

(Tentative Translation)

**Report from the Government of Japan**

**Concerning the Recommendations**

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

March 2012

Note: The content of this report is based on the situation as of December 31, 2011.

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

### **1. Strengthening the EU-Japan Economic Relationship (WP-A/#01/EJ to EJ)**

#### **BRT Recommendation**

Japan and the EU together account for more than one-third of world GDP and 22.4% of world trade. However, EU exports to Japan amount to less than 2% of Japan's GDP, well below the level in the EU's other key markets, indicating that Japan offers the EU enormous untapped trade potential.

Under the existing 2001-2011 EU-Japan Action Plan, non-binding instruments, such as the Regulatory Reform Dialogue, aimed at improving the respective business environments and developing bilateral trade, have delivered only extremely limited results. As a result, this huge growth potential in trade and investment remains untapped.

In 2010, EU-Japan Business Roundtable recommended that negotiations on a balanced and mutually beneficial bilateral agreement should start 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. Working Party A repeats this call for the removal of barriers to trade and investment by addressing a broad range of trade issues, including harmonisation of standards and certification procedures, mutual recognition of product certification and, when possible, and appropriate, the mutual acceptance of functionally equivalent regulations. Other areas, such as competition rules, services, procurement, investment rules, the protection of intellectual and industrial properties, and cooperation on raw materials should also be addressed.

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

Reaffirming the close partnership between Japan and the EU as major economies and their commitment to market-based economy and building on the conclusion of the joint examination which started at the previous Summit in April, 2010, the summit leaders of Japan and the EU agreed, at the 20<sup>th</sup> Japan-EU Summit held in Brussels on May 28<sup>th</sup>, 2011, to start the process for negotiations (the scoping exercise) for a deep and comprehensive Free Trade Agreement (FTA)/Economic Partnership Agreement (EPA). Covering all issues of shared interest to both sides including tariffs, non-tariff measures, services, investment, Intellectual Property Rights, competition and government procurement, this EPA is aimed at utilizing their great trade and investment potential, thereby further strengthening not only the bilateral economic relationship but also comprehensive relationship. At the G20 Summit in Cannes, November, summit leaders of both sides affirmed their commitment and leadership to accelerate the scoping exercise to identify the scope and level of ambition of a balanced and mutually beneficial agreement toward the early launch of negotiation.

#### **Future outlook**

Japan and the EU intend to successfully complete the scoping exercise. In parallel, the European Commission will seek the necessary authorization for the negotiation for an EPA. The 21<sup>st</sup> Japan-EU Summit meeting to be held in the first half of 2012 is expected to further fortify the economic and trade relationship between the two sides. Following wide-ranging economic needs, a variety of bilateral dialogues, such as the Japan-EU IPR dialogue, continue to enhance their economic partnership.

## 2. Support of WTO Doha Development Agenda for fight against protectionism (WP-A/#02/EJ to EJ)

### BRT Recommendation

Although the global economy is growing again, protectionist risks remain high. The Working Party is concerned about global imbalances and sharp currency fluctuations which are pushing countries to intervene in currency markets or through capital controls in what appears to be a classical game of currency devaluation. High commodity prices are pushing countries to adopt highly interventionist policies to secure food and raw materials supplies. Moreover, export restrictions are on the rise.

The G20 Summit in Korea in 2010 gave a new impetus to the Doha Round and technical negotiations have resumed in Geneva. WTO Director General Pascal Lamy has called for the start of a “final countdown” in 2011 in view of the next WTO ministerial conference on 15-17 December 2011 in Geneva. The impasse in the negotiations must be overcome in order to achieve a rapid and ambitious conclusion.

The Working Party recommends that the EU and Japan intensify their efforts to jointly push for a more ambitious outcome. Together with other partners (like the US) they should engage jointly with key emerging countries (in particular Brazil, India and China) to secure market access on industry and services that reflects their growing economic weight. It is important to note in this light that during the economic crisis, countries like China, India and Brazil have increased their competitiveness and trade market share. Improved market access must be obtained in the Doha Round, and not in any future trade round.

The draft agreement on industrial goods (December 2008 texts on NAMA) should be improved to support growth and development more. In the current modality, emerging countries make too few commitments and receive too many exceptions. Specific tariff and non-tariff sectoral agreements in goods (chemicals, machinery, electronics/electrical), agreements on services including elimination of foreign equity limitations, and agreements on trade facilitation of clean technologies – (for renewable energy and energy efficiency products – provided a sector can be delimited in a clear and non-discriminatory manner) should all be part of a more ambitious Doha outcome. Given their dependence on external raw materials supply, the EU and Japan should also strongly make the case for strengthening disciplines on export restriction. The EU and Japan should also move ahead with parallel tracks for action within the WTO, for example on 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.

In the current GPA revision by major trading partners, the EU and Japan should also press for the suppression of unjustified exemptions and derogations of GPA rules.

### Action taken so far

Based on the agreement at the APEC Economic Leaders' Meeting in Yokohama and the Seoul G20 Summit in 2010, since the beginning of the year 2011, WTO members including Japan have actively engaged in negotiations toward conclusion of the Doha Development Agenda and subsequently the “LDC plus” package by the end of the year 2011, but didn't reach such goals. At the WTO Eighth Ministerial Conference (MC8), Ministers of the WTO members, while acknowledging that the negotiations are at an impasse and that it is unlikely that all elements of the Doha Development Round could be concluded simultaneously in the near future, committed to work actively toward a

successful multilateral conclusion of the Doha Development Agenda in accordance with its mandate and explore different negotiating approaches.

Regarding resisting protectionism, at the G20 Cannes Summit and the APEC Summit in Honolulu in 2011, the members reaffirmed their commitments to standstill including refraining from imposing new export restrictions, and issued a strong message for resisting protectionism. At the MC8, all Ministers agreed in a political message in this regard. Further, Japan, with other concerned members, stated its commitment at the same level as the commitment made in the G20 Cannes Summit Final Declaration and the APEC Honolulu Declaration.

With regard to the re-negotiation of the Government Procurement Agreement, the Government of Japan (GOJ) actively participated in the negotiations and contributed to the conclusion of the negotiation at the MC8.

#### Future outlook

With regard to Doha Round negotiations, based on the outcome of the Eighth Ministerial Conference, the GOJ will continue playing an active role in the negotiations.

Further, Japan will work to strengthen and improve the functioning of the WTO including that of the dispute settlement and of enhancing transparency of trade policies.

In particular, with regard to resisting protectionism, Japan will continue to contribute for maintaining and strengthening monitoring system through the WTO.



3. Applying international standards and enhanced cooperation in the promotion of new global standards (WP-A/#03/EJ to EJ)

(1) Adoption of international product standards and certification

**BRT Recommendation**

The Working Party urges both authorities to adopt international product standards and certification procedures where applicable, and, to promote harmonisation of standards and certification procedures, mutual recognition of product certification and, when possible, and appropriate, mutual acceptance of functionally equivalent regulations governing the application process for importing and selling/using products in sectors such as Construction Materials, Organic Products, Cosmetics, Medical Devices, Veterinary Products, Automobiles and Processed Food.

**Action taken so far**

Refer to the responses to WP-A/#07(1)-(3) and (5)-(8).

**Future outlook**

Refer to the responses to WP-A/#07(1)-(3) and (5)-(8).

## (2) Global patent

### 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

IP 5 Heads Meeting held in June in Tokyo, including representatives from the Japan Patent Office (JPO) and the European Patent Office (EPO), agreed to initiate the discussion toward harmonization of patent system. Subsequently, the JPO, the United States Patent and Trademark Office, major European IP offices and the EPO assembled together to discuss patent harmonization at Tegernsee in Germany. Based on these developments, it is expected to see patent harmonization discussions moved forward.

In the meantime, the JPO and the European IP offices have been making efforts to expand the framework of Patent Prosecution Highway (PPH), in order to streamline patent examination practices. Eight IP offices, including Japan, the UK, Finland and Spain, relaxed requirements for filing a PPH request and launched a pilot PPH, called “PPH MOTTAINAI” on July 15th, 2011. In addition, the JPO launched a PPH program with the State Intellectual Property Office of the People's Republic of China in November 2011.

### Future outlook

While continuing dialogue with users, the Government of Japan (GOJ) will strive to accelerate efforts for patent harmonization through every appropriate forum, such as the WIPO Standing Committee on the Law of Patents, patent harmonization meetings held among the developed countries and the IP5 meetings.

Furthermore, the GOJ will continue to work to expand the utilization of the PPH framework, inviting ASEAN countries to participate in the PPH program.

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

#### BRT Recommendation

Given the nature of the issue and the importance for business as well as for society in general, the two Authorities 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 Government of Japan (GOJ), which mainly focuses on household products, currently covers 18 items. 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 that currently covers 5 products.
- Japanese pilot project of Carbon Footprint of Products (CFP) has been carried out since 2009 in order to contribute to realizing low carbon society. This pilot project led to such achievement that more than 70 Product Category Rules (PCRs) have been set out and more than 360 CFPs have been verified.

#### 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 the labeling systems.
- Japanese CFP pilot project are to be transferred to the private sector after 2012 fiscal year, while being harmonized with international standards (e.g. ISO). As acknowledging the importance of visualizing potentials to reduce environmental burden by LCA on value chain scope, the GOJ intends to actively discuss with the EU about international efforts such as "Environment Footprint by EC."

#### (4) Authorized Economic Operators (AEO)

##### BRT Recommendation

Following the agreement on the mutual recognition of the AEOs (Authorized Economic Operators) in June 2010 between the EU and Japan, the Authorities of the EU and Japan should aim at introducing further regulatory cooperation in order to give more concrete benefits to AEOs; for example, once an economic operator is approved as an AEO in Japan, its status should be extended to its subsidiaries in the EU, and vice versa.

##### Action taken so far

In order to further enhance the regulatory cooperation between Japan and the EU, the 4th Japan-EU Joint Customs Cooperation Committee was held in Tokyo on 24 May 2011. The MRA on AEOs between Japan and the EU went into effect on the same day and AEOs in Japan and the EU have received benefits of the MRA in customs procedures of the other side for cargos.

##### Future outlook

With respect to the MRA on AEOs between Japan and the EU, in addition to the review of its implementation, the customs authorities of Japan and the EU will discuss the additional benefits for the AEOs.

(5)(6)Development of practical application of new technologies (such as RFID) & Security and operational efficiency of the supply chain

#### BRT Recommendation

-The two Authorities should create a framework between the EU and Japan in the development of practical application of new technologies, such as RFID and biometrics authentication technologies. This will enable and enhance cooperation among companies in the EU and Japan, and will also promote new international standardisation and lead to its dissemination.

-The two Authorities should disseminate model ICT use that contributes to the security and the operational efficiency of the supply chain. For example, RFID tags, sensors, biometrics authentication technologies and UCR (Unique Consignment Reference) numbers can build a more secure and visible international supply chain.

#### Action taken so far

Based on the agreement in the JAPAN-EU ICT Policy Dialogue on 17 June 2011 in Brussels, the Ministry of Internal Affairs and Communications and the European Commission have been discussing toward implementation of joint ICT research through identifying the joint research sectors, and providing fund to the Japanese and European research institutes that apply to this initiative.

In addition, one example of model ICT use is that the Ministry of Economy, Trade and Industry has been making efforts to establish a global information network for sharing cargo status data based on interoperable standards for optimization of global supply chain.

#### Future outlook

The Government of Japan (GOJ) will continue the discussion with the European Commission toward the implementation of the international joint research in ICT sector.

In addition, based on the result of the pilot project regarding the use of RFID toward the optimization of global supply chain, the GOJ plans to issue recommendation and requests international-standard-making organization to making standard rules.

## (7) Support for the ICT for Efficiency Forum

### BRT Recommendation

The European Commission and the Japanese Government should support the ICT for Energy Efficiency Forum, actively participating in it and disseminating its outcome in order to encourage global collaboration.

### Action taken so far

ICT for Energy Efficiency Forum is a partner of ITU. ITU-T SG5 has been conducting studies on methodologies for evaluating ICT effects on climate change (e.g. GHG emission) and publishing guidelines for using ICT in an eco-friendly way, and is processing its work in liaison with other related bodies and meetings, such as IEC, ISO, and ICT4EE Forum.

Japan has actively participated in ITU-T SG5 meetings and ITU symposiums for climate change in order to contribute to its standardization activities and to disseminate outcomes of Japanese activities.

### Future outlook

Japan will continue to promote international standardization to establish methodologies and best practices for evaluating ICT effects on climate change. We will also participate in ITU symposiums for climate change in order to disseminate outcomes of the activities of Japan. Those activities would contribute to ICT4EE activities against global warming and the reduction of global CO2 emissions.

(8) Internartional harmonization at Codex

BRT Recommendation

The European Commission and the Japanese Government should collaborate on achieving international harmonisation at Codex in the definition and standards for food for specified health use/functional foods.

Action taken so far

The Government of Japan (GOJ) has been collaborating toward achieving international harmonization in standard of foods through the CAC, the Codex Committee of Food Labelling and the Codex Committee on Nutrition and Food for Special Dietary Uses.

Future outlook

The GOJ continues to cooperate internationally through CAC activities.

#### 4. Supporting timely development of business (WP-A/#04/EJ to EJ)

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

###### BRT Recommendation

The Working Party welcomes the conclusion of more agreements between Japan and the EU member states in 2010 and that further agreements are under consideration. However, Japan and the Member States of the EU should make further efforts to expand the network of Social Security Agreements. In addition, they should introduce an interim measure, by which a host country should either exempt contributions to pension funds unilaterally or refund the contributions in full when expatriates return to their home country.

###### Action taken so far

(a) The Government of Japan (GOJ) is making efforts to conclude social security agreements with EU member states. 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, Luxembourg and Sweden, and exchanges of information and opinion between the authorities with 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 as well as exchanges of information and opinion for the conclusion of social security agreements with European countries.



## (2) Personal data protection regime

### BRT Recommendation

(a)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 the 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 realise such a business environment between the EU and Japan, the Government of Japan should make sure that the review currently underway in its Special Commission about Personal Data Protection in the Consumer Commission, in which the revision of the law itself may be considered, should pay due attention to the international aspects of personal data protection and, in particular, the issue of the absence of the adequacy status with Japan under the EU Directive 95/46/EC. The two governments should then launch the adequacy-finding procedure under the EU Directive as soon as feasible.

In parallel with the above process, the authorities of the EU and Japan should launch a dialogue in order to seek an international framework by enhancing cooperation with third countries and international organisations. It should eventually lead to the closer alignment of data protection regimes around the world that would enable global businesses to transfer personal data by complying with one regime.

(b)In addition, the authorities of the EU and Japan should improve legal certainty surrounding the use of new technological tools such as cloud computing applications and services. We believe that such improved legal certainty would support and enhance the application of new technological developments while maintaining the degree of data protection currently provided.

### Action taken so far

(a)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 contained in the OECD guidelines issued in 1980. Enforcement authority of the act is entrusted to each minister in charge of the business sector concerned, and based on guidelines determined by each minister, the precise interpretation, application and appropriate enforcement is conducted.

Until now, our efforts to safeguard personal information have been made in light of international initiatives by organisations such as the OECD, APEC, the EU, ICDPPC, and APPA, and in April 2008 we partially revised our Basic Policy on the protection of personal information in order to respond to these international initiatives and better safeguard the rights and interests of consumers. Based on this Basic Policy, in December 2011, each ministry and agency participated in “APEC Cross-border Privacy Enforcement Arrangement”. And with regard to the guidelines for each

business sector, new guidelines have been established and existing ones have been revised when necessary. Through such efforts, personal information is being effectively safeguarded.

In July 2011, the Special Commission on Personal Information Protection established in the Consumer Commission published “the Report of the Special Commission on Personal Information Protection” (hereunder “the Report”). In the item of international consistency (Part2-4) of the Report, the Special Commission mentions, “In the field of international consistency of the system about the personal information protection, it is important to promote understanding of the international community about legal system in Japan and consider how to coordinate with them, taking into account of the needs of business entities acting outside of Japan”.

(b) Refer to the response to WP-C / # 04/EJ to EJ.

#### Future outlook

(a) Personal information will continue to be safeguarded at an adequate international level by making efforts to ensure 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 Information 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, and the Special Commission submitted the Report to the Consumer Commission. The Consumer Commission expressed their recognition that the problems raised in the report are important, and need to be considered continuously. We will take into consideration the discussion of the Consumer Commission when we formulate our policy on personal information protection.

(b) Refer to the response to WP-C / # 04/EJ to EJ.

