

**(Tentative Translation)**

**Report from the Government of Japan**

**Concerning the Recommendations**

**from the EU-Japan Business Round Table (BRT)**

February 2011

Note: The content of this report is based on the situation as of December 31, 2010.

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## **Working Party A: Trade, Investment and Regulatory Cooperation**

### **1. Strengthening the EU-Japan Economic Relationship (A-EJ-1)**

#### **BRT Recommendation**

In the 2009 Annual Meeting of the BRT, Working Party A supported the joint statement adopted by the EU–Japan Summit in Prague on 8 May 2009 aiming notably for “*strengthening the integration of their economies with a view to better exploiting the full potential of their economic relationship*” and called upon the authorities to work towards this goal by focusing on issues that are of Japanese and European interest and create a win-win situation for both sides.

The Working Party recommends that both Authorities build ambitiously on this goal and start negotiations on a balanced and mutually beneficial bilateral agreement as soon as the EU and Japanese Authorities agree that the right conditions are met, in order to promote an ambitious expansion of trade and investment between the EU and Japan. Aiming for the removal of barriers to trade and investment, a broad range of trade issues should be addressed, including harmonisation of standards and certification procedures, mutual recognition of product certification and, when possible, and appropriate, the mutual acceptance of functionally equivalent regulations. It should also address areas such as competition rules, services, and procurement.

#### **Action taken so far**

Japan and the EU agreed to launch the Japan-EU joint High Level Group (JHLG) at the Japan-EU Summit in April 2010 for the purpose of identifying options for the comprehensive strengthening of all aspects of Japan-EU relations and defining the framework for implementing it. They also agreed that the JHLG would conduct a joint examination of the ways to comprehensively strengthen and integrate the Japan-EU relationship, and decide on any appropriate next steps at the Summit meeting in 2011. The JHLG has met three times, in July, October and December of 2010, and discussed the way to comprehensively strengthen Japan-EU relations. The leaders of both sides met in October and November 2010, and exchanged their views on issues of mutual interests. They took note of the progress of the JHLG and instructed the acceleration of the process of JHLG. As a result, both sides have tackled “a few specific non-tariff issues,” which started based on the agreement of the Japan-EU Summit in 2009, and came to a conclusion for these issues at the 3<sup>rd</sup> JHLG in December 2010. In addition, both sides have been engaging in consultations and dialogues to deepen their mutual understanding toward issues of interests for the other side including tariffs, non-tariff measures, trade in services and investment, and government procurement.

#### **Future outlook**

The JHLG will accelerate its work to finalize the consideration of the ways to comprehensively strengthen Japan-EU relations, so that both sides will be able to agree to launch a negotiation of a Japan-EU EPA at the occasion of the Japan-EU Summit, which is supposed to take place during the first half of 2011.

## 2. Support of WTO Doha Development Agenda for fight against protectionism (A-EJ-2)

### BRT Recommendation

Albeit the world economic outlook has improved significantly over the last six months, European and Japanese firms still face a difficult situation on world export and investment markets. World GDP is expected to increase by around 4% this year and world trade volumes by more than 5%, following a slump of 12.3% in 2009. Competition will be intense as the slow recovery in the developed world keeps global demand levels low. In addition, though the direst predictions of a protectionist wave in response to the crisis have not been realised, many governments have introduced significant new restrictions. Stimulus and stabilisation measures, though necessary, have hugely increased governments' involvement in economies. Behind-the-border regulatory barriers will therefore be of increasing importance. The BRT is very concerned that growing protectionism would prolong the crisis and hold back growth.

Given this background, the WTO must continue its proactive role in both preventing the closing of world-wide markets and the introduction of new restrictions on investments, market access and mobility for workers. Moreover, it should strengthen its stance by requesting WTO members to explain to the whole WTO membership the reasoning and compatibility of their measures with WTO law. This will mitigate the rising risk of protectionist measures and restore business confidence in the system by providing a concrete avenue to counter unhelpful protectionist tendencies. It is also critical that the WTO strongly counters any weakening of commitment to key WTO disciplines such as TRIPS.

The Working Party remains convinced that an ambitious and balanced Doha Round deal is the best way to deliver trade liberalisation for the world economy. The European Commission and the Government of Japan should align to exert their utmost efforts in concluding ambitious negotiations, by the end of this year, and including all major economies. Based on the current modalities of NAMA and other areas, specific sectoral agreements covering both non-tariff barriers and tariffs in non-agricultural goods (e.g. electrical and electronics, industrial machinery, etc.), in trade and environment (e.g. renewable energy, energy efficient goods, etc.) and in services should be part of an ambitious Doha outcome. Key emerging countries, in particular Brazil, India and China, will have to make contributions according to their economic and political weight, and should in addition to that show stronger commitment to participate in specific sector agreements. More serious engagement by the United States will also be necessary to drive the negotiations to a successful conclusion.

Considering the challenges of the Doha negotiations, the EU and Japan should consider parallel tracks for action within the WTO. Without undermining the single undertaking or suggesting an early harvest at this stage, the starting point for these could be existing elements of the negotiations which have wide support and could move forward before agreement on modalities, such as the trade facilitation package. An ambitious and binding Trade Facilitation Agreement would help significantly to facilitate trade for both developed and developing countries and to reduce costs for importers and exporters.

#### Action taken so far

World Trade Organization (WTO) continues the Doha Development Agenda (Doha Round negotiations) for establishing new rules and further liberalizing trade since its launch of the negotiation in 2001, as well as committing itself to resisting protectionism together with other organizations, when the world economy has not yet fully recovered from the financial and economic crisis.

The Government of Japan (GOJ) continues its commitments for the early conclusion of the Doha Round and resisting protectionism. In 2010, the GOJ demonstrated leadership, *inter alia*, in APEC MRT (Ministers Responsible for Trade) meeting (June) and AMM (APEC Ministerial Meeting) (November) as the host economy, which led to the conclusion of stand-alone statements on advancing DDA and resisting protectionism.

Regarding resisting protectionism, we reaffirmed the extension of our commitments to standstill including refraining from imposing new export restrictions, and issued a strong message for resisting protectionism. Furthermore, through utilizing DSB, TPRM and various sub-committees, the GOJ has made efforts to ensure transparency and prevent expansion of WTO-inconsistent and trade-restrictive measures including measures weakening the discipline of TRIPS Agreement.

With regard to the Doha Round negotiations, we increased political momentum for its early conclusion through several ministerial-level meetings, and we also held “brain-storming” in order to resolve remaining gaps. In the AMM, AELM (APEC Economic Leaders Meeting) in Yokohama and G20 in Seoul in November, the leaders and Ministers shared the view that we would accelerate the negotiations recognizing 2011 as a critically important “window of opportunity”.

NAMA negotiations, in addition to comprehensive tariff reduction on all NAMA products through application of the Swiss-formula, we promote a discussion of the sectoral tariff elimination initiatives. In order to further proceed the discussion, the GOJ has suggested the “Product-Basket-Approach” in the sectoral discussion, to pursue ambitious and acceptable for major traders by carefully taking into account sensitivity and export interest of each Member.

As for Trade Facilitation negotiations, discussions are ongoing with a view to enhancing transparency, predictability and impartiality, together with further simplifying and expediting trade procedures. In this context, Japan has been actively engaged in the negotiations in order to formulate effective rules in this area.

In the other negotiating areas such as Trade and Environment (liberalization of environmental goods, etc.) and Services, the GOJ will make further efforts in negotiating for single-undertaking of all those areas.

### Future outlook

With regard to resisting protectionism, the GOJ continues to make contribution in maintaining and strengthening monitoring system through WTO. For the Doha Round negotiations, beginning with the informal ministerial meeting hosted by Switzerland at the margin of Davos Forum, with the EU's trade commissioner, the GOJ will make efforts for proceeding the Ministerial-level process as well as accelerating the discussion for solving remaining issues among senior officials-level with an aim for the final conclusion of the negotiations.

3. Applying international standards and enhanced cooperation in the promotion of new global standards (A-EJ-3)

(1) Global patent system

#### BRT Recommendation

The Working Party recognises the importance of global patent harmonisation and streamlining of the patent system as a way to promote innovation, reduce costs and boost legal certainty. The authorities of the EU and Japan should take the lead in these efforts.

#### Action taken so far

As a result of the cooperation among industrialized countries including Japan and Europe, the WIPO Standing Committee on the Law of Patents (SCP) agreed at its 15th meeting to include substantive issues of interest to these countries such as "Quality of patents" to the future work, which is expected to move forward the substantive discussion.

In addition, with the aim of achieving not just patent system harmonization but also the mutual understanding of examination practices followed by patent offices, the GOJ has been working to expand the Patent Prosecution Highway (PPH). In January 2010, the GOJ launched a bilateral PPH pilot program with the European Patent Office, and a PPH based on PCT international work products involving the patent offices of Japan, the U.S., and Europe.

#### Future outlook

In addition to continuing to engage in dialog with users of the patent system, the GOJ will strive to move the discussion in the SCP forward through a review of the Quality of patents including aspects of substantive law.

Furthermore, the GOJ is working to expand the Patent Prosecution Highway (PPH) network by proposing that Korean Intellectual Property Office (KIPO) and State Intellectual Property Office of the P.R.C.(SIPO) participate in PPH pilot program utilizing PCT work products.

## (2) Control of counterfeiting and piracy

### BRT Recommendation

We also believe that the two authorities should step up efforts against global counterfeiting and piracy and cooperate closely to establish a new common international legal framework for IPR enforcement. In this regard, we support the ongoing negotiation of an international anti-counterfeiting trade agreement (ACTA) and urge the two authorities to exercise active leadership in order to reach agreement as soon as possible.

### Action taken so far

The GOJ has actively engaged in discussions with other participants that are highly concerned about the protection of intellectual property rights, toward the realization of the Anti-Counterfeiting Trade Agreement (ACTA). Participants resolved nearly all substantive issues in the 11<sup>th</sup> round of the negotiations held in Tokyo from September 23 to October 2. Participants then resolved the few issues that remained outstanding and finalized the text of the agreement. Japan and the EU, as well as the United States, Switzerland, Canada, South Korea, Mexico, Singapore, Australia, New Zealand, and Morocco, participated in the negotiations.

### Future outlook

The GOJ will continue to closely cooperate with other participants to bring the ACTA into effect as soon as possible.

### (3) Energy conservation, labelling rules, and carbon footprint schemes

#### BRT Recommendation

Given the nature of the issues and the importance for business as well as for society in general, the two governments should make an effort to harmonise the regulations for energy conservation, relevant labelling rules, and carbon footprint schemes.

#### Action taken so far

- The energy-saving labeling system introduced by the GOJ, which mainly focuses on household products, currently covers 18 items, with the addition of routers and switching units in June 2010.
- Furthermore, the GOJ has launched the labeling system for retailers. It stipulates that retailers provide information of appliances displayed at their shops with the use of 'Uniform Energy-Saving Label' which displays a multistage rating of the given product. Since the addition of household fluorescent light equipment in April 2010, 5 products are covered currently. The GOJ has also reviewed the multistage rating standard of TV in the same month.
- The Trial project of Carbon Footprint of Products (CFP) has been started since 2009 fiscal year in order to contribute to the realization of low-carbon society. Basic rules have been reviewed (for simplifying the procedure) and inventory database has been developed on the basis of problems identified as a result of the project in 2009: 1) necessity to arouse companies' engagement 2) consumers' needs.

#### Future outlook

- In addition to reviewing the multistage rating standard, the GOJ will continue to increase the number of products covered by the labeling scheme for manufacturers and the unified labels for retailers. The GOJ will also provide public service announcement to promote the recognition of labeling.
- Furthermore, the trial project are being promoted while the harmonization with international standards (e.g. ISO) and project transfer to private sector are considered. In addition, it is necessary to arouse companies' early participation in the application to appropriately manage the foreseen increase in the application in the last year of the project (2011).

#### (4) Customs Cooperation: Authorized Economic Operator (AEO)

##### BRT Recommendation

The authorities of the EU and Japan should introduce regulatory cooperation within the customs area through which, once an economic operator is approved as an AEO (Authorized Economic Operator) in Japan, its status should be recognised without additional formalities in the EU, and vice versa.

##### Action taken so far

The customs authorities of Japan and the EU have been developing cooperation based on the Agreement on Cooperation and Mutual Administrative Assistance in Customs Matters which entered into force in 2008. The framework of the Joint Customs Cooperation Committee which shall discuss the issues including any points of common interest regarding customs cooperation has been established. Under this framework, Japan and the EU have been enhancing cooperation on the security and facilitation of international trade and the enforcement of Intellectual Property Rights. In June 2010, Japan and the EU signed the decision regarding mutual recognition of Authorized Economic Operators programmes. This decision includes that each customs authority provides benefits to AEOs, being authorized as having established security controls and compliance programmes, in applying its risk assessment and security-related measures in a trade between Japan and the EU which AEOs are involved in.

##### Future outlook

The GOJ will continue consultations with the EU, aiming for implementation of the mutual recognition of AEO programmes by early 2011.

#### 4. Supporting timely development of business (A-EJ-4)

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

###### BRT Recommendation

The Working Party welcomes the fact that following the agreements between Japan and Belgium and France in 2007, the social security agreements between Japan and the Netherlands and Czech Republic have entered into effect, and those between Japan and Spain, Italy and Ireland, respectively, have been signed. Furthermore, negotiation is underway between Japan and Hungary, and is at preparatory stage between Japan and Luxembourg and Sweden, respectively. 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 contribution to pension funds unilaterally or should refund in full when expatriates return to a home country.

###### Action taken so far

(a) The GOJ is making every effort to conclude social security agreements with EU member countries. The GOJ has already concluded social security agreements with Germany, the UK, Belgium, France, the Netherlands, the Czech Republic, Spain and Ireland, and also signed a social security agreement with Italy, as a result. Furthermore, the GOJ is now forwarding government-level negotiations with Hungary and Luxembourg, and information and opinion exchanges between the authorities with Sweden, Slovakia and Austria, with the aim of concluding social security agreements.

(b) With regard to an interim measure, the GOJ has a measure in the Japanese pension system to provide benefit as a “lump-sum withdrawal payment” based on the contributions that foreign nationals have paid during their stay in case that they return to their countries after their short stay in Japan.

###### Future outlook

The GOJ intends to continuously proceed negotiations for the conclusion of social security agreements from high priority countries, with the consideration of the following points in a comprehensive manner: (i) the level of general social security contributions under the social security system in the other country, (ii) the amount of social security contributions of Japanese citizens and companies as well as other circumstances concerned in the other country, (iii) the existence of specific requests from Japanese business community, (iv) bilateral relationship, and (v) the discrepancy of each social security system between Japan and each EU member country.

## (2) Smoother and swifter movement of intra-corporate transferees (ICTs)

### BRT Recommendation

1) The Japanese and EU authorities should realise far-reaching liberalisation of the movement of intra-corporate transferees (ICTs). Such liberalisation could be achieved by the following systems:

- A framework agreement between the mother company, which sends expatriates, and the host country, stipulates the maximum number of expatriates. Within the agreed limit, the mother company is free to send ICTs to that country without further obtaining individual work permits.
- When the mother company concludes such an agreement with several Member States in which its subsidiaries or branches have operations, movement of ICTs between those countries should be free from obtaining a new work permit as long as the total number of the agreement is respected.

2) The Japanese and EU authorities should automatically grant spouses the same or similar rights as the holder of the entry permit upon their arrival.

### Action taken so far

The Government of Japan has amended the Immigration Control and Refugee Recognition Act in July 2009 (to be enforced on a date prescribed by a Cabinet order within a period not exceeding three years from the date of promulgation (July 15, 2009)), for the purpose of introducing a new residence management system which will contribute to equitable residence management of foreign nationals.

The amended Act includes provisions that allow re-entry within one year, without the need to apply for re-entry permission, to those foreign nationals who have valid passports and residence cards issued under the new residence management system. This measure will enhance the convenience of foreign nationals who legally reside in Japan.

### Future outlook

The GOJ will continue preparations for the enforcement of the amended Immigration Control and Refugee Recognition Act, which is aimed at introducing a new residence management system including provisions to revise the re-entry permit system.

### (3) Personal data protection regime

#### BRT Recommendation

The Working Party believes that the ultimate objective of personal data protection for individual business is to adopt and implement a reliable and cost-effective personal data protection system at a level of a corporate group, within which the flow of data should be free across national borders. In order to achieve this, the national legislation of each country should promote such a system rather than impede by creating different requirements.

To realize such business environment between the EU and Japan, the government of Japan should request the European Commission to launch the adequacy-finding procedure on the basis of Article 25(6) of Directive 95/46/EC.

In parallel with this procedure, the government of the EU and Japan should launch a dialogue in order to create an international framework which allows adoption and implementation of a reliable and cost-effective personal data protection system at the level of a corporate group, within which the flow of data should be free across national borders.

