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

Berlin, 3 - 4 June 2007

Working Party 1
"Creating an open environment for Trade and Investment"
(long version)

Working Party Leaders:

Mr Richard Collasse
European Business Council (EBC)

Mr Itaru Koeda
Nissan Motor Co., Ltd.

Table of Contents

Recommendations to the EU and Japan

1-EJ-1 Initiate a dialogue on the formation of a common institutional environment (Joint recommendation)

<Summary of recommendation>

1. The two governments should promote regulatory reform in the home market by opening up markets and streamlining regulatory practices with a view to fully integrating the two economies. Given this background, the EJBDRT recommends that the two governments initiate preliminary discussions on an EU - Japan Economic Integration Agreement, an agreement that is a step ahead of traditional FTAs and EPAs.

2. While intensifying the efforts to reach a new multilateral trade agreement under the WTO, the EU and Japan should excercise leadership by initiating talks on an agreement that moves beyond the traditional FTA and EPA frameworks. An Economic Integration Agreement (EIA) should deepen the trade and investment relationship by mutually promoting structural changes. Topics currently outside of WTO discussions on the agenda, such as open competition, fair investment rules, harmonisation of regulatory processes, government procurement, intellectual property rights, energy security and universal environmental standards should be included.

<Background>

The European Union and Japan together account for close to 40% of the global GDP, and realise an annual trade turnover of around 145 billion Euros. Over the past five years the EU has increased direct investment in Japan significantly and is now Japan's largest source of foreign direct investment (FDI). Similarly, Japanese businesses have increased the number of Japanese business affiliates in Europe by 50% over the past eight years. In terms of trade volume, the EU ranks as Japan's second largest export market, and is Japan's third largest source of imports. Trade flows in the other direction place Japan as the EU's fifth largest export market, and the fourth largest source of imports to the EU.

Given the scale and value of existing trade flows, both partners stand to benefit from more open and synergistic trade practices. Through reciprocal commitment the EU and Japan can achieve transparency in investment rules, adopt fair competition policies, open public procurement markets, and cut red-tape in order to significantly reduce non-tariff barriers. Moreover, an EIA could become a model economic accord that demonstrates the inherent benefits of cooperation on environmental standards and intellectual property rights protection.

Beyond the broad sphere of cooperation endorsed by the EU and Japan the two sides currently pursue a range of issues within the Cooperative Framework to promote two-way trade and investment. To date, strong bilateral trade and investment links have emerged from this productive, working-level engagement. One of the major pillars of bilateral EU-Japan relations has been the 10-year Action Plan for EU-Japan Cooperation, which started in 2001. Another has been the two-way Regulatory Reform dialogue which aims to reduce obstructive regulations that hamper trade and foreign investment. Another important forum is the EU-Japan Business Round Table that affords business leaders an opportunity to inject

industry viewpoints into regulatory policy discussions.

Over the years these dialogues have identified structural impediments to market growth and have provided a constructive forum for addressing change. Yet, substantial barriers remain. Moving forward, the recommendations that have emerged must serve as a starting point for a comprehensive EIA that will transform discussions into binding agreements for both parties.

In view of the complicated phase in the current Doha Round of WTO negotiations, many global trading partners are pursuing bilateral Free Trade Agreements and Economic Partnership Agreements that target specific areas of trade cooperation. In Asia, more than 70 FTAs have been signed among Asian trading partners since 2000. The resulting accords form what some call a "noodle bowl" of FTAs; an expression that aptly describes the entwined nature of the agreements. China in particular has stepped up trade diplomacy, as has Singapore. Most recently, South Korea completed an FTA with the US and also began trade negotiations with the EU. Both the EU and South Korea are pushing for rapid progress in these negotiations, with the South Korean Trade Minister stating that it was South Korea's chance to become East Asia's "free trade hub linking Europe, Asia and the US".

Until now, the EU has generally eschewed bilateral agreements with its major trading partners in favour of the multilateral approach. Yet more recently, the EU has begun to consider the benefits of deeply integrated economic agreements that do more than lower tariffs and that are firmly based on the market potential for European countries. One initiative that conveys the political support for this changing view is the "The Global Europe: competing in the world," which promotes a competitiveness agenda that reflects the EU's commitment to multilateral trading systems but that likewise pursues bilateral agreements that tackle issues not ready for multilateral discussion.

<Relation to progress reports>

This is a new recommendation.

1-EJ-2 Supporting timely development of business (Joint recommendation)

1. Social security contributions (avoiding double contributions)

<Summary of the recommendation>

Japan and the Member States of the EU should make further efforts to expand the network of Social Security Agreements. In addition, they should introduce an interim measure, by which a host country should either exempt contributions to pension funds unilaterally or should refund in full when expatriates return to a home country.

<Background>

Double payments of social security contributions by and for personnel on assignment between the EU and Japan discourage investment by businesses.

When a company sends an employee on an overseas assignment for a limited period – typically 3 to 5 years – the employee concerned and his/her employer usually continue contributing to the social security system, particularly pension funds, of the dispatching country. If contribution to the social security system of the host country is obligatory, contributions will be paid in both countries. This double payment is a heavy and unnecessary burden for a company and its employees. A social security agreement solves this problem typically by exempting intra-company transferees from contributing to the social security system of the hosting country for a limited period.

So far Germany, the United Kingdom, Belgium and France have concluded bilateral social security agreements with Japan. Agreements between Japan, and France and Belgium are not yet entered into effect. Negotiations between Japan and the Netherlands are underway.

The Working Party calls for swift negotiations and conclusions of agreements between all EU Member States and Japan, acknowledging that this will represent a significant workload, inevitably surpassing current administrative capacities. To date, it has taken several years at least to negotiate, conclude and ratify a social security agreement between a Member State and Japan. At this rate, it could take more than 30 years for Japan to conclude such agreements with the remaining Member States. Moreover, such agreements may never be introduced between Japan and those Member States that host only a small number of Japanese expatriates, and vice versa.

Furthermore, the respective Governments should introduce an interim measure, enabling either unilateral exemption by the host country or a refund of pension fund contributions by the host country when expatriates return to the home country. Since contributions to pension funds are not tax but saving for future, such refunds should be in the full amount.

<Relation to the progress reports>

The Commission Services Progress Report states:

Member States of the EU are responsible for the funding and organisation of their social security systems. They are therefore free to determine details of their own social security systems, including which benefits shall be provided, the conditions for eligibility and the value of these benefits, as long as they adhere to the basic principle of equality of treatment and non-discrimination as laid down in the Regulation (EEC) 1408/71 on the application of social security schemes to employed persons and their families moving within the Community. Japanese workers legally residing in the EU and their families can rely on the Community

provisions in the field of co-ordination of social security systems when moving within the EU (Regulation 1408/71 as amended).

It is also the exclusive competency of Member States to conclude social security agreements with third countries.

In this context, the Commission welcomes the recognition of a need for action with regards to the question of double contributions and acknowledges that bilateral social security agreements constitute an appropriate solution. The Commission welcomes progress on the conclusion of bilateral agreements between Japan and some Member States as well as the ongoing work on the conclusion of additional agreements. The EU also calls for Japan to start exchange of information with each of the EU Member States.

It will take a considerable time at the current pace of progress before the problem of dual pension membership and wasted premium payments can be solved. The foreign workers living in Japan must contribute to the Japanese pension system along with their employers. When leaving Japan, they can receive a partial refund of pension contributions of exceptional and temporary nature, adopted by the Japanese government in the Pension Law in 1994, capped at 3 years, if they have worked in Japan for longer than 6 months and less than 25 years.

The EU has reiterated its suggestion that departing expatriates not yet covered by a bilateral agreement should receive a full refund of the actuarial equivalent of all mandatory pension contributions paid to date, or at least the period and the amount for the refund should be extended to 5 years in line with recent developments to extend the length of stay of certain foreign workers and high skilled workers.

Given the competencies in this area, the conclusion of social security treaties between Member States and Japan has to be discussed on a bilateral basis.

The Progress Report from the Government of Japan states:

Japan is keenly endeavouring to conclude social security agreements with EU countries. It has already concluded such agreements with Germany, the UK and Belgium, while having signed one with France.

Furthermore, Japan is negotiating with the Netherlands and actively exchanging views and information with Spain and the Czech Republic to conclude social security agreements.