## 5. Cooperation in the area of climate change (WP-A/#05/EJ to EJ)

### (1) Collaboration to advance new technologies for more efficient energy use

#### BRT Recommendation

Global warming is a global challenge that is high on the political agenda of both the EU and Japan. Over the next decades the world will drastically have to change the way it produces and uses energy in order to save resources and contribute to limiting global warming to 2° Celsius in this century. This will require a wide range of low-carbon solutions. Much of the required emission savings need to come from more efficient energy use in homes, business and transport. Many goods and services can contribute to environmental improvements including the fight against climate change, and have the potential to create huge business opportunities. European and Japanese companies are at the forefront of developing technologies for low-carbon solutions. The Working Party recommends that the EU and Japan should work together, for example, through common standards and testing procedures, and by fostering industry cooperation to advance these technologies and create larger markets.

#### Action taken so far

After the oil crises in 1970's, the Government of Japan (GOJ) placed energy conservation as a key element in energy policies. In 1979, The Law Concerning the Rational Use of Energy (Energy Conservation Law) was enacted. The industrial sector has played a central role in promoting energy conservation. As a result, Japan's energy efficiency is 3 times greater than the world average. Regarding energy conservation among domestic and industrial electric appliances and automobiles, Top Runner Program was introduced in 1999 that set only standard values. This resulted in much progress in the energy conservation field. This program has encouraged competition between companies and made great progress in energy conservation of house appliances and automobiles.

In November 2011, ITU-T recommendation on energy conservation of data centers, which had been established by the GOJ, the EU and other countries, was approved.

#### Future outlook

After the March 11 earthquake and Fukushima nuclear power plant accident, Japan now challenges to establish new energy policy. To this end, further security and national reliance has to be achieved. To lay out scenario of bold new energy best mix, the Government of Japan (GOJ) will set a new strategy and plan of Japan's mid, long-term energy systems, until next summer. The GOJ strengthens the Energy Conservation Law by restraining demand of the total electricity usage during the peak period, and by re-evaluating standards of the buildings and its materials, etc.

## (2) Integrated approach for CO2 emission reduction

### BRT Recommendation

Although Japan and Europe still have relatively high per-capita emissions, their relative share in global greenhouse gas emissions is steadily decreasing. Both the EU and Japan are adopting challenging targets to reduce the level of CO2 emissions. For example, in the transport sector, 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 that 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, and urges the EU and Japanese Authorities to cooperate in the transport and other sectors to achieve the highest reductions possible at the minimum social cost.

### Action taken so far

The Government of Japan (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 CO2 emissions from the vehicles.

## 6. Better Regulation (WP-A/#06/EJ to EJ)

### BRT Recommendation

The Working Party recommends that Japanese and European policy-makers increase mutual understanding of existing and upcoming regulations on each side to exclude unwittingly taking initiatives that create barriers to trade. Both sides should commit to exchanging annual legislative work programmes at the earliest stage to prevent regulatory divergence and new trade barriers. In addition, the two sides should agree to an early warning system for draft legislation in order to make the dialogue effective.

The EU and Japan should also develop a joint strategy to promote better regulation, learning from each other's experience and adopting a common system of good governance. Currently the views of businesses in Japan and the EU are not sufficiently taken into account in the regulatory process. Better regulation, based on transparency, early public consultation, impact assessment, public access to draft regulations or administrative measures, could lead to a reduction in the cost of regulatory compliance and the overall administrative burden, which would be to the benefit of the Japanese and European economies as a whole.

### Action taken so far

With respect to appropriate enforcement of regulations, each regulation has been reviewed by its responsible Ministry, taking into consideration stakeholders' opinion.

Each Administrative Organ has been legally obligated to conduct ex-ante evaluation of regulations since October 1, 2007. In addition to this, in August 2007, the Ministry of Internal Affairs and Communications (MIC) formulated 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 promote smooth and effective implementation of ex-ante evaluation of regulations. Since then, MIC has made efforts to have the RIA accepted by administrative organs as the method of ex-ante evaluation of regulation so that it would achieve the intended effect.

In addition, in order to investigate and deliberate on existing regulations and institutions, the Subcommittee on Regulatory and Institutional Reform was established under the Government Revitalization Unit in March 2010, and the Subcommittee encouraged responsible ministries to review their regulations and institutions. Further, in September 2011, the Subcommittee launched its third session, and has continued to make efforts to make progress in regulatory and institutional reforms from the viewpoint of constructing a new post Great East Japan Earthquake social economy, and rebuilding Japan that is new and more robust than before the earthquake.

### Future outlook

Each authority continues to ensure appropriate enforcement of regulations. As for regulatory and institutional reform, the Subcommittee will reach and publish its final conclusions around June 2012.

7. Harmonization & mutual recognition of standards and product certifications; acceptance of international standards where applicable (WP-A/#07/E to J)

(1) Construction Products

**BRT Recommendation**

The Government of Japan 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 a foreign institute to be registered as a Registered Overseas Certifying Body (JAS) or a Foreign Accredited Certification Body (JIS) by following a review of the required documentation and an on-site inspection.

Moreover, the registration process is based on ISO/IEC Guide 65, an internationally recognised accreditation standard. In other words, difficult registration are not set in Japan's procedures.

**Future outlook**

The Government of Japan continues working to ensure that the accreditation system functions in an appropriate manner as concerned ministries arrange briefing to foreign institutes when necessary.

## (2) Organic Products

### BRT Recommendation

The Government of Japan should work together with the EU authorities to achieve true mutual recognition of Organic Food Products labelling. Currently, products which are certified as organic in Europe and meet the organic-JAS regulations and are labelled organic in Japan must obtain a supplementary organic certificate from the Embassy of the country of origin every time they are imported into Japan. The working Party requests the abolishment of this need for supplementary organic certificates.

### Action taken so far

In June 2010, the EU recognised the organic JAS system as equivalent to the EU counterpart, and consequently the equivalence recognition of organic rules and standards between Japan and the EU became mutual. Both parties take necessary measures to maintain the integrity of the organic products. When Japan imports products which are certified as organic in Europe, the Government of Japan (GOJ) does not require a supplementary organic certificate issued by the Embassy of the country of origin, but the necessary certificate to confirm organic certification issued in the country of origin.

### Future outlook

The GOJ intends to closely cooperate with the EU in ensuring the integrity of organic labelling.

### (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 Government of Japan (GOJ) has developed and published the positive list of active ingredients and additives for medicated cosmetics, which are classified as quasi-drugs. On the 21<sup>st</sup> July, 2011, the claim of “minimizing the appearance of fine lines due to dryness” had been added as cosmetic efficacy claim 56 to its list of preapproved efficacy claims.

Furthermore, the Ministry of Health, Labour and Welfare, together with the Pharmaceuticals and Medical Devices Agency (PMDA), have had timely a meeting with the industry to exchange views on measures for rapid review process of quasi-drugs.

Regarding the alternative testing methods, the GOJ has already accepted not only OECD alternative animal testing methods but also alternative animal testing methods validated by JaCVAM (Japanese Center for the Validation of Alternative Methods), in cooperation with validation centers of the EU, the United States, Canada, and Korea under the framework of ICATM (International Cooperation on Alternative Test Methods) .

#### Future outlook

The GOJ will continue to exchange views with the industry for the purpose of ensuring the transparency in approval process and rapid review on medicated cosmetics.

When other alternative animal testing methods, which the OECD has not adopted, are requested with appropriate data of validation research, the GOJ will evaluate them accordingly through the validation by JaCVAM.



#### (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 between railway enterprises and exporters.

Anyway, as railway safety standards have been developed reflecting the situation of transportation and rail accidents and other considerations in each country, measures to be taken to ensure

conformity with safety standards can be different between Japan and the EU.

(b) Concerning this issue, Japan and the EU deepened mutual understandings through the railway experts' meetings by the Governments of Japan (GOJ) and the EU as well as the conference between railway-related firms of both sides last October. In particular, all the seven JR companies, Tokyo metro, UNIFE (Union des Industries Ferroviaires Européennes), and the European Business Council (EBC) participated in the latter meeting, which was highly acclaimed by participants in UNIFE.

##### Future outlook

(a) With regard to the field of standardization activity, the Japanese Railway International Standards Center (J-RISC), established last year, mainly proceeds to implement such activities as annual exchange of information between Japan and the EU including continuous JISC-CEN/CENELEC information exchange meeting, harmonization between JIS and ISO/IEC standards including testing methods through positive cooperation on development of international standards.

(b) The GOJ intends to continue to discuss with the EU with a view to promoting such dialogues among experts and railway companies for deepening mutual understanding between both sides.

## (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 not only in a significant device lag, but also together with the insufficient reimbursement system, a device gap. 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. 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 GOJ 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, internationally harmonized regulations were introduced in terms of essential principles and classification of devices, among others. In addition, with regard to the establishment of Approval Standards, Certification Standards and standards for Quality Management Systems, the Government of Japan (GOJ) basically accepts the international standards of the ISO and the IEC.

Foreign clinical trial data has been accepted 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 of reducing the industry's burden and promoting the efficiency of inspection, through the solution of a few specific non-tariff issues (called "Paragraph 34 process"), the GOJ

agreed to align Japanese QMS standard for medical devices with the international standard (ISO13485), which is applied in the EU, but with some exceptions. Furthermore, the GOJ has set up the working group (WG) including industry and promoted further improvement such as growing scope of audit by item and mutual utilization of results between regulators for QMS audit at the WG.

The GOJ is making efforts to clarify GCP operations through various notices and Q&A. Based on the Five-Year Strategy for the Creation of Innovative Pharmaceuticals and Medical Devices, the GOJ is also working on improvements of GCP operation. In April 2009, the ministerial ordinances relating to clinical review board, notification of clinical trials, delivery of investigational devices and others are revised in order to be consistent with the ICH-GCP. The GOJ therefore thinks that Japanese GCP is harmonized with ICH-GCP in principle.

#### Future outlook

The GOJ will continue to properly engage in discussion for the international harmonization of medical device regulations in the GHTF, etc.

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 concerned industrial sector.

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

Discussions on further expanding scope of QMS audit from actual scope of audit by item (by preferred term \*[1] or by certification standard \*[2]) to promote efficiency of inspection are held in the Advisory Committee of Pharmaceutical Regulatory System. Scope of QMS audit is being discussed in the WG.

\*[1] The preferred term means a certain range corresponding to “Preferred Term” of GMDN.

\*[2] Standard for pre-market certificated for controlled device (Class II) by certification bodies.

The global harmonization of Medical Device regulations needs to be discussed with not between Japan and the EU, but also jointly the U.S. and other countries. For this reason, the GOJ will achieve international harmonization of Medical Device regulations relating to GCP, QMS etc. through the activities in the GHTF and others, which represent a multinational initiative.

## (6) Veterinary Products

### BRT Recommendation

Animal health products already approved in the EU have to undergo further rigorous controls and unnecessary tests before being approved in Japan, which increases costs and causes delays. Accordingly, the Working Party:

a) Urges the Government of Japan 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, 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 is newly enforcing the 4 VICH guidelines in fiscal year of 2011. Japan also played a central role by chairing the 26th VICH Steering committee in Tokyo, and jointly compiling various publications, preparing meeting materials and presentation at the Contact meeting on wider international harmonization of VICH guidelines with non-VICH countries in November 2011, 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 100 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 time to approve the products from the EU, since 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.

In conclusion, it is inappropriate to prioritize the mutual recognition of GMP for the time being and suggest to consider mutual cooperation after setting appropriate agendas.

## (7) Automobiles

### BRT Recommendation

In 1998, Japan became the first country in Asia to accede to the UN-ECE 1958 Agreement on the Mutual Recognition of Type Approval for Vehicles etc, which provides that vehicle components which have received type approval according to ECE Regulations in one contracting country are exempt from testing in any other signatory country where those regulations have been adopted. Japan has now adopted 40 out of a total of 127 ECE Regulations. The Government of Japan 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.

As new power-train technologies - electric vehicles, hybrid vehicles and fuel-cell vehicles – are developed, the Government of Japan should work with the EU to establish internationally harmonised technical requirements that will encourage the smooth market adoption of these new environmentally friendly technologies.

Compared with other countries, Japan imposes an excessively heavy tax on the purchase and ownership of motor vehicles. As part of the proposed comprehensive review of the taxation of automobiles which will take place in FY 2011, the Government of Japan should:

- Abolish the Automobile Acquisition Tax and Tonnage Tax.
- Simplify the structure of the tax on automobiles and reduce the overall tax burden on motorists in line with international best practice.
- Adopt and implement as early as possible internationally harmonised standards for measuring fuel efficiency and exhaust emissions to assess environmentally friendly vehicles.

“Kei” or mini-cars are those vehicles legally restricted to a maximum length of 3.4m, a width of 1.48m, a height of 2m, and to an engine displacement of 660cc and below. Kei cars benefit from lower automobile related taxes, automobile liability insurance and motorway tolls and are subject to less stringent overnight garaging requirements. The continued existence of the privileges enjoyed by kei cars is an anachronism which distorts the competition with compact and subcompact cars, which do not enjoy the same prerogatives, even though their performance and specifications are similar. The Government of Japan should take advantage of the review of the taxation system to put kei cars and other motor vehicles on the same fiscal and regulatory footing

### Action taken so far

The Government of Japan (GOJ) has been adopting UNECE Regulations, especially those related to passenger vehicles where substantial needs of harmonization exist for the purpose of import and export, under the condition that the safety and the environmental conservation are ensured. The GOJ has already adopted a majority of the UNECE Regulations for passenger vehicles (31 out of 45 regulations) with the exception of those on emissions, etc.

The amendments of those regulations will be conducted as part of the activities toward the realization of International Whole Vehicle Type Approval (IWVTA), a project on which Japan and the EU have been collaborating in UNECE/WP29 and to which Japan has been proactively contributing.

Regarding new environmentally friendly technologies, at the 155<sup>th</sup> session of UNECE/WP.29 held in

November 2011, Japan, the EU and the United States jointly proposed to develop a new framework addressing the safety and environmental aspects of electric vehicles including safety of lithium-ion batteries to consider establishing Global Technical Regulations and the proposal was agreed by all Contracting Parties participating in the session.

As regards the Acquisition and Tonnage Taxes, a decision has been made to review these taxes in accordance with the priority issues of Japan's ruling party in the tax reform in FY2012 (1 April 2012 -31 March 2013), which strongly called for "abolition or fundamental review". In ensuring stable fiscal revenues, relevant national and local taxation systems will be reviewed, from the viewpoint of simplification, relief of burden and green taxation systems, while giving due considerations to local government finances. For our overall position on tax-system reforms of Japan, please refer to the attachment in the Appendix of this report.

Regarding the measurement of emissions and fuel efficiency, Japan and the EU have been taking a lead in the UNECE/WP29 to establish Worldwide harmonized Light-duty Test Procedure (WLTP), with a view to convincing developing countries such as India to mutually accept test data using WLTP, which reflects each country's transport conditions.

Fiscal incentives for light-weight vehicles have been introduced as a social policy, taking into consideration Japan's specific circumstances such as dense population in narrow lands. The rationale necessitating such measures still validly exists. In addition, these incentives have broad social benefits since they make it easier for people living in local areas, who are in need of cars for their daily life, to buy cars.

For reference, the same safety and environmental regulations apply equally to light-weight vehicles as well as other passenger cars in Japan.

#### Future outlook

Regarding those regulations for passenger vehicles that have not been adopted yet, the GOJ will steadily adopt them after the necessary amendment of those regulations to ensure consistency with IWVTA and WLTP which are being under work in UNECE/WP29.

Regarding new environmentally friendly technologies, Japan, the EU and the United States will closely cooperate promoting internationally harmonized technical requirements related to electric vehicles in UNECE/WP29.

For the overall position on tax-system reforms of Japan, refer to "Action taken so far" mentioned above.

Regarding global standards of emissions and fuel efficiency, Japan will accelerate its efforts to establish WLTP by 2013 on schedule.

As for light-weight vehicles, refer to "Action taken so far" mentioned above.

## (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

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, mandatory regulation to label “date of manufacture” was amended to label “use-by date” or “best before”, in 1995. This modification was done in order to accord with international standards (i.e., General Standard for Prepackaged Foods: CODEX STAN 1-1985). As the example mentioned above shows, the Japanese food labelling system is standardized taking into account of consideration for consistency with the international rules.

(b)&(c)

The Food Sanitation Law prohibits the use of food additives in Japan except when they are designated by the Minister of Health, Labour and Welfare (MHLW) under the law as substances that are unlikely to pose a risk to people’s health. The procedure of designation for food additives, as defined above, is initiated based on an application filed by a business or relevant person. The Government of Japan (GOJ) understands that the EU follows a similar system for the authorization of food additives.