#### Action taken so far

In Japan, the Act on the Protection of Personal Information was passed in May 2003 and all its provisions came into effect in April 2005. Although it has been modified somewhat to reflect realities in Japan, the provisions concerning the obligations of entities handling personal information are based on the eight principles of the OECD guidelines issued in 1980. Enforcement authority of the act is entrusted to each minister in charge of the business sector concerned, and each minister conducts precise interpretation, application and appropriate enforcement based on guidelines set by respective minister. Until now, our efforts to safeguard personal information have been made following international initiatives by organisations such as the OECD, APEC, EU, ICDPPC, and APPA, and we partially revised our Basic Policy on the protection of personal information in April 2008 in order to respond to these international initiatives and better safeguard the rights and interests of consumers. And with regard to the guidelines for each business sector, new guidelines have been established and existing ones revised whenever necessary. Due to such efforts, personal information is effectively safeguarded. In addition, in March 2010, we published the report about Standard Contractual Clauses and Binding Rules for Companies based on Article 26 of Directive 95/46/EC (the EU's personal information protection directive) that would recognise exceptional cases in which personal information can be transferred to third countries that do not have the authorization of adequate levels of personal information protection yet.

#### Future outlook

We believe that personal information will continue to be safeguarded at an adequate level internationally by making efforts to secure the efficiency of the rules based on the Act on the Protection of Personal Information, our basic policy on the protection of personal information

(partially revised on April 25, 2008), and the guidelines set by each ministry. In addition, the Special Commission about Personal Data Protection in the Consumer Commission has been discussing the problem of personal data protection, which does not exclude the possibility of the review of the Act. We will take into account the discussion in the Commission to our policy for personal data protection.

## 5. Integrated Approach for CO2 reduction (A-EJ-5)

### BRT Recommendation

Both the EU and Japan are adopting challenging targets to reduce the level of 11 emissions. In addition to better engine performance, various measures including improvement of road systems and traffic flow, improvement of fuel quality, education of drivers toward eco-driving and fiscal incentives to encourage the purchase of more fuel efficient cars are important. An integrated approach which combines the efforts of all relevant parties involved, including the auto industry, the fuel sector, policy makers and drivers, to achieve the objective of CO2 reductions is the most balanced and realistic way to achieve this goal. Working Party A supports this approach.

### Action taken so far

The GOJ has taken measures to achieve the objective of CO2 reductions in the transport sector through several policies, such as promoting next generation vehicle, disseminating infrastructures such as battery rechargers, improving traffic flow through Intelligent Transport System (ITS), introducing biomass fuels, promoting eco-driving, improving logistics efficiency, and promoting use of public transport system and bicycles as well as improving vehicle fuel efficiency.

### Future outlook

Based on these ideas, the GOJ will advance various policies to reduce the CO2 emissions from the vehicles.

## 6. Better Regulation (A-EJ-6)

### BRT Recommendation

In reviewing existing regulations or establishing new ones, it is extremely important that the authorities consider the relevant regulations from the perspective of competitiveness of the economy and industry. Stakeholder Consultations and Impact Assessment should be duly implemented. Moreover, an Integrated Approach, the concept of appropriate burden sharing by the entire society, is important. The BRT supports the initiative of the European Commission for Better Regulation and urges the Government of Japan to adopt a similar approach.

### Action taken so far

To ensure an appropriate enforcement, each regulation has been reviewed by its supervisory authority with consideration of stakeholder's opinion.

Also, in order to investigate and deliberate existing regulations and systems, the Subcommittee on Regulatory and Institutional Reform was established under the Government Revitalization Unit in March 2010. It reviews existing regulations and systems from the perspective of promotion of new entry etc. and encourages each ministry to review the regulations.

In addition to this, each Administrative Organ was legally obligate to conduct ex-ante evaluation of regulations from October 1, 2007. In August 2007, the Ministry of Internal Affairs and Communications drew up the "Implementation Guidelines for ex-ante Evaluation of Regulations" that provides standard guidance for what kind of analysis should be conducted, what procedures are necessary and other related matters, in order to secure smooth and efficient implementation of ex-ante evaluation of regulations. Since then, the MIC has made efforts to establish the RIA system so that it will take steady effect.

### Future outlook

Each authority continues to ensure an appropriate enforcement of regulations. As for regulatory and institutional reform, the government will decide government policy by March 2011.

7. Harmonization of recognition of standards and product certifications; acceptance of international standards where applicable (A-J-1)

(1) Construction Products

**BRT Recommendation**

The GOJ should work together with the EU Authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials. Procedures for foreign testing institutes seeking accreditation under JAS/JIS should be streamlined. Mere reference to ISO standards within JAS/JIS, has proved not to be adequately helpful in facilitating the process.

**Action taken so far**

It is already possible for foreign institutes to be registered as Registered Overseas Certifying Bodies (JAS) or Foreign Accredited Certification Body (JIS) based on a review of the required documentation and an on-site inspection.

Moreover, registration is based on ISO/IEC Guide 65, an internationally recognized accreditation standard. In other words, we do believe that we are not imposing particularly complicated requirements for registration.

**Future outlook**

We intend to continue working to ensure that the operation of the accreditation system is appropriate, while explaining it to foreign institutes whenever the need arises.

## (2) Organic Products

### BRT Recommendation

The GOJ should work together with the EU authorities to achieve mutual recognition of Organic Food Products labelling. A level playing field for European organic products, including the removal of all redundant regulations, would be the most efficient way to ensure access of quality European organic products to the Japanese market. Japan would benefit enormously from recognising Europe's stringent organic certification standards, and accepting organic and related products from Europe without requiring additional certification or bureaucracy.

### Action taken so far

In June 2010, the EU recognised the organic JAS system as equivalent to the EU counterpart. As a result, the equivalence recognition of organic rules and standards between the EU and Japan became mutual. Both parties have been taking necessary measures to maintain the credibility of the organic products.

### Future outlook

The GOJ intends to closely cooperate with the EU to ensure the credibility of organic labeling.

### (3) Cosmetics

#### BRT Recommendation

European cosmetics firms find it continuously difficult to expand their business in Japan due to the difference in standards for ingredients and permitted efficacy claims between Japan and the EU and the Japan-specific product certification procedures for so-called quasi drugs. The Working Party calls for common regulations on the certification of medicated cosmetics, so-called quasi drugs (disclosure of approved ingredients, standard application times); common regulations on efficacy claims and advertisements; a common positive list of allowable ingredients in cosmetics; and establishment of joint standards for alternatives to animal testing.

#### Action taken so far

The GOJ has developed and published the positive list of active ingredients and additives for medicated cosmetics. Furthermore, the GOJ is discussing with industry to streamline review and approval process of medicated cosmetics.

With consideration of the request from industry, the GOJ consulted Committee on Cosmetics and Quasi-Drugs, Pharmaceutical Affairs and Food Safety Council in August 2010, to allow additional claims for cosmetics on wrinkles. The GOJ will proceed with expanding the scope of claims for cosmetics.

Alternative testing methods adopted by OECD have already been accepted in Japan.

#### Future outlook

To streamline review and approval process of medicated cosmetics, the GOJ will continue to consider developing the list of previously approved ingredients, the illustrations for application, and Q&A for review process.

With regard to claims on wrinkles for cosmetics, the GOJ is proceeding with public consultation, and based on the feedbacks, it will work to implement the revision.

Other alternative testing methods that OECD has not adopted yet will be considered accordingly through the activities of JaCVAM (Japanese Center for the Validation of Alternative Methods) if requested with appropriate data.

MHLW will enhance communication with industries for better mutual understanding.

#### (4) Railways

##### BRT Recommendation

The combined Japan Railways companies run on more than two-thirds of the railways, whereas the remaining one-third is controlled by more than 80 private carriers. This means that JR testing and acceptance standards serve as de-facto requirements for railway equipment to be exported to Japan. Though standards are not so different and data generated at European research facilities are relevant for Japan, duplicate testing in Japan is required for the Japanese market. Duplicate testing raises the costs of imports, making them less competitive than domestic products. The Government of Japan and the EU authorities should work toward establishing a mechanism through which test data and certification of railway equipment provided by European organisations is accepted in Japan, and vice versa.

##### Action taken so far

- (a) BRT's statement as "JR testing and acceptance standards serve as de-facto requirements for railway requirement to be exported to Japan", is concerning business affairs on a transaction among railway enterprises and exporters.  
Anyway, as railway safety standards have been developed based on each situation of transportation and trend of accidents in each country, measures to be taken to ensure conformity for safety standards are different between Japan and EU.
- (b) On the other side, governments of Japan and EU jointly held expert meetings on last February in Tokyo and on last October in Brussels, so as to deepen mutual understandings of both governments in the field of railway safety standards. Experts from such organizations as the Railway Bureau of the Ministry of Land, Infrastructure, Transport and Tourism in Japan (J-MLIT), DG-MOVE of EU Committee (former DG-TREN), European Railway Agency (ERA) and CEN-CENELEC attended these meetings and exchanged information concerning each situation of transportation, framework and difference in the field of railway safety standards, activities of standardization in both countries and so forth.

##### Future outlook

- (a) The GOJ and EU are going to provide an opportunity to deepen mutual understandings for such private sectors as railway enterprises and exporters around coming spring in Japan. (Refer to the comment in paragraph of A-J-4)
- (b) Both Governments are also going to hold the next expert meeting around coming spring in Japan, for further mutual understandings based on discussions in expert meetings held in 2010.
- (c) With regard to the field of standardization activity, Japanese Railway International Standards Center (J-RISC), established last year, mainly proceeds to implement such activities as annual exchange of information between Japan and EU including continuous JISC-CEN/CENELEC information exchange meeting, harmonization between JIS and ISO/IEC standards including testing methods through positive cooperation for development of international standards.

## (5) Medical Devices/Equipment

### BRT Recommendation

The EU's export of medical devices to Japan is limited by the costly and cumbersome approval process. Development costs for EU medical device producers are increased by requests for additional clinical trials from the Japanese authorities. Excessive Japanese standards and regulatory requirements result in a significant device lag. The pricing and reimbursement system creates disincentives for introducing new and innovative products on the Japanese market. The Working Party calls on the government of Japan to intensify the work to simplify and harmonise the regulatory processes in the field of Medical Devices with that of the EU. 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. Japan needs to reduce the time and costs associated with introducing innovative new treatments in the human healthcare market in Japan and to bring Japanese rules in line with global standards.

The Government of Japan is therefore urged to create a more efficient product approval process, in particular by:

- a) Shortening the medical equipment certification process: accepting clinical trial data generated overseas and harmonising Good Clinical Practice (GCP) and Quality Management System (QMS) requirements with international standards. The Working Party recommends that in the meantime, both authorities should officially recognise that either ISO 14155:2003 (and as subsequently amended) or Japan GCP is, in principle, generally acceptable to either party for all medical device clinical investigations and that, in principle, a QMS audit conducted by responsible authorities in Japan (PMDA or third party testing organisation) or by Notified Bodies in the EU is generally sufficient as evidence of compliance with quality management system requirements when applying for market authorisation on either market.
- b) Eliminating differences between Japanese GCP and the GCP established by the International Conference on Harmonisation.

### Action taken so far

Discussions have been held since 1992 on harmonizing regulations within the medical device sector by the Global Harmonization Task Force (GHTF), which is composed of the regulatory authorities of Japan, the EU, the United States, Australia, and Canada as well as the industrial sector. In the revised Pharmaceutical Affairs Law that came into force in 2005, regulations were introduced that conform to internationally harmonized regulations in terms of Essential Principles and classification of devices among others. In addition, on the occasion of settling on standards pertaining to Approval Standards, Certification Standards and Quality Management Systems, they are basically formulated in accordance with the international standards of the ISO and the IEC.

With regard to the acceptance of foreign clinical trial data, Japan has accepted foreign clinical data as

a part of application dossier 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.

For the purpose which reduces the burden by industry and promotes efficiency of inspection, MHLW has facilitated simplification of the documents required for QMS audit and mutual utilization for results of QMS audit among audit authorities. Furthermore, MHLW set up the working group including industries and is discussing in order to promote further improvement for QMS audit at the WG.

In particular, through the completion of a few specific non-tariff issues (called “Paragraph 34 process”), MHLW agreed that the Japanese QMS standard for medical devices is aligned with the international standard (ISO13485), which is applied in the EU, without additional requirements except for some exceptional requirements. Furthermore, MHLW lessens the burden on the medical devices industry, including that of the EU, by improving the operation of QMS audits at manufacturing site.

The GOJ is making efforts to clarify GCP operations through various notices and Q&A. And based on the Five-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices, it has been working on improvements of GCP operation. Then in April 2009, the ministerial ordinances relating to clinical trials were revised, in which the clinical review board, notification of clinical trials, the delivery of investigational devices and others are regulated, to make them consistent with the ICH-GCP. The GOJ therefore thinks that Japanese GCP is harmonized with ICH-GCP.

#### Future outlook

The GOJ will continue to seek to engage appropriately in forums, such as GHTF, to discuss the international harmonization of regulations for medical devices.

Regarding acceleration of medical device review, the GOJ publicized the Action Program for Acceleration of Medical Device Review in December 2008. The GOJ is making efforts to steadily implement the Action Program in cooperation with interested parties.

The GOJ encourages active use of consultation service on individual medical device applications in advance provided by the Pharmaceuticals and Medical Devices Agency (PMDA) to address use of foreign clinical trial data for application of the device.

MHLW will promote the action for mutual utilization for results of QMS audit based on discussion at WG in future, including that PMDA simplify the documents required for QMS audit when a site is confirmed by ISO13485 and submit the Certificate or QMS audit report.

The global harmonization of Medical Devices regulations requires discussions involving not just Japan and the EU, but also the U.S. and other countries. For this reason, we should aim to achieve international harmonization of Medical Device regulations relating to GCP, QMS etc. through the activities in the GHTF and others, which represents a multinational initiative.

## (6) Veterinary Products

### BRT Recommendation

- a) Urges the GOJ to take all measures available to speed up product approvals and fully harmonise domestic regulations with international practices.
- b) Requests Japan to work towards mutual recognition of European and Japanese marketing authorisations for veterinary products. This should start with mutual recognition of GMP certification for veterinary medicines. Harmonisation of regulations on animal vaccines, abandoning National Assays at the earliest opportunity and ensuring product conformance under a unified GMP regime, should also be addressed.

### Action taken so far

Japan has been actively participating in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and reducing duplications of animal tests used as application data, in order to accelerate the approval procedure of veterinary medicinal products. Japan newly enforced the two VICH guidelines in 2010. Japan also played a central role in jointly compiling various publications, preparing presentation materials and chairing sessions at the 4th VICH conference in June 2010, thereby contributing to promoting VICH.

The seed lot system has been implemented to veterinary biologics in Japan since 2008, which led to the approval of approximately 60 products. National Assays are entirely or partially exempted for those products based on the types of products and the past records on safety use.

Setting MRLs is essential in the approval process of veterinary medicinal products. Japan has been actively participating in the development of MRLs at Codex and applied some of them domestically. We believe that Japan's initiative contributes to accelerating the approval process of overseas veterinary products for food producing animals.

### Future outlook

International standards for the approval of veterinary medicinal products have not been established yet and substantial differences in the approval standards remain among Japan, the EU and the United States. It is essential to develop international standards of veterinary medicinal products by trilaterally cooperating among Japan, the EU and the United States which are the members of VICH. In particular, Japan and the EU should cooperate focusing on the standard setting on biological products, with the prospect of letting the United States accept biological products from overseas.

Japan wishes to import in-vitro veterinary diagnostics for infectious diseases from the EU to fill the shortage of such products in Japan. On the other hand, it takes us time to approve the products from the EU, because the efficacies and qualities of products marketed in the EU are not officially evaluated due to the lack of approval system for veterinary diagnostics in the EU. Japan recommends the EU to adopt the Japan's approval criteria and control system and implement them, in order to accelerate the approval procedure in Japan.

The priority issue on mutual recognition of veterinary medicinal products is for both sides to mutually understand the implementation of the approval systems and consider whether mutual recognition is feasible or not. Japan believes that it is a good start for both sides to explore a possibility of launching an exchange program of officials in charge of approving veterinary medicinal products between the EU and Japan.

We would like to conclude that it is inappropriate to prioritize the mutual recognition of GMP for the time being and recommend the EU to consider mutual cooperation after setting appropriate agendas.

## (7) Automobiles

### BRT Recommendation

- (a) The GOJ is therefore urged to accelerate its adoption of ECE Regulations to lower the cost of regulatory compliance for both European and Japanese automobile exporters by extending the benefits of mutual recognition.
- (b) To facilitate the more rapid introduction into the Japanese market of European automobile advanced safety devices, the GOJ should also adopt a more transparent procedure, and a prescribed timetable, for establishing new Technical Guidelines which take into account experience in the use of these device in the EU.

### Action taken so far

- (a) The GOJ has been proposing to amendment ECE Regulations which had not been adopted by Japan so that Japan can adopt them taking into account of Japanese traffic condition.
- (b) To facilitate the more rapid introduction into the Japanese market of European automobile advanced safety devices, the GOJ should also adopt a more transparent procedure, and a prescribed timetable, for establishing new Technical Guidelines which take into account experience in the use of these device in the EU..

