business opportunities.

BDRT Members were, however, concerned by some of the various impacts of Chinese foreign trade on the world economy. Recent price hikes for primary goods, such as energy, and a sudden increase in Chinese exports have had negative consequences for some sectors or countries, in particular for Least Developed Countries.

A harmonious development implies for China a respect for all the obligations to which it committed itself, particularly those relating to IPR, when joining the WTO.

BDRT Members consider that every effort must be made to increase the efficiency of energy and other natural resources, including through cooperation between the EU, Japan and China.

The BDRT underlined that the EU-Japan economic relationship still has to reach its full potential and praised the continuous efforts made by both business communities to support the respective Authorities in strengthening the economic and trade partnership.

## **I. B. Highlights of main Recommendations**

### **Trade & Investment**

The BDRT Members welcomed the adoption of a "Cooperation Framework for Japan-EU Two-way Investment Promotion" by the heads of the EU and Japanese Authorities in June last year. They would like to emphasise, however, that the framework is only a first step and that it needs to be substantiated by concrete measures with substantial impacts on the two-way investment between Japan and the EU.

Optimising returns of investment is crucial in stimulating investment and trade flows between the two regions. BDRT Members would, therefore, encourage both Authorities to address continuously the important issues of avoiding double taxation, reducing compliance costs associated with transfer pricing and participation exemption. The new U.S.-Japan tax treaty could serve as an example for encompassing tax treaties to be negotiated also between the governments of the EU and the government of Japan. In order to give the efforts to reduce compliance costs associated with transfer pricing a fresh start, the Working Party recommends Japan and EU Member States to establish a joint forum, similar to the JTPF (EU Joint Transfer Pricing Forum) established between EU Member States. To expedite the negotiations on Social Security agreements, BDRT Members furthermore recommend the Authorities to consider utilising external resources.

BDRT Members are encouraged by the continuous close dialogue between the EU and Japan on regulatory reforms. Much more effort, however, is still needed if unreasonable authorisation procedures hindering the trade of products and services are to be fully abolished. In order to avoid the creation of a new barrier to trade when introducing new standards, a mechanism should be put in place to ensure standard convergence.

Forms of legal presence and merger measures allowed are of critical importance for the development of foreign business in Japan and the EU alike. BDRT Members therefore maintain that companies investing in Japan and the EU should be protected from sudden changes in rules governing the forms of legal presence. Improvements of Company Laws under way in the EU and Japan should, furthermore, be carried out in full to facilitate smooth cross-border reorganisations between the EU and Japan that involve the exchange of shares and transfer of assets.

The BDRT takes note of real progress made during the past year but maintains that it is important to accelerate the implementation of all Recommendations in order to eliminate the outstanding structural barriers to investment and trade between the EU and Japan.

### **Accounting & Tax Issues**

BDRT Members understand that the Committee of European Securities Regulators ('CESR') has been asked to give technical advice on the equivalence of IAS/IFRS and third-country

GAAP, and the European Commission will take a final decision after considering both the CESR's advice and the actual impact on the economy. They ask the European Commission to take a decision after careful consideration that minimises the cost and inconvenience to users and providers of J-GAAP following receipt of the final technical advice.

BDRT Members ask the public Authorities to observe closely the process of rule-setting and revision by the IASB and to have regard for the interests of companies and investors (whether European or Japanese) in the opinions they transmit to the IASB, in particular in its Performance Reporting project.

BDRT Members welcome the news that the European Commission intends to present in 2006 a Communication on the Member States' bilateral tax treaties and ask that the European Commission use this opportunity to encourage the Member States to revise those treaty provisions concerned with the reduction of certain withholding taxes and to enter into common agreements with the Government of Japan in order to realise fully the benefits of the single market.

### **Information and Communication Technologies**

The year 2005 will be a turning point in light of ICT policies for both the EU and Japan. The BDRT expects both Authorities to steadily continue and intensify their efforts to ensure achievements of the goals specified in policies, and to carry out an objective review of the achievements. Furthermore, both Authorities should create visions and lay out plans ranging to 2010, to promote advanced ICT societies that realise the "quality of life" of every citizen.

In the Recommendations for 2005, the BDRT expects both the European Commission and the Japanese Government to take remaining steps in view of the establishment of infrastructures, security of infrastructures, and efficiency through ICT, while developing a cooperative relationship for the realisation of a "quality of life" with ICT.

Both Authorities should address promotion of broadband usage, establishment of a seamless ubiquitous network environment between fixed and mobile, R&D for ensuring secure ICT infrastructures, and appropriate regulations. Especially in the area of information security, they should have continuous talks in forums consisting of industry, government and academia, for example, to ensure secure ICT infrastructures.

Members of the BDRT highlighted the need to tackle the digital divide. They discussed the importance of both Authorities creating a favourable environment, which acts as an incentive for investment in the dissemination of new ICT technologies.

Moreover, it is expected that both Authorities will realise a "ubiquitous network society", in which every citizen can enjoy the benefits of ICT, by promoting the study and analysis of effects of the rapid spread of ICT on citizens and societies, appropriate policies on IPR, and experiments and proposals on new work-styles with advanced utilisation of ICT, and lead the creation of a new stage of ICT utilisation.

### **WTO**

BDRT Members expect the European Union and Japan to work closely, together with other WTO Members, to ensure the achievement of a substantive agreement at the sixth WTO Ministerial Conference to be held in Hong Kong in December 2005.

Economic progress in developing countries should be pursued further at the New Round negotiation. Developing countries are essential players for a stable and prosperous global

economy, and liberalisation of multilateral trade and investment is truly beneficial for social and economic progress in developing countries.

The ongoing New Round negotiation is immensely important for all stakeholders in the multilateral trading system, in terms of economic growth, stability and development. BDRT Members request the European Union and Japan to pursue solutions, through close bilateral dialogues, to advance the negotiation at every opportunity, and to exert their maximum efforts for a successful conclusion of the New Round.

### **Life Sciences and Biotechnology**

The second joint bio-seminar was held in April 2005 in Lyon, France, in association with BioVision 2005, one of the three biggest bio-conferences in the world. BDRT Members were pleased to have the participation of EU Commissioner Mr. Verheugen, Member of the House of Representatives Mr. Omi, and government officials from Research DG, MEXT, and METI, as well as industry representatives from the EU and Japan.