MHLW makes utmost effort to streamline the designation process for food additives, which is a big concern among the EU industrial group. Specifically, MHLW facilitates communication with the Food Safety Commission (FSC), a risk assessment body, makes efficient clerical work needed before safety assessment is requested to FSC, and co-operates FSC so that assessment can be carried out in a more speedy manner.

Since 2002, the GOJ, on its own initiative, has been proceeding with discussion towards the designation concerning the 46 food additives (excluding flavorings), including substances requested by the EU, whose safety has been confirmed internationally and are widely used.

Of 46, 9 food additives are already under assessment by FSC, which means MHLW has finished request to FSC for the assessment of the 46. The request for the 9 was based on the decision by a



Cabinet meeting held in April 2011. So far, 31 substances have already been designated and are usable. As for one of the remaining 15, assessment by FSC was finished and MHLW is proceeding with formalities for designation, including the initiation of discussion at the Pharmaceutical Affairs and Food Sanitation Council. The remaining 14 are under assessment by FSC.

#### Future outlook

( a)

The GOJ will continue operating the systems in accordance with international standards.

( b)&(c)

MHLW will continue to work to accelerate the designation process that has been carried out until now.

In 2002 MHLW listed the 46 substances with the intent to designate them. At that time, these substances were already proven safe by JECFA and being widely used in many countries including the EU member countries and the United States. MHLW took opinions from the EU and the US into consideration in the listing work. The GOJ believes that when the designation of the 46 substances is completed, the food additives for which the need is globally recognized will become mostly usable.

Japan's action for the 46 substances is a special measure taken to ensure international consistency. The GOJ will follow the ordinary process for designation of substances other than these 46, based on applications from businesses, just as other major countries do.

## (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 Government of Japan 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 Law 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, the Government of Japan (GOJ) researched consumer and business operator which the overseas Japanese juridical person included about their evaluation to the Household Goods Quality Labeling Law and labeling system in other countries. In 2011, the GOJ is studying to review the content of labeling required etc. where it is necessary to do so with reference to the 2010 survey results.

### 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 Law is also increasing. Therefore, with reference to the 2011 study results we will review the content of labeling required etc. where it is necessary to do so. The GOJ will also continue to facilitate understanding of the Household Goods Quality Labeling Law among business operators including overseas business operators by publishing information on the web and other media.

## 8.Ensuring free and open competition in services (WP-A/#08/E to J)

### (1) 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. In particular, the Government should:

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, and 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 on the same day. These revisions include points to keep in mind concerning supervision related to firewall restrictions.

#### Future outlook

The Financial Services Agency 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 Government of Japan 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, banks, and insurance companies. Specifically,

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). Similarly, the insurance business of cooperative societies (*kyosai*) should be subject to the same requirements as private sector insurers.

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 for delivery vehicle parking infringements.

### Action taken so far

With regard to postal reform in Japan, the relevant bills, which were deliberated in 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 (WP-A/#09/E to J)

### (1) Tax deferrals for capital gains

#### BRT Recommendation

Despite its position as the world's second largest economy, Japan's level of inward FDI as a proportion of GDP remains one of the lowest among all OECD countries. The Government of Japan 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.

#### Action taken so far

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

#### Future outlook

For the Japanese Government's position on tax-system reform in general, 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 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

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 Government of Japan (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)Regulatory reform: Financial sector

#### BRT Recommendation

Moreover, while such improvement of the generic investment environment is a precondition, regulatory reform is the best motivator for foreign companies to enter the Japanese market. In the sectors where the formal barriers to foreign investment were removed some time ago, such as automotives and machinery, foreign investment is relatively high. By contrast, two sectors where investments are low are the financial and medical fields. Japan's regulatory environment in these sectors remains much more difficult than the rest of the world to allow for foreign companies to set up any larger operation than the minimal level needed to serve the existing client base. Mutual recognition of market certifications would be an important first step to improving investments in the medical field. 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 the globalization of financial transactions, it becomes 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) considers as an important mission in the financial administration.

For this, FSA works on cooperation with foreign authorities proactively by holding frequent information exchanges and active discussions on 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 policies on cooperation with foreign authorities in supervising 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.

#### (4)Regulatory reform: Medical sector

##### BRT Recommendation

Moreover, while such improvement of the generic investment environment is a precondition, regulatory reform is the best motivator for foreign companies to enter the Japanese market. In the sectors where the formal barriers to foreign investment were removed some time ago, such as automotives and machinery, foreign investment is relatively high. By contrast, two sectors where investments are low are the financial and medical fields. Japan's regulatory environment in these sectors remains much more difficult than the rest of the world to allow for foreign companies to set up any larger operation than the minimal level needed to serve the existing client base. Mutual recognition of market certifications would be an important first step to improving investments in the medical field. 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

Those who provide medical services in Japan have to comply with the Medical Care Act. The GOJ considers medical care should be non-profitable and the reasons why those for profit are not allowed to establish hospitals etc. are as follows:

1. If management agencies enter the business for profit, appropriate provision of medical care might be disturbed, since the medical care necessary for patients could be different from that companies provide to maximize their profits. It might also lead to soaring cost of the healthcare.
2. Community healthcare might be disturbed in the case of withdrawal of those companies from less profitable business.

##### Future outlook

No article of the Medical Care Act is examined to be revised.



## 10.Fight against counterfeited, pirated and contraband goods (WP-A#10//E to J)

### BRT Recommendation

Japan allows the importation of fake goods as long as they are for personal use. Accordingly, there is an inflow of counterfeit goods sold on the internet on sites outside Japan, but which are catering to the Japanese market. These two factors unfortunately lead to quite a large trade in counterfeit goods. The Government of Japan needs to make all trade with fake goods illegal and to better cooperate with overseas authorities to secure the closure of sites trading in fake goods.

Furthermore Japanese authorities should improve and simplify the procedure for right-holders to receive information on suspected merchandise. Today right-holders can only receive information and photographs for a maximum of ten (10) suspended products (even if they are the same product), which means that right-holders are obliged to check most items physically at the custom offices.

### Action taken so far

As in the case of EU Member States, Japan mainly prohibit the importation of counterfeit and pirated goods for commercial purpose, since many counterfeit and pirated goods are imported from China, the Government of Japan (GOJ) has enhanced cooperation with the Chinese Government and has advanced countermeasures to reduce counterfeit and pirated goods on websites.

Both governments promoted exchanges between Chinese e-commerce service providers and Japanese IPR holders, through the 2<sup>nd</sup> Japan-China Internet Symposium held in August 2011. Moreover, both governments at the 3<sup>rd</sup> Japan-China IPR Working Group discussed measures to fight IPR infringements on internet and agreed promoting cooperative projects.

Japan Customs applies the Simplified Identification Procedure to the goods suspected of infringing Trademark right, Copyright and other designated IPRs, in the case the Customs has already approved applications for suspension for such goods. We consider that this system lessens right holders' burden. In Identification procedures(\*), Japan Customs notifies the right holder of the information related to the suspended goods, such as description and quantity of the goods, regardless of the quantity of such goods subjected to such procedures. Japan Customs also transmits the electronic data of photographs of suspended goods so as to increase the level of convenience to right holders who have lodged applications for suspension. For such data transmission, limitation in terms of distance between the customs office and the right holders' office was repealed, and the maximum number of 5 was increased to 10, in April 2009.

(\*) "Identification procedure" is the procedure by which Japan Customs makes a determination as to whether the suspected goods are infringing ones or not. And "Simplified Identification Procedure" is the one of such procedures in which some steps of the procedures are to be omitted.

### Future outlook

The Japanese and Chinese Governments will hold the 3<sup>rd</sup> Japan-China Internet Symposium during the year of 2012. The GOJ will also implement cooperative projects including exchanges between Japanese and Chinese governments' officers in charge of controlling websites and information

exchange on websites which sell the counterfeit and pirated goods.

Japan Customs will continue their consideration on the limitation of the numbers of goods for electronic photo data transmission of, taking into account both the actual needs and the feasibility of enforcement.

## 11. Government procurement (WP-A/#11/E to J)

### 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 as facilitate the use of e-procurement.

### Action taken so far

With respect to thresholds specified by the GPA, Japan established higher thresholds for some sectors, but lower thresholds for other sectors, compared to other members. As such Japan keeps balanced market liberalization as a whole.

Issues of government procurement, such as a single access point or e-procurement, have been continually discussed in 2011 in the framework of the Japan-EU Joint High Level Group 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

The Government of Japan (GOJ) does not accord on the figure above and believes that the government procurement market of Japan already provides an ample opportunity to foreign companies. In this connection, the renegotiation of the WTO Agreement on Government Procurement was concluded on December 15<sup>th</sup> 2011. When the revised GPA is notified by the GOJ and came into effect, the government procurement market of Japan will be further broadened.

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

## 12. Aeronautics, space and defence (WP-A/#12/E to J)

### (1) Space-related matters

#### BRT Recommendation

The Japanese Authorities are contemplating space operations legislation that would require Japanese users of satellite launch services to obtain official approval before they contract for a launch, and would also require them to only use reliable launch service providers approved by the Japanese Authorities. If the Japanese Authorities do promulgate such a system, we request that it be fair and consistent with world practice, i.e., as similar as possible to the regime established by the French Space Operations Act of June 2008 and associated by-laws.

Japan's international procurement of space ground equipment is often broken up in small lots that are, in fact, tailor-made for individual Japanese suppliers. Integrated systems have better cost performance, are more reliable, and should not be excluded.

#### (a) Approval of satellite launch services in the space operations legislation

##### Action taken so far

In accordance with the Basic Space Law, the Government of Japan (GOJ) has been considering legislation on necessary matters in order to implement treaties and other international agreements with regard to regulations on space activities as well as other Space Development and Use. The working group for legislation of space activities published the interim report (see the following URL).

<http://www.kantei.go.jp/jp/singi/utyuu/katudo/bosyu.html>

##### Future outlook

The GOJ is considering legislation continuously. In any case, legislation will be consistent with international rules.

#### (b) International procurement of space ground equipment

##### Action taken so far

Scope of procurements is decided on project by project basis and procurements of integrated systems are not excluded as a general policy.

##### Future outlook

Same as above.

## (2) Level Playing Field in Civil Aeronautics Markets

### BRT Recommendation

Europe's wide-body civil airliners have not made significant inroads in the Japanese market, and Japan's business aircraft have not made significant inroads in the European market. The Authorities of Japan and Europe should encourage competition and facilitate the entry of each other's aircraft on their respective domestic markets on the basis of reciprocity. Customers' procurement decisions should be made on a competitive basis, free from irrelevant influence. For the benefit of customers, shareholders, taxpayers and the general public, airlines and other major customers should be encouraged to diversify their sources of supply. In order to avoid undue influence on the procurement decisions of commercial airlines, cooperation in aeronautics should not be biased towards US industry, but should be significantly increased between the EU and Japan.

### Action taken so far

Decisions to purchase commercial aircraft are made by individual airlines and based on their own judgement. The government is therefore not in a position to influence these decisions.

### Future outlook

The government's position is as stated as above. Therefore, just as in the past, the government will not be pressuring airlines to purchase aircraft from particular manufacturers. Aircraft manufacturers themselves should be responsible for aggressively marketing their products to airlines.

### (3) Establishing EU-Japan dialogues on defence industry issues

#### BRT Recommendation

Europe's defence industries offer highly competitive defence products and services, which often come with transfer of cutting-edge technology. Moreover, its products satisfy Japan's fundamental requirement for full inter-operability with US equipment. There is scope for significantly greater collaboration between the EU and Japan on defence products and services.

Both Europe and Japan face the challenges of increasingly sophisticated threats, while defence budgets are under increasing threat. It is therefore clear that greater collaboration would bring substantial benefits to both sides. To encourage the deepening of this collaboration, we propose:

- A Japan-EU defence industry policy dialogue with the aim of exchanging views and experience about defence industry issues common to both, and identifying any impediments to further collaboration
- Japan allocate to Europe some proportion of its funds for Japanese officials to undertake fact-finding visits to overseas defence industrial sites.

#### (a) Japan-EU defense industry policy dialogue

##### Action taken so far

N.A.

##### Future outlook

The Government of Japan (GOJ) would like to arrange dialogues on defence industry policy between European Defence Agency and related ministries in Japan, responding to the needs of both ministries.

#### (b) Fact-finding visits to overseas defense industrial sites

##### Action taken so far

N.A.

##### Future outlook

The GOJ welcomes an offer to visit the European defense industry, using the opportunity of the dialogue between European Defense Agency and related ministries in Japan. The GOJ appreciates a recommendation on where is worth visiting.

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

### **13. Enhancement of bioventure activities (WP-B/#01/EJ to EJ)**

#### **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. It is also necessary to support bioventures financially under the current economic recession.

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

The GOJ is implementing various measures to support biotech start-ups in order to realize both healthcare innovation as presented in the New Growth Strategy, published in June, 2010.

- Japan External Trade Organization (JETRO) supported Japanese biotech start-ups to attend BIO-Europe Partnering Conference, where start-ups could have a close business networking with overseas firms.
- The Ministry of Economy, Trade and Industry (METI) supported dispatch of an industrial mission group in order to further seek the possibility of cooperating with overseas clusters.
- METI assisted a business networking in BioJapan2011, aimed at expanding its network between Japanese and overseas companies including European firms and clusters.

#### **Future outlook**

The same as this year, through JETRO and so on, we will eagerly promote business networking between Japanese and European companies including biotech ventures through BioJapan, BIO-Europe and other opportunities.

#### 14. Regulatory harmonization and MRA for pharmaceuticals (WP-B/#02/EJ to EJ)

##### BRT Recommendation

The regulatory harmonization and further extension of “Mutual Recognition Agreement” should be proceeded in order to avoid redundant inspections of manufacturing facilities.

##### Action taken so far

Regarding safety measures of pharmaceuticals, the Government of Japan (GOJ) has been proceeding harmonization with international standards, which were developed by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as guidelines “Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting”

Guidelines for clinical development of vaccines were published, after inputting opinion from the industry including the European Federation of Pharmaceutical Industries and Associations (EFPIA).

Consideration on the revision of the Minimum Requirements for Biological Products (MRBP) is now undertaken by an expert group together with experts from the industry including the EFPIA.

With Regard to Japan-EC MRA of GMP, the GOJ conducted discussion with the EU Commission and the European Medicines Agency (EMA) for the progress for the MRA and is considering the expansion of the object country and the operational scope of the MRA.

##### Future outlook

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

The GOJ will continue further discussion with EU Commission and EMA to progress expansion of the object country and the operational scope of the MRA.



## 15. Balance between prevention and treatment in healthcare (WP-B/#03/EJ to EJ)

### BRT Recommendation

Seek balance between prevention and treatment. Thus, confirm inclusion of vaccination programs and include contraception in the scope of public funding.

### Action taken so far

As for routine vaccination\* under the Vaccination Act, almost all the local municipalities implement vaccination for free. The municipalities share financial burden added on the tax allocated to municipalities from the Government of Japan (GOJ).

\*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 the Vaccination Act, the GOJ has established a fund project to promote the efforts of municipalities implementing the vaccinations of these three vaccines, based on the recommendations from the vaccination sub-committee of the Health Sciences Council. The fund is covered by supplementary budget that was passed in the 176th extraordinary Diet.

The GOJ notes that the vaccination policy should be changed by adopting IPV instead of OPV for routine polio vaccination. It is being prepared by holding the investigative commission in which the experts are discussing how they can be changed in a quick and efficient manner after domestic approval of IPV will be granted.

### Future outlook

It has been discussed at the vaccination sub-committee of the Health Sciences Council as to how there should be legal status of diseases and vaccines which are not covered by the Vaccination Act, including three vaccines (human papillomavirus vaccine, Hib(*Haemophilus influenzae* type b), pneumococcal conjugate vaccine for childhood immunization) financed by supplementary budget.

Though there are many tasks such as securing financial resources permanently and the burden sharing between local municipalities, the GOJ will have further discussions at the vaccination sub-committee and give necessary considerations.

16. Mutual recognition of quality management audit results for medical devices between EU and Japan (WP-B/#04/EJ to EJ)

**BRT Recommendation**

Start a mutual recognition of quality management audit results for lower risk medical devices, e.g. those classified as Class II, ARCD under the Japanese Pharmaceutical Affairs Law, as a first step.

**Action taken so far**

For the purpose of reducing the industry's burden and promoting the efficiency of inspection, through the solution of a few specific non-tariff issues (called "Paragraph 34 process"), the Government of Japan (GOJ) agreed to align the Japanese QMS standard for medical devices with the international standard (ISO13485), which is applied in the EU, but with some exceptions. Furthermore, the GOJ has set up the working group (WG) including industry and promoted further improvement such as growing scope of audit by item and mutual utilization of results between regulators for QMS audit at the WG.

