

**(Tentative Translation)**

**Report from the Government of Japan**  
**on the EU-Japan Business Dialogue Round Table (the BDRT)**

**Recommendations**

**March 2008**

(The contents of this report are based on the situation in Japan as of 28 December 2007.)

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

### 1. Initiate a dialogue on the formation of a common institutional environment (1-EJ-1)

#### **BDRT recommendations**

- 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 EJBDR 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.
- While intensifying the efforts to reach a new multilateral trade agreement under the WTO, the EU and Japan should exercise 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.

#### **Efforts to Date**

Taking heed of BDRT recommendations, the GOJ has advanced active commitments to an early conclusion of the WTO Doha Round. The GOJ understands that, in order to deliberate on EIA, a study group on the Japanese side was launched in October 2007 as a private sector activity with JETRO serving as the secretariat, which will publish its study results in due course. It also understands that a study group on the EU side was launched in December, with the participation of industrial associations of member states and sectorial associations, which will also publish its study results.

#### **Future Outlook**

Japan will actively participate in negotiations aiming at an conclusion of the WTO Doha Round within 2008.

Concerning an Economic Integration Agreement (EIA), the Government policy is as set out in *the Economic and Fiscal Reform 2007* (19 June 2007 Cabinet Decision). It

will pay close attention to the results of deliberations by Japan/EU industrial sectors towards BDRT recommendations.

## 2. Supporting timely development of business (1-EJ-2)

### BDRT recommendations

#### (1) Social security contributions (avoiding double contributions)

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.

#### (2) Smoother and swifter application procedures for obtaining work and residence permits

- 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.

#### (3) Personal data protection regime

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.

### Efforts to Date

#### (1) Social security contributions

- (a) Japan has been making every effort to conclude social security agreements with EU member states, having already concluded such agreements with Germany, the United Kingdom, Belgium and France, respectively.

Negotiations are also underway between Japan and the Netherlands and the Czech Republic respectively, while consultations are being advanced in earnest between the relevant authorities of Japan and Spain as well as those of Japan and Italy.

Furthermore, the Ministers in charge of the social securities of Japan and Sweden as well as those of Japan and Ireland share the view that relevant authorities will enter consultations at an early date.

- (b) With regard to an interim measure, Japan 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 contributions they have paid into the national pension scheme.

(2) Smoother and swifter application procedures for obtaining work and residence permits

- (a) The GOJ is taking various measures to simplify and accelerate the said procedure for determining the status of residence for intra-corporate transferees (for details of the specific measures taken, please see our past progress reports).

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 past progress reports.

- (b) One of the aims of the re-entry permit system is to simplify the procedures for entry and landing in Japan for the benefit of 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 fully necessary and reasonable as a system which contributes to facilitating smooth entry and landing procedures.

### (3) Personal Information Protection regime

Japan promulgated the Act on the Protection of Personal Information in May 2003 and fully enforced it in April 2005. The law's provisions for the requirements imposed on business entities handling personal information is a manifestation of the eight principles of the Recommendation of the Council concerning Guidelines Governing the Protection of Privacy and Transborder Flows of Personal Data (1980), combined with the particular situations in Japan. The GOJ has been promoting programs to protect personal information, based on various international commitments carried out by the OECD, as well as APEC, the EU and other bodies. In June 2007, the Quality-of-Life Council of the Cabinet Office gave advice, in its compiled opinions, to review the Basic Policy concerning the Protection of Personal Information (a unified set of guidelines prepared by the government to further enhance the feasibility of personal information protection, in lines with the provisions of the Data Protection Law). The Council also advised on the deliberation for unifying the guidelines being prepared by various ministries and agencies.

## Future Outlook

### (1) Social security contributions

The GOJ intends to proceed with the exchange of information with a view to commencing negotiations in accordance with priority, taking into account scale of contributions to the social security system of the countries concerned, number of people of Japanese nationality as well as number of Japanese companies in those countries, requests from business sector, status of bilateral relations, as well as the differences between Japan's social security system and the system of the countries concerned in a comprehensive manner.

### (2) Smoother and swifter application procedures for obtaining work and residence permits

- (a) We will continue our review on a timely basis concerning the facilitation of accepting foreign workers and acceleration of relevant procedures, taking Japan's immigration control system into consideration.
- (b) A review of the re-entry permit system, which is mentioned in the Three-Year Plan for the Promotion of Regulatory Reform (approved in a Cabinet meeting on 22 June 2007), is scheduled to be conducted based on such factors as the

treatment of highly-skilled foreign nationals in foreign countries and the specific characteristics of each status of residence, on the presupposition that a new system of residence management will be established.

(3) Personal Information Protection regime

The GOJ plans to review the Basic Policy concerning the Protection of Personal Information and advance deliberations for unifying the guidelines being prepared by various ministries and agencies. We believe Japan can in this way ensure the protection that satisfies international criteria, as we continue our commitment, and thereby secure the feasibility of the relevant law. Japan will furthermore seek international harmonization pursuant to the OECD Recommendation on Cross-border Co-operation in the Enforcement of Laws Protecting Privacy. Japan thus continues its efforts to protect personal information and ensure protection that satisfies international standards.

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

#### BDRT recommendations

- (1) The EJBDRT recommends the governments of the EU and Japan to take the lead in the ongoing discussion among the developed countries 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.

#### Efforts to Date

- (1) Harmonizing international patent systems
  - (a) Japan and the EU have actively discussed the issue of international patent harmonisation on the occasions of intergovernmental meetings including Japan-EU Industrial Policy Dialogue, Japan-EU Dialogue on Intellectual Property Rights and Japan-EU Regulatory Reform Dialogue.
  - (b) Leaders of Japan and the EU recognised the importance of harmonizing patent systems through discussions in the G8 Summit and the Japan-EU Summit.
  - (c) Japan and the EU participated in discussions among industrialized countries (Group B+) on Substantive Patent Law Treaty (SPLT). They took part in the informal experts' meeting (the Working Group) held in Denmark in July 2007, to be followed by the Plenary convened in Geneva in September 2007, to discuss the list of issues raised in the Chair's Proposal, including first to file systems and grace period.

- (2) Enhancing enforcement of intellectual property rights

Since then Prime Minister Junichiro Koizumi suggested the necessity of formulating a legal framework aimed at preventing the proliferation of counterfeit and pirated goods at the G8 Gleneagles Summit in 2005, the Japanese Government has conducted active discussions on realizing an Initiative for the Anti-Counterfeiting Trade Agreement (ACTA) (provisional name) with governments of other developed and developing countries that share our high level of commitment in the protection of intellectual property rights (IPR). The initiative aims at the establishment of a new, international

high-level legal framework based on strong legal standards on enforcement of IPR, strengthening enforcement practices, and international cooperation. On October 23, 2007, the press release was made along with the EU, the United States and some other related countries aimed at realizing this framework. Since then, the consultation process has begun among related countries.

(3) Energy conservation regulations and harmonizing the labelling system

Energy conservation standards are formulated for household electronics through the “Top Runner Program” based on the Energy Conservation Law, and relevant labeling system has been introduced as from 2000.

The range of equipment subject to the energy conservation standards is being expanded while target standard values are being strengthened. Currently, 21 categories of equipment are subject to the said standards, while 16 categories of equipment are also subject to the labeling system. In addition, the operation of standardized energy conservation labels began in October 2006 as a labeling system for retailers where a multilevel evaluation along with average annual electricity cost is displayed on televisions, air conditioners, and refrigerators.

As for OA equipment, the International Energy Star Program has been adopted, thus efforts are being made for international compliance.

#### Future Outlook

(1) Harmonising international patent systems

- (a) On the basis of a certain level of common understanding arrived at the September 2007 Plenary of Group B+ on the list of topics for future discussions, the Working Groups will advance further deliberation.
- (b) Japan will actively continue to hold discussions with the EU on the issue of international patent harmonisation via the aforementioned intergovernmental Japan-EU meetings
- (c) Currently in the United States, deliberations are underway on the patent reform bill which includes a shift from the first-to-invent system to the first-to-file system. Taking this prime opportunity, Japan is ready to contribute toward the further advancement of discussions on international harmonisation of patent systems.

(2) Enhancing enforcement of intellectual property rights

The Japanese Government will participate in discussion with like-minded countries with strong interest in protecting IPR, including the EU, the United States, Canada, Switzerland, Australia, New Zealand, Mexico, and the ROK. In doing so, Japan will

present policy and opinions with swiftness and clarity, and carry out a proactive role in promoting this initiative by continuing to lead these discussions while also accelerating efforts aimed at the early realization of the ACTA.

(3) Energy conservation regulations and harmonizing the labelling system

Japan will continue to expand the range of items subject to energy conservation standards and strengthen target standard values. Considerations are also being made to enhance the labeling system.

Furthermore, optimal measuring methods will be organized multilaterally at the IEA and APP, and Japan will participate in discussion on standardizing international measuring methods. Japan will also proactively introduce the effectiveness of the Top Runner Program via international conferences.

#### 4. Recognizing and applying international standards (1-J-1)

##### BDRT recommendations

- (1) 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.
- (2) 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.
- (3) 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.
- (4) Work together with the EU authorities to achieve mutual recognition of Organic Food Products labelling.
- (5) 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.
- (6) 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.
- (7) 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.

##### Efforts to Date

- (1) 46 food additives on the “priority list”
  - (a) In Japan, as in the EU, under the Food Sanitation Law, the use of food additives and flavouring agents are not permitted for use unless they are designated by the Minister for Health, Labour and Welfare as substances that are unlikely to cause

health hazards. Also, the Food Safety Basic Law requires the Minister to hear the opinions of the Food Safety Commission (FSC) before newly permitting the use of any substance as a food additive or a flavouring agent. The Food Safety Commission conducts regular risk evaluations on requests received from the Ministry of Health, Labour, and Welfare.

- (b) Japan is currently taking the initiative to approve the 46 food additives that have been internationally confirmed for safety and commonly used, including items designated by the EU. The opinion of the Food Safety Commission has already been requested regarding the 36 food additives for which materials were prepared, and risk evaluations for 25 of said additives have been concluded.

Additionally, the Pharmaceutical Affairs and Food Sanitation Council has also concluded deliberations on seven of said additives. These have been approved as additives and for use by Japan.

(2) Domestic plant quarantine regulations

In order to take plant quarantine measures that are harmonized with international rules, the Japanese Government is conducting pest risk analyses (PRAs) and classifying quarantine pests. Currently, 162 pests have been designated as non-quarantine pests.

As of present, PRAs is also being conducted on the nine pests requested by the EU, and said pests are being sequentially added to non-quarantine pests if they are determined to fall below a certain level of risk.