### Future outlook

- (a) The GOJ will continue actively proposing amendment of ECE Regulations with a view to accelerating their adoption.
- (b) Based on the above agreement, the GOJ continues to work for prescribing the details of the procedure for drafting and revising the Technical Guidelines with stakeholders.

## (8) Processed Food

### BRT Recommendation

For processed food, the combination of differences between EU and Japanese standards and technical requirements as well as cumbersome border procedures results in high costs for EU exporters. The limited number of permitted food additives in Japan and unaligned standards between the EU and Japan increases costs and prevents EU exporters from utilising scale effects. High conformity costs are incurred because Japanese authorities do not accept evaluations made by the EU or international bodies. The market potential for European exporters would be greatly enhanced by:

(a) Harmonising Japanese regulations with international standards with respect to re-dating, labelling and nutritional standards

(b) Substantially increasing the list of permitted additives, in addition to speeding up the approval process

(c) Introducing mutual recognition of conformity assessment procedures to eliminate the duplicate costs of evaluations.

### Action taken so far

(a)

Regarding the Japanese food labelling systems covering “use-by-date” labelling and nutrition labelling, “date of manufacture” labelling was amended to “use-by date” labelling in 1995. This modification was undertaken to harmonize Japanese systems with international standards including General Standard for Prepackaged Foods: CODEX STAN 1-1985. As this example shows, we believe that the Japanese food labelling system is standardized based on the international rules and in line with international standards.

(b)&(c)

In Japan, food additives are permitted for use only when they are designated by the Minister of Health, Labour and Welfare (MHLW) under the Food Sanitation Law as substances that are unlikely to pose a risk to people’s health. Moreover, the Food Safety Basic Law stipulates to consult with the Food Safety Commission (FSC) when the MHLW approves the use of a new substance as a food additive. The GOJ understands that a similar system is employed in the EU when dealing with the authorization for food additives.

With regard to the 100 food additives (including 54 flavorings), including ones raised by the EU, whose safety has been confirmed internationally and are widely used, the GOJ, on its own initiative, is proceeding with the considerations on the designation of these items.

Among them, 18 food additives (including 14 flavorings) were newly designated as food additives in 2010, and as a result a total of 65 food additives (including 34 flavorings) have already been approved for use in Japan. The MHLW makes utmost effort to streamline the authorization process for food additives to make it faster and more efficiently by shortening the period of time for the

discussion starts at the council after risk assessment, and communicates with the FSC even prior to the request of risk assessment.

#### Future outlook

( a)

We will continue operating the systems, while ensuring the consistency with international standards.

( b)&(c)

For further progress of the coming designation for the remaining food additives, the MHLW will continue to prepare the necessary documents so that it can submit all the data to the FSC to conduct health effect assessment of food. The MHLW will also promote its effort to lead deliberation in the Pharmaceutical Affairs and Food Sanitation Council to reach a result as quickly as possible. With regards to the 100 substances of which the Government of Japan, on its own initiative, is examining possibility of designation, the GOJ listed them in 2002 after conducting hearings of foreign countries including EU and the list is corresponding to the substances (1) which the JECFA had confirmed their international safety and (2) which were widely used as food additives in the U.S., EU member countries. We believe that it will cover almost all substances which are considered to be in great need internationally once those will have been approved. With regard to substances that do not meet criteria of (1) and (2), i.e. substances which have been evaluated by the JECFA since 2002, or substances newly approved for use in the EU, the U.S. and other countries since 2002, the GOJ will carry on its authorization process according to requests from enterprising bodies as is the case with the process in EU, U.S. and other countries.

## (9) Labelling rules

### BRT Recommendation

The Household Product Quality Law and accompanying voluntary labelling guidelines, “hyojikitei”, prescribe in extreme detail how household products should be labelled when sold in Japan. The GOJ should issue clarifying orders to provide retailers with flexible alternatives for providing Japanese consumers with globally sourced products while taking full responsibility for the quality and safety of the products. A simple example of an inflexible labelling rule that has substantial labelling cost implications for European companies is that the dimensions of furniture must be expressed in millimetres and not centimetres, although use of the latter is common practice in other countries using the metric system.

### Action taken so far

The labelling rules prescribed in the Household Goods Quality Labeling Act currently cover a total of 90 goods in the following categories: Textile Goods, Electrical Appliances, Plastic Manufactured Goods, and Miscellaneous Manufactured Goods. The rules stipulate the minimum information which must be carried on labels to provide useful information to consumers, and also demand compliance with these minimum requirements. In 1997 labeling methods for all goods were revised to provide more flexibility in terms of the fonts used and the method of presentation of guidelines concerning use. And later, in 2010, we are researching to consumer and business operator which the overseas Japanese juridical person included about their evaluation to the Household Goods Quality Labeling Act and labelling system in other countries.

### Future outlook

As background of growing importance of consumer protection as well as diversification, complexity and globalization of products, the importance of the Household Goods Quality Labeling Act is also increasing. Therefore, with reference to the 2010 survey results we will review the content of labeling required etc. whenever it is necessary to do so. We will also continue to facilitate understanding of the Household Goods Quality Labeling Act among business operators including overseas business operators by publishing information on the web and other media.

## 8.Ensuring free and open competition in services (A-J-2)

### (1) The initiated reforms of firewall restrictions

#### BRT Recommendation

The Working Party urges the Government of Japan to tackle the lack of free and open competition in Japan's services markets.

Remove obstacles to integrating the operations of financial groups. In particular, the initiated reforms of firewall restrictions should be implemented fully to allow financial groups to structure their organisations in Japan in the same way as they do in the rest of the world.

#### Action taken so far

In June 2008 the Financial Instruments and Exchange Act was partially revised and then the relevant Cabinet Orders and Cabinet Office Ordinances, etc. were also amended. As a result of these changes, which took effect on June 1, 2009, financial institutions and financial groups are required to establish systems for managing conflicts of interest while banks etc. that are part of financial groups are prohibited from abusing their dominant position in soliciting business. In addition, the rules which prohibited directors and employees from holding multiple posts within a financial group have been abolished, while restrictions on sharing non-public information on customers within a group have been eased.

Revisions to guidelines for supervision of financial institutions (i.e. financial instruments business operators; major banks; small, medium-sized and regional financial institutions; and insurance companies) also came into effect the same day. These revisions include points to keep in mind concerning supervision related to firewall restrictions.

#### Future outlook

The Financial Services Agency (FSA) will continue to monitor each financial institution's efforts toward enhancing convenience for customers and establishing systems for managing conflicts of interest.

## (2) Japan Post

### BRT Recommendation

Regardless of the direction the GOJ decides to take on postal reform, Japan has a duty to abide by its WTO obligations, including the national treatment provision of the General Agreement on Trade in Services, or GATS. This means establishing equivalent conditions of competition between the Japan Post entities and EU and other private delivery companies, banking, and insurance companies. Specifically,

- a. 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 expansion of Japan Post's services, including the introduction of new products as well as caps on postal life insurance, until competitive safeguards have been established to prevent cross-subsidies from its existing dominant position. It is also imperative that Japan Post remains under the jurisdiction of the Financial Services Agency (FSA). The above requests are well within the realm of the Government Procurement Agreement (GPA).
- b. Japan Post and private postal delivery operators should be subject to the same customs procedures and formalities. A level playing field for both Japan Post and private postal operators should be ensured in the requirements for dedicated airway bills, obligatory customs, quarantine and security clearance and the funding of these services, as well as in the issuance of parking tickets of delivery vehicle parking infringements.

### Action taken so far

With regard to postal reform in Japan, the relevant bills, which were submitted to the last Diet session, have been carried over to the next session. The bills provide, as one of the basic policies, that when implementing the measures on postal services, consideration shall be given to equitable conditions of competition between Japan Post Group and operators offering similar services.

The *kyosai* cooperative societies are mutual-aid organisations established by people in the same geographical area or field of work. The members invest their own capital and use the insurance services that the organisation provides. These services form part of a broad range of mutual-aid services available to the members (joint ventures, loans, welfare services, etc.). Because of their unique nature they need to be regulated separately, and each of them operates within the scope of the law and under the supervision of the relevant government authority. It would therefore be inappropriate to apply the Insurance Business Act, which governs private-sector insurance companies, to *kyosai* cooperative societies.

### Future outlook

The bills for postal reform have been carried over to the next Diet session.

## 9. Promoting foreign direct investment (A-J-3)

### (1) Tax deferrals for capital gains

#### BRT Recommendation

The GOJ should create a business environment that will foster investment 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 consider allowing tax deferrals for capital gains stemming from direct cross-border mergers and re-organisations. 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.

#### Action taken so far

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

#### Future outlook

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

## (2) Revision of Article 821 of the Companies Act

### BRT Recommendation

In this context, the Working Party calls on the GOJ to use all means available, including revision of Article 821 of the Companies Act, to ensure legal certainty for foreign companies established as branches in Japan.

### Action taken so far

Article 821 of the Companies Act makes regulations concerning pseudo-foreign companies, which have existed for many years in the old Commercial Code, advantageous to foreign companies (see Article 482 of the old Commercial Code). It is therefore unreasonable to suggest that Article 821 of the Companies Act has tightened restrictions on pseudo-foreign companies.

Although the GOJ has been monitoring the impact of Article 821 of the Companies Act in accordance with an additional resolution by the House of Councillors Committee on Judicial Affairs concerning the bill for the Companies Act, at the time of writing the GOJ has not received any complaints concerning specific instances in which a company has been put at a disadvantage due to Article 821 of the Companies Act, and therefore have no particular plans to revise it.

### Future outlook

As stated above, at the time of writing the GOJ has not received any complaints concerning specific instances in which a company has been put at a disadvantage due to Article 821 of the Companies Act, and therefore have no particular plans to revise it.

### (3) Financial services: Mutual acceptance of home regulator

#### BRT Recommendation

Mutual acceptance of principles governing the financial services industry and the mutual acceptance of the home regulator as the core regulator would go a long way to improving the investment environment in the financial sector.

#### Action taken so far

To respond to acceleration in globalization of financial transactions, it is important to pay attention to international harmonization of regulations and supervision, and to grasp global market situations. Thus, we aim at strengthening cooperation with foreign authorities, as one of the concrete plans of “Better Regulation” (improving the quality of financial regulation in order to bring about a better regulatory environment), which the Financial Services Agency(FSA) sees as an overarching theme for the institution’s work.

In such situation, FSA works on cooperation with foreign authorities proactively by frequent information exchange and active discussions of the business conditions of financial institutions in each country through organizing consultations among supervisory authorities.

Furthermore, “Supervisory Guidelines”, which establish supervisory viewpoints, methods and actions, clarify the policies of cooperation with foreign authorities for supervision of internationally active financial institutions.

#### Future outlook

Based on Better Regulation and Supervisory Guidelines, FSA will be continuously engaged in cooperation with foreign authorities by exchanging information and opinions with them.

## 10. Government procurement (A-J-4)

### BRT Recommendation

The Government of Japan should increase its effort to facilitate better access to the public procurement market in Japan. Studies have shown that over 80%(\*) of the total government procurement market in Japan is not covered by GPA (The Agreement on Government Procurement).<sup>1</sup> One way to combat this could be to lower the threshold for public tenders. Currently some sectors are exempted from the threshold of 5 million SDR (special drawing rights). Another example would be to better define the “operational safety clause” within the transport sector. The Working Party furthermore requests Japan to set up a single access point to fully cover all tenders, as well facilitate the use of e-procurement.

(1) To lower the threshold for public tender & (3) To set up a single access point and facilitate the use of e-procurement

### Action taken so far

Issues of government procurement, such as a single access point or e-procurement, have been discussed in the framework of Japan-EU Joint High Level Group (JHLG) set up in 2010. It is worth mentioning that electronic bidding system for goods and services has been already introduced and operated in each Ministry.

### Future outlook

Japan continues to discuss the related issues on various occasions with EU and consider necessary measures.

The GOJ's note: The GOJ does not agree on this figure(\*).

(2) Operational safety clauset

### Action taken so far

The GOJ considers that the safety clause applies to the following clear five categories.

1) Supplies forming railway facilities; 2) rolling stocks and supplies for rolling stocks; 3) supplies for maintenance; 4) construction, reformation and repair of railway facilities themselves; 5) Construction, reformation and repair works which are carried out right above or right below the railway tracks;

Japanese railway operators which are covered by the WTO/GPA make procurement to which the safety clause applies without distinction between domestic and foreign companies and there are results of procurement from foreign companies.

Concerning this issue, the governments of Japan and EU held railway experts' meetings to exchange opinions and increase mutual understandings. The governments held the meeting in this February in Tokyo and in this October in Brussels to exchange opinions constructively.

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<sup>1</sup> Copenhagen Economics, “Assessment of barriers to trade and investment between the EU and Japan”, 2009

#### Future outlook

The GOJ offered a proposal to hold a meeting of railway private sector to exchange opinions and support EU manufactures' business efforts in parallel with a government experts' meeting. The GOJ hopes that Japanese operators and EU manufacturers will increase mutual understandings through the constructive meeting with active participation of EU manufacturers and the meeting will lead to the development of Japanese and EU railway industry.

## 11. Promoting EU-Japan cooperation in aeronautics, space and defence (A-J-5)

### (1) EU-Japan cooperation in commercial aircraft development

#### BRT Recommendation

The Japanese Government should promote fair competition by providing similar support to European – Japan cooperation programmes in the field of commercial aircraft development as is currently given to the cooperation between Japanese manufacturing and their U.S. counterparts. European companies can offer technology, know-how, and production and management techniques that can benefit Japanese manufacturing companies and capitalise on their strengths, for the benefit of both Japan and the EU.

#### Action taken so far

(a) In June 2005 the Society of Japanese Aerospace Companies (SJAC) and GIFAS, the French aerospace industries association, agreed to conduct joint research on the development of a supersonic passenger aircraft (supersonic transport: SST). Later, in July 2008, they agreed to extend the project for another three years. From the Japanese side, the Japan Aircraft Development Corporation (JADC), the Engineering Research Association for Supersonic Transport Propulsion Systems (ESPR), and the Japan Aerospace Exploration Agency (JAXA) are participating in the project, while on the French side, EADS, Snecma, and ONERA, the French national aerospace research centre, are involved.

(b) In July 2006 the Research Center of Advanced Metals and Composites (RIMCOF), which plays a central role in developing basic materials-related technology for the Ministry of Economy, Trade and Industry, and Airbus, agreed to conduct joint research on structural health monitoring (SHM) of aircraft. The project was scheduled to last until 2010, and testing aimed at putting the technology to practical use is currently underway. They agreed to extend the joint research for another two years and the project is scheduled to be continued until 2012.

(c) In December 2008, to promote the use of innovative Japanese technology in aircraft, we organized a workshop with Airbus involving companies etc. with innovative technology. Since then some of the Japanese companies have been negotiating with Airbus on a one-to-one basis with a view to working together on specific projects in the future.

(d) On November 17, 2009 we held a workshop aimed at promoting collaborative research and technical cooperation between Europe and Japan in the aerospace industry.

(e) Japan Aero Engines Corporation (JAEC), Rolls Royce, Germany's MTU, and other firms established a consortium called International Aero Engines to develop and manufacture the V2500 aircraft engine. Japanese companies have also been involved in Rolls Royce's Trent 1000 aircraft engine project, working on development jointly with Rolls Royce.

(f) 21 Japanese companies were involved in the development of the A380, Airbus's super jumbo jet.

#### Future outlook

We welcome the fact that cooperation between Japanese and European companies has been expanding steadily in recent years, and hope that such collaborations will develop further in the future. The Government of Japan also intends to continue to assist in forging ties between the

Japanese aircraft industry and those of other countries, including Europe.

## (2) Purchase of aircraft for official government use from European company

### BRT Recommendation

The Japanese government should set a positive example to the private sector of the advantages of sourcing from more than one aircraft manufacturer by buying aircraft for official government use from a European supplier.

### Action taken so far

Assuming “aircraft for official government use” refers to the government jet, Japan’s current government jet is a B-747-400 that was ordered in 1987 and delivered in 1991. The decision to purchase this aircraft was made after a multi-faceted study that considered flight range, carrying capacity, after-sales support, and so on.

However, the government’s passenger helicopter, which is used to transport persons such as foreign dignitaries, was purchased from a European company.

### Future outlook

The GOJ does not operate on the principle of purchasing government aircraft from specific countries or regions. The Government of Japan also has no current plans to purchase any new “aircraft for official government use”. In light of factors such as our challenging fiscal situation, we intend to use our current jet as effectively and for as long as we possibly can.

### (3) EU-Japan Joint development programmes in aerospace and defence industry

#### BRT Recommendation

Similarly, the Japanese aerospace and defence industry is at times reluctant to work with European companies, due to the long-standing relationship with North American companies, and limited awareness of the European aerospace sector. European aerospace and defence companies are ready to consider joint development of new products and willing, within such programmes, to transfer to the Japanese aerospace and defence companies advanced technology and know-how. The improved capacity and global competitiveness of the Japanese industry following such cooperation should be increasingly important, given the acute need to cut procurement costs and the current discussion in Japan of a re-interpretation of the current very strict export ban. Cooperation with Europe will also allow final Japanese users of equipment such as fighter aircraft to directly manage configuration control, not possible through the “black box approach” employed by current suppliers. Improvement of indigenous capacity in areas, such as on-board avionics and electronics, which constitute a substantial portion of all commercial and military aerospace programmes, can also be envisaged for the Japanese electronics industry.