The action plans for the promotion of LS/BT were issued by the Authorities in 2002. The BDRT acknowledges that some improvements have been made; however, insufficient progress has been seen in certain issues. The LS/BT Working Party requests that more attention be paid to the implementation of those, in particular with regard to plant technology. This year, the LS/BT Working Party proposes the continued implementation of those programmes and also the strengthening of functions for pre- and post-evaluation of R&D projects. In 2006, new mid-term plans for Research and Development will start both in the EU and Japan: Framework Programme 7 and the 3<sup>rd</sup> S&T Basic Plan; the Working Party calls for prioritised engagements of the Authorities with regard to the LS/BT field in those plans.

Although the understanding of the public is essential for the smooth realisation of LS/BT benefits for society, a holistic approach for this has been insufficient both in the EU and Japan. The BDRT proposes that both Authorities establish a “National LS/BT Understanding Promotion Plan” for a nationwide strategic approach to the issue. This will also encourage the proper implementation of the existing frameworks for GMOs, which is the top priority for Industrial as well as Plant Biotechnology.

In the fields of LS/BT, it is important that all stakeholders such as governments, industries, consumers and the public work together for the goals of realising a healthy and affluent society. In order to create awareness of common issues we are facing, communications between governments and industries are valuable and have to be strengthened by maintaining opportunities for constructive discussions on topics such as evaluation and pricing systems for innovative medicines, concrete plans for promotion of BT public understanding, and smooth and efficient implementations of BT strategic action plans.

### **Sustainable Development**

While confirming 2004 Recommendations, the BDRT focused its 2005 Recommendations on Global Warming issues. The Kyoto Protocol became effective in February, and discussions of the post-Kyoto framework (beyond 2012) will start this year. The BDRT stresses major greenhouse gases emitting countries such as the USA, China and India should participate not only to reduce emissions on a global scale but also to secure the competitive position of EU and Japanese industries. They also emphasise the importance of promoting technological innovation including public and private joint funding. Effective use of the Kyoto Mechanisms, such as CDM and JI, is also recommended for reducing emissions on a global basis.

The BDRT recognises that there is potential to reduce CO<sub>2</sub> emissions by developing energy-saving products and services and by diffusing them on a global basis. It is important to work together with participation of the Authorities, industry and the public for prevention of global warming, especially to educate and cultivate the population to contribute to greenhouse gases reduction. The BDRT recommends that technological development of renewable energy as well as hydrogen energy be promoted from a mid- to long-term point of view.

### **I. C. Assessment of the Progress Reports issued by the Authorities**

The BDRT Members think it is important to review how the past Recommendations are implemented or followed up by the relevant Authorities. In this context, the BDRT is very grateful for the Progress Reports in which the EU and Japanese Authorities provide a detailed status to every recommended item several months after the submission of the BDRT Recommendations every year.

Last year the BDRT submitted 89 Recommendations, including sub-items, of which 35 items (39%) have been assessed by the BDRT Members as progress undertaken. Implementation of the Recommendations by the Authorities has shown much better results than last year, and yet, further improvement is desired since the majority of the Recommendations are still awaiting action. This year even more Recommendations have been made by the BDRT Members.

Among the Recommendations which were assessed as ‘Progress Undertaken’, some examples of the major items are as follows:

#### **Trade and Investment**

- 1-EJ-1: Joint declaration on direction to enhance foreign direct investment between the heads of the Authorities of the EU and Japan.
- 1-J-4: Creating a strong competition regime.
- 1-E-1-3: Proposal on cross-border mergers of companies with share capital.
- 1-E-4: Personal Data Protection.

#### **Accounting and Tax Issues**

- 2-EJ-2: Close observation on process rule-setting and revision by the IASB.
- 2-J-1: Promotion by GOJ for consistency of Japanese accounting standards with IAS.
- 2-E-1: European Commission’s consideration to encourage Member States to allow Japanese companies to use Japanese GAAP after 2007.

#### **Information and Communication Technologies**

- 3-EJ-1: Revision of target number of broadband subscription.
- 3-EJ-2: Promotion of broadband utilisation.
- 3-EJ-3: Establishment of secure network environment.
- 3-EJ-4: Establishment of PDCA cycle for evaluation of IT policy development.

#### **Life Sciences and Biotechnology**

- 5-EJ-1: Expedited implementation and review of 2002 Action Plans.
- 5-EJ-2: Dialogue between the Authorities and industry on Action Plans including harmonisation of regulations, public understanding, best practice sharing.
- 5-E-7: Re-commence the process for market approvals of GM-technology products.
- 5-J-5: Establishment of standards for bio-materials such as biodegradable polymers.

5-E-4: Utilisation of Biomass as a sustainable resource.

**Sustainable Development**

6-EJ-1: Voluntary Actions.

6-EJ-2: Sufficient prior consultations.

6-EJ-4: Promotion of Technological Development of Alternative Energy.

<b>I. D. EU-Japan Centre for Industrial Cooperation</b>
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In this context, the EU-Japan Centre is expected to continue to support the EU-Japan Business Dialogue Round Table and to keep adapting its activities to address the new challenges.

## **Part II**

### **Policy Statement concerning the World Trade Organization**

On the occasion of the 2005 annual meeting of the EU-Japan Business Dialogue Round Table (BDRT), business leaders from the European Union and Japan have adopted the following message:

1. The BDRT reiterates its strong support for the multilateral trading system and the DDA, which are crucial to bolstering international economic growth and helping developing countries integrate into the global economy.
2. The BDRT welcomes the progress in the WTO Doha Round achieved since the WTO General Council of July 2004 in Geneva successfully put the DDA back on track. The BDRT welcomes the EU and Japan taking instrumental roles in this, including their flexibilities shown on the so-called “Singapore Issues”.
3. Having some concerns about future prospects, however, the BDRT calls on the EU and Japan to work closely together, and with other WTO Members, to ensure that the Hong Kong Ministerial Conference in December 2005 achieves a balanced and significant result in view of a rapid conclusion of the Round. The BDRT hopes that the General Council Meeting scheduled in July this year will reach the first approximation of the Hong Kong agreement which may provide a clear way forward in all areas.
4. On industrial products, the BDRT underlines the need to maintain ambition in terms of achieving genuine and substantial market opening. To that end, the BDRT supports the Swiss formula which reduces tariff peaks and high tariffs of Member countries. In addition, the BDRT would welcome sectoral initiatives that further liberalise trade by reducing or eliminating tariffs in sectors of interest to Member countries. While believing that special and different treatment for developing countries is an integral part of the modalities, the BDRT is concerned about the potential for excessive flexibilities to undermine our goal of achieving real market opening.
5. On services, the BDRT is particularly concerned about the current state of play. Services are one of the main pillars of the DDA, but so far progress in services negotiations has been slow, and they are lagging behind other negotiating areas. Services negotiations should match the level of ambition of other negotiating areas. All WTO Members have an important stake in these negotiations and should contribute with substantial offers in services trade. Considering the place of this sector in the economy of developed countries, an increased access to the services market will offer new prospects to developing countries.
6. With regard to agriculture, which remains a key factor of the DDA, the BDRT reiterates the importance of achieving progress in the agricultural negotiations and encourages all Members to show the required flexibility to reach a balanced agreement.