Four of these nine pests have already been added to non-quarantine pests. Three have been added to pests not subject to quarantine if the plants concerned are used for direct consumption.

(3) Japan Agriculture Standards (JAS) and Japan Industrial Standards (JIS) for building materials

The JAS/JIS system allows even foreign institutes to be registered as registered overseas certifying bodies (JAS) or to be accredited as foreign accredited certification bodies (JIS) by conducting the required document examination and on-site inspection.

These registration/accreditation procedures are based on ISO/IEC Guide 65, which is the internationally accepted standard for bodies operating product certification systems.

(4) Mutual recognition of Organic Food Products labelling

In March 2001, Japan recognised the equivalence of the European Council Regulation No. 2092/91 (hereafter “the EC Regulation”) with the Japanese Agricultural Standards for organic crops and organic crop products (hereafter “the organic JAS Standards”).

On the other hand, the equivalence of the organic JAS Standards with the EC Regulation has not yet received. In August 2000, the GOJ made a request to the European Commission for make an equivalence determination between the organic JAS Standards and the EC Regulation and completed preparation of the required materials and responses to questions in February 2006, but has not yet received a reply from the European Commission. The GOJ explained its request for the European Commission to promptly undertake procedures for an equivalence determination at the Japan-EU Regulatory Reform Dialogue held in Tokyo in December 2007.

(5) Positive list for cosmetic ingredients

Among cosmetic ingredients, preservatives and UV absorbers are regulated through the positive list. If there is a request for one of these items to be newly added to the list, they can be added after review. Two components have been added in the past year. Cosmetic ingredients other than preservatives and UV absorbers are regulated through the negative list, and the use of new substances is possible by ensuring their safety under corporate responsibility.

A portion of cosmetics which fall within the EU's classification of cosmetics are regulated as quasi drugs (in Japan) ; however, it is possible to submit an application for the use of new substances with the necessary scientific data as individual reviews are conducted for each quasi drug. Two new components have been approved as quasi drugs in the past year.

(6) Regulations governing the import of tableware under the Food Sanitation Law

Japan is currently amending specification standards that are based on the Food Sanitation Law for glass, ceramic, and enameled tableware while referencing ISO specifications.

Furthermore, in confirming conformity to specifications and standards based on Article 18 of Japan's Food Sanitation Law regarding imports, Japan continues to accept examination results conducted over a certain period in order to reduce examination expenses.

(7) Simplification and harmonisation the regulatory processes in the field of Medical Devices

(a) Japan has accepted foreign clinical data as application materials when

- i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed,
- ii) the standards are equivalent or surpass the Japanese medical device GCP and
- iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality.

- (b) Discussion has been held since 1992 on harmonizing regulations within the medical device sector by the Global Harmonization Task Force (GHTF), which is formed by the regulatory authorities of Japan, EU, United States, Australia, and Canada as well as the industrial arena.

#### Future Outlook

##### (1) 46 food additives on the “priority list”

- (a) Aiming at approving these additives, the Ministry of Health, Labour, and Welfare plans to continue to prepare and review the necessary materials and request risk evaluations by the Food Safety Commission and deliberations by the Pharmaceutical Affairs and Food Sanitation Council.
- (b) The 18 additives that have passed risk evaluation by the Food Safety Commission are planned for approval after deliberations by the Pharmaceutical Affairs and Food Sanitation Council.
- (c) The GOJ asks for the continued cooperation of the EU in providing information such as supporting documents from scientific evaluations so as to push forward prompt evaluations as much as possible in the future.

##### (2) Domestic plant quarantine regulations

The Japanese Government will continue to vigorously conduct PRAs and push forward the classifying of quarantine pests.

Moreover, the Japanese Government will continue PRAs on the remaining two pests requested by the EU.

##### (3) Japan Agriculture Standards (JAS) and Japan Industrial Standards (JIS) for building materials

Japan will provide the relevant institutions with explanations as necessary in continuing to work for proper system operations.

##### (4) Mutual recognition of Organic Food Products labelling

The European Commission is expected to reply to GOJ within February 2008. GOJ will respond to the reply from the European Commission in a timely manner as soon as GOJ receives it and discuss this issue at the Japan-EU Regulatory Reform Dialogue to be held in Brussels March 2008.

##### (5) Positive list for cosmetic ingredients

Japan will continue to make additions to the list and approve components as quasi drugs after proper reviews which are conducted based on requests and applications with scientific data attached.

(6) Regulations governing the import of tableware under the Food Sanitation Law

Amendments to specification standards based on the Food Sanitation Law for glass, ceramic, and enamelled tableware, packaging, and containers that are made while referencing ISO specifications will be announced in FY2008 after deliberations by an advisory council. Japan is currently considering implementing said amendments a half-year following said announcement.

(7) Simplification and harmonisation the regulatory processes in the field of Medical Devices

(a) The GOJ encourages active use of consultation on medical device applications provided by the Pharmaceuticals and Medical Devices Agency (PMDA). The GOJ intends to further expand this consultation system..

(b) It is difficult to establish a new forum for discussion due to resource constraint. The GOJ requests that consultation regarding specific matters be brought individually. As is conventionally, the GHTF would be an adequate forum for discussion on harmonizing regulatory schemes as ever.

## 5. Improving regulatory transparency and accountability (1-J-2)

### BDRT recommendations

- (1) 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.
- (2) 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.
- (3) 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.
- (4) 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:
  - (a) Systematically develop, publish and update legally binding guidelines on its interpretation of laws, regulations and guidelines;

- (b) 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;
- (c) 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.

#### Efforts to Date

- (1) Transparency and consistency in regulation

Please refer to (2), (3), (4) in this section.

- (2) Further revision of the Administrative Procedures Law (APL)

Public Comment Procedure based on the APA (Administrative Procedure Act) stipulates that, in the event that one wishes to establish Administrative Orders, etc., they shall publicly notify the proposed Administrative Orders, etc. (Article 39, Paragraph 1), the proposed Administrative Orders, etc. shall have concrete and clear contents (Article 39, Paragraph 2), and the period for submission of comments shall be 30 days or longer (Article 39, Paragraph 3). It also rules that adequate consideration shall be paid to the comments submitted (Article 42), and in the event that Administrative Orders, etc. is promulgated after Public Comment Procedure have been conducted, the results following the consideration of the submitted comments shall be publicly notified along with the ground (Article 43, Paragraph 1). Bills should be deliberated on by the Diet, which is organized by assembly members that represent all national citizens, and are not subject to Public Comment Procedure. The Ministry of Internal Affairs and Communications conducts and publishes annual surveys on the implementation of the Public Comment Procedure by Ministries and Agencies, and encourages improvements to Ministries and Agencies when necessary.

- (3) Rulings and clarifications for the area of taxation

A notification is sent in writing to corporations that file a blue return, which accounts for over 90% of all corporations, in accordance with laws and ordinances when said corporations are going to be taxed regarding the reason for taxation, despite whether said corporation is domestic or foreign.

In addition, care is paid in exchanging opinions to an adequate degree with taxpayers and providing clarifications on the concepts of tax authorities regarding the suitability of taxation during the tax inspection process as well.

(4) Improving understanding and transparency within financial services industry

Regarding recommendations (a) and (b):

The FSA amended the Detailed Regulations regarding Prior Confirmation Procedures on the Application of Laws and Regulations by the FSA on 2 July 2007 in order to further utilize the “no action letter” system.

The main portions amended include: 1) expanding the scope of referential laws and provisions; 2) No public disclosure of the name of the inquirer when publishing inquiries and answers; 3) facilitating receipt procedures such as by unifying reception tellers for reference forms; and, 4) working to shorten processing periods.

The FSA is working to publicize this system by publishing the details of said amendments on its website, announcing them at a press conference, and issuing notices to industry groups.

Regarding recommendation (c):

(Inspection Bureau, FSA)

The financial institutions under inspection can submit their opinions in the event that their opinions differ from the perception of the inspectors even after adequate discussion has been carried out between the institutions and inspectors. In that case, a fair and neutral trial will be carried out, and external specialists attend the trial as a member. From the introduction of this system in January 2000 to the end of December 2007, there have been 348 cases where opinions of financial institutions have been taken and the opinions of said financial institutions have been adopted in 155 (45%) of said cases.

In addition, through the use of on-site inspection monitoring, financial institutions may get opportunities to express their opinions, such as whether inspections are being operated appropriately, with senior officials of the back office of the Inspection Bureau (who are not inspectors), and inspectors can't attend on-site monitoring meetings so institutions can express opinions frankly and freely. Also, there is an off-site inspection monitoring system, where opinions are collected after the completion of each inspection. (There were 248 cases of on-site and 266 cases of off-site inspection monitoring between July 2006 and June 2007.)

(Executive Bureau, Securities and Exchange Surveillance Commission)

Financial institutions under inspection can submit their opinions when they differ from the findings of the inspectors even after substantial discussion. In order to ensure

objectivity in its treatment, such opinions will be reviewed by the Coordination Division of the Securities and Exchange Surveillance Commission's Executive Bureau from a fair and neutral point of view.

Financial institutions have other opportunities to express their opinions. On-site inspection monitoring will be conducted by senior officials of the Coordination Division while the inspectors are still proceeding, where the financial institutions can talk with the officials in the absence of inspectors about their views on whether inspections are being operated appropriately, etc. There is also an off-site inspection monitoring system, where opinions can be expressed after the completion of each inspection. (There were 52 cases of on-site and no case of off-site inspection monitoring between July 2006 and June 2007.)

#### Future Outlook

(1) Transparency and consistency in regulation

Please refer to (2), (3), (4) in this section.

(2) Further revision of the Administrative Procedures Law (APL)

Results from the FY2007 survey on the implementation of Public Comment Procedure will be published during this fiscal year. In addition, the situation of implementation of Public Comment Procedure in the early stage of FY2008 will be surveyed and published, and improvements will be encouraged of Ministries and Agencies as necessary.

(3) Rulings and clarifications for the area of taxation

Japan will continue to provide corporations that file blue returns with the reason for their taxation in writing, while also continuing to exchange opinions to an adequate degree with taxpayers and provide clarifications on the concepts of tax authorities during the tax inspection process as well.

(4) Improving understanding and transparency within financial services industry

Regarding recommendations (a) and (b):

Japan will work to improve transparency in financial administration through the proper operation of this system.

Regarding recommendation (c):

The FSA's Inspection Bureau and Securities and Exchange Surveillance Commission's Executive Bureau have conducted the necessary improvements to the

Opinion Submission System and Inspection Monitoring mechanism, and will continue to enforce and operate the systems properly.