#### Action taken so far

European Space Agency (ESA) and Japan Aerospace Exploration Agency (JAXA) have been promoting cooperation in development of the Earth Clouds, Aerosols and Radiation Explorer/The Cloud Profiling Radar (EarthCARE/CPR). And the Ministry of Economy Trade and Industry (METI) has just started seeking the possibility of cooperation on hyper spectral sensor with Deutsches Zentrum für Luft-und Raumfahrt (DLR), because both DLR and METI are individually developing similar hyper spectral sensors in terms of specifications and schedule.

#### Future outlook

Regarding avionics and electronic devices of commercial aircrafts, the cooperation between the Japanese flight equipment industry and those of other countries is important from the viewpoint of the improvement of Japanese companies’ technological capability and competitiveness. The Government of Japan also intends to continue to assist in forging ties between the Japanese aircraft industry and those of other countries, including Europe.

#### (4) EU-Japan cooperation in space

##### BRT Recommendation

EU-Japan cooperation in space also runs far below its potential, ignoring large potential benefits for both sides. This is in large part due to the absence of a unified Space jurisdiction across the ministries and agencies. Japan, however, recently established a new organisation to remedy this deficiency, and the State Minister in charge of Space Development is currently establishing a unified Space policy. Taking advantage of this new context, Japan's authorities should implement the mutual backup of European and Japanese heavy-lift space launchers for government / institutional launch missions that they have been studying since its feasibility and benefits were established by a bilateral working group in 2003. Bilateral cooperation on government satellite projects should also be encouraged. Finally, Japan's international procurement of space ground equipment should not exclude whole systems.

##### Action taken so far

In Japan, production and launch of the H-IIA launch vehicle was shifted from Japan Aerospace Exploration Agency (JAXA) to Mitsubishi Heavy Industries, Ltd. (MHI) in 2007, thus the mutual backup of European and Japanese heavy-lift space vehicles has been promoted at private-sector level.

##### Future outlook

## **Working Party B: Life Sciences and Biotechnologies, Healthcare and Well-being**

### 12. Cooperation towards the COP10 for CBD in Oct 2010 (B-EJ-1)

#### **BRT Recommendation**

Towards the COP10 for “Convention on Biological Diversity (CBD)” to be held in Nagoya in October 2010, EU and Japan should work together so that the international regime on CBD, especially on “Access and Benefit Sharing (ABS), can accelerate R&D and innovation to soundly develop the bioindustries, which will produce a useful products that bring social benefits, as well as secure access to those products.

#### **Action taken so far**

Japan, as the President of the CBD-COP10 and COP-MOP5, exercised leadership to adopt the "Aichi Target" (New Strategic Plan 2011-2020), Nagoya-Kuala Lumpur Supplementary Protocol on Liability and Redress to the Cartagena Protocol on Biosafety and the Nagoya Protocol on access to genetic resources and benefit sharing (ABS) under the close cooperation with EU at the CBD-COP10 and COP-MOP5 held in Nagoya in October 2010. The Nagoya Protocol on ABS provides for transparency, clarity and legal certainty of ABS domestic legislation or regulatory requirements ensured by provider countries. The Nagoya Protocol is expected to facilitate access to genetic resources, thereby promoting the utilization of genetic resources.

#### **Future outlook**

The GOJ, in close collaboration with EU, will steadily implement major outcomes of COP10 and COP-MOP5 (the “Aichi Biodiversity Targets”, Nagoya-Kuala Lumpur Supplementary Protocol and the Nagoya Protocol on ABS).

### 13. Enhancement of bioventure activities (B-EJ-2)

#### BRT Recommendation

In both the EU and Japan, bio-venture activities should be enhanced further and dynamically integrated with each other. BRT members call for government support to expand these networks of activities through such measures as bio-conferences or the establishment of cluster centres.

#### Action taken so far

The GOJ is implementing various measures, as mentioned below, to support biotech start-ups in order to realize both healthcare innovation and economic growth, based on the New Growth Strategy, which we published in June this year.

- Japan External Trade Organization (JETRO) supported Japanese biotech start-ups to attend conferences, such as BIO-Europe Partnering Conference, where start-ups could have a close business networking with overseas firms and business clusters.
- METI dispatched a mission group in order to further seek the possibility of cooperating with overseas clusters.
- METI, in collaboration with JETRO, had a business networking event in BioJapan2010, aimed at expanding the network between Japanese and overseas companies including European firms and clusters.

#### Future outlook

We believe that such networking with overseas is critical to invigorate Japanese biotech industry and will eagerly promote business networking through BioJapan , BIO-Europe and other chances.

#### 14. Regulatory harmonization and MRA for pharmaceuticals (B-EJ-3)

##### BRT Recommendation

Proceed regulatory harmonization and further extension of “Mutual Recognition Agreement” in order to avoid redundant inspections of manufacturing facilities (delay of new drug launches)

##### *<Background>*

*As currently only oral forms are included within the MRA between Japan and the EU, there are still a lot of redundant inspections of manufacturing facilities. This is not only a costly process, but it also slows down the launching of new drugs in Japan creating a significant disadvantage for Japanese patients.*

*In order to eliminate this problem and to integrate EU-Japan economics more efficiently, harmonization of standards/guidelines and expansion of MRA should be conducted under mutual agreements. Followings are highly prioritized items for harmonization and expansion of MRA.*

##### Harmonization:

- *Safety measures from surveillance to vigilance should be harmonized with international standards*
- *Clinical development guideline and biological preparation standards for Vaccine*
- *Minimum Requirements for Biological Products*

##### Mutual Recognition Agreement:

- *MRA of GMP should expand to non-solid preparations to avoid redundant inspections and testing*

##### Action taken so far

Regarding to safety measures of pharmaceuticals, we have been proceeding harmonisation with the international standard, which was developed by International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as a guideline "Post-approval Safety Data Management:Definitions and Standards for Expedited Reporting"

Guidelines for clinical development of vaccines are published, after input from industry including The European Federation of Pharmaceutical Industries and Associations (EFPIA).

Consideration on the revision of the MRBP is now undertaken by an expert group together with experts from industry including EFPIA.

With Regard to Japan-EC MRA of GMP, MHLW started discussion with European Medicines Agency (EMA) for the progress for MRA.

##### Future outlook

The consideration on the revision of the MRBP is to be continued with industry’s views (including those of EFPIA) taken into account as necessary.

MHLW continue discussion with EMA in the future to consider towards expansion of the operational scope of the MRA.

15. Balance between prevention and treatment in healthcare (B-EJ-4)

**BRT Recommendation**

Seek balance between prevention and treatment. Thus, include vaccination/ programs in scope for public funding

*<Background>*

*Disease prevention and diagnostic/ screening procedures are getting a more important position in healthcare area as they allow to improve the treatment of numerous diseases but also to effectively lower the healthcare cost in mid- and long-term. Therefore, vaccine should be in scope for public funding.*

**Action taken so far**

As for routine vaccination\* under Preventive Vaccination Act, almost all the local municipalities implement vaccination for free. The municipalities share financial burden by adding tax money allocated to local municipalities from Government of Japan.

\*BCG, Polio, DTP, Measles, Japanese Encephalitis , Rubella, Influenza

As for humanpapilloma virus(HPV) vaccine, Hib (*Haemophilus influenzae* type b) vaccine and pneumococcal conjugate vaccine for childhood immunization which are not designated under Preventive Vaccination Act, we have just established the foundation to promote the efforts of local municipalities to implement the vaccinations of these three vaccines, based on the recommendations from vaccination subcommittee of Health sciences council. The money for the foundation is covered by supplementary budget that was passed in the 176<sup>th</sup> extraordinary Diet.

**Future outlook**

At vaccination sub-committee of Health Sciences council, we have discussed issues such as legal positioning of diseases and vaccines which are not covered by Preventive Vaccination Act, including three vaccines (human papillomavirus vaccine, Hib(*Haemophilus influenzae* type b), pneumococcal conjugate vaccine for childhood immunization) financed by this supplementary budget.

Though there are many tasks such as securing financial resources permanently and the burden sharing between The GOJ and local municipalities, we will deepen discussions at vaccination subcommittee and carry out necessary considerations.

## 16.Measures against counterfeit products (B-EJ-5)

### BRT Recommendation

Formulate concrete actions against counterfeit products

<Background>

*Counterfeit products do not only represent significant dangers to the consumers but also harm innovative companies.*

*With EU and Japan together representing over 600 Mio consumers, both governments have be world leaders in the fight against counterfeits in order to protect their population as well as their industries.*

### Action taken so far

Nothing in particular.

### Future outlook

Nothing in particular.

## 17. Regulatory harmonization for animal health products (B-EJ-6)

### BRT Recommendation

Further harmonization and streamlining of regulatory requirements for product registration of animal health products

#### <Background>

*While such global new veterinary medicinal products go through rigorous review process in Europe and the USA prior to registration, it requires additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Regulatory requirements for an innovative veterinary medicinal product based on biotechnology are especially stringent in Japan, and therefore, a product which is readily available to veterinarians and animal owners in Europe cannot be used in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products. An additional important aspect is the negative impact on animal welfare: since the regulatory requirements are not harmonized, the companies are required to repeat tests on animals in Japan, even though results of identical tests are already available and are fully compliant with stringent frameworks like GLP or VICH.*

### Action taken so far

Refer to the response to A-J-1 above.

### Future outlook

Refer to the response to A-J-1 above.

18. Mutual recognition of GMP and marketing authorization for animal health products (B-EJ-7)

**BRT Recommendation**

Mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products

*<Background>*

*While the studies conducted under Good Laboratory Practice or Good Clinical Practice are usually accepted by the Japanese government for inclusion in the dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacture of veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative works.*

*In order to improve decreased speed, predictability and quality of the registration process in Japan which were pointed out in the benchmark surveys conducted by the International Federation of Animal Health in 2007, several new steps were taken by MAFF with some progress. However, there are still delays in review process of some product segments. An EU – Japan Economic Integration Agreement should aim for Mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.*

**Action taken so far**

Refer to the response to A-J-1 above.

**Future outlook**

Refer to the response to A-J-1 above.

## 19. Strengthening activities for industrial biotechnology (B-EJ-8)

### BRT Recommendation

To enhance the global competitiveness of the bio-based economy through increase cooperation between the EU and Japan, we suggest a number of actions that would strengthen activities in the area of industrial biotechnology

- ✓ *Develop and implement EU-Japan common R&D programmes and strategies to encourage use of agro-food by-products and wastes*
- ✓ *Support collaborative development of technologies to produce biomass based products and sustainable biofuels*
- ✓ *Benchmark the EU and Japanese policy strategies and legislation/regulations in order to stimulate the market introduction of bio-based products from innovative technologies*
- ✓ *Set up a common task force to analyse which global incentives can stimulate or support the re-conversion towards a bio-based economy*

### Action taken so far

The Global Bioenergy Partnership (GBEP), which was established to promote the sustainable development of bioenergy, is intending to provide science-based criteria and indicators for biofuel sustainability, on which Japan and other countries, including some EU nations are discussing.

### Future outlook

The GOJ will make use of multinational frameworks such as the GBEP to explore the establishment of science-based criteria and indicator concerning the sustainability of biofuels.

## 20. Formation of action plans for “New Growth Strategies” (B-J-1)

### BRT Recommendation

Formulate concrete action plans for the “New Growth Strategies” focusing on LS & BT fields as well as a new strategy for promotion of R&D and faster applications in LS & BT.

### Action taken so far

In budget request for JFY2011, CSTP (Council for Science and Technology Policy) planed AP (Action Plan) aiming to high-quality budgetary process on the basis of New Growth Strategy before budget request with related ministries for the first time. Therefore CSTP submitted systematic measures package (“Improvement of the Preventive Medicine by Integration of Results between Cohort Study and Medical Record”, “Improvement of Cancer Cure Rate by Development of Innovative Diagnostic and Treatment Method” and “Development of the Robotic Technology for Elderly and Handicapped Persons”) which are defined performance target and achieving deadline for LS Innovation, and have promoted efficient and effective Problem-solving R&D as advance approach.

### Future outlook

We will do PDCA (Plan-Do-Check-Act) cycle to be implemented these measures which construct this AP in accordance with AP (“Improvement of the Preventive Medicine by Integration of Results between Cohort Study and Medical Record”, “Improvement of Cancer Cure Rate by Development of Innovative Diagnostic and Treatment Method” and “Development of the Robotic Technology for Elderly and Handicapped Persons”) roadmap, and review the improvement of next AP and the increment of the number of measure hereafter. In addition, to make the new BT Strategy is a subject of future investigation.

## 21. Nation-wide electronic database for individual health/medical records in Japan (B-J-2)

### BRT Recommendation

Map out the “grand design” of a nationwide electronically integrated database for individual health/medical records as a basic Japan health policy

#### <Background>

*The Japanese government should intend to electronically integrate individual health/medical care related data and information nationwide in order to supply high-quality and patient-suitable medical care, and map out a “grand design” of the systems. The integrated database will also improve the efficiency of medical care by eliminating duplicated examinations or reducing adverse events and treatment for them. Furthermore, the data will be useful for the discovery of new innovative medical treatments and devices. Several European countries have already taken the lead on this issue, so Japan may be able to learn much from the experiences of the EU.*

### Action taken so far

In May 2010, the Strategic Headquarters for the Promotion of an Advanced Information and Telecommunications Network Society (IT Strategic Headquarters, Director-General: Prime Minister) decided "A New Strategy in Information and Communications Technology (IT)" which included the "My Hospital Everywhere" (Japan's Personal Health Record service) concept as one of priority measures in the healthcare field.

By realizing the measure, a national-level information service shall be created to allow the citizens to electronically manage and utilize their own medical and health-related information in order to create an environment where the citizens may receive medical care based on their medical records anywhere in the country and undertake their own health management.

In June, a progress chart specifying schedules of concrete actions and the responsible government agencies was established and in September we started discussion in a task force on a basic framework of the concept such as the methodology of digitizing information, management structure and the ownership and handling of the treatment and health records.

### Future outlook

We shall reach decisions within FY2010 on the basic framework of the concept such as the methodology of digitizing information, management structure and the ownership and handling of the treatment and health records. Subsequently, in FY2011, we will create standard formats and a delivery method to provide to individuals, enforce model projects and conduct other activities to realize the concept. We are planning to notify established standards and the method to medical institutions across the country within the fiscal year.

22. Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing (B-J-3)

**BRT Recommendation**

Finalize the implementation of the new, internationally competitive pharma pricing system in Japan based on the industry proposal and abolish the rule of re-pricing by market expansion

**Action taken so far**

Continuation of “the new drug pricing system” at the next drug price revision is to be discussed at Chuikyo considering the following factors;

- (a) Influence of the new pricing system upon finances
- (b) Development and marketing of off-labeled drugs, etc
- (c) Utilization of generic drug

“The market expansion repricing” is a rule to reduce the reimbursement prices of new drugs by 10 to 25% when the sale of particular drugs expand far beyond the estimation at their initial pricing.

**Future outlook**

Therefore, steady progress in development of drugs to be approved for off-label indications by pharmaceutical companies before the next revision of drug price is considered to be essential for the continuation of “the new drug pricing system”

It is difficult to abolish this rule since it is working as an appropriate apportionment mechanism of pharmaceutical expenditures within the public health care system, which has limited resources.

## 23. Regulatory transparency and review time by PMDA (B-J-4)

### BRT Recommendation

Increase the transparency of evaluation standards / registration process & Shorten review time by PMDA (J)

#### <Background>

*Innovation can contribute to improved patient quality of life, reduction of social cost and robust industry growth. In order to precede proper evaluation of innovation, transparency of evaluation standards and evaluation process should be guaranteed and improved by both governments. Adoption of health economics/ HTA and establishment of National Data Base for medication/ cost are essential for the improvement of transparency.*

*The increase of personal at PMDA in 2007, together with an increase of registration fee, is a welcome move towards a reduction of review time. It is important to continue to monitor if this will be linked with a significant reduction of review time. Also, it is suggested that Japanese authorities make more extensive use of overseas data, as this would significantly reduce cost and time required to register products in Japan.*

### Action taken so far

The GOJ is working systematically to shorten the drug review time based on the “5-Year Strategy for Creation of Innovative Pharmaceuticals and Medical Devices” formulated in April 2007. The Strategy includes several measures: increase the number of new drug review staffs, clarify review standards, strengthen the PMDA review system, and enhance efforts to address international clinical trials in approval review.

As a result, median total review time in 2009 was shortened to 19.2 months (cf. 22.0 months in 2008). Efforts will be continued to improve quality of review and speed up approval process based on the 5-Year Strategy.

The GOJ accepts foreign clinical data based on the ICH-E5 guideline.

### Future outlook

The GOJ will continue its efforts to speed up approval process steadily through strengthening review and consultation system etc.