7. The issue of geographical indications should also be elaborated in an appropriate manner.
8. The BDRT supports the development of an ambitious and specific set of rules on trade facilitation across all elements of the negotiating mandate. The BDRT recognises that the other Singapore Issues (investment, competition and transparency in government procurement) are not for negotiation in the DDA but underlines the importance of keeping them in the WTO. Other rules issues, such as anti-dumping, are an integral and important part of the DDA and need to be effectively addressed.
9. There is a need to continue to build on efforts to address developing countries' concerns, including with respect to capacity building, and to deliver results, including on market access, to ensure that Least Developed Countries participate actively in the DDA. All WTO Members should make serious efforts in this regard.
10. The BDRT congratulates the WTO Members on the choice of Mr. Pascal Lamy as the new WTO Director-General. With his strong trade background and qualifications, Mr. Lamy is well placed to build consensus and lead the WTO at this important stage of the DDA.
11. The BDRT encourages the EU and Japan to keep strong bilateral contacts and co-ordinate their positions closely on the DDA in order to help drive the DDA forward, recognising the significant importance of the negotiation resumption for a successful conclusion.

## **Part III**

### **Recommendations by Working Parties**

The items of Recommendations by both the EU and Japanese Round Table Working Parties are presented in this section.

WP 1 Trade and Investment

WP 2 Accounting and Tax Issues

WP 3 Information and Communication Technologies

WP 5 Life Sciences and Biotechnology

WP 6 Sustainable Development

## Working Party 1 **Trade and Investment”**

### Recommendations to the EU and Japan

1-EJ-1 Concrete and focused actions to follow up the investment framework agreement to enhance foreign direct investment (Joint recommendation)

1. The heads of governments of the EU and Japan should follow up and expand the ‘Cooperation Framework for Japan-EU Two-Way Investment Promotion’ adapted at the EU-Japan Summit in Tokyo 2004. Concrete measures with substantial impact on investment between the EU and Japan should be elaborated.
2. Such measures should be assessable and clearly focused on the following four priorities: the optimisation of the returns on investment; supporting timely development of business; supporting timely and smooth business reorganisation; and promotion of regulatory reforms.
3. The results of the reviews of its progress should be communicated promptly to the BDRT as well as to the general public.

1-EJ-2 The optimisation of returns on investment (Joint recommendation)

(1) Avoidance of double taxation

The two authorities should exempt dividend payments from subsidiaries to parent companies and royalty and interest payments between related companies from withholding taxes. The Japanese government, in addition, should introduce measures to avoid the reduction of the ceiling of foreign tax credits as a result of such an exemption.

The European Commission should promote co-operation between Member States in their efforts to make bilateral tax treaties with third countries. The planned communication for next year on the subject may be an appropriate starting point.

(2) Reducing compliance costs associated with transfer pricing

A reduction of compliance costs of transfer pricing through simplification and rationalisation of transfer pricing regimes in a coordinated manner will increase international competitiveness of businesses in the EU and Japan. The two authorities should establish a joint forum, similar to the JTPF established between EU Member States, for the following purposes:

1. To harmonise and simplify interpretation and documentation requirements between the EU and Japan and among the EU Member States in order to reduce the costs of compliance to various transfer pricing taxation regimes.
2. To make the conclusion of bilateral and multilateral APAs (advance price agreements) between the EU Member States and Japan easier and cheaper by improving procedures.

(3) Participation exemption

The governments of the EU, the EU Member States and Japan should, as a medium to long-term objective, consider the introduction and/or expansion of participation exemption regimes in order to promote direct investment between the EU and Japan.

1-EJ-3 Supporting timely development of business (Joint recommendation)

(1) Smoother and swifter transfer of personnel

1. Social security contributions

The two authorities should introduce measures to avoid double contributions to the social security systems of both home and host countries by intra-corporate transferees through the accelerated introduction of social security agreements. In addition, they should introduce an interim measure since it is likely to take a long time to conclude bilateral agreements between all the EU Member States and

Japan. Such an interim measure could be either unilateral exemption by the host country or refund of contributions to pension funds by the host country when such expatriates return to the home country.

Research work should be outsourced to external think tanks.

To facilitate the negotiations on Social Security agreements, external think tanks should be contracted to do the basic research and provide adaptable agreement texts to be adopted by governments within a period of five years.

## 2. Work and residence permits

The two authorities should simplify and accelerate the procedure to obtain a work and residence permit – or a residence permit for self-employed statutory directors – for intra-corporate transferees between the EU and Japan. The procedure should include the possibility to submit an application for a work-residence permit or a residence permit for self-employment after entering the assigned country.

Furthermore, spouses should be automatically granted the same rights as the holder of the permit, such as a work-resident permit and a residence permit for self-employment, upon their arrival.

## (2)Data Protection: International Data Transfer

1. Japan's Data Protection Law should be amended in a way that it could satisfy the level of protection required by the EU's Data Protection Law to permit the transfer of personal data from the EU Member States to Japan.

2. The EU should re-examine the current standard contractual clauses between a data controller and a data processor whether they are workable and sufficiently flexible in the light of modern business practice and experience.

## 1-EJ-4 Guaranteeing stable rules for choice of legal presence and facilitating business reorganisation from a legal and tax point of view (Joint recommendation)

1. Improvements of Company Laws under way in the EU and Japan should be carried out in full to facilitate smooth cross-border reorganisations between the EU and Japan that involve exchange of shares and transfer of assets. Companies investing in Japan and the EU should be protected from sudden changes in rules governing the forms of legal presence acceptable for conducting business.