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

BDRT recommendations

(1) Shortening the medical equipment certification process

- 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).

(2) Improving the product approval process for animal health products

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.

Efforts to Date

(1) Shortening the medical equipment certification process

- (a) Japan has accepted foreign clinical data as application materials when
  - i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed,
  - ii) the standards are equivalent or surpass the Japanese medical device GCP and
  - iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality.
- (b) The GOJ is making efforts to clarify GCP operations through various notices and Q&A.
- (c) The GOJ is implementing Quality management standards (QMS) requirements for medical devices in consideration of guidelines formulated by the Global

Harmonization Task Force (GHTF), and is making efforts to achieve global harmonization through the introduction of ISO13485.

(d) In October 2007, the GOJ issued a notification regarding the consolidation and rationalization of necessary documents on GCP in response to a report by the Task Force for Clinical Trial Improvement. In March 2007, the PMDA's midterm targets and plan was changed, where the number of reviewers will be increased by 236 in the three years by the end of FY2009. PMDA is currently conducting large-scale recruiting activities.

(2) Improving the product approval process for animal health products

With the objective of conducting a prompt and efficient approval process, the GOJ had decided to conduct all approval operations at the National Veterinary Assay Laboratory from April 2007 by transferring control over operations that were previously assigned to the Ministry of Agriculture, Forestry and Fisheries to the National Veterinary Assay Laboratory.

#### Future Outlook

(1) Shortening the medical equipment certification process

(a) The Pharmaceuticals and Medical Devices Agency provides prior consultation on applications of individual items, so we would like this to be utilized.

(b) The GOJ plans to consider rationalization of scope of cases/situations where clinical trial should be conducted and improvement of operation of the GCP in medical device sector based on the Five-Year Strategy for Creation of Innovative Pharmaceuticals and Medical Devices.

(c) The issue of globally harmonizing QMS has been addressed.

(d) In regards to GCP, the GOJ plans to amend ministerial ordinances pertaining to the Institutional Review Board, the handling of safety information during clinical studies, and the delivery of investigational drugs within this fiscal year. PMDA will push the increase in its staff according to the plan while working to enhance the qualifications and skills of individual staff.

(2) Improving the product approval process for animal health products

The GOJ plans to publish approval procedures in order to conduct the approval process in a more precise and swift manner.

## 7. Ensuring free and open competition in services (1-J-4)

### BDRT recommendations

- (1) 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.
- (2) 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.
- (3) 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.

### Efforts to Date

#### (1) Article 33 of the Financial Instruments Exchange Act

The Plan for Strengthening the Competitiveness of Japan's Financial and Capital Markets, which was drafted at the end of last year, dictates a revision of firewall regulations between banks and securities firms from the perspective of improving convenience for clients and meeting the requests for integrated internal management by financial groups through exercising the synergy brought by mutually complementary and streamlining operations within financial groups. Specifically, in addition to requiring a conflict of interest management system, the plan takes measures to prohibit soliciting by securities firms that abuse the dominant position of banks. The plan also stipulates the removal of The ban on concurrent posts, and the ease of restrictions on the sharing of undisclosed corporate customer information between securities firms and banks.

It is difficult to make revisions so that banks can dually oversee securities operations in view of Article 33 of the Financial Instruments Exchange Law from the perspective

of preventing harmful effects from conflicts of interest, preventing the abuse of dominant positions by banks, and ensuring the financial soundness of banks.

## (2) Privatization of the Japan Post

(a) After privatization, the Japan Post Insurance (Kampo Insurance) has been subject to the same laws and regulations as other private life insurance companies as an insurer under Insurance Business Law regarding capital, solvency margin, tax, and policyholder protection funding by the Life Insurance Policyholders Protection Corporation of Japan. Additionally, regulations (restricting the scope of business , etc.) from the Law of the Privatization of the Postal Services apply to the Japan Post Insurance during the transitional period.

(b) In addition, the relationship between new contracts held by Japan Post Insurance (Kampo Insurance) after privatization and pre-privatized contracts carried over by the Management Organization for Postal Savings and Postal Life Insurance was stipulated in the implementation plan concerning the business succession of Japan Post. The implementation plan was examined and approved by the Financial Services Agency and Ministry of Internal Affairs and Communications after receiving the opinions of the Postal Services Privatization Committee and holding consultation with the Minister of Finance. Through this process, it was confirmed that no unjust transfer of interest was incurred between contracts after privatization and those before privatization.

(c) Cooperative societies are mutual aid structures created via linking entities through certain communities or occupational fields. Members of said societies provide personal funds for the mutual use of their business, and are conducted as a part of reciprocal help activities (joint businesses, loan businesses, welfare programs, etc.) between a wide range of members.

For this reason, there is a need for unique regulations that take into consideration the qualities of organizations such as this, and these mutual aid programs are currently being operated within the scope of the law under the supervision of each respective governing agency. Therefore, it is not appropriate to subject these cooperative societies to Insurance Business Law as with private insurance companies.

## (3) Airfares

An approval system is adopted for airfares based on Japan's Civil Aeronautics Law as approval is required from the aviation authorities of both sides according to bilateral agreements between Japan and other countries.

This approval authorizes fares set by the International Air Transport Association (IATA) and also independent fares set by airlines, namely non-IATA fares including

so-called carrier fares, given that said fares fulfil certain conditions, such as not generating any unjust competition between airlines. The same conditions apply to fares sold to travel agencies by airlines.

Furthermore, no special restrictions are placed on the sale of tickets with approved fares via the Internet or settlement of airfares.

#### Future Outlook

##### (1) Article 33 of the Financial Instruments Exchange Act

The Financial Services Agency will make concentrated efforts in line with the details of said plan, including working with a view to submitting bills.

##### (2) Privatization of the Japan Post

We plan to continue to provide proper supervision over the Japan Post Insurance (Kampo Insurance) in the same manner as other private insurance companies, based on the Insurance Business Law and relevant regulations.

Moreover, the expansion of the scope of business shall be approved by the Financial Services Agency and Ministry of Internal Affairs and Communications in accordance with the Law of the Privatization of the Postal Services, after receiving the opinions of the Postal Services Privatization Committee and while considering a level playing field with other private life insurance companies, etc. We will make proper decisions in line with the framework of the Law of the Privatization of the Postal Services.

Cooperative societies are currently operated within the scope of the law under the supervision of each respective governing agency. It would not be appropriate to subject them to Insurance Business Law as with private insurance companies.

##### (3) Airfares

We would like to conduct necessary discussion through consultations with aeronautical authorities of an individual EU Member State regarding the airfare issue of international air transport while also taking into consideration their respective requests.

#### (Footnote)

The government has entered into an arrangement towards removing the restriction on the minimum floor of non-IATA fares including so-called carrier fares, set at 30% of the IATA price from FY 2008.

8. Eliminating unnecessary bureaucracy for foreign residents (1-J-5)

**BDRT recommendations**

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.

**Efforts to Date**

Please see (ii) Efforts to Date in Supporting timely development of business (1-EJ-2).

**Future Outlook**

Please see (ii) Future Outlook in Supporting timely development of business (1-EJ-2).

## 9. Promoting foreign direct investment (1-J-6)

### BDRT recommendations

- (1) 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.
- (2) 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.
- (3) 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.

### Efforts to Date

- (1) (As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform)
- (2) The GOJ took measures such as approving tax deferral for so-called triangular merger, which has become legally feasible since 1 May 2007.
- (3) Article 821 of the Companies Act concerning pseudo-foreign companies functions for foreign companies as a beneficial amendment to the regulation governing pseudo-foreign companies set forth under the former Commercial Code. Regulation governing pseudo-foreign companies had existed since before the amendment of the Commercial Code (Article 482 of the former Commercial Code). Therefore, it is misleading to suggest that Article 821 of the new Companies Act has tightened regulation for pseudo-foreign companies.

Indeed, the GOJ has been watching any possible influence of Article 821 of the Companies Act, pursuant to a concurrent resolution on Article 821 issued by the House of Councillors. The GOJ has nevertheless received no motions for compliant or other calls based upon actual cases claiming the suffering of disadvantage due to

the provision of Article 821. As such the GOJ has no specific plan to review the said article.

In the “Background” section of these recommendations is a reference to the GOJ’s public comment procedure concerning the regulation governing pseudo-foreign companies. The GOJ solicited opinions focusing on the core issue of whether or not Article 482 of the then-effective Commercial Code, equivalent to Article 821 of the current Companies Act, should be removed, as part of the public opinion solicitation for “Preliminary outline proposals for the modernisation of the Japanese company law,” promoted from October 29, to December 24, 2003. With these activities, it is unreasonable to claim that the opinion solicitation “went completely unnoticed” because it sought opinions only on “general arguments”

#### Future Outlook

- (1) (As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform)
- (2) (As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform)
- (3) As mentioned above, the GOJ thus far has received no claims of disadvantage actually incurred because of the provisions of Article 821 of the Corporate Code. As such, the GOJ has no specific plan to review the article.

## **Working Party 2: Tax and Accounting Issues**

### Accounting Issues

#### 10. IASB, FASB and ASBJ/ security regulators (2 - EJ – 1)

##### BDRT recommendations

We ask the public authorities to ensure continuing wide-ranging dialogue among IASB, FASB and ASBJ.

In addition, we call for cooperation of regulatory authorities such as security regulators in EU and Japan for the international competitiveness of financial and capital markets.

##### Efforts to Date

ASBJ has been holding a joint project with IASB, meeting twice a year since March 2005. The latest time the two met was in October 2007, which was their sixth such meeting. In August 2007, ASBJ and IASB jointly announced the Tokyo Agreement. This Agreement is aimed at resolving the differences of accounting standards: those differences pointed out by the Committee of European Securities Regulators (CESR) in July 2005 should be resolved by the end of 2008 and the rest of the differences by the middle of 2011. In December 2007, ASBJ announced a project plan based on the Tokyo Agreement for achieving convergence. ASBJ has also been holding bi-annual discussions with FASB since May 2006, with the fourth of such discussions held in October 2007. Separately, Japan's Financial Services Agency (FSA) has been exchanging information with the EC from time to time at venues such as the Japan-EU Monitoring Meeting on Developments in Accounting and Auditing Issues. The latest of such meeting was held in Brussels in November 2007, as the third round of the meeting. Also with the US Securities Exchange Commission (SEC), the FSA is seeking to enhance dialogue at venues such as high-level bilateral dialogues.

##### Future Outlook

The FSA intends to further support ASBJ's active commitment for the convergence of accounting standards. The FSA will also monitor the progress of the convergence between ASBJ and IASB in mutual ways and promote dialogue with EC. With the US SEC and other bodies, the FSA will further promote active dialogue over various issues of accounting.