(ii) With regard to an interim measure, the GOJ already has in place a system whereby foreigners who have paid into the national pension scheme and have returned to their home country after a short-term stay in Japan, may receive the Lump-sum Withdrawal Benefit for Non-Japanese citizens, which gives consideration to the premiums they have paid into the national pension scheme.

2. Smoother and swifter application procedures for obtaining work and residence permits

<Summary of the recommendation>

The two governments should make an agreement to simplify and accelerate the procedures to obtain work and residence permits for intra-corporate transferees between the EU and Japan. The procedures should include the possibility of submitting an application for work and residence permits after entering the assigned country as well as automatic granting of the same rights to spouses of the permit holders.

The Government of Japan should abolish the system requiring foreigners with a visa additionally to obtain a re-entry permit, such that permission to leave and re-enter the country freely is automatically granted when the visa is issued.

<Background>

For the smooth and efficient running of international businesses, it is essential that companies are able to assign key personnel, including directors, from one country to work in another. Such transfers do not have any negative impact on the labour market in the host country. On the contrary, they often reflect the expansion of employment opportunities in the host country through the development of the company's business there, and expatriates themselves tend to pay high income tax to the host country.

The requirement to obtain work and residence permits for intra-company transferees between the EU Member States and Japan is usually a formality and it is rare that applications for permits in these circumstances are questioned for substantial reasons. However, the burden on companies as well as employees and their families is substantial, and constitutes an obstacle to the swift development of business.

Japan and the EU Member States should make an agreement to simplify and accelerate the procedures to obtain work and residence permits for intra-company transferees between the EU and Japan. The procedures should include the possibility of submitting an application for work and residence permits after entering the country of assignment. The Working Party notes that, in Japan, this is already possible.

To facilitate swift deployment of personnel, spouses should also be allowed to engage in economic activities in the host country. They should be granted, upon their arrival, the same rights as the holder of the permit without filing a separate application. The Working Party notes that, in the UK, this has already been implemented.

Unlike any of the countries in the European Union, Japan maintains restrictions on the movement of foreign residents through its unique re-entry permit system. Special application procedures for re-entry permits mean that all foreign (including permanent) residents are required to make extra visits to the immigration bureau and to pay fees (up to 6.000 yen) to obtain permission to re-enter the country. The Working Party can see no justification for maintaining this outdated system: controls of foreigners leaving and entering the country can easily be maintained without imposing this extra burden on businesses.

<Relation to the progress reports>

The Progress Report from the Government of Japan states:

(i) The GOJ is taking various measures to simplify and accelerate the said procedure (for details of the specific measures taken, please see the last but one progress report).

Concerning those people wishing to engage in activities related to the status of residence of "Intra-corporate Transferees" (engagement in work), the GOJ allows those people to work at the stage of landing permission, provided that such people satisfy relevant landing conditions, such as that they possess valid visas at the stage of the landing examination, and that they are approved for the status of residence of "Intra-corporate Transferee" by the immigration officer. Conversely, when an applicant enters (lands in) Japan with a status of residence of "Temporary Visitor" (non-work status), and thereafter seeks to apply for a work status in Japan, the applicant is not allowed to work until he/she gets the desired status of residence. Taking this series of procedures into consideration, it can therefore be said that the quickest possible procedure would be made by the acquisition of an adequate visa before entry into Japan and the application for landing.

Concerning work activities of the spouses of intra-corporate transferees, please refer to our latest progress report.

(ii)When foreign residents in Japan who have obtained a valid re-entry permit temporally leave Japan, intending to re-enter into Japan for the same purpose as upon their original stay, they need not return their alien registration certificate issued by the heads of their municipalities. The Alien Registration System is designed to clarify matters pertaining to the residence and status through the registration of foreign nationals staying in Japan. Therefore, except when they have re-entry permits, bearers of alien registration certificate must upon their leaving Japan return their alien registration certificate to the immigration officer.

The re-entry permit system is also aimed at simplifying the procedures for entry into and landing in Japan and at benefiting the foreign nationals residing in Japan. Namely when foreign nationals leave Japan temporarily with the intention of re-entering, they do not need to apply for a visa on each occasion of entry so long as they have obtained a re-entry permit in advance. Therefore, the re-entry permit system is absolutely necessary and reasonable as a system which contributes to facilitating smooth entry and landing procedures.

The Ministry of Justice is also working to facilitate the landing examination further by means of introducing the automated gate system, in addition to the extension of the valid period of the re-entry permit (The period was extended from one year to three years by the amendment of Immigration Control and Refugee Recognition Act in 1999.).

The Commission Service report does not comment on this issue.

3. Personal data protection regime

<Summary of the recommendation>

The two governments should work together to ensure an internationally equal, transparent and secure data protection regime between the EU and Japan. The European Commission should consider launching a study to assess the adequacy of the level of protection afforded by the Japanese Data Protection Act and its implementation measures because the Government of Japan has stated in its 2007 Progress Report that it will ensure an adequate level of protection that satisfies international criteria.

<Background>

Directive 95/46/EC, on the protection of individuals with regard to the processing of personal data and on the free movement of such data, requires Member States to permit the transfer of personal data to countries outside the European Union only where there is an adequate level of protection of such data as prescribed by the Directive, unless a specific exemption applies.

Japan's Data Protection Law is not deemed to provide the required level of protection. The main reasons reside in the fact that the Japanese law lacks clauses on transfer of data to third countries, on the distinctive treatment of sensitive data and on the data subject's 'right' of access to his/her data. The lack of adequate protection has resulted in the prohibition of transfer of personal data, for example, from subsidiaries of Japanese companies to their headquarters.

On 27 December 2004, the European Commission approved a new set of standard contractual clauses for data transfers proposed by seven international business associations, including the Japan Business Council in Europe (JBCE), as offering an "adequate level of data protection" under the EU's data protection law. Companies have been allowed to use the clauses to provide a legal basis for data transfers to the controllers (as importers) outside Europe since 1 April 2005. The standard contractual clauses previously approved by the European Commission in 2001 were less practical and flexible for business use.

On 14 April 2005, the Article 29 Data Protection Working Party, an independent European advisory body on data protection and privacy set up under Article 29 of Directive 95/46/EC, adopted a Working Document Setting Forth a Co-Operation Procedure for Issuing Common Opinions on Adequate Safeguards Resulting from "Binding Corporate Rules." As a result, it is now possible for a corporate group to submit draft binding corporate rules (BCRs), including rules for data transfer outside Europe, for approval by the relevant data protection authorities, with 'one' Data Protection Authority (DPA) acting as the leading DPA. Previously, not all Member States approved Binding Corporate Rules. Although the participation of DPAs in the approval of binding corporate rules is voluntary, it is a significant positive step.

The Working Party welcomes the above two developments.

The above-mentioned new set of standard contractual clauses, however, only covers contractual relations between data controllers and does not cover those between a data

controller and a data processor. To cope with the fast moving business environment, the current standard contractual clauses should also be examined in the light of business practices and experiences to see whether they could be modified to enable subcontracting and outsourcing of data processing in a third country in the process of international business.

Furthermore, the Government of Japan should amend Japan's Data Protection Law in order to meet the required level of protection in the light of the EU law, thus permitting the transfer of personal data from the Member States to Japan. The Working Party believes that the European Commission's decision on the adequacy of the Japanese Law would establish more internationally equal, transparent and secured data protection regimes between the EU and Japan in support of international business development.

<Relation to the progress reports>

The Progress Report from the Government of Japan states:

The Act on the Protection of Personal Information, based on the eight OECD principles, was promulgated and enacted in May 2003, and entered into full enforcement in April 2005. The full enforcement of the Act has enhanced the Japanese people's awareness of the protection of personal information and business entities' efforts at such protection. In addition, ministries and government agencies, in charge of the business entities concerned, have also been making appropriate efforts including formulation and review of the guidelines, etc. based on the actual circumstances of each business field, as well as guidance for and supervision of the business entities.

We believe Japan will ensure an adequate level of protection that satisfies international criteria, as each party's efforts continue based on the Act, the Basic Policy concerning the Protection of Personal Information (Cabinet Decision on April 2, 2004) and guidelines of relevant ministries, etc, leading to their effectiveness ensured.

1-EJ-3 Enhanced co-operation in the promotion of new global standards (Joint Recommendation)

<Summary of the recommendation>

1. The EJBDRT recommends the governments of the EU and Japan to take the lead in the ongoing discussion among the developed counties on the Alexandria Process with a view to swiftly reaching an agreement on harmonisation and streamlining of international patent systems.