2. Tax law should be improved in order to expand the scope of tax deferral on unrealised profits resulting from business reorganisations including those involving exchange of shares and transfer of assets.

## 1-EJ-5 Promotion of regulatory reforms (Joint recommendation)

The EU and Japan should continue to cooperate with each other through their ongoing regulatory reform dialogue with the goal of creating an open environment for trade and investment.

The EU and Japan should abolish unreasonable authorisation procedures related to products and services, and continue to pursue mutual recognition of product standards, certification and notification. It is equally important that both authorities cooperate when introducing new standards to assure standard convergence and avoid the creation of future barriers to trade.

## **Recommendations to the EU**

### 1-E-1 The policy of the EU on taxation (Japan-side recommendation)

1. The European Commission and the Member States should realise a common consolidated corporate tax base as soon as possible.
2. Merger Directive (90/434/EEC)

- (a) Its scope should be extended to include the deferral of taxation on unrealised gains on goodwill.
  - (b) Its scope should be extended to include deferral of taxation on the transfer of real estates and other intangible assets.
  - (c) The requirements in certain Member States to maintain the holding of shares for a number of years should be abolished.
3. Concerning the EU Transfer Pricing Documentation - the EU TPD – the EU and the Member States should commit themselves to exemption from penalties (i.e. penalties related to non-compliance with documentation requirements, penalties related to transfer pricing adjustments and interest related to adjustments) if a company submits an EU TPD acting in good faith and in a timely manner.
  4. Although VAT is a common taxation system in the EU, difference among Member States is so large that companies find it very difficult to centralise VAT administration. The EU and the Member States should simplify and harmonise it to the extent that companies can centralise VAT administration easily without employing people with expert knowledge of the VAT regime in each country in which it is operating.
  5. The European Commission and the Member States should make swift progress in realising the cross-border offset of losses against profits.
- 1-E-2 The policy of the EU on company law (Japan-side recommendation)
1. The proposal for a Directive of the European Parliament and of the Council on cross-border mergers of companies with share capital (a 10th Company Law Directive) should be adopted and implemented without delay.
  2. A 14th Company Law Directive on the cross-border transfer of the registered office of limited companies without liquidation and incorporation should be proposed, adopted and implemented as soon as possible.
  3. A Statute for a European Private Company should be introduced as a short-term priority.
- 1-E-3 The policy of the EU on corporate governance (Japan-side recommendation)
- Corporate governance and its disclosure make sense only if it is applied to the entire group companies in a consistent way. Corporate governance and its disclosure, therefore, should be regulated at the level of listed companies where disclosure to shareholders is crucial.
- The European Commission should coordinate EU Member States and introduce a guideline in order to make sure that corporate governance and its disclosure is regulated at the level of listed companies.
- Adoption of a code should be voluntary and companies should comply with the adopted code based on the principle of 'comply or explain'.
- 1-E-4 Japanese expatriates (Japan-side recommendation)
- The EU should introduce a fast track procedure for Japanese nationals who are already legally resident in a Member State when he or she moves to another Member State for economic activities or other reasons.
- 1-E-5 Pension (Japan-side recommendation)
- The European Commission and the Member States should eliminate double taxation related to occupational and supplementary pensions as soon as possible.
- 1-E-6 Community Patent (Japan-side recommendation)

The proposal for a Council Regulation on the Community patent should be adopted and implemented as soon as possible.

1-E-7 Fight against counterfeited, pirated and contraband goods  
(Japan-side recommendation)

Fight against counterfeited, pirated and contraband goods should be reinforced at the new and extended border of the EU.

1-E-8 Tariffs and tariff classification (Japan-side recommendation)

1. Compared with other developed nations, the European Union (EU) imposes high tariffs on certain manufactured goods (for example, duties on audiovisual electrical appliances: EU 14%, Japan almost 0%; duties for automobiles: EU 10%, Japan 0%, United States 2.5%). These should be eliminated or reduced.

2. Tariff classifications must be appropriate, timely and transparent, based on the primary function of the manufactured good at the time of import. Importers find that classification remains unpredictable because of inconsistencies in the interpretation of the tariff schedule by the EU.

1-E-9 The decision-making system of the EU (Japan-side recommendation)

The EU and its Member States should pursue institutional reforms so that the EU could speed up its decision-making. In the corporate taxation area, in particular, unanimity requirements in the Council should be abolished in the area where uncoordinated taxation policies of Member States could become obstacles to cross-border business activities.

### **Recommendations to Japan**

1-J-1 Maintaining stable rules for the legal presence of foreign companies  
(Europe-side recommendation)

The Government of Japan should use all means available, including revision, to ensure that Article 821 introduced recently without adequate public notice into the Japanese Corporation Law does not constrain forms of legal presence available for foreign companies in Japan. Forcing foreign companies into detrimental reincorporation by suddenly changing the legal framework governing forms of legal presence substantially damages investor confidence in Japan.

1-J-2 Promoting economic growth through decisive reform (Europe-side recommendation)

It is important that the Japanese Government continue pursuing its structural reform agenda so that the current economic recovery can be maintained.

1-J-3 Modernising legal and tax systems to support foreign investment  
(Europe-side recommendation)

The Company Law and relevant corporate tax laws should be revised to allow for cross-border share exchanges on a tax-neutral basis. Swift introduction of the triangular merger scheme into the new Corporation Law is of the highest importance.

1-J-4 Take-over defences should be introduced with caution (Europe-side recommendation)

Take-over defences outlined in the new Corporation Law shall be introduced only with proper shareholders' rights protection in place. We support the Guidelines outlined by the Ministry of Economy, Trade and Industry first and then also the Ministry of Justice but are concerned that these are not yet legally binding.

1-J-5 Championing business activity at the local level (Europe-side recommendation)

More private sector involvement in the delivery of public services should be encouraged through the use of PFI/PPP schemes. Local governments should also take a more proactive role in attracting investment beyond their current promotion efforts, for example, by offering special tax and/or regulatory incentives to potential investors. Cities and prefectures should be better co-ordinated in their incentive packages, and existing regulatory incentives should be made easier to understand for potential investors.