## Tax Issues

### 11. Agreements on tax issues (2 – EJ – 2)

#### BDRT recommendations

We hope that the EU Member States will enter into common agreements on tax issues with the Government of Japan in order to enjoy fully the benefits of the single market.

#### Efforts to Date

With regard to the avoidance of double taxation, the GOJ has been reviewing the income tax conventions with EU member states one by one, taking heed of the existing economic relations with them and from the perspective of vigorously promoting international investment exchange to reflect the close economic ties between Japan and the EU. In January 2007, Japan and France signed a protocol to partially amend their existing convention, which came into effect in December the same year. The amendment has allowed for the reduction of taxation at source imposed on the payments of investment profits (dividends, interest and royalties), as did the new agreement on tax issues between Japan and the United Kingdom, which came into effect in October 2006.

#### Future Outlook

The GOJ is currently negotiating with the Netherlands to amend their agreement on tax issues. The GOJ will further strive to conclude agreements on tax issues with other EU member states as necessary.

### 12. Consolidated tax system reform (2 – J – 1)

#### BDRT recommendations

We repeatedly ask that the Government of Japan quickly reforms the consolidated tax system to allow the carrying forward of tax losses in subsidiaries incurred before the system came into effect, exempting revaluation of subsidiaries at the initiation, and allowing inclusion of donation between consolidated corporations in expenses.

#### Efforts to Date

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

#### Future Outlook

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

### 13. Transparency of tax execution (2 – EJ – 3)

#### BDRT recommendations

We ask the tax administration of Japan to secure transparency of tax execution in order for companies to carry out international expansion smoothly.

From a viewpoint of international common understanding, we request the tax administration of Japan to revert to on international common model such as the OECD model.

#### Efforts to Date

Regarding transparency in enforcement of the transfer pricing taxation, the commissioner's directives on the interpretation of the laws and on the operation have thus far been developed and revised, and transparency has been ensured by clarifying the applicable criteria and enforcement policy through the announcement of these activities. In June 2007, the commissioner's directive was revised, and case studies describing the treatment for the transfer pricing taxation purposes on certain preconditions was newly created and released publicly after the public comment process.

Furthermore, the commissioner's directive stipulates that examinations and APA reviews shall be conducted by referring the OECD Transfer Pricing Guidelines. Japan has endeavoured to enforce the transfer pricing taxation based on international rules.

#### Future Outlook

In order to further increase transparency in enforcement of the transfer pricing taxation, Japan will continue to clarify the applicable criteria and enforcement policy. In addition, Japan continuously enforces the transfer pricing taxation based on international rules by conducting examinations and APA reviews using the OECD Transfer Pricing Guidelines as a reference.

14. Response to new deviations arise between corporate accounting and tax practice (2 – J – 2)

**BDRT recommendations**

With the progress of convergence, since new deviations arise between corporate accounting and tax practice, we ask that the Government of Japan respond flexibly to the deviations.

**Efforts to Date**

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

**Future Outlook**

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

15. Corporate Tax (2 – J – 3, 2 – J – 4)

**BDRT recommendations**

- (1) We ask the tax administration of Japan to review the tax haven rules. We suggest that Japan's tax authority reviews the criteria rate for tax haven regulation, or expand the exemptions, such that companies in countries with tax treaties with Japan can be exempted from tax haven regulations.
- (2) We request the tax administration of Japan to think the reduction of tax rates.

#### Efforts to Date

(1) Tax haven regulation

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

(2) Reduction of corporate tax rates

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

#### Future Outlook

(1) Tax haven regulation

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

(2) Reduction of corporate tax rates

As regards proposals relating to the tax system, see the attached appendix on the general standpoint for tax reform.

### **Working Party 3: Information & Communication Technologies (ICT)**

#### 16. Broad discussion on Next Generation Networks (3-EJ-1)

##### **BDRT recommendations**

By development and utilization of Next Generation Networks with advanced technologies allowing more QoS and Security, it is expected that social issues, such as aging society, nursing/medical care, unemployment, crime/disaster prevention, and energy/environmental issues will be addressed, and the development of a dynamic society will be promoted.

Therefore, both authorities should have wide cooperation to accelerate early introduction of Next Generation Networks. Specifically, promotion of R&D for the core technology of Next Generation Networks, and enhanced cooperation for standardization and interoperability assurance in international organizations should be strengthened. Furthermore, required measures are policies to promote utilization of various broadband services with Next Generation Networks, such services as remote medical care, telework, nursing/medical care, home security, e-learning, and entertainment, and an environmental framework in which open collaboration will be facilitated among various industries.

##### **Efforts to Date**

The New IT Reform Strategy formulated in January 2006 stipulates that priority will be put on promoting ICT, of which Japan is a leader, and research and development for ICT that is the foundation of other sectors, aimed at sustaining and strengthening international competitiveness. The Ministry of Internal Affairs and Communications is currently working to create basic technologies by 2010 that are necessary for creating a Next Generation Network. Moreover, the New Generation Network Promotion Forum was established in November 2006 in order to address research and development of network-based technologies for the future. Through cooperation among industry, academia, and government, related persons are working together to create a strategy and vision and to expand the base of research activities.

In addition, The Telecommunication Technology Committee (TTC), a privately-run standards institute, and the European Telecommunications Standards Institute (ETSI) have exchanged an MoU to form a partnership in creating international standards for Next Generation Networks. Japan will support workings to strengthen Japan-European collaboration between these types of standards-related institutions, and proactively

promote standardization in the ITU (International Telecommunication Union) Telecommunication Standardization Sector in consideration of these activities.

Moreover, as a policy package based on the u-Japan Policy (formulated in December 2004), which was established in view of a ubiquitous networking society by 2010, the Ministry of Internal Affairs and Communications is currently making efforts to raise the level of ICT use, which will make residents' lives more affluent through Next Generation Networks, such as ICT, telework, and e-learning.

#### Future Outlook

Japan will steadily work towards to aim of the early realization of Next Generation Networks through collaborations with relevant institutions in the future.

Regarding international standardization for ensuring interconnectivity, it is necessary to continue to form partnerships and collaborate with Japanese and European standards- related institutions in order to fully promote the standardization of release 2 or later that would allow for the maximum functional use of Next Generation Networks such as Internet Protocol TV (IPTV) and Fixed-Mobile Convergence (FMC). In doing so, Japan plans to proactively utilize achievements from research and development related to Next Generation Networks carried out in Japan.

## 17. Promotion of ICT innovation protecting the natural environment (3-EJ-2)

### BDRT recommendations

It is imperative for us to reduce CO<sub>2</sub> emissions and others to contribute to the environmental preservation. Promotion of ICT innovation considering natural the environment by practical use of energy-efficient technologies and also permeation of them should be viewed as essential. The EU and Japan should promote R&D of the energy-efficient technologies, widely utilize them as environment-protecting products and apply the products to innovative systems, including ITS and telework, for energy saving. For the purpose of magnifying the effect to the environment, both authorities can share their experiences and have dialogues about their activities.

As discussed above, both authorities should promote R&D of energy-efficient technologies and energy saving through field trials of the technologies. In light of international cooperation, it would be highly valuable for both authorities to lead dialogues on this issue and proactively share the results of the trials in a global arena.

### Efforts to Date

The Ministry of Economy, Trade and Industry (METI) has been strengthening the development of the energy conservation techniques for IT equipment and systems such as semiconductors and displays. The ministry has also advanced its commitment to spreading the results of researches by using the top runner system based on the Law Concerning the Rational Use of Energy and by other means.

Additionally, the ministry held a “Green IT Initiative Meeting” on December 6, 2007, inviting top leaders of the IT industry, to promote the concept of “Green IT,” which aims at the dual goals of “energy conservation of IT equipment” and “energy conservation of society by the use of IT.”

The Ministry of Internal Affairs and Communications (MIC) held a Study Group concerning the Development and Environment of a Ubiquitous Network Society from December 2004 to March 2005. The group projected the directions for reducing the environmental burden by the use of ubiquitous systems such as teleworking and ITS. Concerning teleworking, the MIC is carrying out a project for small and medium-sized enterprises and other parties to construct systems to try out and experience teleworking. Many companies and other parties have been joining the MIC's public solicitation for this project.

Concerning ITS, efforts are underway to smoothen traffic and reduce negative environmental impact by means of providing drivers with accurate traffic information and optimizing traffic demand, pursuant to the “Emphasis plan - 2007” formulated in July 2007.

The Ministry of Land, Infrastructure and Transport (MLIT) has been conducting the Smartway experiment program, in which drivers are given audiovisual information through dedicated short range communication (DSRC) in a project joined by private companies. The Smartway program in this way promotes the evaluations and inspections for the feasibility of various support systems for safe driving in order to prevent traffic accidents.

#### Future Outlook

The METI is considering the addition of routers to the list of devices to which the top runner standards apply. From FY2008 onward, Japan will launch a Green IT Project, designed to realize fundamental energy conservation for whole systems instead of for each individual product, as part of the country's active commitment to developing innovative energy conservation technologies. Japan will also launch an “Energy ITS Promotion Program” to upgrade car control technology and traffic flow control, which are the key technologies for ITS to smoothen traffic flows and thus contribute to improving energy consumption efficiency of the transportation sector. The GOJ will, moreover, launch a Green IT Initiative Conference in January or February 2008, in order to hold an international symposium in May to present Japan’s advanced commitments to the world and thereby push forward international movements.

The MIC has been holding a Study Group on ICT Policy for Addressing Global Warming since September 2007 in order to identify both negative and positive impacts of ICT on global warming, seek programs to develop Japan as the Environment Nation, and ICT policies to contribute to the international efforts addressing global warming. As for teleworking, the whole government intends to promote the spread of this work style, in response to a statement by former Prime Minister Shinzo Abe in his policy speech to “seek to double the teleworking population.” The MIC on its part will further work on the spread of teleworking and enhance its recognition.

The MLIT will further advance its joint commitment to preventing traffic accidents in tie-ups with the private sector, aiming to realize the practical use of a safe driving support system in FY2008, while also planning to expand the scales of MLIT’s demonstration tests.

In addition the GOJ will further promote to realize the distribution of more accurate traffic information by the use of car equipment capable of DSRC and Vehicle Information and Communication System (VICS) that runs on broadcast wave, as well as mobile phones and various other communication media.

## 18. Cooperation on ensuring reliability and stability of ICT infrastructure (3-EJ-3)

### BDRT recommendations

Ensuring reliability and robustness of ICT infrastructure, particularly public systems, is a globally shared challenge, since a problem with them has a world-scale negative impact. We welcome that both authorities are already aware of the problems of Information Security as a common issue and are taking related initiatives, but we also think that there is still room for improvements in terms of international cooperation. National implementation can be enhanced by other nations' efforts, since the networks are borderless.