#### 24. Support to research for Plant Protection & Biotechnology (B-J-5)

##### BRT Recommendation

Support research in Plant Protection & Biotechnology

##### Action taken so far

Since April 2008 the Ministry of Agriculture, Forestry and Fisheries (MAFF) has been implementing a five-year project to develop the innovative crops that can help solve domestic as well as international problems relating to food, energy, and the environment by taking advantage of the results obtained in the previous Rice Genome Research Program, which includes the sequencing of the whole rice genome and the elucidation of the functions of agriculturally important rice genes. To be more specific, the project aims to develop rice varieties that are resistant to disease, insect and abiotic stresses such as low temperature by using the Marker Assisted Selection or genetic engineering techniques.

Furthermore, the project is being undertaken to develop higher yield or quality rice varieties by making the benefits of the gene-discovery researches, which identified genes and chromosomal loci regulating yield, maturity, plant shape and height, and anthesis, available for the molecular breeding.

##### Future outlook

MAFF continues to undertake the project to solve both domestic and international problems relating to food, energy, and the environment in line with the plan formulated in April 2008.

## 25. Enhancement of cooperation with industry and academia (B-J-6)

### BRT Recommendation

Enhance international cooperation in development of plants with new beneficial traits/ Promotion of industry & academia cooperation.

### Action taken so far

Since April 2008, the Ministry of Agriculture, Forestry and Fisheries (MAFF) has been implementing a five-year project to develop the innovative crops that are resistant to disease, insect and abiotic stresses such as low temperature, drought, and salt stress. In particular, the joint research program with CGIAR (IRRI, CIAT and CYMMIT) has been conducted to develop drought-tolerant GM rice and wheat lines by introducing a DREB gene.

Moreover, MAFF and the Ministry of Economy, Trade and Industry (METI) provide research funds to promote business-academia collaboration. Some universities and national institutes are now collaborating with private companies, for example, to develop new crop varieties by using the Marker Assisted Selection technology (MAFF's funds) or to develop GM plants which efficiently accumulate high value ingredients (METI's funds). In addition, from April 2010, MAFF has been implementing new project which promotes collaboration between agriculture, forestry and fisheries research and other industry research by placing some project coordinators in each region.

### Future outlook

MAFF continues to conduct the R&D project in line with the plan formulated in April 2008. In particular, MAFF is planning to perform assessments of the stress tolerance of the DREB gene-introduced GM crops at the isolated fields in cooperation with our research partner institutes overseas.

MAFF and METI continue to promote business-academia collaboration in various research fields.

## 26. Efforts on increasing output of agriculture in Japan (B-J-7)

### BRT Recommendation

Continue efforts towards increasing output production of Japanese agriculture.

#### *<Background>*

*Japanese self-sufficiency on a calorie requirement basis is today below 40% so that it can be reasonably expected that the food & feed commodity prices will increase over the mid-long term. In addition, growing global population will also continue to drive demand against increasingly limited supply.*

*To counter this negative development the Japanese government should reform and drive Japanese agriculture toward increasing output production.*

### Action taken so far

The GOJ has been actively promoting the increasing of the output of Japanese agriculture. Specifically, the GoJ developed a New Food, Agriculture and Rural Areas Basic Plan in March 2010. The plan aims at revitalizing agriculture and rural areas and at raising the food self-sufficiency ratio to 50% by calorie-based, and 70% by production value-based by FY2020. To achieve these targets, the GoJ promotes measures such as implementation of an direct income support payment to farmers, conversion to a production system more responsive to the consumers' demands for quality and safety, and promotion of "senary" industrialization of agriculture and rural areas (promotion of farmers' initiatives to expand their businesses into food manufacturing and retailing sectors making use of their products).

### Future outlook

The GOJ continues the promote to increasing of the output of Japanese agriculture throughout the measures such as implementation of the direct income support payment to farmers, conversion to a production system more responsive to the consumers' demands for quality and safety, and promotion of "senary" industrialization of agriculture and rural areas.

## 27. Shortening review times for animal health products (B-J-8)

### BRT Recommendation

Shorten review times for new product applications

<Background>

*In Japan, marketing authorization of a veterinary medicinal product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal drug intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labor and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process, involving three different authorities, is rather complex and certainly has some room for efficiency improvement. Also, the review can take extremely long time to be completed, delaying so the access of animal owners and animals to innovative animal health products.*

### Action taken so far

The relevant Japanese laws provide that the Ministry of Agriculture, Forestry and Fisheries (MAFF) consult with both the Food Safety Commission (FSC) which is the risk assessment body for food safety; and the Ministry of Health Labour and Welfare (MHLW) which is the risk management for food safety, prior to approvals of veterinary medicinal products for food producing animals.

The MAFF concurrently consults with those bodies in order to shorten the time for approval. We take the concern of the EU seriously and initiate the consultations at the earlier stage of the approval process.

### Future outlook

Japan is deliberating guidelines for the preparation of Summary Technical Documents which provide applicants useful advice to further shorten the amount of time for approval. We are currently asking public comments on whether materials attached to applications should be translated from English to Japanese or not.

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

### **28. Sustainable Growth towards Low Carbon Society (C-EJ-1)**

#### **BRT Recommendation**

- (1) The Japanese government stated that Japan will aim to reduce its emissions by 25% by 2020, compared to the 1990 level, on the condition that a fair and effective international framework is established in which all major economies participate. To achieve these goals, authorities should prioritize the role ICT can play in achieving a low-carbon society.
- (2) We recommend that the EU and Japan act as aggressive regions on environmental activities to conduct a campaign for enlightenment. In order to expedite the introduction of solutions, we continue to request the governments of both the EU and Japan to support the development of common metrics and processes for the measurement of GHG reduction by ICT, such as the ongoing efforts in ITU which visualize reduction effects in terms of the environmental burden, thus improving persuasiveness in the market.
- (3) The Green IT Promotion Council is creating the new index “Datacenter Performance per Energy (DPPE)” covering overall productivity, including IT equipment. We propose to use this index for environment-related institutional settings. Both the governments of the EU and Japan are recommended not only to promote R&D and field trials for innovation, but also to share the results.
- (4) It is therefore essential that authorities support and encourage the roll-out of smart meters as much as possible. To accelerate investment in this area, authorities could start a dialogue with industry with regard to the harmonization of meter features, data protocol, data privacy, and data security.

#### **Action taken so far**

- (1) The GOJ selected green innovation as one of the pillars of the “New Growth Strategy” adopted in June 2010. The objective is to create a low-carbon Japanese society and economy through such measures as the practical application of ICT.
- (2) Japan actively participates in the ITU-T SG5 (ICT and climate change) which works on standardization activities for creating methodologies of evaluating GHG reductions by using ICT and sharing of best practices. Japan will pursue this activity. The private sector is also studying creation of these methodologies in fora such as at the ICT4EE Forum, ETSI, and the Green Grid. Japanese companies take part in them. There are also intergovernmental discussions on this issue.
- (3) METI and the Green IT Promotion Council have joined forces to undertake a rapid replacement of the PUE index with the DPPE.
- (4) The New National Energy Strategy shows that all consumers will be equipped with a smart meter in principle. In collaboration with industry trade groups and through the work of its Study Group on Smart Meters, METI is currently investigating systemic challenges to the introduction of smart meters and to the management of their information, among other issues.

#### **Future outlook**

- (1) The GOJ is aiming to create a low-carbon society through the implementation of a smart grid as

well as other measures laid out in the New Growth Strategy.

- (2) The GOJ will continue to support the Green IT Promotion Council's effort to find a method for measuring greenhouse gas reductions, as well as providing information to the ICT4EE Forum.
- (3) Japan will continue to investigate the potential for rapidly implementing the DPPE standard in common with Europe and the US. It will also take into consideration other efforts at international standardization.
- (4) In February of next year, METI is planning to compile the ideas from the Study Group on Smart Meters.

## 29. Knowledge-Based Growth (C-EJ-2)

### BRT Recommendation

Both the EU and Japan are establishing a long-term growth strategy plan for growth not only as a short-term response to recover from the economic crisis. The ICT industry should play a strategic role in economic growth, job creation, and innovation. ICT is functioning as social infrastructure of all industries, and strategic use of ICT is effective in the economic policy for each industry. Thus, ICT strategy should be consistent with growth strategy.

Knowledge-based growth will be achieved by the creation, distribution, and sharing of knowledge among societies. Therefore, the Next Generation Network (NGN), cloud computing, and supercomputers are key components.

Both governments are encouraged to continue their efforts to create regulatory and economic incentives for the utilization of NGN. Cloud computing has the potential to enlarge the application fields of ICT in e-government, healthcare, education, green IT, local revitalization, and agriculture. In order to promote strategic investments in those fields, a regulatory review in each sector for cloud computing deployment is required. Existing information systems need innovative and continuous overhauls to address changing needs from society and the latest technologies.

ICT's role as an engine for knowledge creation also needs to be recognized. The next-generation supercomputer will drive the advancement of simulation technology and provide innovation in R&D. Computing capability of the next-generation supercomputer will enable us to solve highly complex problems in physical science and life science. Using simulation results, development time and the cost of new products will be significantly reduced and bring about innovative ways of manufacturing. Furthermore, supercomputers are also useful for large-scale complex systems like nature. Emulating nature will contribute to addressing global social problems such as climate change.

### Action taken so far

The business service began on Next Generation Network (NGN) in March, 2008. The Government of Japan has been engaged in making the fair competition rule (interconnection rule) by which the telecommunication operators can positively utilize the NGN.

On Cloud Service, we have compiled the "Smart Cloud Strategy" that proposed the spread support in field such as medical treatment, education and agriculture, etc. where the ICT use lags behind, and the promotion of upgrade of society's infrastructures of smart grid and the next generation ITS in May this year. We are proceeding the preparatory audit and the spread support on the proof of an economic social system using Cloud Computing Service of the medical treatment, traffic, distribution, and the social infrastructure, etc. in addition to a research and development necessary to secure safety and reliability on Cloud Computing Service.

The Next-Generation Supercomputer project, that started in 2006, is now undergoing. In the project,

the “K computer” is already in production phase. Operation of the K computer will partly start in March 2011. In April, 2009, the EU and the Government of Japan agreed to promote cooperation in the high-performance computing field under the agreement of the science and technology cooperation.

#### Future outlook

We examine continuously for making NGN more open including the platform function,.

We are planning to promote the measures based on "Smart Cloud Strategy", and execute the research and development necessary for safety and the reliability securing continuously. Moreover, demonstration project of an economic social system in fields of the medical treatment, traffic, distribution, the infrastructure, and the new service, etc. and environmental considerations for productivity enhancement and new business creation of small and medium-sized enterprise are planned.

We promote the construction of "The Innovative High-Performance Computing Infrastructure (HPCI)" that cooperatively uses K computer and domestic various supercomputers and the further cooperation in the high-performance computing field between EU and Japan.

### 30. Taxation System that Supports the New Path for Growth (C-EJ-3)

#### BRT Recommendation

Regulations have been introduced in the UK and Tokyo to make it obligatory to reduce the total amount of CO<sub>2</sub> at each facility in an effort to reduce greenhouse gas emissions.

Data centers house integrated server and network equipment, and as the equipment operates 24 hours a day, the power consumption per floor area is large. However, the outsourcing of equipment to a specialized operator and management in a data center will make for more efficient operation than the individual companies' management of IT equipment, because of the sharing of air conditioning and power facilities and virtualization technology. We request governments to recognize the contribution of data centers to a low carbon society. These must be taken into account when considering additional requirements for operators of data centers, which would hamper their competitiveness in relation to general offices.

#### Action taken so far

The GOJ is considering the introduction of economic countermeasure against global warming such as taxation system greening. However, it does not intend to ask additional requirements that would hamper the competitiveness of data center operators, compared with general offices.

#### Future outlook

### 31. Data Protection, Utilization, and Security in the Cloud Computing Era (C-EJ-4)

#### BRT Recommendation

The significance of cloud services is not only the efficient use of IT infrastructure, but the crossing of business and industry borders. The social system as a whole can promote the integration and sharing of vast amounts of information and knowledge. Consequently, an "information society" with the participation of all individuals and companies can be realized.

Along with the expanded use of ICT, accelerated information storage is enabling new value-added services through cloud computing. In the near future, new services with cloud computing that handles enormous data process such as real-time stream data can be deployed as a new infrastructure for our businesses.

The connected society and cloud computing are crucial elements in that process. Cloud computing is a mechanism to provide computing resources in data centers through fixed or mobile IP connectivity. The development shows that mobile connectivity is rapidly evolving to become the default connectivity of most devices of the future. Indeed, fixed connectivity will fulfill the extreme bandwidth demands of specific areas and devices.

On the technology side, high dependability must be ensured to deploy cloud computing as an infrastructure for businesses of the EU and Japan. Government support is expected for the promotion of R&D and standardization of the basic technologies that underpin operational continuity, security, data storage, and the process of stream data. A technology for anonymizing the large amount of data can convert the data into highly value-added services, and is critical in promoting the use of cloud computing.

Last but not least, governments should foster a secure feeling in the market about cloud computing by deploying it for their e-Governments and presenting successful cases. UK is one example of a country having recently adopted an ICT strategy which is aiming at the establishment of a government cloud, or "G-Cloud". The government cloud infrastructure will enable public sector bodies to select and host ICT services from one secured, resilient, and cost-effective shared network.

Cloud services will provide enterprises and private users with a variety of services. These services may vary from simple text-based information services to high resolution multi-media services providing the user with a rich experience. In order to cater for this, the governments of both Japan and the EU should stimulate the introduction of mechanisms where the cloud and its services can request and get a different quality of service from the underlying network (NGN).

#### Action taken so far

In May 2010, the Ministry of Internal Affairs and Communications organized the “Smart Cloud Strategy”, which aims to make use of cloud services to the extent possible to promote the wide-spread and thorough use of ICT and thus amass and share a wealth of information and knowledge, and thus to achieve a “knowledge and information society”.

The strategy is comprised of the following three perspectives; (1) promoting the use of cloud services (Utilization Strategy), (2) promoting strategic research and development for next-generation cloud technology (Technology Strategy), and (3) promoting an international consensus and global cooperation (International Strategy).

In addition, the Ministry of Internal Affairs and Communications and the Ministry of Economy, Trade and Industry (METI) have been conducting research and development regarding issues such as further reliability and energy efficiency and new security technologies for secure and safe use of cloud computing. METI also is, in partnership with the private sector, undertaking an initiative towards establishing standards for information security management within a cloud environment.

Also, in cooperation with the GICTF (Global Inter-Cloud Technology Forum), which is organized by cloud-related enterprises, organizations and individuals, we have been conducting the consideration on the standardization of the relating technologies.

Also, in December 2010, a private organization called “Japan Cloud Consortium” was organized, which aim to promote widespread and development of cloud related services. The Ministry of Internal Affairs and Communications and the Ministry of Economy, Trade and Industry are supporting its activity as the observers.

#### Future outlook

In order to ensure Japan’s competitiveness and security in the field of cloud computing, we are planning to promote research and development for the basic technologies contributing to the realization of reliable, high-quality and energy-saving inter-cloud technology, which will be available for such important social infrastructures as disaster prevention, finance, healthcare and traffic.

In addition, for further use of cloud computing services, we are going to actively take part in both bilateral and multilateral international discussions for consensus development aimed at making international rules.

## 32. The Right Regulatory Environment for Investment in NGN (C-EJ-5)

### BRT Recommendation

High-speed broadband networks are the decisive input factor for achieving all other ICT-related policy objectives since they provide the basic underlying infrastructure needed to make nearly all other services and applications of the future information society a reality. Cloud computing is just one example of the future applications that depend on high-speed broadband deployment. Academic research and empirical evidence have shown that a widespread and reliable broadband infrastructure will improve productivity, stimulate innovation, accelerate growth, and create jobs. Demand for bandwidth at work, at home, or on the move is growing constantly. High-performance fixed and mobile telecommunications infrastructures have thus become a decisive factor for the global competitiveness of modern knowledge-based economies. Hence, social development as well as future growth and jobs will largely depend on the ability to provide for an innovation- and investment-friendly regulatory framework. When regulating, authorities should take into account the investment risks companies are willing or not willing to take and come up with differentiated regulatory responses targeted to the amount of investment risks companies are willing to take. On top of that, regulation should provide for the necessary legal certainty for investors.

Due to different subscriber density and demand in different regions and over time, different technologies and topologies are best suited for different scenarios. Therefore the principle of technology neutrality in any regulation is crucial. It is also important to let different technologies evolve on their own merits and not to stifle innovation and hamper investment by making regulation prescriptive on technologies.

### Action taken so far

With the aim of establishing a fair competitive environment, the Ministry of Internal Affairs and Communications has been promoting competition in the development of infrastructure. In 2008, for example, it established regulations for 2.5GHz Broadband Wireless Access (BWA) services, and the BWA services began the following year.

With regard to interconnection charges for Category I designated telecommunications facilities that require approval from the minister, conditions are stipulated that charges should be fair and valid based on appropriate cost price, with fixed profits being permitted. Under such a system, the telecommunications carriers that establish a Category I designated telecommunications facility have been in fact investing in the construction and upgrading of the network.