1-J-6 Privatisation of Japan Post (Europe-side recommendation)

The privatisation of Japan Post is an important element of the Japanese Government's ongoing structural reform efforts and, if implemented effectively, will contribute to the reinvigoration of the Japanese economy. It is imperative, however, that the framework for privatisation ensures a level playing field for private sector competitors in Japan Post's three core business lines: insurance, banking and delivery services. The privatisation scheme as presented in the package of bills submitted to the parliament in April 2004 does not go far enough in separating the branches of operation. Cross-shareholding between the holding company and the entities (mail services, postal savings, postal life insurance and the branch network) should not be accepted as it will enable centralised group management after full privatisation in 2017 with the risk of cross-subsidised financial products on the market.

1-J-7 Facilitating business development through regulatory reform  
(Europe-side recommendation)

The Japanese Government's regulatory reform programme should be strengthened by giving the new Regulatory Reform and Privatisation Promotion Council extra powers to implement the Government's "3-year Regulatory Reform Programme" and by expanding the special deregulation zone initiative. Special attention should be paid to regulatory reform recommendations made in the context of the EU-Japan bilateral regulatory reform dialogue and recommendations submitted by European business organisations such as the Council of the European Business Council in Japan.

1-J-8 Ensuring transparency and consistency in the regulatory process  
(Europe-side recommendation)

Japanese regulators should make more efforts to improve the transparency and consistency of regulation, including for tax-related matters. When new laws are formulated they should with no delay be accompanied with clarifying orders.

1-J-9 Modernising Japan's food additives list (Europe-side recommendation)

The remaining 43 as yet unapproved food additives in the list of 46 submitted by the Ministry of Health, Labour and Welfare (MHLW) to the Food and Sanitation Control Council on December 19, 2002 should be reviewed and approved for use in Japan without delay. The time schedule for approval should be made public by the Food Safety Commission.

1-J-10 Protecting test data in new drug applications (Europe-side recommendation)

Protection for data submitted as part of a new drug application should be made equivalent to the protection currently provided for in Europe. We support the Federation of Pharmaceutical Manufacturers' Association of Japan (FPMAJ) call for an eight-year protection period, noting that a similar period of protection was approved by the EU Council on March 11, 2004.

1-J-11 Strengthening market mechanisms in the telecommunications sector

(Europe-side recommendation)

Japan should not introduce universal service funding obligations. Non-traffic-sensitive (NTS) costs should not be transferred from the interconnection charge into a universal service funding scheme.

Japan should maintain its current policy approach of non-intervention in the mobile market, as this strikes the right balance between vigorous price competition and sustainable investment in innovative products and services.

Japan should ensure that the criteria for allocating growth spectrum do not entrench dominance and unfairly disadvantage competitors by starving them of spectrum and frustrating their growth.

There should be a legislative requirement that the regulator make decisions based on objective economic factors, with specific references to internationally accepted tests, such as “the long-term interests of end-users”, “efficiency”, “innovation”, “investment”, and “effectively competitive outcomes”.

The existing obligations on bottleneck facilities do not adequately safeguard abuse of dominance. They need to be strengthened by:

- Requiring NTT to notify and price on tariff in market segments where it is dominant;
- Requiring NTT to publish regulatory accounts horizontally across its different businesses and vertically between the network and retail parts of its horizontal business; and
- Strengthening firewalls to prevent NTT from leveraging its dominant position in the local loop into new business areas.

#### 1-J-12 Promoting EU-Japan cooperation in commercial aircraft development, production and procurement

(Europe-side recommendation)

1. Competition in the procurement of commercial aircraft will benefit all airline companies and passengers and could contribute to promoting the Japanese government’s plan to double the number of foreign tourists to Japan within five years.

2. By buying large aircraft for official government use from various suppliers, the Japanese government would follow the positive example of the private sector which has recognised the advantages of multiple-sourcing.

#### 1-J-13 Foreign tax credit (Japan-side recommendation)

The Japanese government should expand the number of tiers covered by its foreign tax credit system considerably. Furthermore, the minimum shareholding requirement should be reduced from the current 25% to 5 or 10%.

#### 1-J-14 CFC rules (Japan-side recommendation)

We recommend the following three points concerning Japanese CFC rules.

1. To exempt profits for re-investment.
2. To increase certainty in their application.
3. To reconsider of Exception.



ACCOUNTING ISSUES

**2 - E - 1**

**KEY POINTS OF RECOMMENDATIONS**

- (i) We understand that the Committee of European Securities Regulators ('CESR') has been asked to present technical advice on equivalence of IAS/IFRS and third-country Generally Accepted Accounting Principles ('GAAP') and that the European Commission will take a final decision considering both CESR's advice and the actual impact on the economy. We ask that the European Commission decides after careful consideration to minimise the cost and inconvenience to users and providers of J-GAAP following receipt of CESR's final technical advice.
- (ii) In addition we ask that the European Commission makes every effort to adopt a prompt decision, well before the 1 January 2007 deadline, on the equivalence of J-GAAP.

**ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

In our report last year we recognised the need to examine the question of equivalence between International Accounting Standards/International Financial Reporting Standards ('IAS/IFRS') and third-party GAAPs, and we commented that we wished to add our voice to those of other stakeholders calling for broad-based and urgent discussion of the issue. We welcome the European Commission's decision to refer the matter to CESR.

Since we reported, CESR's technical advice has been presented as a consultation paper. CESR found that the GAAPs of the US, Canada and Japan were equivalent to IAS/IFRS. However the advice identified four areas of significant variance between J-GAAP and IAS/IFRS. As matters stand at present, the elimination of these variances will require companies using J-GAAP in the EU after 1 January 2007 to file separate accounts for the areas in question.

**2 - E - 2**

**KEY POINTS OF RECOMMENDATIONS**

Given that the European Union's Emissions Trading Scheme ('ETS') is now in operation, we ask the European Commission to endorse widely accepted accounting rules on emissions rights.

**ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

In advance of the introduction of ETS on 1 January 2005, the International Financial Reporting Interpretations Committee ('IFRIC') issued a draft interpretation to guide accounting treatment of emission rights.

This was not endorsed by the European Financial Reporting Advisory Group ('EFRAG'), which provides technical advice to the European Commission. Thus a new interpretation has to be presented by IFRIC.

**2 - EJ - 1**

**KEY POINTS OF RECOMMENDATIONS**

We ask that the public authorities in Japan and the European Union make steady progress towards adoption and implementation of IAS/IFRS.

**ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

We recognise IAS/IFRS has been adopted in the EU with the exception of certain provisions in fair value accounting for financial instruments.

We note that the Accounting Standards Council is examining how financial documents based on IAS/IFRS are positioned in terms of the Japanese legal system and look forward to early results from this important work.