**Future outlook**

Discussions on further expanding scope of QMS audit from actual scope of audit by item (by preferred term\*[1] or by certification standard\*[2]) to promote efficiency of inspection are held in the Advisory Committee of Pharmaceutical Regulatory System. Scope of QMS audit is being discussed in the WG.

\*[1] The preferred term means a certain range corresponding to "Preferred Term" of GMDN.

\*[2] Standard for pre-market certificated for controlled device (Class II) by certification bodies.

17. Mutual recognition of medical devices product licenses (WP-B/#05/EJ to EJ)

**BRT Recommendation**

Introduce a mutual recognition of medical device product licenses between the EU and Japan

**Action taken so far**

With regard to the establishment of Certification Standards or standards for Quality Management Systems, the Government of Japan (GOJ) basically accepts the international standards of the ISO and the IEC.

**Future outlook**

The global harmonization of Medical Device regulations needs to be discussed with not between Japan and the EU, but also jointly by the U.S. and other countries. For this reason, the GOJ will achieve international harmonization of Medical Device regulations through the activities in the GHTF and others, which represent a multinational initiative.

18. Mutual recognition clinical trial results for medical devices (WP-B/#06/EJ to EJ)

BRT Recommendation

Introduce a mutual recognition of clinical trial results for medical device development

Action taken so far

Foreign clinical trial data has been accepted 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.

Future outlook

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

## 19. Strengthening activities for industrial biotechnology (WP-B/#07/EJ to EJ)

### 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 demonstration experiments of bio-based products in different environment model areas in the EU and Japan to assess the possibilities and limitations of the development and use of bio-based products*
- ✓ *Encourage the introduction of composting systems to promote the use of bio-based products and bio-based polymers*
- ✓ *Consider common standards and certification systems for each product category between the EU and Japan to establish a global de facto standard for bio-based products*
- ✓ *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

Through the Global Bioenergy Partnership (GBEP), which was established to promote the sustainable development of bioenergy, science-based criteria and indicators for biofuel sustainability are given serious consideration. Through discussions with other countries, including some EU nations for four years, Japan announced science-based criteria and indicators for biofuel sustainability in May 2011.

### Future outlook

The Government of Japan will make use of multinational frameworks such as the GBEP in order to make and use the evaluated methodologies of science-based criteria and indicators concerning the sustainability of biofuels.

## 20. Enhancement of cooperation with industry and academia (WP-B/#08/EJ to EJ)

### BRT Recommendation

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

#### *Potential Research Topics:*

*Genetic improvement of plant growth and yield to stabilize crop production in variable growth conditions by*

- *enhancing plant gene discovery and regulatory network research*
- *studying cellular growth and plant development*
- *elucidating growth-promoting plant hormones*

### 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 . In particular, the joint research program in which of CGIAR (IRRI, CIAT and CYMMIT) participate has been conducted to develop drought-tolerance 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. Using these funds, 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 a 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 project in line with the plan formulated in April 2008. In particular, assessments of the stress tolerance of the DREB gene-introduced GM crops are conducted at the isolated fields in cooperation with partner research institutes overseas.

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

21. Nation-wide electronic database for individual health/medical records in Japan(WP-B/#12/EJ to J)

**BRT Recommendation**

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

**Action taken so far**

The application of medical information of electronic health record for medical information database, which could be established and operated, is important from the perspective of promoting safety measures on pharmaceuticals. For this, the Government of Japan (GOJ) has considered how to apply medical information for safety measures on pharmaceuticals.

The expert committee that had been established in FY2010 made a recommendation to establish necessary guidelines for medical information database, such as ethical guideline.

**Future outlook**

Based on the recommendation proposed in FY 2010, the GOJ has launched a project for establishment of medical information database. The GOJ has been considering frameworks for the extraction of adverse drug reaction from the database and for epidemiological investigation using the database with the cooperation of the Pharmaceuticals and Medical Devices Agency (PMDA).

The GOJ will set forth the required ethical guideline and other necessary guidelines, start sorting out information required in pharmacoepidemiological research, and investigate the architecture of the medical information database and universal electronic format for establishing 10 “hub” medical institutions in Japan. In addition, the GOJ will start investigating the framework for application of medical information database.

## 22. Citizens ID numbering system for social security in Japan(WP-B/#13/EJ to J)

### BRT Recommendation

Commence non-partisan discussions on earlier introduction of citizens ID numbering system to provide better and impartial public services especially in social security fields.

### Action taken so far

From February, 2010 onwards, a full-scale examination had been advanced, and based on an old examination result, "The Outline of the Social Security and Tax Number System" was officially adopted in government and ruling party social security reform examination headquarters at the end of June, 2011. The Outline indicates the Government and ruling parties' direction in concrete terms on the content of system design that establishes laws and regulations, smooth system introduction, implementation, and stabilization, action plans for improved convenience, and so on, with the work of settling on a bill in mind.

### Future outlook

In the near future, the Government of Japan will submit a bill on the Number System and related bills as soon as possible beginning in autumn 2011, assign the Numbers to individuals and Corporate Numbers to incorporated bodies and so on in June 2014, and commence use of Numbers to the extent possible in the social security and tax fields beginning in January 2015.



23. Full-fledged implementation of the new drug pricing system and abolition of market expansion re-pricing(WP-B/#14/EJ to J)

**BRT Recommendation**

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

Furthermore, we urge to abolish the current rule of the re-pricing by market expansion, which is opposite to the policy to evaluate pharmaceutical innovation.

**Action taken so far**

Whether “the new pricing system” is maintained will be determined at the next revision of drug pricing system and is currently under discussion at the Central Social Insurance Medical Council (Chuikyo) expert committee on drug pricing taking the following factors into account;

- (a) Financial impact of the new pricing system,
- (b) Development and marketing of off-labeled drugs, etc., and
- (c) Utilization of generic drug.

The European Federation of Pharmaceutical Industries and Associations (EFPIA) expressed its opinion at the expert committee on 24 August and 14 December, 2011.

The re-pricing for market expansion is a rule to reduce the reimbursement price of a new drug by 10 to 25% when the sales of the particular drug far exceed its estimated initial price. The Government of Japan (GOJ) understands that the industry including EFPIA is against this rule which can be disincentive for developing new drugs. However, it is difficult to abolish this rule since it is working as an appropriate apportion mechanism of pharmaceutical expenditures within the limited resources of public health care system.

**Future outlook**

The GOJ continues discussion on drug pricing system.

The rule of re-pricing for market expansion is to be further discussed at Chuikyo also fully respecting opinions of the industry including the European industrial association.

## 24. Regulatory transparency and review time by PMDA(WP-B/#15/EJ to J)

### BRT Recommendation

Increase the transparency of evaluation standards, / registration process and consistent consultations & and shorten review time for pharmaceuticals and medical devices by PMDA.

### Action taken so far

To provide effective and safe drugs and medical devices more quickly, the Government of Japan (GOJ) is working systematically to shorten the drug and medical device review time through several measures: increase the number of 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 drug review time in 2010 was shortened to 14.7 months (cf. 19.2 months in 2009) and median total medical device review time has remained at approximately 20 months (cf. 19.3 months in 2009, 20.5 months in 2010). Continued efforts will be made to improve quality of review and speed up approval process.

The GOJ accepts foreign clinical data as an application document for approval 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.

## 25.Measures against counterfeit products(WP-B/#16/EJ to J)

### BRT Recommendation

Private imports of medicines provide a channel for counterfeits, mostly in OTC non-reimbursed drugs.

### Action taken so far

Japan has joined in the International Medical Products Anti-Counterfeit Taskforce (IMPACT) and cooperated internationally since it was established in 2006.

The Government of Japan (GOJ) makes the booklets to notice the people about the danger of self-importing falsified medicines. Furthermore, the GOJ notices about it and the case of the health hazards caused by dosing falsified medicines by posting on the homepage of the Ministry of Health, Labour and Welfare.

Through the internet monitoring, the GOJ regulates the importation of falsified medicines in self-importation websites by warning to the illegal websites (foreign and Japanese websites) advertising and selling illegally.

### Future outlook

The GOJ is going to construct a mechanism of enabling more effectively to share the information about falsified medicines and regulate importation by cooperating and working with the concerned institutions.

The GOJ is going to make a database about the utilization of self-imported unapproved medicines for strengthening its notice for the public by publishing information, and has a plan to enforce safety measures.

26. Support to research for plant protection & biotechnology(WP-B/#17/EJ to J)

**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 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 involves 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 benefits from 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 conduct 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.

## 27. Efforts on increasing output of agriculture in Japan(WP-B/#18/EJ to J)

### BRT Recommendation

Continue efforts towards increasing output production of Japanese agriculture

### Action taken so far

The Government of Japan (GOJ) actively promotes to increase the output of Japanese agriculture. Specifically, the GOJ elaborated the New Basic Plan on Food, Agriculture and Rural Areas in March 2010. The plan aims at revitalizing agriculture and rural areas and at raising the food self-sufficiency ratio to 50% on a calorie supply basis, and 70% on a production value basis by FY2020. To achieve these targets, the GOJ promotes measures such as implementation of an income support direct payment to farmers, conversion to a production system more responsive to the consumers' demands for quality and safety, and promotion of the Sixth 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 to promote to increase the output of Japanese agriculture throughout the measures such as implementation of the income support direct payment to farmers, conversion to a production system more responsive to the consumers' demands for quality and safety, and promotion of the Sixth Industrialization of agriculture and rural areas.

28. Regulatory harmonization for animal health products(WP-B/#19/E to EJ)

**BRT Recommendation**

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

**Action taken so far**

Refer to the response to WP-A/#07(6) above.

**Future outlook**

Refer to the response to WP-A/#07(6) above.

29. Mutual recognition of GMP and marketing authorization for animal health products(WP-B/#20/E to EJ)

BRT Recommendation

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

Action taken so far

Refer to the response to WP-A/#07(6) above.

Future outlook

Refer to the response to WP-A/#07(6) above.

30. Application of GMP on medical gases(WP-B/#22/E to J)

**BRT Recommendation**

Harmonize with the EU the regulation for GMP on medicinal gases in Japan

**Action taken so far**

With regard to the medical gas in Japan, the Government of Japan (GOJ) advances the establishment of domestic guidelines, corresponding to the PIC/S guidelines and taking the differences of manufacturing and distribution with Europe into consideration.

**Future outlook**

The GOJ plans to adopt the domestic guidelines corresponding to the PIC/S guidelines.



### 31.Shortening review times for animal health products(WP-B/#23/E to J)

#### BRT Recommendation

Shorten review times for new product applications

#### Action taken so far

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, which is the risk management body for food safety, prior to approvals of veterinary medicinal products for food producing animals.

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

#### Future outlook

MAFF is deliberating guidelines for the preparation of Summary Technical Documents which provide applicants useful advice to further shorten the amount of time for approval. MAFF has issued a notification to exempt the Japanese translation from English of the materials attached to application dossier.

32. Implementation of the Veterinary International Cooperataion on Harmonization of Technical Requirement(VICH)(WP-B/#24/E to J)

BRT Recommendation

No dual standards

Action taken so far

Refer to the response to WP-A/#07(6) above.

Future outlook

Refer to the response to WP-A/#07(6) above.

33.Promote people's understanding of GMO's based on scientific knowledge by both the governments and the private sectors(WP-B/#25/J to EJ)

**BRT Recommendation**

To fulfil people's acceptance of GMO's, governments and private sectors should cooperate in educating people about the efficiency and safety of GMO's based on scientific knowledge, considering world food supply and demand prospects.

**Action taken so far**

In Japan, people have both expectations and concerns about the utilization of GM technologies. In order to gain public understanding with regard to GMO, the Government of Japan (GOJ) provides to the public scientific and objective information about the GM technologies and the safety of GM food via web sites and communication activities.

**Future outlook**

The GOJ continues to provide to the public scientific and objective information about the GM technologies and the safety of GM food via web sites and communication activities.

34. Formulation and steady implementation of action plans for realization of “Japan’s New Growth Strategies”(WP-B/#27/J to J)

**BRT Recommendation**

Formulate concrete action plans for realization of “Japan’s 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 requests for JFY2012, the Council for Science and Technology Policy (CSTP) planed Action Plan (AP) aiming to high-quality budgetary process on the basis of New Growth Strategy before budget request with related ministries this year again. CSTP submitted focused Initiatives (“R&D of prevention, diagnostics and treatment focusing on complication of metabolic diseases such as diabetes”, “R&D of prevention, early diagnostics and delay for progression based on diagnostic markers/ imaging for neuro-psychiatric disorder like depression, dementia”, “R&D for regenerative medicine” and “Promotion of regulatory science to accelerate development of novel medical technology for medicine, medical device and regenerative medicine” in addition to “Improvement of preventive method by integration of results of genome cohort study and medical record”, “R&D in early diagnostic and treatment technology for cancer” and “Development of technology to compensate and support dysfunctions in elderly and handicapped persons”) which are defined performance target and achieving deadline for Life Science (LS) Innovation, and have promoted efficient and effective Problem-solving R&D.

**Future outlook**

The GOJ will do a PDCA (Plan-Do-Check-Act) cycle to be implemented these measures which construct this AP, in accordance with the AP (including “Improvement of preventive method by integration of results of genome cohort study and medical record”, “R&D in early diagnostic and treatment technology for cancer” ;“Development technology to compensate and support dysfunctions in elderly and handicapped persons”; “R&D of prevention, diagnostics and treatment focusing on complication of metabolic diseases such as diabetes”; “R&D of prevention, early diagnostics and delay for progression based on diagnostic markers/ imaging for neuro-psychiatric disorder like depression, dementia”; “R&D for regenerative medicine” and “Promotion of regulatory science to accelerate development of novel medical technology for medicine, medical device and regenerative medicine”) , and review the improvement of the next AP and the increment of the number of measure hereafter. In addition, to formulate the new BT Strategy is a subject of future assessment.

## **Working Party C: Innovation, Information & Communication Technologies**

### **35. Execution of Growth strategy and ICT strategy(WP-C/#01/EJ to EJ)**

#### **BRT Recommendation**

Both Authorities should implement detailed action plans with specific targets and use PDCA cycles to monitor the status of each item. ICT Strategy Progress Reports for each action should be published on the Authority's websites.

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

The Roadmaps were prepared in June 2010 and are posted on a website. According to the Roadmaps, the following up and evaluation of undertaking and progress of each measure conducted by relevant Ministries were carried out and the roadmaps were revised in August 2011.

#### **Future outlook**

Each Ministry shall conduct their own measures according to the Roadmaps. Following up and evaluation of undertaking and progress of each measure and revising of Roadmaps shall be conducted in the Strategic Headquarters for the Promotion of an Advanced Information and Telecommunications Network Society, whereby the implementation of PDCA cycles shall be ensured.

### 36. Deployment of Next Generation Broadband Networks (WP-C/#02/EJ to EJ)

#### BRT Recommendation

- (1) Regulations should provide necessary legal certainty for investors. Technologies should be able to evolve on their own merits – innovation and investment decisions should not be hampered by technology-prescriptive regulations.
- (2) Both Authorities should provide the necessary stimuli to industry to encourage the provision of high-speed fixed or mobile broadband services in the areas where deployment by private sector investment is difficult. (such as less-populated areas).
- (3) To promote the use of ICT, both Authorities should enhance the social benefits of the next generation broadband network by encouraging education, healthcare and other government services.
- (4) To permit a more efficient use of the spectrum, both Authorities should free up as many frequencies as possible for use by mobile broadband. Moreover, both Authorities should strive for a harmonised use of the spectrum to ensure economies of scale and thereby lower service prices incurred by consumers.

#### Action taken so far

- (1) The Ministry of Internal Affairs and Communications (MIC) has made efforts to ensure transparency and fairness in reviewing regulations in the ICT industry through holding councils and meetings open to public and following necessary procedures, such as public comment, in advance. Additionally, it endeavors to take neutral position in various technologies and always works on keeping the competitive environment in which telecommunication carriers enables to roll out various services under their own business judgement.
- (2) As stated above, the ICT industry is a sector to be developed by private companies in principle. But in areas in which they have difficulty investing, such as in underdeveloped areas, MIC partially provides financial support for local governments that deploy infrastructure for ultra-high-speed broadband including optical fibers.
- (3) Aiming to promote ICT utilization in the field of education, MIC has been carrying out demonstration experiments on ICT related challenges in the area of schools (the Future School Promotion Project) by creating a networking environment using tablet PCs, interactive white boards, and other equipment since 2010, in collaboration with the Ministry of Education, Culture, Sports, Science and Technology, As for the medical / health care sector, since 2008, in collaboration with the Ministry of Health, Labour and Welfare, and other ministries, MIC has been conducting demonstrative projects to experiment with the health information application platform (Electronic Health Record), which allows people to manage their medical and health information electronically, and realizes seamless medical services by sharing and distributing medical and health information in a secure and smooth manner.
- (4) In September 2011, MIC has revised the Action Plan for Spectrum Reallocation on the basis of the basic policies for securing spectrum towards implementation of a wireless broadband environment in future.