2. We also recognise the importance of preventing counterfeiting and piracy. We believe that the two governments should make the utmost effort and cooperate closely to establish a new common international legal framework for IPR enforcement against global counterfeiting and piracy.

3. The two governments should make an effort to harmonise the regulations for energy conservation and relevant labelling rules.

<Background>

We believe that the governments of the EU and Japan should take the initiative to build a common institutional environment and set new global standards. Harmonization of international patent systems, creation of a common international legal framework for IPR enforcement against counterfeiting and piracy, and harmonization of relevant regulations and rules are all very important for the global business of corporations, both in the EU and Japan.

<Relation to the progress reports>

This is a new recommendation.

Recommendations to Japan

1-J-1 Recognizing and applying international standards

<Summary of recommendation>

The Government of Japan should facilitate trade with and foreign direct investment from European firms by promoting further harmonisation between local and international product standards and by recognising as far as possible, widely respected international markings, such as the CE marking indicating compliance with European (EN) standards.

The Working Party recommends the Japanese Government in particular to:

- Approve without further delay the 39 food additives still remaining out of the 46 on the original "priority list" it adopted in 2001, as a step towards a longer-term objective of completely harmonising domestic regulations on food additives with those of the WHO and FAO.
- Harmonise domestic plant quarantine regulations with WTO agreements (GATT and the related Sanitary and Phytosanitary Agreement), which would improve market access for cut flower and perishable products, without compromising plant protection for domestic species.
- Work together with the EU authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials, and streamlining of accreditation procedures for foreign testing institutes.
- Work together with the EU authorities to achieve mutual recognition of Organic Food Products labelling.
- Harmonise the positive list for cosmetic ingredients in Japan with that of the EU and establish a mechanism enabling swift acceptance of ingredients widely used or recently recognised in Europe and the U.S.
- Adjust the current regulations governing the import of tableware under the Food Sanitation Law to be more in line with similar regulations in the EU and other parts of the world by recognising ISO certification.
- Work together with European Governments to simplify and harmonise the regulatory processes in the field of Medical Devices. In particular, mutual acceptance of regulatory practices and standards concerning principles of safety and performance, marketing authorisation, clinical trials and on-site audits of manufacturing facilities should be promoted.

<Background>

All WTO Members commit to progressive liberalisation and elimination of both tariff and non-tariff barriers to trade in goods. Very often, however, European firms seeking to develop businesses in Japan find differences in product standards and markings. There are numerous examples, but to take six:

a) A major factor obstructing the introduction of high quality European food products to the Japanese market is Japan's approved food additives list. Over 600 substances accepted as safe by FAO/WHO and widely used all over the world are not allowed in Japan. While the Ministry of Health, Labour and Welfare started to review its list of accepted food additives in 2001 and submitted a list of 46 "priority" substances for revision, so far just 7 out of the 46 substances have been approved.

b) The Japanese authorities amended the regulations affecting plant quarantine in March 2006, but these regulations still fall short of the GATT and the related Sanitary and Phytosanitary Agreement. As a result, importers of cut flowers continue to face unnecessary delays and unacceptable cost levels that severely limit business development. The list of non-quarantine organisms allowed into Japan must be extended to include all non-harmful organisms found in cut flowers. Moreover, the current practice of insisting on fumigating imported flowers when organisms common to Japan are found on them should be abolished.

c) Building materials exported from Europe to Japan continue to be tested according to both European and Japanese standards, even though most of the tests are very similar. Few European testing institutes are accredited to test building materials for Japan. Inevitably, this pushes up the costs of imports to Japan and makes them less competitive than domestic supplies.

d) With the implementation of the new organic JAS law in April 2006, the mutual recognition agreement between EU and Japan on organic product certification and labelling ceased to be valid. Although organisations in Europe have been accredited to certify local manufacturers, the new law constitutes a market entry barrier, not only for certified European organic food producers but also for Japanese local organic farmers and producers.

e) Major differences exist between Europe and Japan in the way cosmetic products are categorised and the claims manufacturers are allowed to make regarding their efficacy. In Europe there is only one product category - cosmetics – whereas, in Japan, products are divided between cosmetics and so-called "quasi-drugs". The positive lists in the EU remain different. Moreover, while Europe permits manufacturers to make efficacy claims according to scientific findings and focuses on a post-marketing verification system and self-regulation, Japan has a very limited list of allowable claims. The result is that European firms face severe difficulties in developing business in Japan, because they struggle to differentiate and market new products here.

f) One of the main purposes of the Food Sanitation Law in Japan is to protect the end consumer from using tableware that may in some way be harmful to health. However, current regulations and procedures for importing tableware require an investment of time and money in testing, which is both unnecessary and places European importers of tableware at a disadvantage compared to domestic manufacturers. A simple recognition of ISO certification would improve access to the market considerably and make importing tableware economically viable even in small volumes.

g) The time and cost associated with bringing new products to the Japanese market are having a serious, adverse effect on the type and quality of treatments available to Japanese patients. The Pharmaceutical Affairs Law was revised in 2005 but the revision has not made the introduction of Medical Devices to Japan any smoother. Regulatory requirements in the areas of quality, safety and performance are substantially equivalent in Japan and in the EU, yet some differences remain. The respective Governments should,

therefore, consider how to provide, in the long run for CE marked products to be freely sold in Japan and Japan approved products to be freely sold in the EU. All requirements (requirements for "data", for "clinical evidence") for clinical trials should be reviewed with a view to bridging differences. There is also plenty of room for improvement in the field of on-site audits of manufacturing facilities. Audits by both EU and Japanese authorities are based on international standard ISO 13485:2003. Duplicate inspections, with EU and Japanese auditors inspecting the same facilities, asking similar questions and getting the same replies, leading in most cases to similar conclusions, are still commonplace and very costly for companies marketing their products in both markets. The same holds for on-site inspections of materials to be used in Medical Devices. Repeating the same tests in all countries does not add significant additional assurance of safety or performance. A joint EU-Japan task-force, comprising members of both Industry and Government, should be created with the purpose of producing practical recommendations on how standards, regulatory processes and testing results can be mutually recognised and/or harmonised in the field of Medical Devices.

<Relation to progress report>

"Promotion of regulatory reform"

The GOJ has implemented the reviews on mutual recognition of product standards, certification and notification in line with "Three-Year Plan for the Promotion of Regulatory Reform and the Opening-Up of Government-Driven Markets for Entry into the Private Sector (re-revised)" (see Item 19 (Standards, Certification and Others) of III (Specific Measures)). Drastic reviews have been undertaken as to whether the government involvements are genuinely needed in those standards/certification systems that can be viable through voluntary actions by enterprises. From a viewpoint of international harmonisation on standards and upon validity studies on such harmonisation, the GOJ has worked for making its domestic standards consistent with existing international standards. In areas where international standards do not exist, the GOJ has proposed and promoted the adoption of such international standards as in accordance with the Japanese ones. The GOJ has also promoted the acceptance of overseas data and the mutual recognition. To further those efforts, the GOJ will also take measures to reduce the burdens on business. This includes the elimination of duplicating inspections for similar inspection items.

"Modernising Japan's food additives list"

The GOJ has been proceeding with the examination of 46 food additives, including those proposed by the EU, which have been proven safe internationally and are widely used, with special priority under the leadership of the Government. The Minister has already asked the opinions of the Food Safety Commission on the 33 food additives for which full documents have been prepared, and procedures for designation such as risk assessment have been initiated.

In addition, among these 33 food additives, 7 have been designated and permission has been obtained to be used in Japan, after the evaluation by the Food Safety Commission and consideration by the Pharmaceutical Affairs and Food Sanitation Council.
Should the Food Safety Commission request additional data for scientific evaluation, certain time will be required for additional tests.

Since March 2005, the Ministry of Health, Labour and Welfare has announced the schedule for initiating the risk assessment of the remaining food additives out of the 46 items including the above-mentioned items requested by the EU, which are not yet submitted to the Food Safety Commission for assessment, and the ministry will make efforts to work to that schedule.

1-J-2 Improving regulatory transparency and accountability

<Summary of recommendation>

The Government of Japan should reinvigorate its efforts to improve transparency and consistency in all areas of regulation and the accountability of regulators, including as regards the development of new regulations, in order to facilitate business in Japan for both foreign and domestic firms.