Therefore, both authorities are expected to closely communicate, such as sharing their latest policies, and cooperate to define and take necessary actions against problems that require immediate international cooperation, such as Denial of Service attacks.

### Efforts to Date

The Japanese Government formulated the First National Strategy on Information Security (February 2, 2006) as a three-year medium-to-long-term plan for overall information security issues, and Secure Japan 2006 (June 15, 2006) and Secure Japan 2007 (June 14, 2007) as annual plans, and is currently making efforts to improve the reliability and safety of ICT infrastructure.

Japan is adequately aware of the necessity for international collaboration, and, under the same plan, is making efforts with focus on "Promoting International Collaborations and Cooperation." On October 3, 2007, Japan formulated the "Efforts for International Collaboration and Contributions in the Japanese Information Security Sector," which designated basic policy for the entire government in strategically addressing international cooperation and contributions.

The annexed paper "Promoting Research and Innovation towards Prosperity," which was attached to the joint press statement from the June 2007 Japan-EU Summit, stated that Japan and the EU would cooperate to create a safe and secure environment for ICT use. Japan and the EU have worked closely together in sharing information regarding bilateral Japan-EU dialogue on information society.

### Future Outlook

In consideration of the various efforts conducted by the government and private sectors under the First National Strategy on Information Security along with changes in the social environment, including a trend of technological innovation and system revisions, the Japanese Government plans to launch deliberations on the next middle-to-long-term plan, the “Second National Strategy on Information Security” (tentative name), beginning in January 2009.

Furthermore, deliberations will be advanced on concrete measures for further strengthening international collaborations based on the Efforts for International Collaboration and Contributions in the Japanese Information Security Sector.

## 19. New systems and policies in preparation for promotion of digital contents (3-EJ-4)

### BDRT recommendations

As ICT evolves, the way contents are produced, distributed and utilized is largely changing. Through various developments in response to those changes in the Digital Era, the market of contents is expected to expand significantly. We expect both authorities to keep on engaging in regulatory improvements that consider a balance of rights between copyright owners and users, for further promotion of utilization of digital contents. As for a levy system, it is expected to update it to form a more reasonable system which would be based upon the current and potential capability of ICT technologies. Therefore, the levy should be limited or phased out, with a view to wider deployment of technologies to protect copyright. We expect that the legal framework of the levy system will be fundamentally rethought in the Council for Cultural Affairs and reach a concrete conclusion in Japan, and consideration about systemic reforms will be continued in the EU.

Meanwhile, IPR violations remain of high concern in some Asian territories, despite increasing efforts in recent years, by both local governments and trade partners, to tackle counterfeiting and piracy. Continuous efforts by both Europe and Japan to fight against IPR violation and ensuring effective enforcement of intellectual property rights, including capacity building of countries concerned, should remain a priority of their collaborative initiatives to protect copyrights of digital contents.

As stated above, the levy should be limited or phased out, with a view to wider deployment of technologies to protect copyright. To tackle counterfeiting and piracy, both governments should strengthen their initiatives to protect copyrights of digital contents, considering sound market expansion.

### Efforts to Date

From the perspective of balancing the improvement of consumer convenience and proper protection of rights, the Japanese Government has gained the cooperation of a wide range of related entities (including consumers, rights holders, broadcasters, and manufacturers) in working to formulate new rules that suit the digital era regarding the distribution and protection of content through the Information and Communications Council and exploratory committees on promoting the distribution of digital content.

From FY2006, discussion on a fundamental revision of the levy system has continued in the Commission on Private Recording, Subdivision on Copyright, Council

for Cultural Affairs. The discussion specifically focuses on the topics of revising the scope of limitations concerning private reproduction, the relationship between copyright protection technology and the need for compensation, and revising the devices and blank media to be included in the scope of compensation. Discussion is currently conducted in consideration of opinions gathered from the people.

Meanwhile, in addressing counterfeiting and piracy, Japan is making efforts to strengthen cooperation to enhance the sharing of information to third-party countries in Asia and other regions based on the Japan-EU Joint Initiative for the Enforcement of Intellectual Property Rights in Asia on which agreement was reached at the June 2007 Japan-EU Summit. Moreover, a press statement on the Anti-Counterfeiting Trade Agreement was simultaneously released by Japan, the United States, and the EU and some other related countries in October 2007, beginning a conference between countries that share our high level of commitment in the protection of intellectual property rights.

#### Future Outlook

The Japanese Government will continue to gain the cooperation of consumers, rights holders, broadcasters, and manufacturers in advancing discussion, at exploratory committees on promoting the distribution of digital content, aimed at expanding a content market that possesses a balance between protection and use. The government plans to conclude discussions in 2008.

The Commission on Private Recording will continue to discuss necessary revision of the levy system, and will implement measures for developing a legal framework in consideration of the results of said discussions once an agreement has been reached between related parties.

Furthermore, while aiming for the prompt formation of consensus on the Anti-Counterfeiting Trade Agreement, Japan and the EU will continue collaborations for strengthening the protection of rights for Asia and other regions under the aforementioned Japan-EU Action Plan.

## 20. Self-regulation regarding protection of children - a responsible approach (3-EJ-5)

### BDRT recommendations

All types of content are being distributed via mobile and broadband internet services. A responsible approach for content providers, internet and mobile service providers to protect viewers, in particular children and teenagers, against inappropriate content is “self-regulation”. Numerous corporate and national initiatives do already deliver safer use of content by children. It is of utmost importance to empower parents with information and tools to facilitate their oversight. Awareness-raising campaigns informing parents and educational material targeted at children on the safe use of the new media or the possibility for parents to customise the access to content of their children are issues addressed by existing codes of conduct. Another option is to classify content according to national / societal standards regarding decency, appropriateness and the legislation already in place. Self-regulation is a future-proven approach for the protection of children, as it allows reacting within a short time frame on technical and societal developments. It also has the advantage of being very efficient, as the industry which has been involved in drafting codes of conducts or other types of self regulation does feel strongly committed to achieve the agreed results.

Therefore, we invite the European Institutions and the Japanese authorities to continue to play a facilitating role regarding the development of self-regulation in order to ensure protection of children.

### Efforts to Date

Beginning in August 2005, the Ministry of Internal Affairs and Communications has hosted the Study Group on Countermeasures against Illegal/Harmful Information on the Internet, and the study group’s final report was concluded in August 2006. In response to the report, under the cooperation of the Ministry of Internal Affairs and Communications, an industry group formulated a model covenant that stipulates standards for creating and deleting various guidelines. Concerning the filtering of harmful information, in December 2007 the Internal Affairs and Communications Minister requested that mobile service providers enhance efforts for promoting the implementation of a filtering system in mobile phones used by young persons. Also, in June 2007, a related business established the “2007 Action Plan for Spreading and Educating about Filtering,” which aims to further spread filtering (users of mobile

phone filtering services were approximately 2.10 million as of the end of September 2007, which is 3.3 times the figure for the previous fiscal year.).

Additionally, collaborations were made with the Ministry of Education, Culture, Sports, Science and Technology and businesses in implementing “e-Net Caravan,” a nationwide educational campaign on the safe use of the internet aimed at parents and teachers, mainly.

The “Study Group on Countermeasures against Illegal/Harmful Information on the Internet” has also been held from November 2007, conducting discussions on comprehensively addressing illegal and harmful information such as by promoting the introduction of further filtering for youth, supporting measures by providers for deleting content, and spreading internet literacy.

Promotions are also underway for the sound use of ICT media in the future, and the “ICT Media Literacy Development Program” (including a guidebook for parents) was developed in FY2006 in order for children to safely and comfortably use the internet and mobile phones. This program was made public in July 2007 and is currently being put into practical use.

#### Future Outlook

The abovementioned “Study Group on Countermeasures against Illegal/Harmful Information on the Internet” is to compile a midterm report around March 2008, and, based on the results of that report, discussion is to be held on comprehensively addressing illegal and harmful information such as by further promoting the introduction of filtering for youth, supporting measures by providers for deleting content, and spreading internet literacy.

Moreover, the ICT Media Literacy Development Program will be further spread and updated as necessary.

## 21. Relationship of regulation and investment (3-EJ-6)

### BDRT recommendations

The telecommunications industry is changing significantly in response to developments in the sector as new types of competitors, new business models and user expectations for innovative services arise. New broadband technologies will offer an additional benefit to the consumer and can potentially lead to long-term sustainable competition, if consumers can access broadband through competing platforms. For that to happen, we need to ensure the best conditions for investment and stimulate the emergence of truly infrastructure-based competition.

The substantial investment needed in network transformation carries high economic risks due to increasing competition and uncertain future demand, as well as high regulatory uncertainty regarding the burden of long-term ex-ante price and access regulation and its impact on the profitability of the investment. The regulatory environment should provide incentives for network investment, allowing proper return on ICT investment. In this regard, policy-makers play a key role in determining the future of ICT investments.

Japan and Europe should create a favourable business and investment climate to face the new challenges arising from the changing market conditions.

### Efforts to Date

The Ministry of Internal Affairs and Communications has conducted a review of the competition rules in the telecommunications sector in consideration of large-scaled transformations in the market construction, including the rapid transition of communication networks to using IP and changes in business models within the broadband market. In September 2006, the ministry released the New Competition Promotion Program 2010, which brought together measures needed by the beginning of 2010 in order to further promote competition. The Ministry also created a progress report on the program in October 2007, and has now conducted revisions of the program.

### Future Outlook

Japan plans to continue proactive efforts based on the abovementioned revised program towards realizing a healthy competitive environment for the broadband market.

Moreover, there are plans to compile a progress report for the program annually, report those results to the Information and Communications Council and make said results public. A reappraisal of the program will also be made while ensuring that procedures are handled in a transparent manner, including those for gathering opinions when developing various measures as necessary.

A comprehensive verification of the overall communications legal framework is also planned for 2010 in consideration of the program's progress.

## 22. Conformity requirements and assessments of ICT equipment (3-EJ-7)

### BDRT recommendations

It is vital to ensure the international flow of ICT equipment. As the ICT sector is a global, competitive and dynamic industry in a permanent state of evolution, the fluidity of trade flow is required to offer services and competitive ICT equipment. Self-declaration of conformity should be adopted as a principle requirement of conformity assessment. Conformity requirements and assessment procedures should be harmonized to avoid multiple testing and the fragmentation of the markets providing a level playing field for manufacturers both in the EU and Japan.

Both authorities should ensure a level playing field for Japanese and European manufacturers in reference to conformity requirements and assessment.