### Future outlook

The Ministry of Internal Affairs and Communications will continue to make proactive efforts to ensure a competitive environment, including through promoting facility based competition.

### 33. ITA & Trade Security (C-EJ-6)

#### (1) ITA

##### BRT Recommendation

The expansion of the Information Technology Agreement (ITA) is crucial for Japan's and Europe's future, not only as a factor of development of a major industrial sector in its own right, but also as a driver of productivity, innovation, job creation, improved competitiveness, and service quality in virtually all other industrial sectors and public services. In particular, the focus should be on the following aspects.

The scope of the expansion should cover the products determined as being included within the scope of the current agreement plus additional products.

The broadest possible expansion of the scope of the ITA, including at least large portions of chapters 84, 85, and 90 is needed in order to ensure that current and future innovative technological developments do not result in uncertainties regarding product classification. It is noted that there are concerns around the world over ITA-covered products being reclassified as dutiable. In fact, some new convergence-technology ITA products have already lost their zero-tariff status. Such expansion would boost trade in the whole electronics sector, remove uncertainties regarding product classification, and would ensure the reflection of technological developments in the sector as future products would also be expected to fall within these chapters.

The removal and prevention of non-tariff barriers is of utmost importance for the Japanese and European electronics industries. Every positive development in terms of both extended product scope and additional participants of the ITA would be compromised if non-tariff barriers were not properly addressed, resulting in a deteriorated level playing field in the other current and future ITA member states. Unfortunately, the use of Non Tariff Barriers (NTB's) often increases after abolition of duties and taxes.

Many more countries should be encouraged to participate in the new agreement. Many non-participants still levy high duties on and impose many NTB's against imports of IT products. Thus membership should be promoted as a means of boosting efficiency and productivity, improving the investment climate as well as a necessary tool to bridge the digital divide and enable the move to a more energy-efficient and climate-friendly society.

Finally, the establishment of effective mechanisms is needed to keep the new agreement up to date to ensure that technological developments are reflected in the agreement.

Taking into account these aspects, Japan and the EU should drive not only maintenance of the current ITA but should jointly strive for a review of the ITA as soon as possible.

##### Action taken so far

IT innovation not only gives birth to new industries and makes life more convenient, and it also

contributes to the development of industry and society in general. For example, digital devices that combine the functions of a printer, copier, scanner, and fax allow office space to be reduced and business processes to be performed more efficiently. By reducing barriers to trade, ITA has made a great contribution to the worldwide use of such IT products, but for maintaining its contribution in the future, it goes without saying that it will need to respond flexibly to innovative technology and not impede its dissemination.

EU, however, against these trends, has imposed tariffs on products with new functions developed through technological innovation and/or on products that combine multiple functions, since ITA was signed, insisting that they are not covered by ITA. Although the Government of Japan has raised this issue at WTO meetings including ITA committee and repeatedly expressed its concern to the European Commission at the EU-Japan Regulatory Reform Dialogue, EU has offered no solutions. In light of this situation, Japan requested, jointly with the U.S and Chinese Taipei to establish a panel pursuant to the WTO dispute settlement procedures regarding the EU's tariff treatment of multifunctional digital machines, flat panel display devices, and set-top boxes. The panel report, accepting the claims made by co-complainants was adopted by the Dispute Settlement Body in September, 2010.

Seeking to solve the classification disputes relating to IT products, the discussion to review the scope of ITA has resumed in ITA Committee as well.

#### Future outlook

EU is required to take measures to comply with the WTO panel recommendations with respect to the tariff treatment of multifunctional digital machines, flat panel display devices, and set-top boxes within a reasonable period of time agreed among parties to the dispute. The Government of Japan will communicate with the EU Member States to ensure that the tariff treatment of IT products be implemented appropriately through various occasions including the ITA Committee.

With regard to boosting trade in the whole electronics/electrical sector, the WTO NAMA (Non-Agricultural Market Access) negotiations are currently providing a forum for discussing the tariff elimination in the electronics /electrical sector. Considering breathtaking speed of evolution of IT products, the tariff elimination on all electrical and electronic products would be a highly effective step, and would also contribute to resolve the problem in tariff classifications for these ITA products. To work out the tariff eliminations in this sector, it is essential that EU participate in this initiative, so the GOJ hopes their positive commitment in cooperation with the proponents.

## (2) Trade Security

### BRT Recommendation

In such an environment, we repeat that the EU and Japan must lead the international harmonization of trade institutions to strike a balance between security and the facilitation of trade, and to realize efficient public-private operation.

More specifically, governments are expected to:

- (1) Implement the mutual recognition of AEO programs between the EU and Japan as soon as possible, and exempt from the application of the EU advance cargo manifest declaration rules, just like the case admitted by the mutual recognition of AEO between the EU and Switzerland;
- (2) Standardize the importing and exporting declaration data based on the WCO Customs Data Model (\*) and exchange electronic information. Finally, we hope that export declaration data in Japan become import declaration data in the EU.

As the world economy is still sluggish, the EU and Japan should take a leading role in striking a balance between international supply chain security and the facilitation of trade by a launching positive initiative with ICT infrastructure.

\*: Mandate in Lyons summit (G7) in 1996

### Action taken so far

- (1) In June 2010, the customs authorities of Japan and the EU signed the decision on the mutual recognition of AEO programmes. The GOJ has been engaged in consultations with the EU for early implementation of the mutual recognition. So far, the EU has not exempted Authorized Economic Operators involved in a trade between the EU and Japan from the application of the advance cargo declaration rules. The customs authorities of Japan and the EU agreed to continue discussions on the advance cargo manifest declaration rules.
- (2) Regarding the WCO Data Model (note: the former name was the *WCO Customs Data Model*), the GOJ had originally led the development works on standardization and simplification of data elements for import/export procedures and standardized electronic formats through G7 Initiative. A pilot project demonstrating the WCO DM v.2 was once conducted with Canada in December 2005, but there had been only a few transactions with a lack of interest of the private sectors. As the WCO DM v.3 was released in December 2009 and the WCO has encouraged broad use of the model as a global standard, since July 2010, the GOJ has started examining the data elements of NACCS(Nippon Automated Cargo and Port Consolidated System) and WCO DM v.3, so that NACCS would be compatible with the WCO DM v.3 whenever necessary. In addition, the GOJ has attended the meetings of Data Model Project Team held at the WCO to grasp the situations on the WCO Data Model, including engagements in other countries and private sectors.

#### Future outlook

- (1) The GOJ will continue consultations with the EU, aiming for implementation of the mutual recognition of AEO programmes by early 2011. The GOJ will also discuss further benefits with the EU in the review process of implementation of the mutual recognition.
- (2) Regarding the implementation of the WCO Data Model, the GOJ will consider pilot projects with interested countries as necessary, taking into account the situations in other countries, interests of private sectors, etc.

### 34. Fundamental Review of the Copyright Levy System and the Compensation System for Audio and Video Private Copying (C-EJ-7)

#### BRT Recommendation

In order to promote further lawful use of digital content, it is necessary to implement dialogue/cooperation between the EU and Japan concerning a fundamental review of the compensation system for private copying. Currently compensation is paid by means of copyright levies, a system which dates back to the analog era (at least in Europe). Copyright levies are a way of compensating for revenue loss caused by private copying, but they are not intended to fight piracy.

This move is based on existing common business models utilizing DRM, as well as other emerging business models, including the on-line distribution of content on the basis of contracts with individual users, which is also expanding. In these cases copyright levies may impose a double payment for consumers. Furthermore, the rules of the current levy system vary enormously across Europe. There is no European benchmark for determining what products are subject to levies, or what amount is to be charged.

In reviewing the systems, we should take into consideration in a comprehensive manner the methods available, including the above new content distribution practices, to secure compensation for private copying for right holders and creators. The goal should be to enable the establishment of a system which is transparent, fair, and equitable to such interested parties as consumers, right holders, service providers, and equipment providers.

This increased transparency and legal certainty can be achieved only through the application of objective European criteria by a political and legislative intervention at the European level. The European Commission and member states must therefore ensure that private copy compensation remains firmly on the agenda as a priority in the wider copyright debate on the European digital economy agenda.

#### Action taken so far

Consensus between concerned parties is essential for a fundamental reform of the compensation system for private sound and visual recording. The Japanese government held deliberations regarding said reform at the Subdivision on Copyright of the Council for Cultural Affairs, which is a subcommittee made up of interested parties, but consensus was unable to be reached. Consequently, the January 2009 report of the Subdivision on Copyright proposed that it was necessary for the Agency for Cultural Affairs to set up a place separate from the Council for Cultural Affairs for concerned parties to reach a consensus. However, the difference of opinions among these parties was too great, which has prevented this from being realized. The Japanese government is to set up working-level review meetings to be held regularly from May 2010 onwards. These meetings will be led by director-generals from the Ministry of Education, Culture, Sports, Science and Technology and the Ministry of Economy, Trade and Industry, and will involve collecting opinions on how to make the use of contents more convenient as well as on the current system for protecting the rights of

creators, with the aim of building consensus between concerned parties.

#### Future outlook

Given the urgency of the private recording issue, the Japanese government aims to continue trying to build consensus among concerned parties regarding the compensation system, taking into account the progress that has already been made on this issue in discussions of the Council for Cultural Affairs.

## **Working Party D: Financial Services; Accounting and Tax Issues**

### 35. Progress in the financial market reform since the financial crisis (D-EJ-1)

#### **BRT Recommendation**

- In response to the global financial crisis, the G20 countries have agreed to the common principles for financial market reform, which are: (1) strengthening transparency and accountability, (2) enhancing sound regulation, (3) promoting integrity in financial markets, (4) reinforcing international cooperation, and (5) reforming international financial institutions. The G20 countries are now taking actions for their implementation.
- Specifically, under the G20 framework the Basel Committee of Banking Supervision (BCBS) has made proposals regarding bank's capital requirements, leverage regulation and liquidity regulation in order to enhance the soundness of the bank's management. And the Financial Stability Board (FSB) has presented the international principles for the compensation practices in the financial institution. Now it seems that a new regulatory order based on the untraditional way of thinking is about to be built, including such measures as imposing additional regulations on the "systemically important financial firms," which are large and complex financial institutions.
- We agree in general that these financial reforms will stabilize the financial system and enhance the transparency and accountability of financial institutions, financial markets, and financial products, while ensuring their fairness and integrity. The stabilization of the financial market and financial system is important for market users including the companies that raise capital.

#### **Action taken so far**

Based on discussions on global financial regulatory reform, we have been working on developing initiatives to ensure stability in the financial system, and transparency and fairness in the financial market. Such initiatives include the following:

Introduction of the legal and supervisory framework for credit rating agencies

- Mandatory use of central counterparties (CCPs) for clearing OTC derivatives transactions, etc.
- Improvement in the disclosure of cross-shareholding and of remuneration of listed companies' directors.

#### **Future outlook**

In order to ensure stability in the financial system, and transparency and fairness in the financial market, we will continue to take part in international cooperation based on discussions on global financial regulatory reform.

## 36. Issues to be mindful of when processing with reform (D-EJ-2)

### BRT Recommendation

- At the same time, we point out that there are several issues we should bear in mind as we proceed with regulatory reform. Innovation in the financial market is important and a careful balance must be struck between innovativeness and regulation.
- We also have to recognize that maintaining the liquidity in the secondary market is important. One of the most serious problems in the financial crisis was the lack of liquidity in the secondary market. Although the regulatory reform should move forward in order to prevent the next financial crisis, we also have to be mindful of preventing the lack of liquidity in the secondary market. Asian countries are expected to be the driver of economic growth after the financial crisis. In these countries, the role of capital markets is still limited and their financial system is still market and the credit restraint due to the bank's capital requirements should happen in such countries, the corporate finance could face constraints from both capital market and banking system, and this could give a negative impact on economic activities and growth.
- Even though the financial industry is one of the most globalized industries, we should still bear in mind that the regulation and practices greatly vary from country to country. For example, in East Asian countries including Japan, banks' financing (debt) is basically through stable small deposits, and their dependence on the short term capital is not so large as financial institutions in the US and Europe. If the uniform regulation on the leverage leads to the restrictions on deposit taking and thus the reductions in lending regardless of the risk to the financial system, this could give a negative impact on economic activities. Also, in economies including Japan the credit risk has been concentrated in the banking sector, and thus the need for risk diversification through securitization is still very high in order to mitigate systemic risk.
- When the regulation is discussed in the global context, the characteristics of each country and region should be fully considered. We believe that we should build harmonized regulations through multilateral discussions on a global basis.

### Action taken so far

As for global financial regulatory reform, we recognize that it is extremely important to: (1) make the regulations well-balanced, taking into account the differences among the financial systems of various countries, and (2) set an adequate period for transition, taking into due consideration the impact on the real economy, while new regulation should contribute to strengthening the financial system and improving the soundness of financial institutions in the mid to long term. We have asserted these two points accordingly at international forums, and they have been reflected in G20 Declarations, etc.

### Future outlook

We will continue to actively take part in international discussions on financial regulatory reform in order to prevent future crises and strengthen the financial system, based on our views as stated above.

### 37. Accounting Issues in EU and Japan (D-EJ-3)

#### BRT Recommendation

- Working Party D (previously Working Party 2) has recommended enhancement of the governance of the accounting standard setting bodies and the convergence of accounting standards. The Financial Stability Board (FSB) is going to undertake a strategic review of the policy development work of international standard setting bodies, and the IASB has established an external Monitoring Board, members of which include the International Organization of Securities Commissions (IOSCO), the European Commission, the US Securities and Exchange Commission, and Japan's Financial Services Agency. In addition, IASB and FASB have established the Financial Crisis Advisory Group (FCAG), which is comprised of senior leaders with broad international experience in financial markets. FCAG will advise the IASB and FASB on the standard-setting implications of the global financial crisis and on potential changes to the global regulatory environment. Since its inception, FCAG has announced the wide-ranged report on the activities of Accounting Standard Board. We support these trends and look forward to further developments. We also support the progress towards the IFRS introduction in Japan and look forward to further discussions on the convergence.
- While the purpose of financial accounting is to provide financial information to a company's outside stakeholders such as shareholders and creditors, we strongly point out that the view of a company's management is also important when setting standards. Changes in accounting standards have impact on corporate activities and thus on the economy. We believe that net income with recycling arrangement is useful as accounting information. Companies set the prices for goods and services they sell based on cost. If items not recycled such as the actuarial gains and losses in the pension accounting are expanded and thus profit and loss not reflected in the net income are expanded too, we are concerned that underlying business activities such as cost management and selling price formation could be disrupted.
- IASB is in the process of revising its financial instrument accounting standard and we support the approach to recognize the net unrealized gain on available-for-sale securities as other comprehensive income (OCI). However, it is also proposed that if the net unrealized gain is recognized as OCI, the dividend is recognized as net income but the realized gain is recognized as OCI, not as net income. We cannot agree with this approach.
- The net realized income has been described by some as a kind of income manipulation, but we believe that the sale of the securities is one way of showing the management's decision, and thus recognizing the net realized income as net income gives more useful accounting information. In the insurance context, assets held by insurers are managed consistently with the asset liability management and the risk management of the company in order to back insurance liabilities and to meet insurers' commitments toward policyholders and not in the interest only of the shareholders (and so not for "managing earnings" over time). Furthermore, the removing of the available for sale (AFS) category is inconsistent with the business model approach on which the IFRS 9 is based: the long term business model of insurance should be recognized through the AFS.

- As part of the process to strengthen the immediate recognition in the accounting standards for employee benefits, the actuarial gains and losses may be recognized immediately upon accrual as OCI. The immediate recognition of the actuarial gains or losses coming from short term financial market fluctuations could cause the pension plans, which are long term promises between employers and participants, to give excessive fluctuation to net income. We support the approach to recognize the actuarial gains and losses as OCI and not as net income. On the other hand, we believe the actuarial gains and losses should be recycled for the above mentioned reason.
- We ask IASB to discuss the revenue recognition criteria with careful consideration of the actual business practices in countries around the world. It is necessary to recognize the possibility that changing the accounting standards affect the business practices. We believe that accounting standard reform is necessary when there are concrete problems that may hinder investor's decision making, but if not, the established accounting practices should not be overruled.
- With regards to the IASB's financial statement presentation project, in addition to OCI issues and the removing of the two separate statements (income statement and statement of comprehensive income) we are concerned about the requirement for the use of direct method in cash flow statement. The users of financial statements are able to acquire sufficient useful information from disclosures with indirect method. Based on the fact that companies will incur large amount of cost, we do not see any overriding benefit coming from the requirement of direct method.

#### Action taken so far

In light of the globalization of financial/capital transactions and corporate activity, and to address the recent financial crisis, further efforts toward the establishment and application of a single set of high-quality global accounting standards have been called for at the G20 Summit (Summit on Financial Markets and the World Economy) and other meetings. The Accounting Standards Board of Japan (ASBJ), the accounting standard-setter in Japan, has been working with international accounting standard-setters to improve the quality of international accounting standards, and has been moving forward with the convergence of accounting standards into the International Financial Reporting Standards (IFRS). The Financial Services Agency (FSA) assists the ASBJ's efforts toward the convergence.