The Working Party recommends that the Government of Japan takes the necessary measures, including further revision of the Administrative Procedures Law (APL), in order to ensure that:

- All proposed laws, regulations, guidelines and agency recommendations are made available for public comment, by enforcing and monitoring compliance with existing public comment requirements.
- Complete draft laws are made available for public comment, rather than mere summaries, before bills are submitted to the Diet for deliberation.
- A 30-day waiting period is implemented between the expiration of the public comment period and the submission or release of the final law, regulation, guideline or agency recommendation, in order to give officials time to consider the comments received.

Specific attention needs to be given to the area of taxation, where European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. The Working Party recommends that the National Tax Agency (NTA) should provide rulings and clarifications, such as the rationale for additional assessments, in writing as a matter of course and not only in response to specific requests received under the formal *Kaito Bunsho* system. Rulings and clarifications should be made available to the public on a routine basis, in a format that safeguards the anonymity of the taxpayers involved.

Furthermore, the Working Party believes that trade in Financial Services and the development of new financial products could be substantially augmented, if the Regulator acted to improve understanding and transparency within the Industry. The Working Party therefore recommends that the Financial Services Authority (FSA) should:

- Systematically develop, publish and update legally binding guidelines on its interpretation of laws, regulations and guidelines;
- Provide ad hoc advice on the interpretation of laws, regulations and guidelines to the financial services community as a whole, by issuing ex parte “interpretive statements”, in a format that safeguards the anonymity of any entity involved;

- Give regulated entities the opportunity to appeal against interpretations delivered by individual officers and inspectors, free of the threat that this may attract additional or more onerous sanctions.

<Background>

European firms continue to report that a lack of regulatory transparency and consistency is holding back investment in Japan, by limiting business potential and elevating risks and costs. Perceived difficulties in contributing views when new laws/guidelines are being developed exacerbate this situation. In too many cases, only summaries of the regulatory proposals are made public, without sufficient substance to allow for meaningful analysis and comment. Moreover, it is common practice to provide only a couple of weeks' response time and to delay release of the most sensitive measures until after the window for public comments has closed.

Once a new law or regulation has been decided, the APL requires the relevant ministry or agency to publish simultaneously (1) the final version and (2) any comments received on the original proposal, together with an explanation in those cases where the comments are not reflected in the final version. Regrettably, however, the Law also provides that, as an alternative, the relevant ministry or agency may publish just a summary of the comments received rather than the full text of the comments, so long as it makes the full text available for public inspection at its office. This provision undermines one of the fundamental aims of having a public comment process, that is, to ensure that new laws, regulations, guidelines or agency recommendations are based upon an open, well-informed and thorough debate of the underlying proposals and issues. It is crucial that all comments received be posted in their entirety and in a timely manner on the relevant ministry/agency website, so that it is clear whether public opinion is adequately reflected in the rule-making process. A reasonable period of time must also be allotted for such public consideration, before the final version of the applicable law or regulation is published.

In the particular area of taxation, welcome changes to the *Kaito Bunsho* system enacted in March 2004 have meant that taxpayers across industry may now seek written clarification of specific transactions. Despite this, however, European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. The NTA should act to remedy this situation, since it effectively impedes the development of businesses in Japan and discourages further investment.

Within the financial services industry, the FSA has pledged to increase regulatory transparency and consistency by publishing its internal guidelines on the correct interpretation of laws, regulations, etc. However, the guidelines published to date have lacked the detail needed to increase business confidence and it remains difficult to determine whether an activity not explicitly covered in the guidelines can be pursued legally. Theoretically, under the FSA principle of "self responsibility", a regulated entity can attempt to determine for itself what activities are permitted, but if it does so, it lays itself open to administrative sanctions if its interpretation (or that of its professional outside advisers) turns out to differ from that of the FSA. The regulated entity may instead request formal guidance from the FSA, either by seeking a no-action letter or an answer to a written inquiry. However, both these procedures are cumbersome and time-consuming. As a result, the preferred route taken by many

regulated entities is to seek informal guidance. The fact that the FSA is willing to give such guidance is welcome but the drawback is that only the requesting entity benefits, while the rest of the industry remains in the dark.

The lack of openness and transparency in the financial services industry has unfortunate consequences, both for individual firms and for the industry as a whole. At the level of the individual firm, the first indication that there is a problem with its interpretation of the law may only appear during a routine visit from the FSA inspectors. However, by then it is already too late: the inspectors' interpretation will effectively be deemed to be final and the regulated entity will have little choice but to agree with the inspectors' findings and accept the resulting sanction, or face the threat of additional or more onerous sanctions because it "lacks compliance consciousness". At the industry level, any opportunity to learn from such situations is severely limited: the only information made public is an announcement of the sanction on the FSA website, but no further details are given. Inevitably, this situation fosters uncertainty, impeding innovation across the whole financial services industry and damaging the prospects for further investment.

<Relation to progress report>

"Ensuring transparency and consistency in the regulatory process"

Council for the Promotion of Regulatory Reform carried out research and deliberation pursuant to themes such as "Reviewing regulations based on the review criteria after the passage of a certain period of time." The deliberation results were covered in "The Third Report on the Promotion of Regulatory Reform and the Opening Up of Government-driven Markets for Entry into the Private Sector" which was submitted by the Council to the Prime Minister on 25 December 2006.

The revised Administrative Procedure Act, entered into force on 1 April 2006, which covers the legislation for the Public Comment procedures. In the BDRT recommendation above, it is not clear what "plans" refer to. If they refer to the concept of "Administrative Orders, etc." under the Administrative Procedure Act, proposed "Administrative Orders, etc." publicly notified shall have "concrete and clear contents" pursuant to Paragraph 2, Article 39 of the said Law.

(Future outlook) Council for the Promotion of Regulatory Reform was reorganized on January 26, 2007. The GOJ is scheduled to lay out a new three-year plan on regulatory reform around June 2007, based on the results of the "Third Report on the Promotion of Regulatory Reform and the Opening Up of Government-driven Markets for Entry into the Private Sector" and of the deliberations made by the new Council.

The Ministry of Internal Affairs and Communications will conduct and publish comprehensive annual surveys on the implementation of Public Comment Procedures by Ministries and Agencies and will maintain close communications with relevant administrative organs on this matter.

1-J-3 Creating a more efficient product approval process in the human and animal health sectors

<Summary of recommendation>

The time and costs associated with bringing innovative new products to the Japanese market continue to limit the type and quality of treatments available in the human and animal health sectors in Japan. This is not simply an issue for business but also for the people of Japan. The Government of Japan is therefore urged to create more efficient product approval processes, in particular by:

- Shortening the medical equipment certification process: accepting clinical trial data generated overseas; harmonising Good Clinical Practice (GCP) and Quality Management System (QMS) requirements with international standards; and, following the revision of the Pharmaceutical Affairs Law (PAL) in 2005, establishing objectives and clarifying guidelines that are accessible to all applicants. Foremost, GCP-related requirements need to be modified, since they currently impose an unsustainable burden on applicants in terms of work and application fees.

- Eliminating differences between Japanese GCP and the GCP established by the International Conference on Harmonisation; and increasing the number and quality of staff working on consultation and approval review in the Pharmaceutical and Medical Devices Agency (PMDA).

- Improving the product approval process for animal health products by adhering to the standard administrative review period of one year. This could be achieved by streamlining and accelerating administrative procedures and eliminating unnecessary and scientifically unjustified requirements.

<Background>

The need to reduce the time and costs associated with introducing innovative new treatments to the human and animal healthcare markets in Japan and to bring Japanese rules in line with global standards underpinned the Government's decision to revise the Pharmaceutical Affairs Law (PAL). However, two years after the implementation of the revised Law, it is obvious that a lack of clarity in the guidelines, along with the introduction of new, unique Japanese requirements on top of international standards, have resulted in even longer approval times and less consistency with international practices. This situation needs to be urgently rectified.

Although the Ministry of Health, Labour and Welfare has introduced a process for improving the clinical trial environment and a new "pharmaceutical industry vision working group" has been considering how to improve the environment for clinical trials and approval review, concrete reforms are still needed in the pharmaceutical sector, including relaxation of GCP regulations and a boost to the numbers and quality of PMDA reviewers.

The slowness of the approval process for animal health products can be attributed in particular to delays between the time an initial dossier is submitted and its "hearing" at the Ministry of Agriculture, Forestry and Fisheries; the slowness of the review process at the Food Safety Commission; and the delay in issuing notification after the Executive Committee

(Yakuji-Bunkakai) has approved the application. Because of these delays, the entire product approval process far exceeds the standard administrative review period of 12 months set by MAFF. In addition, in spite of global trends to streamline approval processes, Japan-specific data still have to be added to dossiers for new product applications, at times without any obvious scientific justification. If these conditions persist, international animal health companies will be increasingly likely to stop developing products for the Japanese market.