### Efforts to Date

In regards to certification for telecommunication equipment, the Japanese authorities have implemented the Self-Confirmation of Technical Regulations Conformity system that includes ex-post measures such as ordinances and penalties. Japanese authorities also revised the Radio Law and Telecommunications Business Law in 2003 in order to transfer conformity assessment bodies to a registration system with no national discretion, and are currently operating certification in a systematic manner.

### Future Outlook

It is not absolutely the case that technological standards and certification systems are the same for every country. Therefore, Japan believes that it is still necessary to ensure that equipment conforms to the technological standards prescribed by Japanese national ordinances even for equipment where a supplier's declaration of conformity to supplier specifications has been made by a foreign manufacturer.

### 23. Market access for ICT equipment vendors (3-EJ-8)

#### BDRT recommendations

Only when the barriers to market access of ICT equipment are abolished, can the ICT sector boost economic growth and productivity gains. It is of common interest for the ICT industry of both Japan and the EU to safeguard the success of the Information Technology Agreement (ITA). In recent years, and in light of continuous technological developments, concerns about the increasing degree of discrepancies in interpretation of product coverage of the ITA by some ITA signatory countries have arisen. It is desirable that ITA Member Countries agree on a periodical review of the ITA to ensure that technologically sophisticated versions of Information Technology products continue to receive duty-free treatment. ITA Member Countries should be moving in the direction of providing more, not less, market access opportunities for Information Technology products, independent of the current state of play of the Doha Development Round.

Both authorities should work towards a regulatory environment that would encourage open and affordable access to ICT equipment markets. The EU authorities should take actions to prevent and redress the imposition of duties on certain multifunctional and/or enhanced products\*, reflecting the basic principle of the ITA, which aims at the promotion of continued technological innovation and industrial development through improvement of market access on Information Technology products.

\* For example: Multifunction printer, LCD computer monitor, Digital Camera, Set-top-box

#### Efforts to Date

Technological innovations in the IT field contribute to industry and society by saving office space and streamlining operations in addition to improving convenience through the use of, for instance, multifunction digital equipment. The ITA has greatly contributed to the global spread of IT products such as these by reducing trade barriers. Nevertheless, in order for the ITA to continue such a role in the future, it is extremely important that the ITA flexibly respond to technological innovations and not hinder the spread of said technologies.

However, as if opposing these efforts, the EU is imposing taxes on products that have added new functions or integrated functions using technological innovations that

followed the ITA's enactment labelling said products as not covered by the ITA. Japanese authorities have repeatedly expressed concern to the European Commission through the WTO ITA Committee and Japan-EU Regulatory Reform Dialogue. These issues were also pointed out at the WTO's ITA Workshop held in January 2007, the ITA Ten-Year Symposium held in March 2007, and the ITA Commission meetings held in January, March, and November 2007. A great number of countries currently demand that the spread of IT devices be conducted in alignment with the purpose of the ITA.

#### Future Outlook

The APEC-IT Workshop is to be held in February 2008, where it is planned to attract attention to the importance of IT devices and the necessity for eliminating trade barriers for IT products.

Meanwhile, Japan will continue to vigorously request that the EU Commission honour the principles of the ITA in various forums, including the ITA Commission, and work for a resolution in alignment with the agreement's main purpose.

## **Working Party 4: Joint Statement on World Trade Organisation**

### 24. WTO and Trade Facilitation Agreement

#### **BDRT recommendations**

1. EJBDRT is a strong supporter of the WTO Doha Development Agenda (DDA) negotiations and continues to urge the European Commission and the Government of Japan to exert their utmost efforts in concluding ambitious negotiations by the end of this year. In particular, the EU and Japan need to focus their efforts among major players to make the case for a successful and ambitious conclusion of the round.
2. EJBDRT hopes that the political momentum from world leaders will enhance current movement and concrete progress in the WTO negotiations in Geneva. It warns political leaders that business support for the Doha Round depends on achieving rapid agreement on negotiating modalities in order to conclude the round by the end of this year before negotiating fatigue sets in.
3. EJBDRT member companies are leading global traders and investors. Although, the world economy has been expanding with the advancement of free trade and the revolution of information and transportation technologies, we are concerned that protectionist sentiment is once again on the rise. In order to obtain the sustainable and powerful growth of the world economy in the 21<sup>st</sup> century, EJBDRT believes that it is essential to strengthen the WTO multilateral trading system and that the DDA is the right vehicle to take this agenda forward.
4. EJBDRT strongly believes that ambitious liberalization proposals need to be agreed on the reduction or elimination of industrial trade barriers, including non-tariff barriers, improving agricultural market access and reducing trade distorting subsidies, vastly improving services liberalization and agreeing to much better harmonized WTO rules on trade facilitation, anti-dumping and anti-subsidy. Priority negotiating issues for the EJBDRT are as follows:
  - (1) First, EJBDRT stresses the importance on removing tariff and non-tariff barriers against industrial products in both industrialized and leading emerging countries. Notably, EJBDRT expects the Swiss formula without apriori exclusions to deliver ambitious across the board tariff reductions by adopting industrial and emerging country coefficients in sight of each other, and a coefficient of 15 for developing countries. On top of the formula, EJBDRT calls for willing sectors to adopt sectoral tariff agreements, for instance in chemicals and in electronics. On NTBs,

- EJBDRT calls for new rules to forcefully tackle for export taxes and restrictions, and for further work on the creation of a new NTB mediation mechanism.
- (2)Second, EJBDRT expects the services negotiations to deliver ambitious new market access equivalent to other DDA issues. It calls on the European Commission and the Government of Japan to press for a services ministerial signalling conference at the time of agreement on agricultural and industrial modalities and for submission of the next revised offers as quickly as possible.
- (3)Third, EJBDRT calls for an ambitious and binding Trade Facilitation Agreement. It calls on respective governments to press the US and emerging country governments to go for a far-reaching deal that will bring concrete benefits for business. Furthermore, it emphasizes the need to improving and harmonizing the disciplines of the trade remedy measures.
5. For a successful DDA negotiation, commitment and cooperation of developing countries are indispensable. We expect that the European Commission and the Government of Japan send a strong message that the multilateral trade system will indeed contribute significantly to the interests of developing countries and take due consideration of these countries through, for example, capacity building activities. Japan should also exercise stronger leadership in Asia to build support for more ambition from leading Asian countries in China or ASEAN.
6. The conclusion of DDA negotiation requires strong political will by the leaders of major countries and strong support from business. The EJBDRT offers the support of its members and earnestly requests the European Commission and the Government of Japan to take a strong political initiative in realizing the resumption of DDA negotiation and intensify efforts in reaching the successful round of negotiations.

#### Efforts to Date

As for the WTO Doha Round, although the negotiations were momentarily suspended in July 2006, demarches on the part of member countries including Japan allowed a resumption of negotiations in earnest at the end of January 2007.

After ministerial talks of G4 (the United States, the EU, Brazil and India) broke up in Potsdam, Germany in June 2007, the chairs of the WTO agriculture and NAMA negotiating groups issued texts on draft modalities of agriculture and NAMA respectively in July. Japan then stressed the importance of using these texts as a basis for discussions and thereupon actively promoting talks in the multilateral fora.

Since September in Geneva, the active discussions on the working level in the negotiation groups of agriculture and NAMA were held on the basis of those texts. On November 30, the chair of the negotiating group on Rules also issued a text. Although it became hardly possible to achieve a conclusion of negotiations by the end of 2007, WTO Director General Lamy suggested, at the General Council in December, the conclusion would be possible by the end of 2008, if WTO members reach agreements on the modalities of agriculture and NAMA at early times of the year.

Throughout 2007, Japan worked actively to achieve an early conclusion of negotiations with a balanced and comprehensive outcome covering not only agriculture and NAMA, but also other areas such as services, rules, trade facilitation (TF) and development.

#### Future Outlook

- (a) The GOJ will continue its proactive efforts to bring the negotiations to a conclusion by the end of 2008 with an ambitious and balanced outcome.
- (b) For a successful conclusion of the DDA negotiations, close coordination is indispensable among interested parties including those between Japan and EU. Japan wishes to contribute beneficially to the negotiation process through exchanges of views not only with developing countries as well as developed ones.
- (c) The GOJ will continue to deepen its cooperation with the private sector, including exchanges of views with, among others, the business community.

## **Working Party 5: “Life Sciences and Biotechnology”**

25. The Biotechnology Action Plans set by both governments in 2002 (5-EJ-1)

### **BDRT recommendations**

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

### **Efforts to Date**

Seven technologies for strategic ally prioritized S&T were selected in the life science sector promotional strategy of the 3rd Science and Technology Basic Plan, which was formulated in consideration of the Biotechnology (BT) Strategy Guidelines. Those seven technologies are currently being strategically promoted. In doing so, a structure was developed to reorganize science and technology projects under the leadership of the Cabinet Office’s Council for Science and Technology Policy into the categories and to more effectively and efficiently advance the technologies for strategic focus. The reorganized categories are “life science foundation and infrastructure,” “clinical research and translational research bridging to clinics,” “food and biological production,” and “emerging and reemerging infectious diseases.”

### **Future Outlook**

Five years have passed since the creation of the guidelines and the action plan has made clear progress. Additionally, new issues have emerged, including gene-recombination technology, and its public acceptance, and the need to address a newly evolving situation surrounding biomass. The BT Strategy Guidelines present an action plan to promote biotechnology in anticipation of 2010. Plans are underway to revise the strategy in order to address these changes in circumstances.

## 26. Establishing “National LS/BT Understanding Promotion Plans” (5-EJ-2)

### BDRT recommendations

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

### Efforts to Date

The life science sectoral promotional strategy of the 3rd Science and Technology Basic Plan lists the promotion of public understanding of LS&BT as one measure to advance the promotion of public understanding of achievements. Under the Cabinet Office’s Council for Science and Technology Policy, a system is currently being developed for efforts to promote public understanding of the practical use of results from research on genetically modified crops, for instance, and to handle new bioethics issues generated from new research achievements.

### Future Outlook

An opinion poll will be conducted by the Cabinet Office on people that transmit information regarding genetically modified crops with a view to disseminating the results from research and development on genetically modified crops. Additionally, symposium(s) will be held on genetically modified crops through “food and biological production research” in a group of collaborative science and technology measures.

27. Enhancing international communication between EU and Japan in LS&BT areas  
(5-EJ-3)

**BDRT recommendations**

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

**Efforts to Date**

As an industry cluster policy in Japan with the purpose of enhancing the international competitive strength of Japanese industries and revitalizing intrinsic regional economies, the Ministry of Economy, Trade and Industry has been working towards an industrial agglomeration since FY2001 where community businesses and entrepreneurial ventures are newly created in a continuous fashion.