To add frequency for cellular phone communications system, particularly the basic policy for frequency allocation of 700/900MHz band spectrum has been reviewed by standpoint of ensuring

consistency with the frequency allocation status of other countries.

Future outlook

(1)(2)MIC will make efforts to ensure transparency and fairness of regulations and to keep the competitive environment based on technologically neutral regulations, and continue to deploy the broadband infrastructure.

(3)MIC continues its efforts of promoting ICT utilization by steadily implementing the above demonstration projects in collaboration with related ministries.

(4)Based on the Action Plan for Spectrum Reallocation, MIC plans to secure frequencies to realize wireless broadband environment.

Regarding 900MHz band spectrum, a regulatory framework will be established in order to introduce cellular phone communications system from July 25th 2012. For 700MHz band spectrum, a technical study on cellular phone communications system has been conducted in order to allocate the spectrum quickly.

### 37. Using ICT to address social challenges(WP-C/#03/EJ to EJ)

#### BRT Recommendation

To promote ICT use by the public sector, both Authorities should prioritise budget allocation for innovative ICT projects in areas such as healthcare, education, central and local government. Where appropriate, laws and rules which could impede advanced ICT usage should be deregulated.

#### Action taken so far

The Strategic Headquarters for the Promotion of an Advanced Information and Telecommunications Network Society decided in August 2011 on “A policy pertaining to regulatory and institutional reforms in order to utilize Information and Telecommunications technology”. The policy involves a wide-ranging fields such as electronic administration, health care and education, and concerned government Ministries are engaged in realizing the reforms in line with the policy.

#### Future outlook

The Planning Committee, under the IT Strategic Headquarters, chaired by the Minister of State for Science and Technology Policy shall follow up the progress of the reforms in line with the policy and report the progress to IT Strategic Headquarters.



38. Harmonisation of regulations for cloud computing usage in the EU and Japan(WP-C/#04/EJ to EJ)

BRT Recommendation

- (1) Given the importance of data portability and interoperability in cloud computing and to ensure the private sector can develop innovative cross-industry applications and services, both Authorities should review regulations prohibiting applications from using cloud computing. The European Commission should coordinate with relevant authorities in the Member-States to ensure there is a seamless deployment across the whole EU.
- (2) The EU and Japanese Authorities should begin a cloud computing dialogue to harmonise regulations on cloud computing and thereby facilitate cross border transactions and international data transfers within the EU and with Japan while enhancing the balance of privacy, data protection and the free flow of information.

Action taken so far

(1) Cloud computing plays an important role in promoting the utilization of ICT, and the Government of Japan (GOJ) is making efforts to arrange a secure and safe environment in using cloud services on the basis of "the Smart Cloud Strategy" arranged in May 2010.

For example, the GOJ has clarified the guideline about the treatment of container-style data centers, in the Building Standards Act and Fire Service Act after the consideration of each presiding Ministry. Such data centers are introduced swiftly and are used worldwide for the arrangement of domestic location environments of data centers, which are important infrastructure to provide cloud services. (March 2011).

(2) We adopted cloud computing as an issue for the 18<sup>th</sup> Japan-EU ICT Dialogue (June 2011 at Brussels, Belgium) and discussed recognising the importance of international sharing of information for cloud computing, which has a cross-border nature.

Future outlook

(1) Based on "Smart Cloud Strategy," we will continue our efforts to promote using the applications which utilize the cloud computing environment.

(2) We are discussing the holding of an expert meeting between Japan and the EU about the cloud by the spring of 2012 on the basis of the agreement made at the Japan-EU ICT Dialogue in June 2011, for future consultation on cooperation in light of cloud computing services that contribute to adding to the value of social and economic activities, and increase efficiency.

### 39. ITA maintenance and expansion (WP-C/#05/EJ to EJ)

#### BRT Recommendation

- (1) Both Authorities should ensure that the current ITA is reviewed at the earliest opportunity and that additional electronic goods should be granted duty-free status in addition to those that already have that status. The broadest possible expansion (including large portions of Chapters 84, 85 and 90) of the scope is needed so that current and future innovative technological developments should not cause product classification uncertainties. Such effort would also be realized through successful negotiation and agreement on the Electronics/Electrical sectoral initiative proposed in the WTO/NAMA. The EU should implement the WTO panel in the ITA dispute by the end of June 2011 to address new convergence technology ITA products being reclassified as dutiable.
- (2) The geographical coverage of the ITA should be expanded by encouraging more countries to join the ITA and the electronics/electrical sectoral initiative. Membership should be promoted as a means of boosting efficiency and productivity, improving the investment climate, helping bridge the digital divide and enabling the move to a more energy-efficient and climate-friendly society.
- (3) Effective mechanisms (such as fora for industry to explain state of the art technology to government) are needed to ensure the ITA is kept up to date and reflects technological developments

#### Action taken so far

The 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.

The 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. In light of this situation, the Government of Japan (GOJ) requested, jointly with the United States 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, and the EU agreed to implement measures for complying with the panel report by the end of June, 2011 (the EU implementing measures took effect in July, 2011). The GOJ is now monitoring whether appropriate tariff treatment is actually accorded to the IT products in the EU.

As well as the products above, in 2008, there was a sudden change of the tariff classification for a certain electronic device (a packaged IGBT device), in some EU member states, so that tariff was imposed to the product that had been subject to ITA. The GOJ brought this issue to the WCO to

clarify the tariff classification for packaged IGBT devices, and has request corrective actions to the EU and the member states governments.

Seeking to solve classification disputes relating to IT products, the discussion to review the scope of ITA has resumed in the ITA Committee of the WTO as well. At the ITA Committee in October 2011, discussion was held on some products among the ones for which tariff codes are not determined, members could not have reached an agreement because of the technical reasons such as the unfinished work of some developing countries.

In addition, the expansion of ITA was discussed in APEC. At the ITA workshop held by the U.S. in September 2011, the government and the industry of Japan made presentations. In November, ministers declared to exercise the leadership for starting the negotiation for the ITA expansion.

#### Future outlook

The EU is required to provide appropriate tariff treatment pursuant to the WTO panel recommendations with respect to multifunctional digital machines, flat panel display devices, and set-top boxes. The GOJ will communicate with EU Member States to ensure that the tariff treatment of IT products be implemented appropriately through various occasions including the ITA Committee of WTO.

On the ITA expansion, the GOJ will intensively cooperate with the EU and other members, to start the negotiation as soon as possible.

With regard to boosting trade in the whole electronics/electrical sector, tariff elimination negotiations in WTO NAMA (Non-Agricultural Market Access) are also beneficial. 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 the EU participate in this initiative, so the GOJ hopes their positive commitment in cooperation with the proponents.

#### 40. Balancing of trade facilitation and security(WP-C/#06/EJ to EJ)

##### BRT Recommendation

Both Authorities should cooperate and lead the international harmonisation of rules and operations to achieve efficient public and private sector operations, balance trade facilitation and the assurance of safety and security. Both Authorities should drive aggressively an initiative to remove barriers to realising a balance between trade facilitation and the ensure security. In particular:

- (1) Security regulations that have been tightened despite the existence of the MRA on AEOs should be examined and considered for deregulation.
- (2) The EU and Japan should consider adopting an international standard for security regulations (like the ICAO) as although companies have to comply with international standards such as UL or IEC, the implementation of current regulations varies between countries.

##### Action taken so far

- (1)A MRA on AEOs between Japan and EU was signed in June, 2010, and has been implemented from May, 2011.
- (2)Japan has been playing an active role in the promotion of global harmonization of security measures under the multilateral framework such as the World Customs Organization (WCO) in cooperation with relevant international organizations including International Civil Aviation Organization (ICAO).

##### Future outlook

- (1)Japan will continuously negotiate with the EU in order to relax its security measures such as 24 hours rule which are applied to AEO operators of Japan.
- (2)Japan will strengthen cooperation with relevant international organizations such as the World Customs Organization (WCO), and continuously promote the international harmonization of security measures by utilizing its expertise and experiences in this field.

41. Cooperation between the EU and Japan on 21<sup>st</sup> Century societal challenges(WP-C/#09/EJ to EJ)  
(1) Support for flagship projects

BRT Recommendation

Both Authorities should support flagship projects and innovative solutions to common societal challenges through deregulation and inviting investment and expertise from EU and Japanese industry.

Action taken so far

The New Growth Strategy, adopted at the Cabinet meeting in June 2010, clearly indicates as follows:  
( [http://www.npu.go.jp/policy/policy04/pdf/20100706/20100706\\_newgrowstrategy.pdf](http://www.npu.go.jp/policy/policy04/pdf/20100706/20100706_newgrowstrategy.pdf) )

1.(page 57)

The Government of Japan (GOJ) will establish a “comprehensive special zone” system (tentative name) which will utilize to the fullest extent the perspectives of responsible strategies carried out by local municipalities, the use of know-how and financial resources of the private sector, and “selection and concentration” of national measures. Specifically: (i) “Comprehensive global strategic special zones”(tentative name) will be established in specified areas such as big cities which have potential to drive growth of the nation as a whole and have a competitive advantage on a global scale. In order to promote the accumulation in these areas of industries and foreign firms which can be an engine of growth of the Japanese economy, we will comprehensively implement special regulatory measures and tax, financial and fiscal support measures in these areas. At the same time, we will consider taking measures related to corporate tax . (ii) In “comprehensive local revitalization special zones” (tentative name) to be established nationwide, the GOJ will carry out policy package in line with the “New Public Commons,” including special regulatory measures and tax, financial and fiscal support measures. These measures are expected to lead to enhancement of global competitiveness through building international hubs and improvement of vitality of local communities through utilizing local resources to the maximum extent possible.

2. (2<sup>nd</sup> paragraph page 3)

The key to creating demand is a “problem-solving oriented” national strategy. The GOJ will seek to create new demand and jobs by squarely tackling the pile of new problems faced by the economy and society and presenting solutions for them. Based on this idea, the New Growth Strategy has identified such growth areas as “green innovation, “life innovation,” “the Asian economy” and “tourism and the regions.” The GOJ will also implement strategies related to “science and technology and information and communications technology,” “employment and human resources” and the “financial sector,” which are areas essential to supporting growth.

Future outlook

Japan is moving toward realization of the New Growth Strategy.

## (2) Establishing a dialogue on research and innovation

### BRT Recommendation

An EU-Japan dialogue should be established to evaluate how best to stimulate research and innovation in general and how to ensure they benefit consumers and industry. Best practice from around the world (such as allowing venture capital to be used for investment in innovation or entrepreneurship) should be studied and adopted.

### Action taken so far

In March 2011, the agreement between the Government of Japan (GOJ) and the European Community on cooperation in science and technology came into force, and we discussed the issues of mutual concern, such as low carbon society/technologies and substitution of critical raw materials, in order to strengthen the cooperation at the First Japan-EU Joint Committee on Scientific and Technological Cooperation in Tokyo, June 2011.

### Future outlook

The GOJ seeks the possibility of new cooperation, including the cases which could be commercialized in the future, by following up the progress of the joint research which has been launched in 2011 under the initiative of the Agreement between the GOJ and the European Community on Cooperation in Science and Technology.

42. Continuous Investment for Innovation (Education, test-bed project, Government procurement)(WP-C/#10/EJ to EJ)

(1) Using public procurement as an instrument for creating innovation

**BRT Recommendation**

Given current budgetary constraints it is vital that both Authorities mobilise all necessary policy tools to ensure smart spending by the public sector and that they use public procurement as an instrument for creating and harnessing innovation.

The EU, Member-States and Japan should allocate strategic budgets for innovation investment particularly on education in science, technology, engineering and mathematics fields, and on developing competent human resources in S&T, R&D and test-bed projects.

**Action taken so far**

N.A.

**Future outlook**

The main purpose of government procurement is to obtain what is necessary, and the secondary purpose of promoting innovation should not be prioritized over its main purpose. When we undertake government procurement, we have to also ensure fair competition, transparency and consistency with international rules including those of the WTO. The GOJ may consider the possibility of adopting an innovation-oriented methods of government procurement, taking into consideration the situation of implementation in each country from abovementioned viewpoints.

## (2) Strategic budget allocation for innovation investment

### BRT Recommendation

The EU, Member-States and Japan should allocate strategic budgets for innovation investment particularly on education in science, technology, engineering and mathematics fields, and on developing competent human resources in S&T, R&D and test-bed projects.

### Action taken so far

In order to improve the highest priority science and technology budget, "FY2012 Action Plan for the Implementation of Important Science and Technology Policy Measures" ("Action Plan") was formulated in July 2011. One of the pillars of Action Plan is "promotion of basic research and enhancement of human resource development", and promoting the dissemination and establishment of the tenure track system<sup>2</sup> (the Ministry of Education, Culture, Sports, Science and Technology) is Action Plan measure.

Also, in the Priority Project Package in the S&T budget for FY2012 as well as above approach, "Improvement of career paths for young researchers" for the purpose of training creative quality researchers and "Development of human resources who can lead the next generation" for the purpose of developing children's faculties were appointed.

### Future outlook

With an aim to realize a society in which develops and ensures various human resources, the Government of Japan will implement initiatives of optimizing the budgets allocation for developing researchers for S&T, particularly to focus budgets on Action Plan and Priority Project Package.

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<sup>2</sup> A system that enables young researchers employed through a fair and transparent screening process to accumulate experiences as an independent researcher in the form of employment with a fixed term of service before gaining a more stable position through review process.



### 43. Incentives to drive innovation at Private sectors (WP-C/#11/EJ to EJ)

#### (1) Creating better conditions for businesses

##### BRT Recommendation

To facilitate private sector's role as an engine for growth, the Authorities should create better conditions for businesses be they domestic/foreign, large or small. In particular, given on-going technological developments, the Authorities in the EU and Japan should periodically review rules and regulations, to reform outdated rules and regulations or harmonise others within the EU and Japan thereby creating a bigger market and incentivising the commercialisation of new products and services.

##### Action taken so far

To strongly promote investments in the high-value-added growth areas which support the future economic growth of Japan, the Government of Japan (GOJ) will provide active support to establish R&D bases.

Under the initiative of the government, to promote in earnest the mid- and long-term R&D which will create our future industries and employments, the GOJ decided to take measures in its budgets 2012FY on "R&D for the future" in order to overcome our restrictions on resources and those on energy and environment. In addition, the GOJ has implemented tax reduction through introduction of R&D tax system for companies to promote their investments for R&D.

##### Future outlook

The GOJ continues to make an effort to improve the R&D environment for private sector and expand the investment for R&D.

(2) incentivising the commercialisation of products and services

**BRT Recommendation**

In particular, given on-going technological developments, the Authorities in the EU and Japan should periodically review rules and regulations, to reform outdated rules and regulations or harmonise others within the EU and Japan thereby creating a bigger market and incentivising the commercialisation of new products and services.

**Action taken so far**

In order to reform outdated rules or regulations and harmonize others within Japan and the EU, Japan has been addressing these matters in the framework of Japan-EU regulatory reform dialogue.

**Future outlook**

Japan will continuously engage in this work.

### (3) Tax credit for R&D

#### BRT Recommendation

The scope of tax credits for R&D should be expanded to encourage private sector investment in R&D.

#### Action taken so far

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

#### Future outlook

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

#### 44. Continuous investment for R&D Infrastructure (WP-C/#12/EJ to EJ)

##### BRT Recommendation

We recommend the EU and Japan for continuous investment on R&D Infrastructures in national laboratories and universities.

##### Action taken so far

The Government of Japan (GOJ) recognizes importance of continuously investing in R&D infrastructure. The specific case in the field of ICT is as follows:

To establish a system technology base of the New Generation Network through verification and evaluation, National Institute of Information and Communications Technology (NICT) operates JGN-X (Japan Gigabit Network extreme) as a large-scale testbed network which unified fundamental technologies indispensable to realization of the New Generation Network.

JGN-X is used for R&D and verification of the New Generation Network and application technologies with foreign research institutes, including EU ones, through connection with foreign research networks.

##### Future outlook

The GOJ have intention to continue investing R&D infrastructure.

#### 45. Business cooperation between EU and Japanese clusters (WP-C/#13/EJ to EJ)

##### BRT Recommendation

Strengthen business cooperation between EU and Japanese clusters

##### Action taken so far

The Industrial Cluster Policy has strengthened the global competitiveness of Japanese industries and invigorated Japan's local economies by businesses, universities, and other institutions, in regions throughout Japan, forming wide-area networks through partnerships between businesses in the same industry, and across industrial sectors from fiscal 2001. Those networks, through synergetic sharing of participant's intellectual and other resources, will then reach the state in which they have generated new industries and businesses, mainly in their regions.