<Relation to progress report>

"Promotion of regulatory reform"

The Brussels Meeting of Japan-EU Regulatory Reform Dialogue in December 2006 mainly discussed the EU Proposals to Japan on Regulatory Reform. The EU side expressed their appreciation to the commitment by the Japanese side on the following areas: the public comment procedures; promotion of competition in the ICT sectors; reviews on regulations for banking/insurance services; privatisation of Japan Post; improvement of the approval process for pharmaceuticals and medical devices; facilitation of expert meetings on wood standards; and introduction of new testing methods for safety verification of retort packages.

Japan and the EU, taking opportunities of the above Tokyo Meeting, held expert-level discussions at the Expert Meetings and Directors Meeting for the respective issues including healthcare and cosmetics, animal health products, food safety and agricultural products. Japan and the EU also held expert-level dialogues on wood standards in March 2006 (Brussels) and in October 2006 (Tokyo), with a view to promoting information/opinion exchanges among the experts.

"Facilitating the use of overseas clinical trial data for certification of medical equipment in Japan"

The following outlines the state of measures taken for applications for approval of medical device:

(1) In its notice dated March 31, 2006, the GOJ once again presented its basic policy of accepting clinical trial data conducted outside Japan in an application for approval of medical device, in line with a revision of the Pharmaceutical Affairs Law, under which the Good Clinical Practice (GCP) was newly stipulated in a ministerial order. In advance of this notice, the GOJ had already presented such policy in notices such as one issued in 1997.

(2) Specifically, under condition that the GOJ lays out the standards for performing clinical trials for medical device, based on these standards, when a clinical trial is deemed to reach a level that is equivalent or superior to the GCP adopted in Japan, such trial can be used as data submitted in the application.

(3) When the data of such trial, designated in (2), further proves its competency to ensure effectiveness and safety after its prospective approval in Japan, it will naturally be possible that the medical device in question will be approved in Japan without undergoing a further domestic clinical trial. An additional domestic clinical trial will be required for

those cases in which effectiveness and safety fail to be assessed in the records of the clinical trial that has been performed outside of Japan.

(4) Among 50 medical devices that were approved in FY2005 based on data of their respective clinical trials, 33 were reviewed based on only overseas clinical trial data, without any additional trial in Japan.

1-J-4 Ensuring free and open competition in services

<Summary of recommendation>

WTO Members are committed to progressive liberalisation of trade in services. With this in mind, the Working Party urges the Government of Japan to tackle the lack of free and open competition in Japan's services markets, in particular to:

- Remove obstacles to integrating the operations of financial groups. In particular Article 65 of the Securities and Exchange Law (Article 33 of the new Financial Instruments Exchange Law) should be revised to bring the regulatory framework in line with global norms and to allow financial groups to structure their organisations in Japan in same ways as they do in the rest of the world.

- Implement the privatisation of Japan Post so as to ensure a level playing field. This means that the *Kampo* insurance business should be subject to the same capital, solvency margin, tax and policyholder protection funding requirements as private sector insurers. Limits are needed on its expansion until competitive safeguards have been established to prevent cross-subsidies from its existing dominant position. Similarly, the insurance business of cooperative societies (*kyosai)* should be subject to the same requirements as private sector insurers.

- Deregulate the distribution, pricing and settlement of airfares in Japan so that carriers can offer fares in a transparent fashion directly to the consumer, including over the Internet.

<Background>

Japan's firewall regulations contrast with the drive for efficient group management within the global financial industry. Measures taken to-date to relax the firewall regulations applicable to banks and securities companies have had little practical impact. Japan's firewall restrictions pose problems for global financial services groups operating banking, secturities and other financial services businesses in Japan. Foreign groups are not permitted to be represented by a single country manager in Japan, but instead must appoint separate managers accountable for each business line. This makes the integration of the Japanese business into the global business extremely complicated: reporting lines and responsibilities have to be specially adjusted to fit the Japan-specific situation. Each of the business lines needs to maintain certain separate functions and organisational structures, which could otherwise have been shared on a group basis. Such duplication creates inefficiencies and extra costs. Moreover, the forced separation of the different business lines clearly stifles the development of new products.

The Working Party supports the privatisation of Japan Post and its three core businesses: postal services, savings, and insurance. The benefits of privatisation will only be realised, however, if the Government of Japan establishes a framework for privatisation that ensures a level playing field in the market. This is particularly important, considering the sheer size of Japan Post's current operations. The Working Party is concerned about the report issued by the Study Group for the Privatisation under the Cabinet Office, suggesting that the Postal Insurance Company should be given the freedom to expand its business in order to become profitable before listing. Since Kampo provides the same services as private-sector competitors, all should be subject to the same legal and regulatory requirements. The Study Group seems to support these conclusions but nevertheless regards expansion as the higher priority.

Airfares used to be regulated by bilateral air service treaties in most markets of the world. However, most countries liberalised pricing decades ago, leading to increased competition and considerable consumer benefits. Japan is one of the few countries strictly adhering to bilateral air service treaties as the main instrument for setting international airfares. These treaties stipulate that new fares have to be agreed by both the Governments concerned. This highly rigid system prevents competition, especially on Europe-Japan routes, which are governed by particularly old agreements. Distribution, pricing and settlement of airfares remain therefore highly regulated in Japan. Airlines are only allowed to advertise and sell fares for international travel to and from Japan at rates officially approved by the IATA, or in the case of group travel, at lower rates set by the Ministry of Land, Infrastructure and Transportation.

<Relation to progress report>

"Privatisation of Japan Post"

Any future expansion of scope of business of the Postal Savings Bank and Postal Insurance Company after the privatisation requires a series of transparent and fair procedures to be implemented to rule on the expansion. This involves the Prime Minister (who entrusts his authority to the Commissioner of the Financial Services Agency) and the Minister of Internal Affairs and Communications seeking the opinion *of the Postal Services Privatization Committee and deciding on whether to approve business expansion, based on what the operating status of the new company would be, and whether it would be established on an equal footing with other private sectors companies.*

The Japan Postal Services Holding Company, the Postal Service Company, the Post Office Company, the Postal Savings Bank and the Postal Insurance Company shall, likewise with any other private companies, disclose their financial information pursuant to the competent regulation encompassing the Corporate Code, the Banking Law, the Insurance Business Law and any other relevant legislation. Should these entities be traded on public exchanges, they would be subject to the disclosure regulation of the Financial Instruments and Exchange Law (Securities and Exchange Law). Transactions between the Postal Savings Bank the Postal Insurance Company and the Post Office Company, etc. shall be adequately made under the supervision of the Financial Services Agency and upon the application of the arm's length rules, as well as pursuant to the Banking Law and the Insurance Business Law. In applying the accounting rules under the Banking Law and the Insurance Business Law, these companies are identified with the conditions of the "specific parties" set forth by these two

laws. The cross shareholding between the holding company and the four business companies is restricted in the same way as for private sector companies and financial organisations under the general regulations of the Anti-Monopoly Act and the Banking Law, among others. The point raised about the risk of cross subsidised financial products entering the market is therefore groundless.

Neutrality is ensured for the regulation of Japan Post, the entity in charge of postal services, since fair and transparent procedures are applied to the implementation of regulation to Japan Post by the Ministry of Internal Affairs and Communications, independent from Japan Post, pursuant to relevant legislation.

The correspondence delivery service business has already been fully liberalised under certain conditions since 1 April 2003, pursuant to the Law Concerning Correspondence Delivery Provided by Private-Sector Operators. Hence the business is currently allowed to entities other than Japan Post. In fact, in the areas of high value-added services, competition is being enhanced by the entry of private companies.

"Improving flexibility in setting airfares between Europe and Japan"

Concerning international airfares, since bilateral agreements concluded between Japan and other countries require approval by aeronautical authorities of both parties, Japan has adopted the approval system based on the Civil Aeronautics Law.

With regard to individual airfare authorization criteria, however, aviation authorities of Japan implement their operation flexibly; in the case of PEX fares (i.e. discount Y-class fares applied to air tickets directly available for individual passengers at the airline ticket counter, etc.), individual fares set by each operator are approved on the condition that the price level is not under 30% of the IATA PEX fares. As a result, flexible fare setting reflecting market trends is possible. .