In relation to enhancing the governance of the International Accounting Standards Board (IASB), the FSA has been strengthening cooperation with foreign authorities and has been actively involved, as a member of the Monitoring Board (MB). For further improvement of the governance of the IASB, the IFRS Foundation MB Governance Review Working Group reviews the governance framework and the FSA leads the project as chair country.

The setting of each accounting standard involves a variety of issues, so for high-quality standards to be established, it is essential that substantial dialogues are held between the accounting standard-setter and stakeholders, such as users and preparers of financial statements, auditors, and regulators, in accordance with appropriate due process, from the standpoint of ensuring the robust governance of the accounting standard-setter. The FSA, therefore, has worked with foreign authorities in order to ensure the appropriateness of the standard-setting processes of the IASB,

including dialogues with stakeholders.

#### Future outlook

The FSA will continue to assist the ASBJ's efforts toward the international convergence of accounting standards and continue to play an active role in strengthening the governance of the IASB. The FSA will also continue to work with foreign authorities to ensure the appropriateness of the IASB's standard-setting processes, including dialogues with stakeholders.

## 38. Tax Issues in EU and Japan (D-EJ-4)

### (1) Tax treaties

#### BRT Recommendation

The government of Japan and Europe should ensure that dividend payments from subsidiaries to parent companies and royalty and interest payments between related parties are, to the greatest possible extent, exempted from withholding taxes in the source country. While there have been some improvements with respect to the dividend taxation between Japan and some EU member countries, we believe that the removal of double taxation is still an important issue, and we hope that all the EU Member States and Japan will conclude tax treaties. In order to reduce the risk of economic double taxation, furthermore, it is important to ensure an arena for wide-ranging dialogues between the tax authorities. In particular, they should introduce clauses that will enable corresponding adjustments and arbitration in tax treaties. In addition, they should harmonise and simplify documentary requirements in transfer pricing taxation and promote and facilitate the conclusion of bilateral and multilateral APAs.

#### Action taken so far

With regard to the tax treaties between Japan and the EU member states, in view of promoting investment and economic activities between Japan and the EU, the GOJ is actively expanding and enhancing the tax treaty network.

In this context, the GOJ signed the new convention with the Netherlands in August 2010. This convention gives broad exemption from source taxation of investment income and incorporates arbitration procedure (N.B. it is the first case for Japan to introduce such procedure in a tax treaty.). Moreover, in light of preventing international fiscal evasion and tax avoidance, the GOJ also signed the amending protocols with Belgium and Luxemburg in January 2010, which revised the provisions of the exchange of information.

#### Future outlook

The GOJ will continue to work on the reinforcement of the tax treaty network with the EU member states as necessary, which contributes to further strengthening investment and economic ties between Japan and the EU in the globalized business environment.

## (2) Deviations between corporate accounting and tax practice

### BRT Recommendation

With the progress of convergence of Accounting Standards, new deviations arise between corporate accounting and tax practice. We ask that the Governments of Japan and Europe respond flexibly to the deviations.

### Action taken so far

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

### Future outlook

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

### (3) Transparent and fair tax reform

#### BRT Recommendation

When companies conduct their businesses on a global basis, transparent and fair taxation in countries are extremely important. If the taxation on some specific industry or sector is introduced, it could distort the resource allocation and damage the sound growth of companies and economies. We hope that transparent and fair tax reform and implementation are continued.

#### Action taken so far

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

#### Future outlook

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

## 39. Financial Services Issues in Japan (D-J-1)

### (1) Japan Post

#### BRT Recommendation

The Japanese Government changed the Postal privatization policy and announced the policy that would allow its entry into new business areas and special regulation while the government share ownership is maintained, and financial institutions in EU and Japan have expressed strong concerns. We believe that new product development and business expansion, as well as the increase or the abolishment of the limit on both postal savings amounts and insurance, should not be implemented until a level playing field is established. In addition, it is necessary to establish transparency procedure and involve constructive discussion through reform process.

#### Action taken so far

With regard to postal reform in Japan, the relevant bills, which were submitted to the last Diet session, have been carried over to the next session. The bills provide, as one of the basic policies, that when implementing the measures on postal services, consideration shall be given to equitable conditions of competition between Japan Post Group and operators offering similar services.

The GOJ conducted a number of public hearings and invited public comments on the postal reform so that it could consider various opinions inside and outside Japan when drafting the bills.

#### Future outlook

The bills for postal reform have been carried over to the next Diet session.

## (2) Deregulation of insurance sales through banks

### BRT Recommendation

FSA has deregulated insurance sales through banks and consumer convenience is improving. However, there are still some regulations to avoid banks' pressure sales. For example, corporate clients who have a loan cannot purchase insurance products through their lender bank. The regulation will be reviewed by the end of 2010, and the regulatory reform should be discussed for further enhancement of the consumer convenience, while paying attention to the protection of consumer's interest.

### Action taken so far

FSA will review the effectiveness of the restrictions in light of policyholders' protection and their benefits after about 3 years of the deregulation. So FSA is currently monitoring the effectiveness.

### Future outlook

FSA will review the effectiveness of the restrictions in light of policyholders' protection and their benefits after about 3 years of the deregulation. So FSA will conduct the review in light of the results of the monitoring. In order to advance the consideration, FSA plans to have discussions with experts and concerned parties when necessary.

#### 40. Accounting Issues in Japan (D-J-2)

##### BRT Recommendation

In IFRS the compensated absences are recognized as liability. However, since the reserve for the compensated absences has never been recorded in Japan and such requirement could have a relatively heavy impact, we believe prudent discussion should be held.

##### Action taken so far

The setting of each accounting standard involves a variety of issues, so for high-quality standards to be established, it is essential that substantial dialogues are held between the accounting standard-setter and the stakeholders such as users and preparers of financial statements, auditors, and regulators in accordance with the appropriate due process, from the standpoint of ensuring the robust governance of the accounting standard-setter. The FSA, therefore, has worked with foreign authorities in order to ensure the appropriateness of the standard-setting processes of the IASB including dialogues with stakeholders.

##### Future outlook

The FSA will continue to work with foreign authorities to ensure the appropriateness of the IASB's standard-setting processes, including dialogues with stakeholders.

## 41. Tax issues in Japan (D-J-3)

### (1) Transfer –price taxation

#### BRT Recommendation

In order for companies to carry out international business expansion smoothly, we ask the tax administration of Japan to implement transfer-price taxation using an international common model such as the OECD model, and secure further transparency.

#### Action taken so far

(1) The GOJ makes it own practice to publicly release, on websites, not only the laws and regulations on the transfer pricing taxation, but the Administrative Guidelines on its interpretation and on its operations. Also, in order to increase predictability for taxpayers by further clarifying its operations, the National Tax Agency of Japan (NTA) has been updating the Administrative Guidelines with public consultations.

(2) The Administrative Guidelines prescribe that examinations and APA reviews are conducted with due reference to the OECD Transfer Pricing Guidelines (TPG), and the NTA has been making efforts to administer the transfer pricing taxation system based on such international rules.

#### Future outlook

From the viewpoint of ensuring transparency and facilitation in transfer pricing administration, the NTA will continue to bring further clarifications to its application standards and administrative policies by updating the Administrative Guidelines with reference to the TPG.

## (2) Reducing corporate tax rates

### BRT Recommendation

We request the Japanese government to consider reducing corporate tax rates. While many countries are lowering effective corporate tax rates rapidly, Japanese corporate tax rate remains at around 40%, the highest level around the world. In terms of securing Japanese companies' international competitiveness and also furthering foreign investments, Japan should lower its corporate tax rate to the international equivalent of around 30%.

### Action taken so far

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

### Future outlook

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

(3) Assets management for retirement and tax breaks for medical, long term care and pension insurance

#### BRT Recommendation

As Japanese society ages, Japanese individuals in the workforce will need to invest and accumulate more assets for retirement. The role of private sector insurance will be more important in such fields as medical (hospital), long term care and pension insurance. We ask the Japanese tax authority to continue to expand the tax breaks to encourage the development of individual preparation for retirement.

#### Action taken so far

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

#### Future outlook

For our overall position on tax-system reform of Japan, refer to the attachment in the Appendix of this report.

## **Working Party E: Innovation, Environment and Sustainable Development**

### 42. International cooperation, assignment and mechanisms on water problems (E-EJ-1)

#### **BRT Recommendation**

Recommendation for Japan and the EU to intensify cooperation on water problems as one of the most important issues relating to global warming and climate change. EU and Japan should establish common EU-Japan venues for joint development of contributions towards international cooperation, assignment and mechanisms.

#### **Action taken so far**

The GOJ is actively engaged in the international discussion on the water issue with EU at the United Nations, World Water Forum and G8. For instance, the UN resolution on the follow-up of the international year of sanitation in 2010 in which Japan was one of the drafting countries, contributes to raising awareness in the international community over the importance of the sanitation issue, redoubling the efforts to fill the sanitation gap and promoting the efforts for extending basic sanitation in developing countries, in order to realize “Sustainable Sanitation: five-year drive to 2015”.

#### **Future outlook**

The global water issues including the lack of access to safe drinking water and basic sanitation facility in developing countries increase its importance from the perspective of increased threat caused by global warming and climate change. The GOJ continues to be actively engaged in the international cooperation in the field of water, collaborating with EU.

#### 43. Forming consensuses with stakeholders in watersheds(E-EJ-2)

##### BRT Recommendation

Recommendation on supporting the establishment of mechanisms to enable sustainable use of water through forming consensuses with stakeholders in watersheds, in order to ensure the conservation of water sources and safe, useable water.

##### Action taken so far

In order to effectively and efficiently use water resources toward the future, the formulation of a water resource management plan including the integrated water resource management (IWRM) plan is indispensable. The GOJ is supporting the self-help efforts of developing countries in the monitoring, forecasting, and evaluation of long-term trends relating to water, and the formulation and implementation of a long-term water management plan. For example, in Tanzania, based on the water sector development program of the Tanzanian government, Japan started technical cooperation in 2010 which supports capacity building on the formulation and implementation of the integrated water resources management and development plan in one of watershed areas. It is expected that the formulation of the plan gives due consideration to environmental and social impact.

##### Future outlook

In order to realize sustainable water use particularly in developing countries, it is necessary first to grasp the volume of available water resources, monitor, forecast and evaluate the trends in water demand and the effects on the environment through water use. Based on the results, it is important to form a consensus among stakeholders relating to watersheds on appropriate measures in both policy and project levels.

#### 44. Developing water purification methods to reduce the cost of water (E-EJ-3)

##### BRT Recommendation

Recommendation on further developing water purification methods to reduce the cost of water. Support the matching of local water prices to be adequate considering the water quality, weather conditions and purposes of use in each region, and promote further improvements in innovative membrane treatment technologies and water treatment membranes.

##### Action taken so far

Each water supplier selects the most appropriate method of water purification depending on the quality of raw water and the price of water should be fair and proper given by each water supplier. In addition, drinking water suppliers and industrial water suppliers apply to separate water quality standard by each law, so they supply water in accordance with the intended use.

Furthermore, the Government is moving to establish a collaborative relationship among industry, government and academia to advance the development of membrane process technology and other technologies by supporting Japan Water Research Center, National Institute of Public Health, New Energy and Industrial Technology Development Organization (NEDO) and manufacturers of water treatment membranes and so on.

##### Future outlook

Continuously, the GOJ will promote the technology development for upgrading the water treatment technologies.

45. Observation/prediction of groundwater storage potential distribution and water quality inspection technology (E-EJ-4)

BRT Recommendation

Recommendation on the need for raising the accuracy of technology and to standardize technology for observation/prediction of groundwater storage potential distribution and water quality inspection technology, and put these to use in drawing up plans for the establishment of water re-use/flood control systems.

Action taken so far

Japan do not consider for raising the accuracy of technology and to standardize technology for observation/prediction of groundwater storage potential distribution and not also do not planning for the establishment of the results of those water reuse system. The rainfall that doesn't flow into the river originates in various factors. It is difficult to guess the amount of rain that doesn't flow into the river only from the groundwater storage potential. When considering the flood control plan, the groundwater storage potential is not measured. • Regarding water quality inspection, both the groundwater quality standards and the methods of inspection are stipulated in the law.

Future outlook

Nothing in particular.

#### 46. Human resources development in the water sector utilizing ODA (E-EJ-5)

##### BRT Recommendation

Recommendation on the need for Japan and the EU to cooperate in the field of human resource development in the water sector utilizing instrument such as ODA to developing countries.

##### Action taken so far

Based on “Water and Sanitation Broad Partnership Initiative (WASABI)” which is a policy document on the assistance in the field of water and sanitation, the GOJ, as the world’s largest donor in this field, is implementing comprehensive support both in hardware and software aspects, collaborating with stakeholders including other donor countries and the private sector. Japan is attaching its importance on capacity development in supporting developing countries in the field of water. Japan promotes the development of the organizations, policies, systems, information and data, and human resources of the governments of developing countries as well as the development in technological and managerial capacities for the proper maintenance, management and operation of developed infrastructure at the local level, such as local governments.

##### Future outlook

Development of human resources in developing countries is important for realizing human security which protects and empowers individuals. From this perspective, Japan supports local people’s self-help efforts through promoting their participation in maintenance, management and operation of the infrastructure and building their capacities, in addition to developing experts.

47. Developing methods and technologies to reduce the amount of water used for irrigation (E-EJ-6)

BRT Recommendation

Recommendation on developing methods and technologies to reduce the amount of water used for irrigation and to avoid the negative consequences of irrigation like increasing the salinity of land.

Action taken so far

Water resources all over the world are predicted to become tight under the influence of population increase, economic growth and global warming. In this situation, Japanese government promotes efficient agricultural water use by introducing “participatory irrigation management”, which farmers themselves operate and manage irrigation facilities and control water distribution, in addition to constructing irrigation facilities utilizing knowledge and experience stored in Japan, in order to realize sustainable water use by utilizing limited water resources effectively. Also, Japanese government promotes examination of constructing methods which are adaptable to climate change and that of methods of appropriate water and land management which contribute to reduction of damage from salinization.

Future outlook

The GOJ continues to promote introduction and spread of participatory irrigation management which enables to efficient agricultural water use and to promote examination of construction and management method of irrigation facilities which are adaptable to climate change, in order to realize sustainable water use and increasing food production by appropriate irrigation.

48. Developing technologies to reduce the enormous losses in water distribution (E-EJ-7)

BRT Recommendation

Recommendation on developing and promoting methods and technologies to reduce the enormous losses in water distribution in many countries,

Action taken so far

The GOJ offers the technological support for updating aged water supply facilities and reinforcing these facilities against earthquake by producing guidelines such as “The guideline of functional diagnostic of water supply facilities”, “The guideline of quake-resistant construction method of water supply facilities” because those maintenances are efficient for leakage control. Additionally, it takes enormous expense to implement these maintenances, so the Government showed the scheduled and efficient method of rebuilding, updating, maintenance and operation of the water supply facilities and the financing method by issuing “The guideline of asset management of water supply businesses”

Future outlook

Continuously, the GOJ will advance both the approach above and the support for the new technology and construction method for updating and quake-resistant water supply facility.

#### 49. Developing technologies to improve the sanitation situation (E-EJ-8)

##### BRT Recommendation

Recommendation on developing and promoting methods and technologies to improve the sanitation situation, which is critical in many countries with respect to human dignity and negative health implications

##### Action taken so far

Japan has been promoting domestic wastewater treatment system such as sewerage system and Johkasou system (advanced onsite domestic wastewater treatment system), for improving living environment and ensuring public health. In such case, effluent water quality from sewage treatment plants is stipulated by sewage law. Moreover, in some locations, Comprehensive Basin-wide Planning of Sewerage Systems is drawn up for preserving the quality of water in public water regions for each river basin. In areas where domestic wastewater is treated by on-site system, Johkasou system, Japan has been promoting appropriate domestic wastewater treatment based on the Johkasou Law enacted in 1983. Amendment to the law in 2005 sets the technical standard for effluent water quality as 20mg/l or below in BOD.

##### Future outlook

Japan continues to promote appropriate domestic wastewater treatment internally based on the Sewage Law and the Johkasou Law. In the context of the issues on access to basic sanitation facility in developing countries, the GOJ continues to be actively engaged in the international cooperation in the field of water and sanitation.

## 50. Developing “Point of Use” water treatment technologies (E-EJ-9)

### BRT Recommendation

Recommendation on developing and promoting methods and technologies to provide “Point of Use” water treatment technologies for the many human settlements, which will not have access to treated and piped water within the next 30 years.

### Action taken so far

In Japan, the coverage of water supply is 97.5% (2008), and the Government advises as to the drinking water at non-water supply district, so it can be said that people in Japan can access to the safe water basically. In addition, the Government financially supports the project of resolving non-water supply district.

To the developing countries, National Institute of Public Health does research of the total supporting method on international cooperation in the water supply field.

And to ensure water at the water shortage regions or countries, the government has been developing the re-use technologies of sewage water and industrial wastewater.

### Future outlook

Continuously, the GOJ will support such research and promote to apply the Japanese superior water supply technologies to overseas water suppliers.