In addition, the Ministry of Education, Culture, Sports, Science and Technology has been developing policy for projects to create intellectual clusters since FY2002 in order to tap the potential of various regions and cultivate new businesses and industries through government-industry-academia collaborations focused on universities.

Through these measures, attention is currently being devoted to forming innovation clusters in Japan.

**Future Outlook**

Japan expects that international collaboration will be promoted to an even greater extent in the future.

## 28. Innovations in pharmaceuticals and other healthcare industries (5-EJ-4)

### BDRT recommendations

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

### Efforts to Date

Based on the New 5 Yearly Clinical Trial Activation Plan, which has been in effect since April 2007, MHLW is promoting clinical trials by selecting 10 Core Research Centers and 30 Major Clinical Trial Institutions in order to improve the infrastructure of medical institutions that conduct clinical trials and researches.

The Health, Labour and Welfare Minister hosted the Public-Private Sector Dialogue for Innovative Drug Discovery three times in 2007 with the purpose of sharing understanding between top-level industry-government-academia representatives on the direction of policy related to medicine sector innovation and enhancing global competitiveness of the industry. At the second installment of the dialogues, the Five-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices was decided on and publicly announced. The strategy details the concentrated injection of research funds, developing the clinical test environment, improving the promptness and quality of reviews, and proper evaluations for innovations.

### Future Outlook

Continued efforts will be made in promoting clinical trials and activating research and development based on the New 5 Yearly Clinical Trial Activation Plan.

Additionally, private-public sector dialogue will be continued, and the Five-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices will be steadily implemented while also conducting the necessary follow-ups.

## 29. Innovation in medical devices

### BDRT recommendations

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

### Efforts to Date

In 2007 the GOJ formulated and announced the Five-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices and compiled the state of its progress. The Five-Year Strategy is aimed at: concentrated injections of research funds; development of the clinical trial environment; improvement of the promptness and the quality of reviews; and adequate evaluations of innovations, among other goals. The GOJ also held a Meeting concerning the Promotion of the Policies for the Medical Device Industry and listened to opinions from the industry, in order to deliberate on new visions for the medical device industry.

Pursuant to the Medium Term Plan for the Pharmaceuticals and Medical Devices Agency (PMDA), a number of measures have been carried out at PMDA, an independent administrative legal entity, such as consultation on clinical trials and implementation of reviews by the same team, and a designed increase of the reviewers.

### Future Outlook

The GOJ will endeavour for the steady implementation of the Five-Year Strategy, by offering necessary follow-ups and through other means. The GOJ will also compile new visions for the medical device industry by the targeted deadline of the spring of 2008.

Moreover, the PMDA will further advance the increase of necessary reviewers and other measures pursuant to the Medium Term Plan.

30. Cooperation between EU and Japan to increase global competitiveness in bio-mass based and bio-fuel products (5-EJ-6)

#### BDRT recommendations

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

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

#### Efforts to Date

(a) Japan is promoting partnerships regarding the use of biomass within Asia and with other regions based on the Biomass Nippon Strategy, which was adopted by the Cabinet in March 2006.

In March 2007, Japan hosted the World Biofuel Policy Forum in Tokyo, where invited representatives from EU producers' associations and French policymakers. Also, in November of the same year, Japan invited researchers from various Asian countries to Malaysia to attend the Fourth Biomass-Asia Workshop, where opinions were exchanged on the current situation of bio-fuel production in each country and future issues.

(b) Japan is making aggressive efforts for cooperation between developed countries, including Japan and the EU cooperation, through presentations in multinational frameworks such as the IEA's Working Party on Renewable Energy (REWP), explaining the Japan's efforts for promoting the use of biomass and the situation of cooperation within Asia.

(c) Japan is continuing the development of technology for cultivating resource crops for bio-fuel and low-cost cultivation techniques, and for producing ethanol from woody biomass, nonfood resources such as rice straw, and general resource crops at high efficiency.

- (d) Based on Japan's cooperation initiative in the East Asia Summit (EAS), the Asia Biomass Energy Research Core (ABERC) was established, the Asia Biomass Energy Cooperation Promotion Office was opened, bio-fuel seminars were held in Japan, and 500 researchers over a five-year period are to be given relevant trainings in Japan.

#### Future Outlook

- (a) In order to construct a system for sustainable use of biomass in Asia, spread of common knowledge and enlightenment for promoting the use biomass will be envisaged through the creation of a database and guidebooks with organized information of each country's situation, and baseline surveys will be conducted along with the cultivation of human resources for developing a biomass town concept. In addition, Japan plans to host, in Thailand, an international symposium on sustainable bio-fuel with the participation of policymakers from various Asian countries in February 2008.
- (b) Utilizing multinational frameworks such as the IEA, Japan will proactively explain about its efforts to promote biomass along with the status of progress regarding cooperation in Asia, while also continuing to share information and exchange opinions with various countries.
- (c) From a mid- to long-term perspective, Japan will pay consideration so that the steady supply of food and animal feed is not impacted while making concentrated efforts to develop efficient ethanol production technology that uses cellulose materials such as rice straw and thinned wood as well as resource crops.

Furthermore, Japan will commence efforts to develop super high yielding, low-cost crops by utilizing its past achievements from rice genome research.

- (d) Cooperation will be steadily made based on Japan's cooperation initiative in the framework of the EAS.

### 31. Existing regulatory frameworks of EU and Japanese central government on GMO crops (5-EJ-7)

#### BDRT recommendations

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

#### Efforts to Date

The long-term strategic guidelines “Innovation 25” adopted by the Cabinet in June 2007 clarify the necessity for campaign activities for public understanding on the production and consumption of GMO crops and foods.

In May 2007, the Ministry of Agriculture, Forestry and Fisheries established a conference on the advancement of R&D for GMO crops, and in December 2007 the conference compiled a list of areas that should be emphasized in advancing R&D, goals for each area, and a strategy for efficiently and effectively advancing R&D while analyzing of the current situation and issues surrounding R&D of GMO crops. In addition, since September 2007, two types of communication tables have commenced with the participation of more than a dozen or a few hundreds members of the general public, including farmers and consumers, along with experts. The communication tables are carried out for formatting of public understanding about GMO crops through the transmission of easily understandable information and dialogue between the public.

#### Future Outlook

The Ministry of Agriculture, Forestry and Fisheries will continue the R&D of GMO crops in a planned and efficient manner according to reports from “Innovation 25” and “the Conference on the Advancement of R&D for GMO crops”. The ministry will also conduct proactive communication activities in aim to increase public understanding.

## **Working Party 6: Sustainable Development**

### 32. Promoting the efficient use of energy (6-EJ-1)

#### **BDRT recommendations**

Industry has been a forerunner in energy-efficiency improvements because lowering energy costs is a prerequisite for competitiveness. In addition, industries in the EU and Japan have been developing energy-saving products. To decrease greenhouse gases (GHG), it is important to diffuse higher efficient equipment and products as well as fuel-efficient vehicles by using a front runner approach. This is based on the 3Rs (reduce, reuse, recycle) which minimize energy consumption of products through their total life cycle of procurement, usage and recycling. We therefore ask the Commission and the Japanese government to have their citizens utilise energy-efficient products and technologies.

#### **Efforts to Date**

Energy conservation standards for appliances are stipulated by the Top Runner Program based on the Energy Conservation Law, and relevant labeling system was introduced in 2000. The operation of uniform energy-saving labeling commenced in October 2006, displaying a stepwise evaluation and approximate annual electricity costs.

Furthermore, the Energy-Saving Appliances Popularization Forum was established in October 2007, by a tie-up between electronics manufacturers, retailers, and consumer groups, under the cooperation of the Ministry of Economy, Trade and Industry and the Ministry of the Environment. Regarding automobiles, vehicles with superior fuel consumption are given preferential treatment under automobile taxation systems that support environmentally friendly automobiles.

Moreover, assistance is also being provided for promoting the spread of facilities and appliances with high levels of energy-saving capabilities, such as highly-efficient water heaters.

#### **Future Outlook**

Japan will continue to widen the scope of energy conservation standards and strengthen target standard values, and is currently considering a further enhancement of the labelling system.

Furthermore, collaborations will be made with the Energy-Saving Appliances Popularization Forum in proactively spreading the use of energy-saving appliances as a national campaign. At the same time, Japan also plans to continue enforcing automobile taxation systems that support the greening of automobile tax and subsidy systems.

### 33. Promoting the removal of reliance on fossil fuels (6-EJ-2a, 6-EJ-2b)

#### BDRT recommendations

##### (1) The spread of existing technologies (6-EJ-2a)

From a mid-term point of view, it is indispensable to spread existing technologies such as nuclear energy and renewable energy so that they replace fossil fuels. This is necessary not only for low carbon emissions but also for energy security. Spreading the use of nuclear energy more than at present requires the restoration of trust and the establishment of a consensus by citizens from the aspect of safety. Additionally, in promoting renewable energy, such as solar, wind, and biomass energy, challenges exist regarding cost and stability. We therefore ask the authorities of the EU and Japan to establish a plan to promote these energies. However, the plan needs to be designed so that competition in energy markets is not distorted. And also in promoting biomass energy and bio-fuel, the supply of wood raw material for the industry as well as the food supply such as sugar and corn should not be affected.

##### (2) Development of innovative technologies (6-EJ-2b)

The development of innovative technologies such as clean coal, carbon dioxide capture and storage(CCS), hydrogen energy, nuclear fusion, and fuel cells required long-term efforts to reduce GHG. Developmental subsidies from governments as well as international public-private cooperation are also necessary.

#### Efforts to Date

##### (1) The spread of existing technologies (6-EJ-2a)

Japan believes that, in order to develop a sustainable economy, not only global environmental perspective but also perspective in terms of enhancing energy security is important. Japan is thus making aggressive efforts to spread nuclear power generation and renewable energy. Specifically, as for nuclear energy, Japan is taking measures to ensure safety as its major premise, while at the same time working for securing uranium resources, developing technologies, and cultivating human resources. In order to aggressively push the construction of nuclear power generation facilities and nuclear fuel cycle facilities, Japan provides support through close PR activities for facility locations as well as grant aid measures. Furthermore, in regards to new energy, Japan provides assistance in introducing cutting-edge energy facilities, aid for technological development of highly-efficient, low-cost solar batteries, and the development of manufacturing technologies for cellulose bio-fuel. In addition, Special Measures Law

on Use of New Energy, etc., by Electric Utilities (RPS Law) mandates the use of new energy by electrical power suppliers.