Those networking activities are currently carried out as regional clusters mainly led by private organizations and local governments.

##### Future outlook

From now on, the business-level international exchange and cooperation is expected to further progress through cooperation between the clusters of Japan and the EU member states.

#### 46. Government-Led Industrial Cooperation in Aerospace (Civil and Defence)(WP-C/#14/EJ to EJ)

##### BRT Recommendation

The Authorities of Japan and the EU should accelerate work to significantly upgrade the scale of EU-Japan industrial cooperation in both civil and defence aeronautics and space, stimulated by government funding.

##### Action taken so far

- (1) 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.
- (2) In July 2006 the Research Center of Advanced Metals and Composites (RIMCOF), which plays a central role in developing basic material-related technology for the Ministry of Economy, Trade and Industry, and Airbus, agreed to conduct joint research on structural health monitoring (SHM) of aircraft. They agreed to continue the joint research until 2012.
- (3) In December 2008, to promote the use of innovative Japanese technology in aircraft, we organized a workshop inviting Airbus and Japanese companies with innovative technology. Since then some of the Japanese companies have been negotiating with Airbus on an individual basis with a view to working together on specific projects in the future.
- (4) On November 17, 2009, the Japanese and European aerospace business and public sectors held a workshop aimed at promoting collaborative research and technical cooperation between Japan and Europe in the aerospace industry. On December 7, 2010, the Ministry of Economy, Trade and Industry (METI) and the European Commission (EC) held a workshop inviting both sides' aerospace industries. On July 20, 2011, METI and the EC publicly solicited ideas for joint research projects in the field of aeronautics and air transport. The five topics covered included, namely, aeronautical communications, anti-icing system, surface heat exchanger for aero-engines, engine ceramic bearings, and high speed aircraft.
- (5) The Japan Aero Engines Corporation (JAEC), Rolls Royce, Germany's MTU, and other firms established a consortium called International Aero Engines to jointly 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.

- (6) 21 Japanese companies were involved in the development of the A380, Airbus's next-generation super jumbo jet.
- (7) In September 2011, Hyper spectral sensor data analysis team: the members of Tokyo University, National Institute for Environmental studies and Rakuno Gakuen University visited Deutsches Zentrum für Luft- und Raumfahrt(DLR) and discussed about each developing Hyper spectral sensor. They had a conference regarding the developmental status of each sensor, data policy, ground data system, sensor operation, calibration technology and cooperation items.
- (8) No answer about the defense areas.

#### Future outlook

- (1) The Government of Japan (GOJ) welcomes the fact that steady progress has been made recently in the cooperation between Japanese and European companies and hopes for further development of such cooperation. The GOJ will continue its support for the collaboration between the Japanese aerospace industry and those of other countries, including Europe.
- (2) The GOJ will consider possible defense-related cooperation based on the new criteria stipulated by Guideline for Overseas Transfer of Defence Equipment etc. in December 2011.

#### 47.Environmental Issues in Aeronautics Technology(WP-C/#15/EJ to EJ)

##### BRT Recommendation

The Authorities of Japan and Europe should establish broad bilateral cooperation on environmental issues.

##### Action taken so far

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. The collaboration has been continued in the areas of advanced composite manufacturing materials, jet noise reduction technologies and etc. which are indispensable for the future realization of an SST.

##### Future outlook

With respect to efforts for developing environmentally-enhancing aircraft technologies, the cooperation between the Japanese aircraft industry and those of other countries is vital from the viewpoint of improvement of Japanese companies' technological capability and competitiveness. The Government of Japan intends to continue assisting in forging ties between the Japanese aircraft industry and those of other countries, including Europe.



#### 48.Cooperation in aircraft certification(WP-C/#16/EJ to EJ)

##### BRT Recommendation

Establish cooperation between Japanese and European aircraft certification authorities.

##### Action taken so far

Civil aviation authorities of Japan and the EU have concluded the working arrangement that defines the working relationship to provide practicable procedure for technical inspections, evaluations and testing of civil aeronautical products.

In order to enhance cooperation between Japan and the EU for a high level of civil aviation safety, the Ministry of Land, Infrastructure, Transport and Tourism and the European Commission agreed to launch preliminary discussions toward the conclusion of the Bilateral Aviation Safety Agreement (BASA) at the Japan-EU Transport Dialogue held in July of 2011.

The BASA will enable mutual acceptance of certificates issued by each civil aviation authority, which leads to facilitation of export and import of civil aeronautical products, as well as reduction of the economic burden imposed on the aviation industry by avoiding redundant technical inspections, evaluations and testing.

Taking advantages of the experiences of cooperation under the above-mentioned working arrangement, both sides have been working closely toward early conclusion of the BASA.

##### Future outlook

Based on the agreement at the Japan-EU Transport Dialogue held in 2011, Japan and the EU have been preparing for the 1<sup>st</sup> meeting of preliminary discussions scheduled in January 2012. Since Japan's first passenger jet is currently under development, and a variety of types of aircraft designed and manufactured in Europe are scheduled to be introduced into Japan, the work for an early conclusion of the BASA will be accelerated.

49.Civil Purpose Satellite Technology(WP-C/#17/EJ to EJ)

BRT Recommendation

In the civil satellite technology field, Japanese space Authorities (at Cabinet level) and European space Authorities (EU Commission, European Space Agency, and Europe's national space agencies) should establish a common mechanism for a formal and permanent dialogue with the purpose of identifying further mutually beneficial subjects of cooperation.

Action taken so far

N.A.

Future outlook

After considering the proposal internally, the Government of Japan will consult with the appropriate European space Authorities as necessary.

## 50. Defence Purpose Satellite Technology(WP-C/#18/EJ to EJ)

### BRT Recommendation

The Authorities of Japan and EU Member States should establish a regular dialogue aimed at sharing experience on defence purpose satellites.

### Action taken so far

Japan's policy on the development and use of the outer space in the defense area is consistent with the Basic Space Law (enacted in 2008) which stipulates that space development and use shall be carried out in accordance with treaties and other international agreements with regard to space development and use, based on the pacifism of the Constitution of Japan. The National Defense Program Guidelines, which was approved with its Cabinet decision in December 2010, stipulates as the basic policies to ensure Japan's security that Japan will promote its efforts to develop and utilize outer space from the perspective of strengthening information gathering and communications functions.

Currently, satellites for telecommunication, remote sensing and meteorological, including TerraSAR-X (German commercial SAR satellite) and METEOSAT (meteorological satellite of European Space Agency), are used in the field of defense. In addition, Japan is currently engaged in policies to build a high-capability X-band satellite network.

### Future outlook

Currently, Japan and the EU have regular exchanges through meetings where the defense authorities also participate. It is possible that the development and use of the outer space can be discussed in those meetings as necessary.

## 51. Mutual Backup of Government Satellite Launches(WP-C/#19/EJ to EJ)

### BRT Recommendation

Japanese and EU space authorities should bring about a mutual backup cooperation scheme of all government launches using their respective satellite launcher fleets.

### Action taken so far

The backup agreement between Mitsubishi Heavy Industries, Ltd. and Arianespace covers launching services for both government and commercial satellites.

### Future outlook

Same as above.

## 52.Exchange and Protection of Classified Information(WP-C/#20/EJ to EJ)

### BRT Recommendation

Japan and European countries should make official agreements for government and industry to exchange and protect classified information pertaining to joint development.

### Action taken so far

When the national defense equipment is jointly developed, for delivering to national authority, the main undertaker should contract the MOU with firms which jointly develop the equipment, and is MOU provides for the arrangements for information sharing and protection. Therefore the problem pointed out in the recommendations would not be expected.

### Future outlook

N.A.

### 53. Relaxation of the Three Principles on Arms Exports (WP-C/#21/EJ to J)

#### BRT Recommendation

Japan should relax the three principles on arms exports ('3Ps') to allow it to participate, in certain defined circumstances, in joint R&D and production of defence equipment with NATO and other like-minded countries. Changes should be made in the form of clear guidelines, rather than one-off exceptions for specific purposes.

#### Action taken so far

The Government of Japan (GOJ) has paid a series of careful considerations on the measures to respond to the changes in international environment regarding defense equipment, based on the National Defense Program Guidelines for Fiscal Year 2011 and beyond.

The GOJ, in line with the ideas behind the individual exemption made so far, came to the conclusion that it would take comprehensive exemption measures in overseas transfer of defense equipment etc. for cases related to peace contribution and international cooperation as well as for cases regarding international joint development and production of defense equipment etc. that contributes to Japan's security.

The Three Principles on Arms Exports and their related policy guidelines are based on Japan's basic philosophy as a peace-loving nation to avoid the exacerbation of international conflicts. The GOJ firmly maintains this basic philosophy.

#### Future outlook

Hereafter, the GOJ will deal with each individual case in accordance with the above guidelines.

54. Facilitation of Re-export of Defence Equipment Imported for Demonstration Purposes (WP-C/#22/EJ to J)

BRT Recommendation

Japanese Authorities should implement arrangements to facilitate re-exports of defence equipment imported for the purposes of demonstrations at forums such as trade fairs and exhibitions.

Action taken so far

The Three Principles on Arms Exports and their related policy guidelines are based on Japan's fundamental principles as a peace-loving nation basic philosophy to avoid the exacerbation of international conflicts. The Government of Japan firmly maintains these principles.

Based on the Foreign Exchange and Foreign Trade Act and the Export Trade Control Order, an export license is necessary to re-export defense equipment imported for the purposes of demonstrations.

Future outlook

As for the current prospect, an export license is still necessary to re-export defense equipment imported for the purposes of demonstrations based on the Foreign Exchange and Foreign Trade Act and the Export Trade Control Order.

55. Removal of unlimited liability for public tenders (WP-C/#23/EJ to J)

**BRT Recommendation**

Unlimited liability should be removed from the terms and conditions of public tenders, as this puts foreign bidders at a considerable disadvantage in relation to local contenders.

**Action taken so far**

The meaning of "Unlimited Liability" is not clear.

It is necessary to specify the concrete terms and conditions of public tenders that contain the words, "Unlimited Liability".

**Future outlook**

Same as above.



## 56. Approval of Sattelite Launch Service Providers(WP-C/#24/E to EJ)

### BRT Recommendation

The approval by Japanese Authorities of foreign launch service providers through the envisioned approval system of Japanese commercial satellite launch projects should be fair and consistent with commercial world practice as recognised and formalised by the French Space Operations Act of June 2008 and associated by-laws.

### Action taken so far

Refer to the response to WP-A/#12/E to J above.

### Future outlook

Refer to the response to WP-A/#12/E to J above.

57. Legitimate use of Private Finance Initiative projects (WP-C/#25/E to EJ)

BRT Recommendation

Authorities should explicitly ban their own use of Private Finance Initiative (PFI) projects to protect local satellite makers and launch service providers.

Action taken so far

Japan's private finance initiative projects are subject to the Act on Promotion of Private Finance Initiative (PFI) which came into force in 1999.

Future outlook

PFI is and continues to be carried out in accordance with international rules.

58. Opening the market for space ground equipment(WP-C/#26/E to J)

**BRT Recommendation**

Procurement of integrated systems should be encouraged.

**Action taken so far**

Refer to the response to WP-A/#12/E to J above.

**Future outlook**

Refer to the response to WP-A/#12/E to J above.

59. Internationally recognized procurement processes for defence equipment and services (WP-C/#27/E to EJ)

#### BRT Recommendation

The following should be applied to all defence procurement processes. (1) Clear statements of requirements, communication of any changes (2) Advising of timelines and adherence to them (3) Notice of evaluation criteria and the weightings given each criterion (4) Acceptance of English-language documentation (5) Application of NATO standards (6) Full public disclosure of the basis of awards (7) Opportunities to appeal award decisions, without the requirement to withdraw from the competition.

#### Action taken so far

In June 2010, the Contract System Study Group (an expert meeting) was established to put forward new measures from a broad perspective, dealing with issues related to the system of contract between the Ministry of Defense and industry such as accounting, distribution, marketing, corporation laws, public acquisition etc.

An interim report has been made at the Group with the results of research focusing on such areas as contract systems with cost-down incentives, multiple-financial-year contracts (especially on PFI and PBL contract systems) etc.

#### Future outlook

Various issues on defense acquisition will be continued to be discussed at the Group, including the topics such as contract clauses able to respond to risks in project continuity, contract clauses able to deal with M&A (merger and acquisition), measures for the introduction of international accounting standards, acquisition process etc.

60. Greater emphasis on life cycle costs in awarding contracts (WP-C/#28/E to EJ)

**BRT Recommendation**

Life Cycle Costs should form the basis of all relevant defence contract awards.

**Action taken so far**

At the Ministry of Defense, the equipments etc., to which Life Cycle Costs management applied, are determined with consideration on the significance of the equipment within the total defense capability buildup, the scale of the equipment program, and the required costs of the equipment etc.

**Future outlook**

Currently, LCC management is applied to major equipments of aircraft, guided weapons, artilleries, vessels, ground vehicles etc. Based on the Defense Program Guidelines 2010 (Cabinet decision on December 17, 2010) and Mid-Term Defense Programs FY2011-2015, gradual future expansion of the scope of the LCC management application is under consideration.

## 61.Examination of innovative procurement approaches for defence equipment(WP-C/#29/E to J)

### BRT Recommendation

We recommend Japan study implementing innovative procurement schemes, including receiving information on the experience of Europe in these areas.

### Action taken so far

In June 2010, the Contract System Study Group (an expert meeting) was established. The group is intended to put forward new measures from a broad perspective, dealing with issues related to the system of contract between the Ministry of Defense and industry such as accounting, distribution, marketing, corporation laws, public acquisition etc.

An interim report has been made at the Group until today with the results of research focusing on such areas as contract systems with cost-down incentives, multiple-financial-year contracts (especially on PFI and PBL contract systems) etc.

### Future outlook

Various issues on defense acquisition will be continued to be discussed at the Group, including the topics such as contract clauses able to respond to risks in project continuity, contract clauses able to deal with M&A (merger and acquisition ), measures for the introduction of international accounting standards, acquisition process etc.

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

62. Progress in the financial market reform since the financial crisis (WP-D/#01/EJ to EJ)

### **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. Since the G20 summit in November 2010 in Seoul, the process for these regulatory reforms has moved from the phase of the consideration to implementation.

Specifically, under the G20 framework, the Basel Committee of Banking Supervision (BCBS) published the rule book for Basel III in December 2010, which stipulates the details for the banking regulation and which is to be implemented internationally. Each country shall carry out procedures in preparing its domestic rules as the next phase for application of Basel III starting from January 2013.

Regarding Systemically Important Financial Institutions (SIFIs), the concrete regulations for SIFIs are now being built at the global level following the adoption of the proposal by the Financial Stability Board (FSB) at the G20 summit in Seoul. Global SIFIs (G-SIFIs) will be specified in 2011. In consideration that G-SIFIs are not only large in scale but also considered to be important in the markets and to have significant impact on society and the economy as a whole, G-SIFIs will be required to have higher capacity for loss absorptions than other institutions, and the framework for those orderly resolutions will be built.

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 financial markets and the financial system is important for market users including companies that raise capital.

However, given that measuring systemic risks is very difficult and the acquisition of consistent data across countries and industries would be difficult as well, the criteria (or benchmarks) to measure the “SIFIness” should be cautiously set out. In addition, when the FSB specifies SIFIs it would need to mitigate moral hazard and to avoid an excessively politicized process. Considerations of financial reforms with systemic risks should be delivered through the framework of comprehensive and macro-prudential supervision.

### **Action taken so far**

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

- 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.

As for financial institutions which internationally operate large-scale and complex businesses, the FSA clarifies its supervisory policy focusing on

- the viewpoint of macro-prudence, taking recent economic and financial trends in Europe and the U.S. into consideration, and
- enhanced risk management systems to support initiatives for stronger profitability such as expansion into Asia

in Annual Supervisory Policy for Major Banks for Program Year 2011.