## 51. Developing technology for water recycling (E-EJ-10)

### BRT Recommendation

Recommendation on developing and promoting methods and technologies to improve the technology for water recycling to be more generally used in the cities of the future and arid countries.

### Action taken so far

Ministry of Land, Infrastructure, Transport and Tourism(MLIT) has financial support scheme for local governments' experiments of new sewage technologies. MLIT adopted 5 local governments in 2009(FY). Moreover, a committee of experts was set up for spreading new membrane technologies of sewage treatment in Japan. The committee is revising a technical guideline for introducing technologies of sewage treatment to local governments' facilities. Especially, Membrane Bioreactor(MBR) system is supposed to become popular in sewage treatment in Japan. Then, MLIT conducted experiments in 2009(FY) in order to prove applicability of MBR system in improving present sewage treatment or introducing satellite sewage treatment.

### Future outlook

Continuously, MLIT supports local governments activities for developing new sewage technologies. And, the technical guideline about membrane technologies will be revised in 2010(FY) based on results of the experiments of MBR system.

## 52. Fossil Energy and Raw Materials (E-EJ-11)

### (1) Accelerating the introduction and spread of utilizing new and renewable sources of energy

#### BRT Recommendation

Recommendation on accelerating the introduction and spread of utilizing new and renewable sources of energy to replace fossil energy wherever feasible.

#### Action taken so far

Because of the significance of renewable energy, GOJ set the target to achieve 10 percent of primary energy with renewable energy by 2020 in the energy master plan and new growth strategy endorsed by the Cabinet on June, 2010. The GOJ is now reviewing various regulation relevant to the introduction of facilities to harness renewable energy and committing itself to designing Japan's FIT scheme. In addition, in order to cope with negative aspects of renewable energy, the GOJ is carrying a wide range of research and development such as that to achieve cost reduction and the increase in power conversion efficiency of PV, that to deal with power system stabilization and so on. Moreover, as for Japan-EU energy technical cooperation concluded in 2008, Japan and EU confirmed the future cooperative structure on the area of photovoltaic generation and storage of electricity. In addition, GOJ has started a demonstration project of offshore wind park (landing systems and floating systems).

#### Future outlook

In order for the expansion of renewable energy the GOJ continues to design Japan's FIT scheme. In regard to research and development the GOJ will start the research on ocean energy in earnest beginning the next fiscal year, while continuing the ongoing projects. Furthermore, Japan and EU are planning to conduct joint research and development program on photovoltaic generation in regard to the Japan-EU energy technical cooperation.

(2) Developing new standards and adapting international standards for energy related equipment and systems

**BRT Recommendation**

Japan and the EU should lead in developing new standards and adapting international standards for energy related equipment and systems.

**Action taken so far**

Ministry of Economy, Trade and Industry (METI) of Japan established a Strategic Group on Standardization of Smart Grid in August 2009, and developed a report in January 2010, which includes a road map to international standardization in cooperation with other countries.

And in April 2010, METI set up a public-private consortium consisted of many interested parties in Japan towards international standardization of Smart Grid

**Future outlook**

We would like to promote the international standardization in cooperation with various countries including EU.

### 53. Supporting adequate usage of fossil energy and raw materials (E-EJ-12)

#### BRT Recommendation

Recommendation on supporting the development of business concepts and ideas on how to profitably contribute to mitigation and adaptation to climate change through adequate usage of fossil energy and raw materials.

#### Action taken so far

Power generation by coal in the world is projected to double in 2030 according to the IEA. Japan has the world's most environmentally friendly coal-fired power generation systems, and know-how for operation & maintenance which are able to sustain the initial performance levels over the long term. The GOJ has supported activities to improve efficiency, such as performance diagnosis and engineer training for inefficient overseas coal-fired power plants to develop business schemes reducing CO2 emissions.

In addition, the GOJ has been promoting the dissemination of high efficiency coal-fired thermal power generation, such as Supercritical and Ultra Supercritical technologies that contribute to reduce CO2 emissions.

#### Future outlook

The GOJ will continue to promote the dissemination of high efficiency coal-fired power generation, and support performance diagnosis and engineer training to improve energy efficiency for the development of business concepts that contribute to reduce CO2 emissions.

#### 54. Actions to be taken against access to raw materials (E-EJ-13)

##### BRT Recommendation

Recommendation on raising awareness on access to raw materials. EU and Japan should identify actions to be taken in international fora such as the OECD and WTO, and promote a coherent set of rules on access to raw materials in their bilateral relations as well as WTO accession negotiations. Especially both sides should work on further supporting the “EITI Principles and Criteria” and actively encourage other countries and international companies to commit themselves to the “EITI Principles”.

##### Action taken so far

The GOJ engages in further strengthening the initiative with the framework of G8/G20. Also the GOJ supports EITI as a member of supporting countries, and the several Japanese extracting companies have provided financial assistance via the International Council on Mining and Metals (ICMM).

In the WTO, GOJ has supported the efforts for ensuring transparency through utilizing the Trade Policy Review Mechanism (TPRM) as well as various sub-committees and through negotiations of accession to the WTO.

##### Future outlook

The GOJ, in the position of promoting EITI, continues to consider means to provide further support to EITI.

55. Promoting a level playing field for raw materials (E-EJ-14)

**BRT Recommendation**

Recommendation on promoting a level playing field for raw materials through their respective development policies. Improvements in governance should be obtained through specific commitments on natural resources management in Governance Action Plans and strict enforcement of budget support criteria.

**Action taken so far**

Refer to E-EJ-13

**Future outlook**

Refer to E-EJ-13

56. Common standards for environmentally friendly products and technologies (E-EJ-15)

BRT Recommendation

Recommendation on developing common standards for new environmentally friendly products and technologies as early as possible in close consultation with the industries concerned. However, such standards should not hamper the search for alternative solutions or technological advancements and thus may not be applicable in all industries.

Action taken so far

Japan and EU regularly hold Japan-EU Working Group Standards and Conformity Assessment under Japan-EU Industrial Policy and Industrial Cooperation Dialogue, and JISC-CEN/CENELEC information exchange meetings. We closely communicate by each party.

Future outlook

We have a intention to continuously make close communications with EU by utilizing meeting schemes that was raised in the Action taken. Moreover, we will also make efforts so that standards will not hamper the search for alternative solutions or technological advancements by observing WTO TBT Agreement.

## 57. Common standards for electro-mobility (E-EJ-16)

### BRT Recommendation

Recommendation on the development of common standards for electro-mobility and related infrastructure.

### Action taken so far

Concerning the safety of electric vehicles, the ECE Regulation on passenger protection against electric shock has been established. The GOJ plans to transpose this Regulation into national regulation by around the end of the year 2011.

### Future outlook

The GOJ is planning to adopt the new ECE Regulation and, if necessary, exchange information on safety and environmental regulations on electric vehicles with EU.

## 58. Cooperation mechanism for environmental technology (E-EJ-17)

### BRT Recommendation

Recommendation on widening the cooperation mechanism for environmental technology, currently undertaken in the fields of photovoltaic, power storage, and carbon capture and storage (CCS). Promote cooperation and exchanges between Japan and EU.

### Action taken so far

The Ministry of Economy, Trade and Industry (METI) and the Directorate-General for Research of the European Commission held meetings of experts in the fields of power storage and carbon dioxide capture and storage (CCS). Experts from government, research institutions, business, etc. from both sides discussed ways of cooperating on research and development in their respective meetings. Both sides are continuing to study specific issues related to cooperation.

In the field of photovoltaics, from July to November 2010 the two sides conducted a joint call for research and development bids for a concentration photovoltaics project, the budget for which would be approximately 5 million euro over 4 years.

### Future outlook

Both sides are working to arrange the “Japan-EU officials’ meeting on cooperation on energy technology R&D”, to be held in Japan in February or March 2011. In terms of the photovoltaics project, both sides have been examining project proposals received. Plans call for selection of a proposal in February 2011, with the project to start in June or July. In the fields of power storage and CCS, the two sides plan to hold expert meetings. Through these efforts, the Japanese government will promote cooperation on energy technology between Japan and the EU.

59. Exchange programs of Japanese and European students in technical and research areas (E-EJ-18)

BRT Recommendation

Recommendation on promoting and intensifying exchange programs of Japanese and European students especially in technical and research areas. In particular, develop student exchange programs with a mandatory internship component in European and Japanese industries such as the Vulcanus programs.

Action taken so far

METI supports the Vulcanus Program for the purpose of enhancing the long-term development of human resources in charge of industrial cooperation between Japan and the EU. Twenty five students have been sent to the European enterprises that operate in nine EU countries. They have been engaged in system development, technology research and data analysis etc, and have contributed to new product development and sales promotion.

Approximately 10% of all students got jobs with European companies and 30% of those with Japanese companies that operate in Europe, representing a great result for the program.

Future outlook

Taking into consideration the situation of budget constraints, METI is going to continue support the Vulcanus Program.

## 60. Promoting the efficient use of energy (E-EJ-19)

### BRT Recommendation

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.

### Action taken so far

- The GOJ launched the Top Runner Standard based on the energy conservation law amended in 1999, to diffuse highly energy efficient appliances and vehicles by setting energy-saving target standards. The law makes it obligatory for manufacturers and importers to report how much they have reached the standard by the target fiscal year. At first, 11 product items (including automobiles and air conditioners) were covered by this program, but due to continuous efforts to increase the range, the present coverage of product items is 23. The GOJ reviewed the Top Runner standard for TV sets, lighting equipment, computers, and magnetic disk units in April 2010, and will be aiming for further energy-saving performance.
- Green innovation is set to be one of seven pillars in the “New Growth Strategy” which was adopted by the Cabinet in June 2010. The strategy states that the GOJ will promote the reuse of domestic resources by the 3Rs.

### Future outlook

- The GOJ will continue to increase the number of categories subject to the Top Runner project and review the energy conservation target standards for each product category. As for the international arena, not only will the GOJ be stepping up discussions on the harmonisation of measurement methods through organizations such as the IEA and ISO, but also actively introducing the Top Runner project, as well as its effectiveness, at international conferences.
- The "Comprehensive Emergency Economic Measures in Response to the Yen's Appreciation and Deflation" was adopted by the Cabinet in October 2010. On the basis of the measure, the GOJ will accelerate promoting the 3Rs.

## 61. Promoting the reduction of reliance on fossil fuels (E-EJ-20)

### (1) Spread of existing technologies

#### BRT Recommendation

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. In promoting renewable energy, such as solar, wind, and biomass energy, challenges still exist regarding cost and stability of energy supply.

#### Action taken so far

- To promote the utilization of nuclear energy more than current level, recovery of trust on the safety aspect and consensus-building toward nations are essential. Until today, the GOJ has been deepening mutual understanding with the people, through publicity work and public hearing.
- In order to cope with issues of renewable energy, the GOJ has been carrying out a wide range of research and development such as that to achieve cost reduction and to increase in power conversion efficiency of PV, that to deal with power system stabilization and so on. Moreover, as for Japan-EU energy technical cooperation agreed in 2008, Japan and EU confirmed the future cooperative structure on the area of photovoltaic generation and storage of electricity. In addition, the GOJ has started a demonstration project of offshore wind park (landing systems and floating systems).

#### Future outlook

- The GOJ will improve publicity work and public hearing to implement these activities related to nuclear energy more effectively, in accordance with the policy for improvement of mutual understanding through the way of direct communication between the government and the people and the policy for the rise of effects of those.
- On the challenge of renewable energy, in regard to research and development the GOJ will start the research on ocean energy in earnest beginning the next fiscal year, while continuing the ongoing projects. Furthermore, Japan and EU are planning to conduct joint research and development program on photovoltaic generation in regard to the Japan-EU energy technical cooperation.

## (2) Development of innovative technologies

### BRT Recommendation

The development of innovative technologies such as clean coal, carbon dioxide capture and storage(CCS), hydrogen energy, nuclear fusion, advanced energy storage and fuel cells require long-term efforts to reduce GHG. It is also essential to increase Governments' expenditure on research and development and to promote international public-private cooperation.

### Action taken so far

In line with the “Cool Earth – Innovative Energy Technology Program” established in 2008 to promote energy technology development leading to substantial reductions in CO<sub>2</sub> by 2050, the Japanese government has allocated resources in order to promote important innovative energy technologies.

Furthermore, in the Strategic Energy Plan established in June 2010, the Japanese government detailed its intent to realize the “three Es” – energy security, environmental suitability, and economic efficiency – while also implementing specific measures to achieve energy-based economic growth.

One of the principal measures is “Developing and Diffusing Innovative Energy Technologies,” in connection with which the Japanese government has been drafting a new energy innovation technology roadmap to promote increased energy technology R&D in the medium- and long-term. Additionally, it is stated that Japanese government promotes the “Green Innovation” in the environment and energy fields in the “New Growth Strategy” compiled in June 2010. R&D regarding innovative technologies such as conversion of solar energy and superconducting systems are being implemented, which contribute to reduction of greenhouse gases emission.

### Future outlook

Technologies that contribute to significant, long-term reductions of CO<sub>2</sub> emissions, such as nuclear power and coal thermal power, will be promoted in an intensive, planned manner in accordance with the technology roadmap.

Also the R&D such as conversion of solar energy and superconducting systems will be promoted.

Additionally, the Japanese government will promote international cooperation between the public and private sectors through meetings on Japan-EU energy technology R&D cooperation, incorporating meetings between both government officials and experts from relevant fields.

## 62. Diffusing environmental and energy-saving technologies in developing countries (E-EJ-21)

### BRT Recommendation

To advance the reduction of GHG emissions on a global scale, it is critical to initiate measures in developing countries. Deploying 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 financial cooperation and private investments. Protection for intellectual property rights is essential in this regard.

### Action taken so far

- The GOJ has been conducting technical-cooperation in the field of environment & energy toward developing countries including Asia through ODA in association with private sectors.
- Except for ODA, the GOJ has been conducting the technology transfer and its dissemination through the demonstration project in the area of energy efficiency in association with the counterpart companies. From 1993 to 2009, 46 projects had been done, and the total amount of the GHG emission reductions in those areas has reached to the 18 million tons equivalent to the carbon dioxide. In order to appropriately evaluate Japan's contributions to reduce GHG emission that has been made globally through measures including provision of Japan's low-carbon technologies, infrastructures, and products, 33 feasibility studies have been launched in 13 developing countries for the establishment of bilateral offset mechanisms.
- As for the intellectual property protection, for example, between Japan and China, in case of the problem with the intellectual property among both countries' companies, the framework to resolve it in the committee established by both countries is prepared. And in the multilateral fora, Japan also strives to protect IPR in technology transfer at the UN climate change negotiations.

### Future outlook

The GOJ will continue technical-cooperation in the field of environment & energy including demonstration using ODA and other schemes. The GOJ will work on to concretize the new mechanism such as bilateral offset mechanism that can contribute to effective emissions reduction in developing countries, and implement assistance to these countries.

### 63. Continuation of “green policy” (E-EJ-22)

#### BRT Recommendation

Many countries have expanded fiscal expenditure on “green policy” programs and governments’ efforts towards a low-carbon society/economy are highly appreciated. In current and future “green policy”, reduction of GHG emissions from the view point of the total life-cycle basis must be promoted.

#### Action taken so far

The government of Japan promotes Carbon Footprint of Products (CFP), which shows the amount of GHG emissions associated with products throughout the life cycle, from raw material acquisition to disposal or recycling, in CO2 equivalent to help consumers’ consideration in goods selection. Currently, 144 products have been approved to use official label.

Furthermore, the government of Japan launched the eco-point system last year. The eco-points are given to consumers who purchase televisions, refrigerators, or air conditioners that meet certain energy-efficiency criteria and to consumers who build or renovate eco-friendly houses with good insulation. Consumers are able to exchange the eco-points, worth 1 yen each, for various goods such as environmental friendly products or gift certificates.

#### Future outlook

The government will continue Carbon Footprint of Products and aim to increase the number of entitled products.

The government extended the closing date of the eco-point system until March 2011 for home appliances and until December 2011 for housing with expansion of the program for housing to cover solar heating systems, water-saving toilet system, and super-insulated bathtub associated with current coverage, new house construction or insulated window renovation.

(Attachment)

Tax-system-related proposals

Changes to the tax system are made every year, and the decisions on what changes to make are made following deliberations by bodies such as the government's Tax Commission. These deliberations focus on requests and opinions submitted by government ministries and agencies to the tax authorities, and take into account the economic climate, fiscal situation. In addition, opinions from various levels, including proposals from the BRT, are referred to by ministries and agencies when they prepare their requests for changes to the tax system, and ultimately reflected in the changes that are actually made each year.

Working Party A:

9. Promoting foreign direct investment

(1) Tax deferrals for capital gains stemming from direct cross-border mergers and re-organisations

Working Party D:

38. Tax issue proposal for EU and Japan

(2) Corporate accounting and tax practice

(3) transparent and fair taxation

41. Tax issue proposal for Japan

(2) Reducing corporate tax rates

(3) Expanding tax breaks

Proposals have been issued concerning each of the above issues, and we intend to refer to those that seem reasonable from the standpoint of whether they can contribute to an improvement in the business environment.