## 2 – EJ - 2

### **KEY POINTS OF RECOMMENDATIONS**

We ask the public authorities to observe closely the process of rule-setting and revision by IASB and to have regard for the interests of companies and investors (whether European or Japanese) in the opinions they transmit to the IASB, in particular in its Performance Reporting project.

### **ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

We welcome and support the progress that has been achieved in adopting IAS/IFRS.

We have registered in earlier recommendations our concern that the opinions of business users of accounting standards, as distinct from those of technical experts and standards setters, do not always appear to be as fully reflected as we should wish, and we reiterate that concern here, in view of development in discussion of the Performance Reporting project.

The IASC is now reviewing its governance and we welcome efforts of the EC and the Government of Japan that published their views on such matters as due processes to set accounting standards in the IASB.

## 2 – EJ – 3

### **KEY POINTS OF RECOMMENDATIONS**

Concerning research on the introduction of reports on internal control over financial reporting, we ask that both governments sufficiently discuss the function of internal control, correlating with each mechanism to improve credibility of financial reporting, such as corporate governance, audits on financial statements and oversight over companies and independent auditors.

### **ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

In Japan, introduction of management's assessment and auditors' attestation on companies' internal control over financial reporting has been discussed by the Accounting Standards Council. On the other hand, the EU proposed to adopt International Standards on Auditing (ISA) for statutory audits of financial statements and International Auditing and Assurance Standards Board (IAASB), which sets ISA, considers the possibility to put reporting on internal control on its agenda.

In the US, which introduced such a system earlier, while it was appreciated that reinforcement of internal control reviews contributes a deterrent effect on accounting frauds to some extent, it was also pointed out that costs of compliance were far higher than anticipated. It is necessary to carefully examine the balance of benefits and costs, reflecting needs in the capital market, and a deliberate attitude should be taken to introduce such a mechanism.

## 2 – EJ – 4

### **KEY POINTS OF RECOMMENDATIONS**

Recognising that convergence of international standards of accounting, auditing, and disclosure is an objective, we ask that the public authorities adopt mutual recognition as a short-term target on a course toward convergence in the future.

### **ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

We fully support convergence of standards of accounting, auditing and disclosure, and we recognise that this is an objective that will take some time to achieve because sufficient discussion and building consensus among participants in the market are necessary. To eliminate practical obstacles quickly for smooth capital financing, even at a stage that convergence is not completed, we ask that the public authorities adopt timely mutual recognition as a short-term target on a course toward convergence in the future, under the condition that those standards fulfil common minimum standards.

## TAX ISSUES

### 2 – E – 3

#### **KEY POINTS OF RECOMMENDATIONS**

We welcome the news that the European Commission intends to present in 2006 a Communication on the Member States' bilateral tax treaties and ask that the European Commission use this opportunity to encourage the Member States to revise those treaty provisions concerned with the reduction of certain withholding taxes and to enter into common agreements with the Government of Japan in order to realise fully the benefits of the single market.

#### **ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

The income tax treaty between the USA and Japan has come into effect in January 2005. The main feature of the revision is the reduction or elimination of certain withholding taxes. We hope that it can be replicated in relations between the GOJ and the EU's Member States.

We believe that the relevant treaties between Japan and the EU Member States would benefit from renewal. For example, the treaties with Germany, Italy and the UK are over 30 years old. We welcome that the Netherlands and the United Kingdom have started to negotiate with Japanese tax authorities to revise their tax treaties in 2004.

We recognise that the Member States and not the Commission decide taxation. We ask the Commission to take whatever steps it can to invite the Member States to ensure that there is consistency between new treaties they may agree with the GOJ. The integrity of the single market would be damaged if there were to be significant differences between Member States' treatments of withholding taxes.

### 2 – J – 1

#### **KEY POINTS OF RECOMMENDATIONS**

We ask that the Government of Japan quickly reform the consolidated tax system, allowing the carrying forward of tax losses in subsidiaries incurred before the system came into effect, exempting revaluation of subsidiaries at the initiation, and allowing tax deduction of transfers between consolidated entities.

#### **ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

We believe that the GOJ should reform the system because discriminatory treatments of consolidated taxation remain though the 2% surtax was abolished.

### 2 – J – 2

#### **KEY POINTS OF RECOMMENDATIONS**

In order to promote mutual investment between the EU and Japan, the BDRT asks the Government of Japan to reduce or eliminate certain withholding taxes.

#### **ADDITIONAL INFORMATION IN SUPPORT OF RECOMMENDATIONS**

Last year we noted that the Governments of Japan and the USA reached agreement in November 2003 to revise the income tax treaty between their two countries with the intention of reducing or eliminating certain withholding taxes. We welcomed this decision and hoped that it could be replicated in relations between the GOJ and the EU's Member States. We repeat this request.

Working Party 3  
**Information and Communication Technologies**

**Further Challenges for Quality of Life with ICT**

**1. Introduction**

2005 is a decisive year for Japan and Europe as it is the final year for the e-Japan Strategy and the Science and Technology Basic Plan in Japan, and the starting point for a new era under the revised Lisbon agenda focusing on growth and jobs in Europe. At this turning point for the EU and Japan, both authorities should steadily continue their efforts to ensure higher utilisation of ICT by setting up and implementing programmes, based upon objective reviews of the achievements of previous plans. ICT is already having a disproportionate impact on productivity and growth, but it should and can play an even bigger role in economic and social development in both regions in the future. The sector is ready to increase investment substantially in order to introduce the next generation of networks, services and develop new business models. Both authorities should remove existing barriers, in particular regulatory, to major investment in networks and services in order to facilitate the role that ICT can play for the economic development of Japan and Europe. Through an enabling framework and progressive deregulation, policy makers in Japan and Europe can play a key role for the stimulation of the sector.

**2. Issues and recommendations**

**3-EJ-1: Promotion of broadband usage**

Widespread availability and use of broadband networks are driving factors for the improvement of competitiveness of both economies. E-entertainment services are important for the take-up of broadband access. End users attracted by services beyond the PC, for example, through mobile phones or digital TV, have an incentive to subscribe to broadband services. Both authorities must ensure that the provision of e-entertainment services is not hindered by regulatory obstacles, such as, for example, inappropriate legislation on e-payments. Another way to enhance broadband take-up is the development of large-scale e-public services. The public sector is a service intensive sector, which would gain a huge benefit by further implementing ICT. Better and lower-cost services would be the result of the introduction of large-scale e-public services. Governments should ensure that no legal requirements prevent the delivery of public e-services to citizens.