#### 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.



63. Issues to be mindful of when proceeding with reform (WP-D/#02/EJ to EJ)

**BRT Recommendation**

- We shall, at the same time, point out that there are several issues we should bear in mind as we proceed with regulatory reform. Innovation and appropriate risk appetite are important and necessary for financial actors to perform their role of financing economic growth. A careful balance must be struck between innovativeness, risk appetite and regulation. Also we should bear in mind that strengthening the regulation on large financial institutions could result in distorting the conditions for a level playing field and could end up creating “too-big-to-fail” institutions.
- One must not give in to the temptation of a “one size fits all” solution. The new regulatory framework should take into account the circumstances that are specific to each country and/or the variety of financial players, and respect their business models and their time horizons. The different economics of financial activities should be appropriately reflected in the new regulatory regimes. Failing to do so would lead to herd behaviour and heightened volatility rather than to stability and transparency.
- We also have to recognize that maintaining 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 regulatory reform should move forward in order to prevent the next financial crisis, we also have to be mindful of preventing a 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 based on the traditional banking system. If low liquidity in the secondary market and credit restraint due to the capital requirements for banks should happen in such countries, corporate finance could face constraints from both the capital market and the banking system, and this could result in 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 regulation and practices vary greatly from country to country, particularly for small and mid-sized financial institutions.
- According to “Basel III”, investments in the capital instruments of banking, financial and insurance entities would be deducted. However, for countries where reciprocal cross holdings in the capital between financial institutions are prevalent, sensitive handling such as giving an adequate transition period would be necessary. And regulatory capital instruments such as contingent capital or debt instruments with bail-in clauses designed by financial regulatory authorities need to be introduced with sufficient consideration for market capacity. Furthermore tightening regulation on shadow banking, led by the FSB, needs to fully consider the role of the shadow banks to the real economy and to take measures not to disturb bona fide business activities.

- When 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. Among other things, we should take fully into account the impact on the economy and the outcome of the combined impact of several individual regulations when they are concurrently implemented.

#### Action taken so far

As for global financial regulatory reform, the Government of Japan (GOJ) 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 considerations the impact on the real economy, while new regulation should contribute to strengthening the financial system and improvising the soundness of financial institutions in the mid to long term. The GOJ has asserted these two points accordingly at international forums, which have been reflected in G20 Declarations, etc.

#### Future outlook

The GOJ 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 the views as stated above.

#### 64. Accounting Issues in EU and Japan (WP-D/#03/EJ to EJ)

(1) Enhancement of the governance of the accounting standard setting bodies and the convergence of accounting standards

##### 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 a wide-ranged report on the activities of the Accounting Standard Board. We support these trends and look forward to further developments. We also support the progress towards the introduction of IFRS in Japan and look forward to further discussions on convergence.

##### 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. In Japan, ASBJ started to move forward with the convergence of accounting standards into the International Financial Reporting Standards (IFRS), and based on the Tokyo Agreement on August 2007, the International Accounting Standards Board (IASB) and ASBJ agreed to seek to eliminate by 2008 major differences between Japanese GAAP and IFRSs (as defined by the Committee of European Securities Regulators (CESR)), with the remaining differences to be removed on or before 30 June 2011. As a result, the ASBJ completed the target in 2008 and is expecting to substantially achieve the target.

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

#### Future outlook

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

## (2) Accounting standard

### BRT Recommendation

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 a recycling arrangement is useful as accounting information. Accounting costs affect the behaviour of enterprises. If items not recycled such as actuarial gains and losses in pension accounting are expanded, and thus profit and loss not reflected in net income are expanded too, we are concerned that underlying business activities such as cost management and selling price formation could be disrupted.

### Action taken so far

The setting of each accounting standard involves a variety of issues, such as impact on corporate activities. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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.

In addition, the standard-setter in Japan, the Accounting Standards Board of Japan, recognizes the importance of recycling OCI to preserve the notion of profit or loss, and sends a comment on the importance of recycling OCI to IASB as a response to Agenda Consultation 2011.

### Future outlook

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

### (3)Revising financial instrument accounting standard:available-for-sale securities

#### BRT Recommendation

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.

Net realized income has been described by some as a kind of income manipulation. We believe, however, that management is able to send out its message by the sale of the securities. Thus, recognizing the net realized income as net income gives more useful accounting information. For example, on the measurement of assets and liability in insurance companies which IASB calls one of its priority projects, 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 IFRS 9 is based: the long term business model of insurance should be recognized through the AFS.

#### Action taken so far

The setting of each accounting standard involves a variety of issues. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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

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

#### (4) Immediate recognition in the accounting standards of employee benefits

##### BRT Recommendation

As part of the process to strengthen immediate recognition in the accounting standards of employee benefits, the actuarial gains and losses may be recognized immediately upon accrual as OCI. The immediate recognition of actuarial gains or losses coming from short term financial market fluctuations could cause pension plans, which are long term promises between employers and participants, to give excessive fluctuation to net income. We support the approach to recognize actuarial gains and losses as OCI and not as net income. On the other hand, we believe actuarial gains and losses should be recycled for the above-mentioned reason.

##### Action taken so far

The setting of each accounting standard involves a variety of issues. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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

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

#### (5) Revenue recognition criteria

##### BRT Recommendation

We ask IASB to discuss 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 would affect business practices. We believe that already-established accounting practices should not be overruled unless the accounting standard reform is truly necessary, such as when concrete problems that may hinder investor's decision-making already exist.

##### Action taken so far

The setting of each accounting standard involves a variety of issues. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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

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



## (6) Leasing accounting standard

### BRT Recommendation

The IASB and the FASB published the exposure draft (ED) in August 2010 in which they proposed drastic revisions. The exposure draft proposes a single model for operating and finance leases by eliminating separate treatments. However, we point out that this rule that treat operating and finance leases together has quite a few challenges since there is plenty of room for arbitrariness in that it is necessary to carry operating leases on the balance sheet and to reevaluate the estimate of the leasing period or variable lease fees regularly. We call for an application that adequately reflects business practices. Moreover, if the leasing accounting standard is applied to the entire contracts in the case in which the contracts of leases and services are not separable, even elements other than utilization rights of an underlying asset, such as "services offered to help an original asset work appropriately" or " added value offered through the transaction concerned" would need to be recorded on the balance sheet. These elements might not only be corresponding to the definition of the lease, but also could lead to the transformation of the concept of the asset and the liability of financial statements of such an element. We request accounting treatment that reflects the business realities appropriately.

### Action taken so far

The setting of each accounting standard involves a variety of issues. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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

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

(7)IASB's financial statement presentation project

**BRT Recommendation**

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. Users of financial statements are able to acquire sufficient useful information from disclosures with the indirect method. Based on the fact that companies will incur large amounts of costs, we do not see any overriding benefit coming from the requirement of direct method.

**Action taken so far**

The setting of each accounting standard involves a variety of issues. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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**

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

## 65. Tax Issues in the EU and Japan (WP-D/#04/EJ to EJ)

### (1) Tax treaties

#### BRT Recommendation

The governments 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, as seen in the recently revised Japan Holland Tax Treaty, 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

The Government of Japan (GOJ) and the Governments of the EU member states, in view of promoting investment and economic activities between Japan and the EU, are actively expanding and enhancing the network of the tax treaties between Japan and the EU member states.

In this context, the GOJ signed the Convention with the Republic of Portugal, which incorporates arbitration procedure, in December 2011. Moreover, the GOJ commenced the intergovernmental negotiations with the Republic of Germany for the revision of the current Agreement in December 2011. In addition, the new Convention with the Netherlands, which incorporates arbitration procedure, the Amending Protocol with Switzerland and the Grand Duchy of Luxembourg entered into force in December 2011.

#### 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) Corporate accounting

### 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 the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

### Future outlook

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

### (3) Transparent and fair taxation

#### 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 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 the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

#### Future outlook

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

#### (4) Introducing participation exemption

##### BRT Recommendation

Participation exemption, by which dividends and capital gains received from business investment are exempted from further corporate taxation, is one measure to encourage mutual direct investment. The authorities of the EU and Japan should consider introducing participation exemption and exempt dividends and capital gains received from business investment from further corporate taxation.

##### Action taken so far

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

##### Future outlook

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

## 66. Tax Issues in Japan (WP-D/#05/EJ to J)

### (1) Japan Post

#### BRT Recommendation

The Japanese Government changed its Postal privatization policy and announced a policy that would allow its entry into new business areas under special, privileged 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 lifting or 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 procedures with transparency and to involve a constructive discussion through the reform process.

#### Action taken so far

With regard to postal reform in Japan, the relevant bills, which were deliberated in 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 Government of Japan 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, small- to medium-sized corporate clients who have a loan or even larger corporations borrowing from a regional bank cannot purchase insurance products through their lender bank. The regulation will be reviewed this year, and the regulatory reform should be discussed for further enhancement of consumer convenience, while paying attention to the protection of consumers' interests.

### Action taken so far

The Government of Japan (GOJ) has examined the current regulations from the perspective of both the need to improve convenience for users and the need to protect users, in light of the results of monitoring the status of bank sales of insurance. The GOJ revised the relevant Cabinet Office Ordinance this year.

For example, of the products subject to the regulation on solicitation of borrowers, savings-like ones will be exempted from the regulation.

### Future outlook

The GOJ will closely monitor the situation and conduct a review when necessary, rather than setting a timetable for future review.



(3) Flexible coordination among agencies in dealing with foreign businesses

**BRT Recommendation**

We believe that a rapid recovery from Great East Japan Earthquake is and should be a top priority. The Government of Japan has shown unprecedented coordination among agencies in dealing with foreign businesses in a flexible way during this emergency and we hope that will continue. At the same time, due consideration should be given to soundness of fair market competition while the Japanese government provides support to enterprises that were seriously hit by the disaster. Furthermore, the stability of the secondary market for bonds or restraint of inflation should be cautiously considered when the Japanese government raises funds for revival, such as through the issuance of government bonds.

**Action taken so far**

N.A.

**Future outlook**

With Japan's stringent fiscal condition, the financial resources for recovery and reconstruction shall basically be borne by the entire current generation, collectively sharing the financial burden by solidarity and not be left as cost of future generations.

In regard to reconstruction bonds which will be issued as a temporary means to finance preceding recovery and reconstruction demands, its issuance will be managed carefully by taking into consideration the impact on markets.

## 67. Accounting Issues in Japan (WP-D/#06/EJ to J)

### BRT Recommendation

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

• Under IFRS, income is classified into “net income” and “other comprehensive income.” We request organizing the concept of a profit and the range of recycling in the early stage. In particular, “net income” is regarded as the basis of performance indicators in Japan and compatibility between the Companies Act and the Tax Code is secured. Therefore, the conventional treatment for recycling should be maintained even after the convergence of Japanese standards to IFRS advances.

### Action taken so far

The setting of each accounting standard involves a variety of issues. Therefore, for high-quality standards to be established, substantial dialogues are essential between the accounting standard-setter and the 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 Financial Services Agency (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

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

68. Tax issues in Japan (WP-D/#07/EJ to J)

(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 review its transfer-price taxation based on an international common model such as the OECD model, and to secure further transparency in its implementation.

Action taken so far

- (1) The GOJ makes it a 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.

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

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.

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

## (2) Reducing corporate tax rates

### BRT Recommendation

We request the Japanese government to consider further reducing corporation tax rates. We support the proposal of the government stated in Proposed 2011 Tax Reform of December 2010 to reduce effective corporation tax rate by 5%-point from the current 40%, which is the highest level throughout the world. However, while many countries are accelerating the reduction of effective corporation tax rates, Japan should lower its corporation tax rate even further to the international equivalent of around 30% in order to ensure Japanese companies' international competitiveness and also to stimulate investments from home and abroad.

### Action taken so far

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

### Future outlook

For the Japanese Government's position on tax-system reform in general, 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 tax breaks to encourage the development of individual preparation for retirement.

**Action taken so far**

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

**Future outlook**

For the Japanese Government's position on tax-system reform in general, refer to the attachment in the Appendix of this report.

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

### **69. Identification and prevention measures for natural risks (WP-E/#01/EJ to EJ)**

#### **BRT Recommendation**

The EU and Japan should put in place appropriate mechanisms to identify the potential risks of natural disasters and the probability of their occurrence, and objectively verify their impact. Cost-effective measures should be taken to prevent and reduce the consequences of these risks.

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

Building upon the works of the Japan-EU Joint High-Level Group (JHLG) established at the Japan-EU Summit in 2010 and reflecting on the occurrence of the Great East Japan Earthquake, Japan and the EU adopted its Annex to the Joint Press Statement on the occasion of the Japan-EU Summit held in May 2011, and affirmed that Japan and the EU would exchange views on natural disaster preparedness and prevention.

#### **Future outlook**

Japan and the EU will continue to explore possibilities of cooperation in the area of natural disaster risk reduction.

## 70. Facilitating international support in case of disaster(WP-E/#02/EJ to EJ)

### BRT Recommendation

International support is indispensable in times of a major natural disaster. The necessary measures need to be adopted to facilitate the swift acceptance of support from overseas.

### Action taken so far

In response to the Great East Japan Earthquake, Japan has so far received rescue, medical support, disaster relief, and other assistance teams from 29 countries/regions/organizations, as well as relief goods and donations from 126 countries/regions/organizations. From the EU, Japan received relief goods including blankets, and donation of 10 million Euros through the International Red Cross.

### Future outlook

In accepting assistance from overseas, Japan will continue to coordinate those assistance and the needs in disaster-stricken areas while utilizing experiences from the Great East Japan Earthquake.

## 71. Independent assessment of Fukushima accident(WP-E/#03/EJ to EJ)

### BRT Recommendation

With regard to the Fukushima Daiichi nuclear power plant accident, we call strongly for the independent, objective, and immediate verification of the situation. In addition, we believe that the EU and Japan should promote discussions on improving the safety of nuclear energy in international fora.

### Action taken so far

The Government of Japan (GOJ) has communicated the status of the accident to the international community in both an accurate and expeditious manner, and shared the lessons we have learned with the international community for the purpose of raising the safety of nuclear power to the highest level .

In particular, the GOJ made a great effort to present reports on accident and its preliminary assessment to the IAEA in June and September 2011.

In May, the GOJ established an “Investigation Committee on the Accidents at the Fukushima Nuclear Power Station(NPS) of Tokyo Electric Power Company” in order to provide an overall investigation of the utility of countermeasures being taken against the accident that has occurred in Fukushima NPS. This Investigation Committee, with independence from Japan’s existing nuclear energy administration, openness to the public and international community, and comprehensiveness in examining various issues related not only to technical elements but also to institutional aspects, strictly investigates all activities undertaken so far, including accident responses taken by the Government .

### Future outlook

The GOJ will continue to inform the status of the accident to the international community in both an accurate and expeditious manner, and shared the lessons learned with the international community to improve the safety of nuclear power to the highest level .

Close study and assessment on all activities undertaken by the Government will be released to the international public.



## 72. Enhancing high-level EU-Japan dialogues on energy(WP-E/#04/EJ to EJ)

### BRT Recommendation

The EU and Japan should enhance their dialogue on energy policy, including the set-up of a dedicated high-level dialogue on nuclear energy.

### Action taken so far

Energy policy dialogue between the Agency for Natural Resources and Energy of Japan and the Energy Directorate of the European Commission has been held three times since its establishment in 2007.

Also, Japan and the EU concurred that they would work together to ensure internationally the highest level of nuclear safety as mentioned in the “*Japan- EU Cooperation Following the Great East Japan Earthquake and the Accident at the Fukushima-Daiichi Nuclear Power Plant,*” which was announced as an Annex to the Joint Press Statement at the 20<sup>th</sup> Japan-EU Summit in Brussels in May 2011.

### Future outlook

Japan and the EU plan to hold a next energy policy dialogue in the spring of 2012.

Also, Japan and the EU will promote dialogue on Japan-EU cooperation in the field of nuclear safety in accordance with the “*Japan-EU Cooperation Following the Great East Japan Earthquake and the Accident at the Fukushima-Daiichi Nuclear Power Plant*”.

### 73. Leadership role to establish world safety standards (WP-E/#05/EJ to EJ)

#### BRT Recommendation

The EU and Japan should take a proactive, leading role in supporting the establishment of world safety standards for nuclear power plants through the Ministerial Conference, the IAEA,... and more generally promote international cooperation on nuclear energy.

#### Action taken so far

The Government of Japan (GOJ) has promoted discussion at international fora with an aim to elevating the safety of nuclear power to the highest level by reporting the status of the accident in an accurate and expeditious manner, and sharing the lessons learned with the international community.

In particular, the GOJ has actively shared with the IAEA its experience and knowledge from the accident for IAEA reviewing their standards and guidelines.

Additionally, the GOJ has actively taken part in international efforts such as reviewing IAEA safety standards.

In particular, in November, staffs in NISA attended the Committee on Safety Standards held by the IAEA and briefed about the relationship between the 28 “lessons learned” indicated in the GOJ’s report to the IAEA and IAEA safety standards.

#### Future outlook

The GOJ will further promote discussion at international fora to improve the safety of nuclear power to the highest level by reporting the status of the accident to the international community in an accurate and expeditious manner, and sharing the lessons learned with the international community. Additionally, the GOJ will actively take part in international efforts such as reviewing IAEA safety standards.