(2) Development of innovative technologies (6-EJ-2b)

“Cool Earth 50” proposes the long-term objective of halving GHG emissions across the globe by 2050. In order to achieve this sort of long-term objective, it is essential to develop innovative technologies that are not extensions of existing technology, such as zero emission coal power generation.

The Ministry of Economy, Trade and Industry is currently holding discussion in a council of experts to compile a Cool Earth - Innovative Energy Technology program in order to consider technical areas for focus and the ways of international partnerships. Furthermore, the FY2008 budget which was proposed by the Government, has secured a budget of 63 billion yen for the innovative technology sector, realizing a large budget increase.

With regard to international private-public partnerships, Japan provides cooperation for international technology development, including participation in FutureGen, GNEP, GIF, IPHE\*, etc.

In the fusion sector, Japan is leading the ITER Plan along with the EU, and is also implementing the “Broader Approach (BA) project”, which supplements and supports the ITER Plan, through cooperation with the EU. A fusion related FY2008 budget, proposed by the government, focusing on the ITER and BA projects has been secured for 10.3 billion yen, which is almost double the FY2007 budget.

\*As for FutureGen, Japan is currently considering a concrete form for its participation. Japan is participating in all other international frameworks.

### Future Outlook

(1) The spread of existing technologies (6-EJ-2a)

By continuing to advance the aforementioned efforts, Japan aims to “increase the ratio of nuclear energy on total generated energy to 30%-40%” in 2030, which is a numerical target from Japan’s New National Energy Strategy. In addition, by FY 2010 Japan aims to introduce new energy at the crude oil equivalent of 19.1 million kl, a numerical target established by the Kyoto Protocol Target Achievement Plan.

(2) Development of innovative technologies (6-EJ-2b)

The Cool Earth - Innovative Energy Technology program is planned to be completed within FY2007, towards the G8 Energy Ministerial Meeting (June 2008) and

G8 Summit (July 2008). In addition, the FY2009 budget request is planned to further emphasize the innovative technology development sector, which is a sector that requires focus. Japan will be actively involved in existing international partnerships while further promoting international cooperation in technology development.

Construction activities are planned to begin in earnest for the ITER Plan and BA project. Japan will procure equipment for which it is in charge in accordance with international commitments.

#### 34. Cap-and-trade emissions trading scheme (6-EJ-3)

##### BDRT recommendations

It is difficult to establish a fair and equitable cap-and-trade emissions trading scheme. Also, this approach forces industries to control their activities. It may also harm the development of technologies and the investments in facilities in the long term. Moreover, there is a risk that this approach will cause the acceleration of the transfer of emissions to developing countries, which are production bases for emissions, leading to an increase in GHG emissions on a global scale through carbon leakage. Therefore, a cap-and-trade emissions trading scheme is not suitable for establishment as an international framework.

##### Efforts to Date

Ministry of the Environment has launched Japan's voluntary emissions trading scheme since FY2005, and 150 companies are participating as of present. The first round, which started from FY2005, achieved an emissions reduction of 29% against the base year over all 31 companies that participated, surpassing their initial commitment of 21%.

The introduction of an emission trading scheme is under continued deliberation in a joint meeting of the Industrial Structure Council and Central Environmental Council, and its final report on evaluation and review of the Kyoto Protocol Target Achievement Plan noted that "This is an issue that should be comprehensively considered, including the evaluation of a concrete plan and appropriateness of its introduction, while also taking into account the considerable emission-reducing effects of enlarged and enhanced voluntary action plans including from the perspective of realizing Japan's mid-term global warming strategy."

##### Future Outlook

Regarding the domestic emissions trading scheme, Japan would like to consider comprehensively, focusing on a wide range of issues such as comparisons with other methods and their effects, impact on industry activities and the national economy, and international trends, including the evaluation of a concrete plan and appropriateness of its introduction, while also taking into account the considerable emission-reducing

effects of enlarged and enhanced voluntary action plans including from the perspective of realizing Japan's mid-term global warming strategy.

35. Creating environmental and energy-saving technologies in developing countries  
(6-EJ-4)

**BDRT recommendations**

To advance the reduction of GHG emissions on a global scale, it is critical to initiate measures in developing countries. Implementing energy-saving technologies in such countries that are expected to increase their use of energy, such as China and India, is an especially big challenge. Together with European and Japanese businesses providing technical cooperation to these countries, the governments should establish an environment that stimulates subsidy cooperation and private investments. Kyoto mechanisms such as the Clean Development Mechanism (CDM) should be actively promoted. However, systems that are more user-friendly should be implemented.

**Efforts to Date**

As a premise for expanding energy efficiency and conservation technologies into developing countries, it is vital to cultivate a foundation where countries can voluntarily make their own efforts for advancing energy conservation. At the Second East Asia Summit held in January 2007, Japan expressed that it would greatly increase the number of experts to be dispatched and researchers to be accepted, in order to promote the development of energy efficiency and conservation systems in developing countries, and the said measures are currently implemented in a wider scope. Forums have also been held on the energy conservation fields with China and India, where great participation was received from the business world as well. In addition, with the purpose of promoting the CDM in developing countries, Japan has provided support for host governments in developing the frameworks and conducted feasible studies for implementing potential projects over nearly 10 years. Furthermore, Japan proactively participates in international dialogue on improving the structure of the Kyoto mechanism.

**Future Outlook**

Japan will steadily dispatch experts and accept researchers as promised at the Second East Asia Summit, and provide support for developing countries in their efforts for promoting energy conservation through institution-building, human resource development, and improving awareness. Continued efforts will also be made to

overcome challenges in the business environment. Japan will also continue to assist in promoting CDM projects in developing countries, while also making efforts to continue reflecting its views in structural improvements to the Kyoto mechanism.

### 36. Promoting forestation (6-EJ-5)

#### BDRT recommendations

Forestation and plantation shall be promoted because forests provide a renewable carbon sink and sustainable raw material source not only for the industry but also for biomass energy and bio-fuel. The demand for wood raw material is increasing. A growing forest binds CO<sub>2</sub> effectively. With advanced forest management practices both output and stock of CO<sub>2</sub> in forests can be optimized by keeping the sustainable biodiversity in balance. Biomass based energy policies shall ensure that competition of wood raw material will not be realised through illegal logging or similar phenomena. For a sustainable use of forest raw material, policy measures are also required to ensure that the right fractions of forest raw material go to the most value adding use.

#### Efforts to Date

Based on the statutory Forest Planning System, Japan is conducting forest management in such an appropriate manner as through thinning of forests, regeneration of cleared areas or forestation, so that forests can continuously fulfill the function of absorbing carbon dioxide and sustainable production of wood materials. Domestically, there is no serious concern of excessive demand for wood materials, but rather a need for increase in demand. For that purpose, Japan promotes the various use of wood products in accordance with tree species and traits, while working to tap new demands such as the use as biomass energy resources. Furthermore, Japan maintains the level of forest management, in spite of insufficient demand for wood to generate the maintenance cost, by promoting the products made of thinned wood, so as to establish the sustainable use of forest resources. Japan does not put any restriction on how to utilize forest resources and let the market allocate them to those who value most.

#### Future Outlook

In order to ensure the 13 million tons of carbon absorbed by forests as prescribed by the Kyoto Protocol, Japan is promoting forest management and conservation. To this purpose, Japan is conducting nation-wide campaign involving the government and the private sector to promote forest management by various bodies and to expand the use of wood resources generated from thinning.

### 37. Post-Kyoto framework (6-EJ-6)

#### BDRT recommendations

The participation of major carbon-emitting countries such as the United States, China, and India is essential for the post-Kyoto framework. Also, it is essential that reduction targets be equitable and reflect the efforts by each country to improve its energy efficiency to date. Moreover, it is necessary to implement sound measures for developing countries, which are exempt from the Kyoto Protocol's emission requirements, through a policy mix that includes technological assistance. G8 initiatives and methods to reduce emissions studied by the Asia-Pacific Partnership (APP) should also be promoted. For the target period, short-term, medium-term, and long-term targets should be appropriately combined and a variety of approaches should be made considering the conditions of each country. Because absolute targets by country may restrict economic growth, use of the sectoral approach based on energy-efficiency targets in cooperation with the public and private sectors, shows promise. It must be noted that the sectoral approach requires a system that allows flexible responses based on the characteristics of target industries and countries.

#### Efforts to Date

Japan has asserted three principles of post Kyoto Protocol framework - "participation by all major emitters," "a flexible and diverse framework" and "harmonizing environmental preservation and economic growth" - at forums, including the Heiligendamm Summit and APEC. At the Ministerial Meeting for the Asia-Pacific Partnership (APP) on Clean Development and Climate held in October, the sectoral approach was proactively promoted as a joint declaration confirming the effectiveness of the APP approach adopted by the seven member countries, now with the participation of Canada. In response to these workings, it was agreed at COP13 held in Bali in December 2007, to newly create an Ad Hoc Working Group (AWG) under the UN framework convention, to adopt a post 2012 framework by 2009 after gaining a consensus, and to hold a first meeting of the AWG in March or April of 2008. In the joint declaration, the sectoral approach, which is an important factor emphasized by Japan, as well as long-term targets, reduction measures by both advanced and developing nations, the development of innovative technologies, and the transfer and spread of technologies were included as the issues which should be considered.

### Future Outlook

While utilizing opportunities such as the new forum (AWG) created after agreement was reached at COP13 and the G8 Hokkaido Toyako Summit to make constructive assertions regarding concrete discussion on long-term targets, reduction measures by both advanced and developing nations, the sectoral approach, the development of innovative technologies, and the transfer and spread of technologies, Japan will exercise leadership in international dialogue as the pivot among countries of diverse national circumstances.

(Appendix)

### Proposals relating to the Tax System

In the annual tax reform process, contents of the reform were decided based on requests and opinions submitted to the tax authorities by related ministries and agencies, taking into account various factors including economic circumstances, financial situation and discussions by the Government Tax Commission and the Tax Commission of the ruling parties. Related ministries and agencies refer to opinions from various levels, including proposals raised by the BDRT, when compiling their tax reform requests. These opinions have been reflected in past annual tax reforms.

Proposals relating to the tax system have been made for the following items in the recommendations from the 9<sup>th</sup> Japan-EU BDRT meeting.

- WP 1: Trade and Investment
- 9. Promoting foreign direct investment
- WP 2: Accounting and Taxation
- 12. Reforms the consolidated tax system
- 14. Response to new deviations arising between corporate accounting and tax practice
- 15. (1) Tax haven rules
- (2) Reduction of corporate tax rates

The GOJ will refer to these proposals when they seem appropriate, from the standpoint of improving the business environment.