- Both authorities should enable development of mass market e-entertainment services and give priority to large-scale public e-services.

**3-EJ-2: Establishment of a seamless ubiquitous network environment**

Both authorities should promote the development of seamless ubiquitous network environments to allow users to access networks “anytime, anywhere” regardless of which kind of network is used. In Europe and Japan, the issues of effective utilisation and system improvement of wireless networks must be included in R&D activities. Radio spectrum policy of both regions should be forward-looking.

- Both authorities should coordinate as widely as possible when it comes to the preparation of the next World Radio Conference in 2007.

### **3-EJ-3: Ensuring secure ICT infrastructure**

Managing security, trust and privacy at all levels of ICT infrastructure is of key importance for the future development of the market.

Therefore, ensuring availability of the ICT infrastructure by activities for the improvement of reliability of the infrastructure is quite important, including prevention of disruption of communications, clearance of exceptional traffic, and early recovery of services in case of disasters such as terrorism. Additionally, governments should work together to address the growing problem of computer-related crime. Worldwide open and transparent negotiations, following the example of the negotiations leading to the Council of Europe's Convention on Cybercrime, should be the way forward.

As ICT develops, some negative impacts of some human uses of ICT are growing, such as defamation on a network, which takes place frequently nowadays in Japan. It is worrying that further growth in these negative trends, which are becoming overt, will hinder technology development and the spread of ICT. In this context research on the physiological and psychological effects of the widespread use of ICT is useful in order to learn more about how citizens and societies can benefit as much as possible from ICT.

For users Spam is a significant and growing problem, networks and the Internet as a whole. Spam and cyber-security should be dealt with at appropriate national and international levels. We therefore welcome the joint declaration Europe and Asia issued at an Asia-Europe (ASEM) conference on eCommerce, held in London on 21-22 February 2005. In the statement on international anti-spam cooperation, government participants in the conference agreed to take action to fight spam nationally and to promote anti-spam efforts in international organisations and by industry.

From a user perspective data protection laws, which guarantee privacy, are the most important step to a secure ICT infrastructure.

- Both authorities should have continuous talks to raise their awareness of the quality of ICT infrastructure for ensuring secure ICT infrastructure, by promoting highly reliable and secure system/products, information exchange and matching regulations between them, and establishing a framework that can draw lessons from terror events and disasters.

### **3-EJ-4: Bridging the digital divide**

ICT has the potential to combat the digital divide by empowering the unemployed, elderly, sick and disabled to participate in society. Due to the complexity of digital divide issues ranging from age over education to skills, a broad set of measures should be envisaged by governments. The plan of the European Commission to propose an Action Plan on e-government for citizen-centred services in 2006 is one of several useful initiatives helping to overcome the geographic and social digital divide. A similar programme is incorporated in "e-Japan Priority Plan 2004" as well as "u-Japan Policy". The basic aim should be the improvement of ICT literacy. A priority for governmental measures must be the promotion of ICT education in schools.

- Both authorities should adopt every possible measure to improve ICT literacy, especially by promoting ICT education in schools. We encourage an exchange of information between Japan and Europe on the success of these initiatives in order to mutually benefit from experiences gained by the partner country when developing future initiatives.

### **3-EJ-5: Ubiquitous and interoperable platforms**

Recognising the primary role of industry in developing voluntary, consensus-based standards that promote interoperability, both authorities should foster the development of interoperable software and systems allowing various networks, services and equipments to interconnect in a seamless way. Governments can assist by ensuring a smooth cooperation between different industries and by including interoperability issues in their R&D efforts.

- Interoperability of software and systems should be a relevant matter in R&D programmes set up by governments.

### **3-EJ-6: IPR in a network society**

The network society is a huge opportunity for right holders, as it is creating a new and complementary market for their offers. However copyright protection, effective copyright enforcement and a secure environment for content is crucial for the development of this market. Especially the take-up of open, interoperable and standardised protection solutions such as DRM should be fostered by governments, where appropriate.

On the other hand, data protection rules for individuals are also part of the regulatory framework that has to be taken into account when dealing with this issue. Data protection is important in order to keep a relationship of mutual trust with customers. Furthermore, it has been proven that a large choice of attractive and user-friendly legal content is a very effective way to prevent users from piracy, regarding music and motion pictures, for example.

From a customer point of view it must be ensured that customers pay only once for content through DRM systems and not twice due to levies on devices.

Another aspect the governments should take into account is the importance of patent protection for IT-related innovations and the need for improvement of patent systems worldwide. The EU and Japan also have a shared interest in seeing increased capacity of other governments to protect IPR through effective policy infrastructures and adequate resources for enforcement.

- Governments should intensify their dialogue on the best way how to protect intellectual property rights e.g. by promoting the use of protection solutions such as DRMs.

### **3-J-7: Barriers to market access (Recommendation from EU)**

It is vital to ensure the international flow of both ICT products and services. Only when the barriers to market access are abolished, can the ICT sector help to facilitate economic growth and productivity gains. Japan has recently reviewed its regulatory system for radio equipment by introducing the Suppliers' Declaration of Conformity (SDoC) concept. However, the application of this concept has been currently restricted to very few radio interfaces and only terminal equipment. Terminals increasingly accommodate several radio interfaces hence requiring terminal manufacturers to resort to third-party certification when placing radio products on the Japanese market. Japan should consider expanding the list of products subject to the SDoC regime in terms of radio interfaces and type of equipment (i.e. including also network equipment).

- The Japanese government should continue to work towards eliminating barriers to market access.

### **3-EJ-8: Diverse working styles for ensuring quality of life (Recommendation from Japan)**

The realisation of diverse working styles that are fit to individuals' lifestyles contributes to the quality of life of every citizen. A seamless and ubiquitous network environment must be realised in workplaces. The environment must be configured so as to enhance businesses' efficiency and extensively create job opportunities by realising a "ubiquitous office" and "enhancement of knowledge creativity". This is to promote an advanced ICT utilisation for workers in workplaces.

For that purpose, proposals on new working styles in the ubiquitous society are required.

- Both authorities should take an active role in encouraging work-style conceptual frameworks by promoting societal experiments and their evaluation by experts in various areas of industry, academia, and government.