There are no special restrictions on Internet sales within the framework mentioned above and settlement of airfares.

(Future outlook) Air service issues, including those related to airfares, have been and will be discussed in individual civil aviation talks with the aviation authorities of each EU Member State.

1-J-5 Eliminating unnecessary bureaucracy for foreign residents

<Summary of recommendation>

The Government of Japan should abolish the system requiring foreigners with a visa additionally to obtain a re-entry permit, such that permission to leave and re-enter the country freely is automatically granted when the visa is issued.

<Background>

Unlike any of the countries in the European Union, Japan maintains restrictions on the movement of foreign residents through its unique re-entry permit system. Special application procedures for re-entry permits mean that all foreign (including permanent) residents are required to make extra visits to the immigration bureau and to pay fees (up to 6,000 yen) to obtain permission to re-enter the country.

The Working Party believes that this requirement imposes an unnecessary burden not only on foreign residents, in terms of their time and money, but also on the immigration bureau, by drawing on scarce resources that might be more usefully deployed in countering violations of immigration law. It therefore welcomed the recommendation made by the Council for Promotion of Regulatory Reform and Opening Up the Private Sector on 25 December 2006 that the re-entry permit system should be re-viewed, following the submission of a reform request from the European Business Council in Japan (EBC).

<Relation to progress report>

"Supporting timely development of business" subsection (b) "Work and residence permits" and "Improved access in and out of Japan for Foreign Residents"

When foreign residents in Japan who have obtained a valid re-entry permit temporally leave Japan, intending to re-enter into Japan for the same purpose as upon their original stay, they need not return their alien registration certificate issued by the heads of their municipalities. The Alien Registration System is designed to clarify matters pertaining to the residence and status through the registration of foreign nationals staying in Japan. Therefore, except when they have re-entry permits, bearers of alien registration certificate must upon their leaving Japan return their alien registration certificate to the immigration officer.

The re-entry permit system is also aimed at simplifying the procedures for entry into and landing in Japan and at benefiting the foreign nationals residing in Japan. Namely when foreign nationals leave Japan temporarily with the intention of re-entering, they do not need to apply for a visa on each occasion of entry so long as they have obtained a re-entry permit in advance. Therefore, the re-entry permit system is absolutely necessary and reasonable as a system which contributes to facilitating smooth entry and landing procedures.

The Ministry of Justice is also working to facilitate the landing examination further by means of introducing the automated gate system, in addition to the extension of the valid period of

the re-entry permit (The period was extended from one year to three years by the amendment of Immigration Control and Refugee Recognition Act in 1999.)

1-J-6 Promoting foreign direct investment

<Summary of recommendation>

The Government of Japan should promote growth through further participation of Japanese firms in the global economy and of foreign firms in the domestic economy. To this end, and in line with the treatment applied to stock swaps involving purely domestic companies, it should allow tax deferrals for unrealised capital gains arising from stock swaps between domestic and foreign firms.

As an important FDI promotion tool the Government of Japan should ad interim grant tax deferrals for stock swaps occurring under the triangular merger scheme introduced in May 2007, once it has been confirmed that the merger fulfils the general synergy conditions.
The Government should also ensure that rules of fundamental importance to foreign companies are not altered without prior notice and consultation. In this context, the Working Party calls on the Government to use all means available, including revision of Article 821 of the Corporation Law, to ensure legal certainty for foreign companies established as branches in Japan.

<Background>

Japan's record on FDI in-flows still lags far behind the levels achieved by other countries. Mergers and acquisitions (M&As) account for the highest proportion of foreign investments into Japan and would certainly increase if corporate and tax laws made it easier for foreign companies to use their own shares as consideration in an acquisition on a tax-neutral basis. Yet unlike most tax jurisdictions in Europe, Japan has not so far allowed tax on unrealised capital gains to be deferred on stock swaps involving foreign firms. The new Company Law promises to go some way towards facilitating modern approaches to corporate organisational restructuring, by introducing in particular the cross-border triangular merger scheme. Under this scheme, due to be implemented in May 2007, transactions resulting from certain types of mergers will likely be granted tax deferrals, although it remains to be seen how the guidelines outlined by the Ministry of Finance in its Cabinet Order from March 13, will play out in practice. The Working Party commends the Government for resisting calls to make listing of foreign stocks in Japan a de-facto condition for transactions under the scheme but regrets the decision not to alter the tax law to allow deferrals in cases where special purpose companies are set up.

Meanwhile, the Working Party continues to draw attention to Article 821 of the new Corporate Law headed "pseudo-foreign companies", which maintains that "*No foreign company having its principal place of business in Japan or primary purpose of which is to carry on business in Japan may engage in transactions on a continuous basis in Japan …..Any person who engaged in the transactions shall be jointly and severally liable to any counterpart for such transactions*." The Working Party regrets this wording and believes that it represents a fundamental departure from Article 482 on "pseudo foreign companies" of the

previous commercial code, which merely stated that" *foreign companies with head office in Japan established for the main purpose of doing business in Japan have to, regardless of the fact they are established abroad, obey the same rules as Japanese companies*". The Working Party appreciates the efforts made by the Government to ensure that Article 821 is not interpreted as a new restriction on forms of incorporation. The question and answer sessions in the Parliament, the resolution added to the Law when passed in the House of Councillors and the subsequent notification issued by the Ministry of Justice at the end of March 2006 were all instrumental in easing concerns amongst potentially affected companies. Nevertheless, the fact remains that the introduction of Article 821 was not sufficiently communicated publicly, indeed proved to be a surprise to many foreign companies, causing considerable worry and loss of trust in the Government. Only general arguments, and certainly nothing even close to the final text, were submitted for public comment. The final text was inserted into the Law only days before submission to the Parliament and went completely unnoticed before being passed by the lower house of the Diet.

The Working Party shares the view of the Government of Japan that the new Law *should* not impose restrictions on types of legal presence but feels that the current wording does not provide sufficient comfort for that interpretation to remain unchallenged. The Law should therefore be revised to fully reflect the intent of the Law as expressed by the Government in the deliberations in Parliament, the resolution added to the bill by the House of Councillors, and the notification issued by the Ministry of Justice.

<Relation to progress report>

"Facilitating business reorganizations from a legal and tax point of view"

The Corporate Code enacted in 2005 allows any asset to be used for merger considerations, which will make triangular mergers available. The provisions of the Corporate Code related to this "deregulation of merger considerations" will enter into force on 1 May 2007.

"Maintaining stable rules for legal presence of foreign companies"

The stipulation of Article 821 of the Corporate Code regarding pseudo-foreign companies is equivalent to Article 482 of the previous Commercial Code. Article 821 is favourable to pseudo-foreign companies as compared with Article 482 of the previous Commercial Code, since, among other reasons, it treats such companies as legal entities while the definition of pseudo-foreign companies remains the same. Therefore, it is clear that Article 821 does not adversely affect foreign companies, as long as they have been conducted their operations in Japan in a lawful manner under the previous Commercial Code. This aspect is clearly stated in the concurrent resolution adopted at the House of Councillors at the time it passed the Corporate Code, as well as in the internal notification issued by the Ministry of Justice in March 2006.

(Future outlook) The above-mentioned concurrent resolution of the House of Councillors requires consideration to be given to an amendment to Article 821 of the Corporate Code, if necessary, based on any impact of Article 821 on foreign companies after the Corporate Code has entered into force. Thus, the GOJ intends to continuously monitor any possible impacts

on foreign companies caused by the stipulation of Article 821 of the Corporate Code. However, no amendment is scheduled at this stage with respect to Article 821.

"Modernising legal and tax systems to support foreign investment"

In relation to the deregulation of merger consideration which will make triangular mergers available, the provision of the Ministerial Regulation of MOJ defining the scope of "Transfer Restricted Shares, Etc. (jouto seigen kabushiki tou)" is scheduled to be reviewed pursuant to the supplementary provision of the above Ministerial Regulations in terms of whether it should be amended, taking into consideration the circumstances after the entry into force of the Corporate Code.

The necessity of review of the above provision is currently discussed at the Commercial Law Sub-Committee of the Liberal Democratic Party , the Company Law Project Team of New Komeito and other groups concerned.