## **Recommendations 2005**

### **Working Party 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 realise 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 was produced by biotechnology such as a protein drug. However, recently, biotechnologies are utilised 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 utilisation 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 Authorities. 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 programmes. 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 3<sup>rd</sup> 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 as top priority in the 3<sup>rd</sup> term Science & 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 programmes 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 harmonised regulation for human cell and tissue-based. Europe is currently not taking advantage of its innovative potential by letting this field linger on without harmonised 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 EU 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 15<sup>th</sup> 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, it was pointed out that there still remained several issues to be considered or solved.

During the discussion, it was commonly recognised 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 a “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 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 harmonisation 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 harmonisation. Review the regulatory requirements for vaccines between the EU & Japan.
- Work with industry to make further improvements to the regulatory framework for medicines, such as supporting the development in biomarkers, 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 should be supported and encouraged. Large collections of human tissues and DNA samples should be developed and be readily 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 recognise contributions of the industry not only for public health but also for the economy such as improving medical 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 polyhydroxyalkanoates. 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 organised 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.**

### 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.
- 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 those 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 the 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 of 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 environmentally-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 the 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 bye-law that was adopted by Hokkaido prefecture this year is especially strict, because criminal penalties could be imposed on those 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 resulting from cultivation of GMO crops, considering apprehension of 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 backwards.

## **Recommendations from the Sustainable Development Working Party (WP 6)**

As outlined in the 2004 recommendations, Sustainable Development implies the right balance between economic, social and environmental strategies, in true partnership with every stakeholder. Promotion of voluntary actions, enhanced dialogue between the Authorities and the industry, promotion of innovation and partnerships, as well as education of the population and aid of developing countries on greenhouse gases (GHG) reduction were key messages last year. We thank the Japanese Government as well as the European Commission for their feedback.

This year, we have decided to deepen last year's recommendations on **Global Warming and the Post-Kyoto Protocol**.

### **Basic Thoughts**

The EU and Japanese industry are committed to reduce GHG and did not wait for the Kyoto Protocol to initiate drastic reductions. Within existing technologies, room for drastic improvements is limited. Therefore breakthrough solutions which balance the 3 pillars of sustainable development while securing the competitiveness of the EU and Japanese industries have to be found. It is essential that every country, every industry, and every population contribute to GHG reduction. Innovation through joint cooperation between the governments and the industry is of prime importance.

More specifically, we insist on a broader international participation in reducing emissions, inclusion of more sectors, a push for innovation, the continued use of flexible market-based instruments (The Kyoto Mechanisms) for reduction of emissions globally, and an adaptation of policies to secure the competitive position of the EU and Japanese industries.

Regarding Corporate Social Responsibility, we continue to encourage voluntary commitment together with guidance from international organizations.

### **Recommendations**

#### **<Cooperation of the EU and Japan on Global Issues>**

##### **6-EJ-1 Effective Use of the Kyoto Mechanisms**

The Kyoto Mechanisms, including CDM (Clean Development Mechanism) and JI (Joint Implementation), are an important scheme for international cooperation approved by the Kyoto Protocol, and effective utilisation of this mechanism will help to reduce GHG on a global scale. CDM, in particular, contributes to GHG reduction in developing countries by the investments of energy-efficient infrastructures from developed countries, and can be implemented at lower cost than domestic countermeasures. Therefore, this scheme should be actively promoted without being seen simply as a complementary initiative. The authorities should adopt active use of the Kyoto Mechanisms as a government policy and create such systems as internationally harmonised accounting and tax incentives which lead industries to easily utilise this mechanism.

##### **6-EJ-2 Post-Kyoto Framework**

- It is indispensable that major GHG-emitting countries such as the USA, China and India participate in the post-Kyoto framework (beyond 2012) in order not only to reduce global

GHG emissions but also to secure the competitive position of the EU and Japanese industries. We recognise that it should be considered to set different targets from the initial Kyoto Protocol, which encourage those countries to join the framework. Energy efficiency or emission intensity by major sub-sectors on a cross-border basis is one of the targets to be set instead of the current country-by-country basis.

- We recognise that the technological development for reduction of GHG emissions including joint efforts of the authorities and public-private partnership of the EU and Japan is important. The European Commission and the Japanese Government should work together to include the technological development as an item for post-2012 negotiation.

### **6-EJ-3 Impact Assessment**

The impact of materials and products should be assessed in an extended manner which includes the economic, social and environmental dimensions. It is important for the authorities to adopt the methods of life-cycle assessment and/or full value chain assessment in any impact assessment, and not exclusively for GHG reduction.

### **<Promotion both in Japan and in the EU>**

### **6-EJ-4 Development of Energy-Saving Products and Services and Diffusion on a global basis**

As stated in Basic Thoughts, industries of the EU and Japan have already made considerable efforts for GHG reduction, and room for drastic improvements by using current technologies is limited. However, we recognise there is potential of reduction of GHG emissions by implementing the following measures by the industries and people, together with the support from the authorities:

- Adopting higher efficient electric and electronics equipment by using a top runner approach.
- Using the full potential of IT society such as higher efficiency of production and logistics, and diffusion of e-commerce.
- Adopting energy-saving offices and houses equipped with high performance insulators.
- Diffusion of fuel-efficient vehicles.

### **6-EJ-5 Cultivation for People and Initiatives of the Authorities**

It is important to work together with the participation of the authorities, industry and the public to reduce emissions of greenhouse gases. Industry has been working hard not increasing CO<sub>2</sub> emissions with voluntary actions. Its emissions have remained flat or are even decreasing for some sectors. But CO<sub>2</sub> emissions from households are largely increasing. Therefore, it is necessary to reduce emissions especially from this sector, and to educate and cultivate the population to contribute individually to GHG reduction. It is also important that the authorities take initiatives to promote such a movement as a model for the nation/community.



## **6-EJ-6 Diversification of Energy**

From a mid- to long-term point of view, it is indispensable to promote technological development for nuclear energy, renewable energy such as wind, solar, biomass, and hydrogen energy, or other forms of energy which will replace fossil fuels. Renewable energy needs cost reduction and stability of output power. Hydrogen energy has huge potential as generation of electricity and fuel batteries, however, there are big issues such as production methods without CO<sub>2</sub> emissions as well as secure safety of storage/transportation. It is important to promote the joint development between industry and the authorities to solve those issues. Technologies of CO<sub>2</sub> capture and storage should be also developed. We call for government initiatives, including joint ones between the European Commission and the Japanese Government.

[End]