(Future outlook) The GOJ will take adequate responses in time before 1 May 2007, the effective date of the deregulation of merger considerations, in line with the outcomes of the deliberations being progressed at the above mentioned sub-committee, the project team of the ruling parties and other groups concerned, and taking into consideration the system of the Corporate Code that basically requires an "extraordinary resolution"(instead of a "super extraordinary resolution") of shareholders' meetings to approve mergers, etc. If it is decided that the relevant provision of the Ministerial Regulations should be amended, the ministry will launch the public comment procedure, securing 30 days or more for the period of soliciting opinions pursuant to the applicable law.

Recommendations to the EU

1-E-1　EU policy on company law (Japan-side recommendation)

<Summary of recommendation>

1. The 14th Company Law Directive should be proposed and implemented to provide a legal framework within the EU company law thus enabling an intra-EU cross-border transfer of a registered office of a limited company without forcing liquidation and re-incorporation.

2. The Statute for European Private Company should be introduced as soon as possible.

<Background>

1. A 14th Company Law Directive

The cross-border transfer of a registered office currently involves liquidation and incorporation of companies, which could trigger exit taxation even if the underlying business does not change.

According to the European Commission, the preliminary results of consultation carried out in early 2006 show strong support for the legislation.

A 14th Company Law Directive, which would provide the EU company law framework for the cross-border transfer of the registered office of limited companies, should be proposed, adopted and implemented as soon as possible.

2. Statute for European Private Company

The European Company Statute has enabled the establishment of a European Company (SE) since October 2004. The European Company Statute is for public companies and has been criticised as unsuited to the needs of SMEs, which constitute 90% of companies in the EU.

The European Commission published a Communication to the Council and the European Parliament, 'Modernising Company Law and Enhancing Corporate Governance in the European Union – A Plan to Move Forward' in May 2003. In the Communication, the European Commission states that it will launch a feasibility study in order to assess the practical needs for – and problems of – a European Private Company Statute by 2005 and that, if the outcome is positive, it will propose a Statute for European Private Company between 2006 and 2008.

According to the European Commission, the preliminary results of consultation carried out in early 2006 show strong support for the legislation.

The introduction of a Statute for a European Private Company should be realised as soon as possible.

<Relation to the progress report>

The Commission Services Progress Report states:

The Cross-border mergers Directive was adopted in a single reading by both the Council and the European Parliament on 26 October 2005. It is to be implemented by the Member States by 15 December2007.

The Directive will facilitate mergers of limited-liability companies on a cross-border basis, which at present are impossible or entail prohibitive costs. It sets up a simple framework drawing largely on national rules applicable to domestic mergers and avoids the winding up of the acquired company. The Directive fills an important gap in company law.

The Directive covers all limited-liability companies, with the exception of undertakings for collective investment in transferable securities (UCITS). Also, there are special provisions for cooperative societies. Given the diversity of cooperatives in the EU, Member States can, with the Commission's agreement, prevent a cooperative from taking part in cross-border mergers for a limited period of five years.

Under the adopted Directive, employee participation schemes should apply to cross-border mergers where at least one of the merging companies already operates under such a scheme. Employee participation in the newly created company will be subject to negotiations based on the model of the European Company Statute.

The public consultation of spring 2006 has shown a very strong support for a proposal on the 14th Company Law Directive among stakeholders. They were of the opinion that such directive would facilitate the mobility of European companies, in particular SMEs, and allow them to locate their business in the Member State that best suits their needs. Commissioner McCreevy has stated in his speech before the European Parliament (Legal Affairs Committee) on 21 November 2006 that he intends to propose the directive on the transfer of the registered office in the first semester of 2007. Currently the Commission services are working on the costs/benefits impact assessment of the possible directive. The intention is to adopt a proposal in June 2007.

The public consultation of spring 2006 has shown a considerable support for a proposal on the European Private Company Statute among stakeholders as it would facilitate the mobility of companies, in particular small and medium-sized, in addition to other European measures and would be in line with a better regulation principle by creating more choice for the companies without imposing any new burdens on them. Commissioner McCreevy has stated in his speech before the European Parliament (Legal Affairs Committee) on 21 November 2006 that the Commission services would study the feasibility of the possible Statute. Currently an impact assessment on the possible Statute is being carried out with the aim to complete it by the end of 2007. A political decision on further steps on this initiative will depend on the results of the impact assessment.

1-E-2 Japanese expatriates (Japan-side recommendation)

<Summary of recommendation>

1. The deadline of the transposition of Directive 2003/109/EC on long-term residence status has expired. We look forward to hearing from the European Commission about the actual state of its implementation in each Member State without delay.

2. The Directive is not applicable in the UK, Ireland and Denmark. Japanese nationals in the UK, where their number is the highest among EU countries, therefore, do not benefit from this Directive. The UK government should take action in order to enable them to benefit from the EU directive.

3. The EU Commission states in its 2007 Progress Report that it will start drafting the Directive on "intra-corporate transferees" in 2008. Such a draft directive should include;

   1) possibilities for intra-corporate transferees to submit an application for a work-residence permit or a residence permit for self-employment after entering the assigned country;

   2) provisions on intra-EU mobility;

   3) possibilities for spouses, to be automatically granted the same or similar rights as the holder of the permit upon their arrival.

<Background>

For the smooth and efficient running of international businesses, it is essential that companies are able to dispatch key personnel including directors. Such transfers do not have any negative impact on the labour market in the host country.

Companies transfer more and more employees across the EU. They could be EU nationals as well as Japanese nationals. Facilitating the mobility of workers from one Member State to another would enable companies to adapt to the development in the Single Market more quickly and more effectively.

To facilitate swift deployment of personnel, spouses should also be allowed to engage in economic activities in the host country. They should be granted, upon their arrival, the same rights as the holder of the permit without filing a separate application. The Working Party notes that, in the UK, this has been already implemented.

<Relation to the progress report>

The Commission Services Progress Report states:

Japanese companies (and the Japanese government) showed a keen interest in the Policy Plan on legal migration, in particular in the announced directive on intra-corporate transferees (due to be presented in 2009). The Commission is grateful for the input on this issue received to date and will welcome further comments when starting to draft the directive, in 2008. For sake of clarity, we should underline that this directive will most likely only aim to ease procedures for granting the relevant visas and permits, and perhaps introduce a sort of intra-EU mobility for third-country citizens. As a matter of fact, the conditions for entry and stay of Intra-Corporate Transferees will continue to be dealt with in the framework of GATS mode 4 negotiations, under the common commercial policy legal base. As far as access to the labour market for spouses, the Commission will in due time evaluate whether or not to include a provision in this sense in the draft proposal.

1-E-3 Community Patent and Patent Prosecution Highway (Japan-side recommendation)

<Summary of recommendation>

1. We welcome the European Commission's Communication to the European Parliament and Council, Enhancing the Patent System in Europe, published in April, 2007 which advocates a Community Patent. We would like to urge the EU and its member states to adopt and implement a Community Patent as soon as possible.

2. The Patent Prosecution Highway (PPH) aims to facilitate, and enhance the quality of, patent examination at a participating IP office, by utilizing and sharing the result of examination at another participating IP office. Therefore the PPH is highly beneficial for patent applicants as it will expedite and improve examinations. The JPO will start a pilot program of the PPH with the UK-IPO in July, 2007. We would like to urge patent offices of other EU member states as well as the EPO to participate in the PPH, for the benefit of patent applicants both in the EU and in Japan.

<Background>

Intellectual and industrial property rights in the EU have been protected by national systems of law. Unified European systems, which co-exist with the traditional systems at the national level, have been established with the Community trademark and Community designs. An agreement to adopt a Regulation on the Community Patent was reached in a Council meeting in March 2003.

After more than three years, however, the proposal has not been adopted and there has been no progress. The European Commission published a Communication 'Enhancing the patent system in Europe' (COM(2007)29-03-07) in March 2007 in order to break the deadlock among the Member States.

Regarding the Patent Prosecution Highway, there will be a pilot program to be started between JPO and UK-IPO in July, 2007.

< Relation to the progress report>

Concerning “Community Patent” the Commission Services Progress Report states:

There has been no progress on the Community patent since spring 2004, when agreement in Council was blocked because of two issues relating to translations of patent claims. The Community patent remains a priority objective under the renewed Lisbon strategy on more growth and employment.

The difficulties to make progress in the field of patents led the Commission to launch, in January 2006, a broad consultation to collect stakeholders' views on the future patent system in Europe. Responses have shown that industry favours the introduction of a COMPAT and the improvement of the existing European patent system (EPLA on jurisdiction and the London Protocol on languages). However, the Common political approach of the Council in 2003 on COMPAT is strongly criticised in relation to translation costs and the jurisdictional system.

As a follow-up to the consultation, the Commission has adopted on 3 April 2007 a Communication on Patent Strategy which gives a fresh look at the patent system and makes some constructive suggestions on the way forward, especially on the jurisdiction issue. The aim of this communication is to break the deadlock, re-launch the debate in the EU Council of Ministers and the European Parliament, and try to build consensus among Member States on patent jurisdiction and translation arrangements.

“Patent Prosecution Highway” is a new recommendation.

1-E-4 Fight against counterfeited, pirated and contraband goods

<Summary of recommendation>

1. The number of EU member states has increased to 27 since January 1st, 2007. We would like to see further stepped up efforts of all the EU member states to fight against counterfeited, pirated and contraband goods, both inside and outside of the EU.

<Background>

With the development of technology, enlarged Member States, and increasing international trade, the fight against counterfeited, pirated and contraband goods has become increasingly important. This also requires international cooperation.

< Relation with the progress report>

The fight against counterfeiting and piracy continues to be a priority for EU enforcement bodies. Following on from the adoption of the Directive on the Enforcement of Intellectual Property Rights ('Enforcement Directive') on 29 April 2004 the (now-27) Member States of the EU were required to transpose the provisions of the directive into national law. The deadline for this transposition expired on 29 April 2006. The Commission is now involved in checking the notifications by national authorities of the transposition of the Enforcement Directive in order to ensure that the provisions have been given the full legal effect which is required.

The government of Japan and the EU have intensified their cooperation over the last year. In the TRIPs Council, the EU and Japan (together with the US and Switzerland) presented a Joint Communication on 23 October 2006 recalling the importance of effective IPR enforcement for developing and developed country economies, in particular in terms of innovation and investment. The Communication also called for the exchange of experiences and best practices in the TRIPS Council among all Members in order to better understand where the problems are, how they can be addressed and what the TRIPS Council can do.

Also within the G8 forum Japan and the EU have worked together to keep the enforcement issue high on the agenda, by cooperating on several projects focusing on customs cooperation, coordination of technical assistance and strengthening of the international framework on enforcement. Cooperation within the G8 also targets violation of IPR by organised together trans-national crime (within the so-called Lyon-Roma group).

At bilateral level, exchange of information takes place on a regular basis. EU participated in a technical assistance event in Tokyo on copyright awareness-raising organised by the Japan Copyright Agency.

1-E-5 Competitiveness of the EU economy (Japan-side recommendation)

<Summary of recommendation>

1. Revision of high customs tariffs of audio visual products and passenger cars;

   The EU is protecting some sectors of its industries by setting high customs tariffs even though these industries are at the forefront of international competition and need stimuli for competition rather than protection. Such protection has lead to weakening of the international competitiveness of those sectors rather than to helping them become more competitive. Furthermore, it is only their users and consumers in the EU who unfortunately have to pay the resulting higher prices. To improve the international competitiveness of the EU economy, the European Commission and the Member States should drastically reduce high customs tariffs in these sectors.

2. Customs Classification;

We understand that the classification must be done in accordance with the Harmonized System Convention rules. However, we believe it to be a fact that the rules do not provide a clear method of classification for such products as electric-electronics products, where the technical convergence of IT and non-IT products has emerged. This situation makes interpretation and classification more difficult and complicated than ever, and has undermined transparency, predictability and promptness for businesses. It is requested that the EU continues efforts to take this initiative towards a substantive solution.

3. Integrated approach for CO2 reduction;

In EU, there are voluntary agreements for CO2 reduction in place between the European Commission and automobile associations of Europe, Japan and Korea. In addition, the Commission announced its CO2 Communications in February 2007; this calls for technical improvements of passenger cars to the level of an averaged CO2 emission of 130 g/km in order to achieve the EU objective of 120 g/km in 2012. Discussions for legislation have already started.

Efforts by auto manufacturers to make technical improvements in the automobile are very important for CO2 reduction. However other measures, including but not limited to improvement of the road system and traffic flow, improvement of fuel quality, education of drivers toward eco-driving and fiscal incentives to encourage the purchase of more fuel-efficient cars, are equally important. All the stakeholders of society should make concerted efforts to achieve the objective of CO2 reductions, which is called the Integrated Approach, and the EJBDRT supports this goal.

4. Better Regulations;

In reviewing the existing regulations or establishing new ones, it is extremely important to consider the relevant regulations from the perspective of competitiveness of the economy and the industry. In this connection, the agreed processes of Stakeholder Consultations and Impact Assessment should be duly implemented. Moreover, the Integrated Approach, which is a concept of appropriate burden sharing by the entire society, is important.

5. REACH;

The EU regulation of Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) has been put into effect since June, 2007. In view of the globalising operations of corporations both inside and outside of the EU, we recommend that the EU government takes appropriate and necessary actions for education and capacity building in developing countries for compliance with REACH. We also request consideration by the EU government to establishing certain lead-times or grace periods for compliance in cases involving developing country parties in supply chains.

<Background>

“1. Revision of high customs tariffs on audio visual products and passenger cars”

The European Council meeting in March 2000 adopted the ‘Lisbon Strategy’ in which it set itself a new strategic goal for the next decade: to become the most competitive and dynamic knowledge-based economy in the world. In its meeting in March 2005, the European Council reviewed the progress of the Lisbon Strategy, described its results as mixed and called for urgent action.

In our opinion, the reduction of customs tariffs in the following sectors is necessary for improving the international competitiveness of the EU economy.

Audiovisual products

The dynamic fusion of information technology, communication and audiovisual technology is occurring. For users and consumers in the EU to benefit from innovation and to contribute to global development in these sectors, rapid and extensive diffusion of new audiovisual products is essential. The current customs tariffs on audiovisual products are up to 14% and are an obstacle to such development.

Passenger cars

Automobiles and auto parts constitute a large share of the global trade, and the developed nations should make an utmost effort for the trade liberalisation. Compared with other developed nations, the EU imposes a high tariff of 10% on passenger cars, which should be eliminated or substantially reduced. It should be noted that trade liberalisation will enhance competitiveness of the automotive industries in the EU by way of expanded export opportunities, and will further technical innovation by virtue of the inexpensive imports of advanced-quality parts from other regions.

<Relation to the progress report>

The Commission Services Progress Report states regarding “1. Revision of high customs tariffs“:

The EC recognises the importance of promoting liberalisation and it is intensifying its efforts to make sure that this can happen within the framework of the DDA negotiations. The EU is firmly convinced that the appropriate context to achieve liberalisation in the sectors mentioned in the recommendation is the NAMA negotiations, as part of an ambitious "package" agreement.

As to the "inconsistencies" in the interpretation of the EU tariff scheduled mentioned in the recommendation, in particular on IT products, the EU would like to stress that it classifies these products based on objective and identifiable criteria set by the World Customs Organisation, which sometimes means that some IT products are not covered by the ITA (whose scope is confined to products destined to professional use). The EC is aware of the need to expand the coverage of the ITA and has tried, without success, to achieve that by means of the procedural tools provided by the ITA itself. The EC believes that a solution to this issue can be found as part of a broader approach looking at the expansion of the geographical coverage of the ITA (very poor at the moment) as well as to the elimination of the many Non-Tariff Barriers which are hindering the access of IT products to several

markets. The EC is constructively working in this direction and has invited its trading parties, including Japan to engage in these discussions.

Concerning "5. REACH", the Progress Report states:

REACH has been developed in a climate of consultation. The Commission has taken the views of stakeholders – including foreign trade partners – into account and have used them to ensure workability.

The Commission welcomes the final adoption of the REACH Regulation by Council and Parliament and the efforts both European Institutions made to come to a balanced agreement at the end of 2006.

The Commission recognises the need for clear guidance for stakeholders to ensure consistent, cost-effective and smooth operation of the system. This is currently under development, together with stakeholders, and will be available to producers and importers alike in due time to comply with the related parts of REACH.

REACH will significantly improve the consistency with regard to how Member States apply the chemicals legislation within the EU, compared to the situation under the current legislation, and therefore facilitate trade flows.

The Commission recalls that it is preparing a proposal for the implementation of the GHS (Globally Harmonised System of Classification and Labelling of Chemicals) in Community law and that an Internet consultation has been carried out from 21 August till 21 October 2006, to which around 370 stakeholders responded.

"3. Integrated approach for CO2 reduction" and "4. Better Regulations" are new recommendations.