#### 74. Nurturing skilled independent nuclear safety authority (WP-E/#06/EJ to EJ)

##### BRT Recommendation

Japan and EU member countries should maintain a highly skilled nuclear safety authority in each country and ensure its independence.

##### Action taken so far

The Government of Japan (GOJ) is engaged in restructuring of agencies responsible for nuclear safety regulation with a view to recovering public trusts for the nuclear safety administration and improving its functions. In line with the Cabinet Decision in August 2011, the GOJ is preparing to establish the Nuclear Safety and Security Agency (tentative name) under the Ministry of the Environment by separating the Nuclear and Industry Safety Agency (NISA) from the Ministry of Economy, Trade and Industry and integrating the tasks of the Nuclear Safety Commission (NSC) and the other organizations, from the viewpoints of “the separating functions of nuclear regulation and promotion” and unification of the related nuclear safety tasks. In this way, the GOJ will ensure independency of the agency of nuclear safety regulation, and enhance the effectiveness of the regulation through strengthening the legal regulation for safety and human resource development.

##### Future outlook

The GOJ will strengthen legal regulation for nuclear safety through establishing the Nuclear Safety and Security Agency (tentative name) by April 2012 that is an independent institution and implements an effective nuclear safety regulation.

## 75. Cooperation on renewable energy development(WP-E/#07/EJ to EJ)

### BRT Recommendation

Japan and the EU should cooperate on the development of renewable energies, such as wind and photovoltaic power generation, and on other low-carbon.

### Action taken so far

The Ministry of Economy, Trade and Industry and the Directorate-General for Research of the European Commission held the “Japan-EU officials’ meeting on cooperation on energy technology R&D” in March, 2011. Experts from governments, research institutions, business of both sides discussed ways of cooperating on research and development in the fields of photovoltaics, power storage, carbon dioxide capture and storage (CCS).

In the field of photovoltaics, the two sides launched a joint technology development project for concentrated photovoltaics, 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 the EU in March 2012.

The Government of Japan will discuss ways of cooperation on energy technology between Japan and the EU.

## 76. Promoting reciprocal access to R&D facilities(WP-E/#08/EJ to EJ)

### BRT Recommendation

The EU and Japan should support joint R&D activities or mutual access to unique, capital intensive R&D facilities located in either the EU or Japan.

### Action taken so far

Japan-EU Summit leaders stated that *taking advantage of the Agreement between the Government of Japan and the European Community on Cooperation in Science and Technology*, which entered into force in March 2011, *Japan and the EU will deepen and broaden the scope of their cooperation and launch new collaborative activities* in the 20th Japan-EU Summit Joint Press Statement issued in May 2011. Japan and EU held the First Joint Committee on Scientific and Technological Cooperation in June in Tokyo under the Agreement and conducted discussions for deepening and broadening the scope of their cooperation of mutual interest.

Japan makes available constructs advanced research facilities possessing incomparable functions in accordance with the "Act on the Promotion of Public Utilization of the Specific Advanced Large Research Facilities" (Law No. 78 of 1994) and those facilitates for researchers in various fields. Japan publicizes the access information on these facilities for overseas users and proceeds in a system open to foreign researchers.

### Future outlook

Toward the Second Joint Committee on Scientific and Technological Cooperation, Japan and the EU will review the discussion at the First Joint Committee, follow progress in joint researches from 2011 and explore possibilities of new/further cooperation.

As for three facilities (SPring-8, SACLA and J-PARC) , which were available for shared use, application for utilization of these facilities will be accepted periodically in around May and November as a general rule. And the consultation for utilization will be accepted at any time. Japan plans final adjustments toward shared use of K Computer from the fall 2012.

77. Sharing best practices for safety and regulation with emerging nuclear power countries (WP-E/#09/EJ to EJ)

#### BRT Recommendation

The EU and Japan should position nuclear power as an alternative energy and provide assistance to each other and to other countries, giving priority to sharing best practices in the fields of regulation and safety. The EU and Japan need to effectively support emerging nuclear power countries through a combination of bilateral, regional, and cooperative activities through international organisations.

#### Action taken so far

The Government of Japan (GOJ) has effectively advanced cooperation with emerging countries of nuclear energy through a combination of bilateral and regional cooperation, and cooperative activities through international organizations.

Concerning bilateral cooperation, the GOJ provided training programs for the capacity building of regulators and licensees of China and Vietnam. The GOJ has communicated the status of the accident to the international community in an accurate and timely manner, and shared the lessons learned at a Trilateral Top Regulators Meeting on Nuclear Safety held in Tokyo last November and other meetings.

As for regional support, the GOJ has actively taken part in the Asian Nuclear Safety Network (ANSN) of the IAEA for supporting to establish safety infrastructures in emerging countries in Asia and attended the steering committee held this November.

To international organizations, the GOJ took part in the mission on finding needs of support activities in emerging countries implemented by OECD/NEA in Indonesia and Vietnam February 2011.

The GOJ has communicated the status of the accident to the international community in an accurate and timely manner, and shared the lessons we have learned at General Conference of RCF whose task is effective and efficient supports to emerging countries and GNSSN round table held this September 2011.

#### Future outlook

The GOJ will continue to implement to effectively support emerging nuclear power countries through a combination of bilateral, regional, and cooperative activities through international organizations.

78. Promoting involvement of international institutions to finance capacity –building actions for nuclear safety (WP-E/#10/EJ to EJ)

BRT Recommendation

To achieve a high level of safety, Japan and the EU should encourage the World Bank, the European Bank for Reconstruction and Development (EBRD), and the European Investment Bank (EIB) to allocate funds for, and to promote the establishment of, dedicated nuclear safety programmes.

Action taken so far

For the regions of the former Soviet Union and Central and Eastern European countries, the GOJ has been funding activities for promoting nuclear safety through the account and fund at the European Bank for Reconstruction and Development (EBRD).

Future outlook

The GOJ will steadily implement its financial commitment on the Nuclear Safety Account and the Chernobyl Shelter Fund at the EBRD.

## 79. Ensuring fair competition in exports(WP-E/#11/EJ to EJ)

### BRT Recommendation

The EU and Japan need to create equally competitive fields for export industries, including fulfilment of world safety standards, and strictly adhere to the OECD's Arrangement to Officially Support Export Credits. The EU and Japan should request other countries to make every effort to also adhere to these provisions.

### Action taken so far

With the economic growth of the emerging countries, companies in non-OECD member countries have more export projects that compete with projects by companies in the OECD member countries. Under these circumstances, it has become critically important to ensure a level playing field on officially supported export credits regarding financial terms and conditions with non-OECD member countries.

From this background, Japan considers that it is necessary to actively continue the outreach efforts to the non-OECD member countries regarding the ARRANGEMENT ON OFFICIALLY SUPPORTED EXPORT CREDITS ("Arrangement") and the RECOMMENDATION ON COMMON APPROACHES ON THE ENVIRONMENTAL AND OFFICIALLY SUPPORTED EXPORT CREDITS ("Common approaches").

Based on this recognition, Japan has cooperated in the efforts made by the OECD to encourage those non-OECD member countries, which are currently in the observer status, to participate in the related OECD meetings for officially supported export credits.

### Future outlook

In order to further encourage non-OECD member countries to understand and follow the Arrangement and the Common approaches, and thereby to ensure a level playing field for officially supported export credits, Japan will continue to actively cooperate in the outreach efforts to other OECD member countries.



80. Fostering international harmonization for EV safety and charging infrastructure(WP-E/#12/EJ to EJ)

**BRT Recommendation**

The EU and Japan should work together in UN-ECE WP 29 and other fora to develop internationally harmonized requirements for the safety and type approval of electrically charged vehicles and common standards for accessing the battery-charging infrastructure.

**Action taken so far**

At the 155<sup>th</sup> session of UNECE/WP.29 held in November 2011, Japan, the EU and the United States jointly proposed a new framework that studies internationally harmonized standards on the safety and environmental aspects of electric vehicle including safety of lithium-ion batteries. This proposal was agreed by all Contracting Parties participating in the session.

**Future outlook**

Japan, the EU and the United States are expected to closely cooperate in promoting internationally harmonized technical requirements related to electric vehicles under UNECE/WP.29.

## 81. Cooperation on pre-commercial development of batteries(WP-E/#13/EJ to EJ)

### BRT Recommendation

The EU and Japan should seek opportunities for partnerships between governments and research institutes to develop pre-competitive technologies for next-generation batteries (e.g., for lowering cost, improving battery life, enhancing safety, and raising energy density).

### Action taken so far

The Government of Japan (GOJ) has been currently conducting the national project of R&D with the goal of achieving high-performance battery through lowering their cost, facilitating long operation life, ensuring the safety, and improving their energy intensity. In particular, researches have been conducted on advanced materials, modules and systems for the purpose of performance improvement of lithium-ion batteries, and studies have been undertaken with an aim to establishing the methods to estimate their lifetime and to test their safety. Also, a research has commenced to develop innovative battery that is superior to lithium-ion batteries (so-called post-lithium-ion batteries) . The results of these studies are constantly shared with the EU researchers through various simposiums including regularly held discussion parties on battery.

### Future outlook

The GOJ will continue to advance the R&D in order to improve the performance and safety of batteries in the future.

82. Sharing best practices for reuse and recycling of batteries(WP-E/#14/EJ to EJ)

BRT Recommendation

The EU and Japan should share best practices with respect to the reuse and recycling of rechargeable batteries to enhance their secondary use.

Action taken so far

With regard to recycling of portable rechargeable batteries, the Japan Portable Rechargeable Battery Recycling Center (JBRC) was established jointly by their manufacturers, and importers, based on the Act on the Promotion of Effective Utilization of Resources enacted in 2001. JBRC promotes recycling through collecting portable rechargeable batteries at no charge from the recovery base installed in collective retail stores, local governments, and recycling entrepreneurs.

Future outlook

JBRC continues to promote the collection and recycling of portable rechargeable battery. With regard to used lithium-ion rechargeable batteries of which discharge is increasing in the future, general improvements such as the evaluation method for the deterioration of used lithium-ion rechargeable batteries will be necessary. Therefore, taking into account the trends of the generated markets, it is necessary to consider together reuse and recycling of used lithium-ion rechargeable batteries.

### 83. Promoting demo projects of smart cities and smart grids(WP-E/#15/EJ to EJ)

#### BRT Recommendation

The EU and Japan should promote demonstration experiments of smart cities and smart grids with respect to rechargeable batteries and related products and should provide open access to allow each other's industry to participate in such experiments.

#### Action taken so far

In Japan, four areas ,namely Yokohama city, Toyota city, Kyoto Keihanna district and Kitakyushu city, were chosen for the “Demonstration Project on Next-generation Energy and Social Systems.” in 2010, where and substantiative experiment using renewable energy, rechargeable batteries and energy management system has been conducted. In order to complement this project, “Demonstration Project on Next-generation Energy technology” also started at 7 selected sites in 2011.

In addition, a demonstration project on communication standards of ICT systems for the reduction of environmental burden was conducted in 2010. In the green ICT field, for the purpose of verifying local ICT system infrastructures with reduced environmental impacts adapted to the characteristics of each area, so as to support the development of environmentally-friendly communities, demonstration projects were undertaken in 2010.

Furthermore, in 2011, the substantiative experiment of ICT relevant to the realization of Building Energy Management System (BEMS) or Home Energy Management System (HEMS) is being conducted, and the concrete introductory effect in the area etc. is verified.

#### Future outlook

With regard to “Demonstration Project on Next-generation Energy and Social Systems,” substantiative experiment such as demand response will start in full swing since 2012, following the introduction of photovoltaic (PV), batteries, smart meters, and equipments relevant to energy management system such as HEMS, BEMS and Community Energy Management Systems (CEMS). With regard to “Demonstration Project on Next-generation Energy technology,” in addition to the substantiative experiments in 7 sites, new demonstration sites will be selected by public offering.

In addition, the Government of Japan (GOJ) will start studies on communication standards related to smart grids, in order to realize the efficient use of energy in regional communities. In the green ICT field, the GOJ will continue to disseminate successful results toward promoting the local ICT system infrastructures with reduced environmental impacts in each area.

#### 84. Promoting of level playing field for access to raw materials(WP-E/#16/EJ to EJ)

##### BRT Recommendation

The EU and Japan should promote a level playing field for access to raw materials. In this respect, they should identify common actions to take in international fora such as the OECD and WTO in order to promote a coherent set of rules on access to raw materials in their bilateral relations as well as in multilateral negotiations, including WTO membership negotiations.

##### Action taken so far

The Government of Japan (GOJ) and the EU have taken co-initiative in the OECD Trade Committee to forward the project related to export restrictions on raw materials. The relationship between domestic policy and export restriction has been analyzed through this project which contributes to clear understandings of the recent situation. In the WTO, the 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 continues to work affirmatively for the progress of the efforts in international fora such as the OECD and the WTO.

## 85. Requesting practical commitment on governance(WP-E/#17/EJ to EJ)

### BRT Recommendation

The EU and Japan should engage in partnerships with countries endowed with natural resources. In their development policies, they should promote the improvements of the governance of resource-producing countries by requesting specific commitments to effective natural-resource management in governance action plans and the strict enforcement of budget-support criteria. In addition, investments in infrastructure and actions to enhance a favourable business environment should be promoted.

### Action taken so far

In various international conferences and bilateral dialogues, Japan works proactively toward further strengthening of comprehensive relationship with natural resource-producing countries for securing of steady supply of natural resources to Japan. Especially, for oil and gas, Japan strengthens the cooperation with oil and gas producing countries by having numerous dialogues throughout the International Energy Forum (IEF), the Asian Ministerial Energy Roundtable Meeting and so on. Recently, the IEF Special Ministerial Meeting, the Asian Ministerial Energy Roundtable Meeting and the 13<sup>th</sup> IEF Ministerial Meeting were held in February 2011, April 2011 and in March 2012 respectively, where high officials in METI and MOFA attended. In addition, for rare metal resources, Japan works toward a further relationship with resource-producing countries through the bilateral cooperation, dialogue and so on. Japan also has implemented some technical assistance on natural resource management in some developing countries.

### Future outlook

The Asian Ministerial Energy Roundtable Meeting will be held in 2013. Japan continues to strengthen the cooperation with natural resource-producing countries.

86. Promoting adhesion and enforcement of EITI (WP-E/#18/EJ to EJ)

BRT Recommendation

The EU and Japan should work closely with other governments, industrial bodies, and NGOs to enable resource-producing countries to fulfil the EITI's "Principles and Criteria" and to advance from candidate to compliant EITI countries.

Action taken so far

Since the Government of Japan (GOJ) announced a decision to become a supporting country of the EITI in February 2009, it has proactively supported EITI activities through various measures such as hosting an EITI outreach seminar titled "Emerging Trend Responsible Natural Resources Development" in Tokyo in January 2010 with participation from other governments, business sectors, NGO and other groups. In addition, the GOJ provided financial assistance for the first time to the EITI Multi Donor Trust Fund (MDTF) this fiscal year. Moreover, The GOJ has continuously engaged in further strengthening the EITI in the framework of G8/G20.

Future outlook

The GOJ continues to consider means to provide further cooperation for the EITI and positively supports the EITI activities of implementing countries and outreach countries.

87. Following OECD guidelines when operating in or procuring minerals from conflict-affected area (WP-E/#19/EJ to EJ)

#### BRT Recommendation

The EU and Japan should prevent resource development from funding conflicts. When developing open and responsible supply chains, governments and industries should cooperate with each other to adopt acceptable and viable approaches and processes. The OECD's guidance for responsible supply-chain management of minerals from conflict-affected and high-risk areas provides a good basis.

#### Action taken so far

Regarding the OECD Due Diligence Guidance for Responsible Supply Chains of Minerals from Conflict-Affected and High-Risk Areas, which was adopted at the 50th Anniversary Ministerial Meeting on May 25, 2011, the Japanese Government had participated in the drafting process of the Guidance and Japanese business sectors also had inputted their opinions on the draft. After the OECD Guidance was adopted, the information sessions was held for business industries. METI also made an outline of the Guidance in Japanese language, which is shared on request basis.

Currently, backed by the OECD Secretariat, the working group on drafting the Supplement on Gold of the OECD Guidance and the ICGLR-OECD-UN GoE multi-stakeholder forum on implementation of OECD Guidance are in progress. The Government of Japan (GOJ) is a member of these two fora.

Note:

- ICGLR : International Conference on the Great Lakes Region-
- UN GoE : UN Group of Experts on the Democratic Republic of the Congo

#### Future outlook

Japan recognizes three points made by BRT as issues to be continuously tackled with and intends to cooperate with EU and other related countries. In consultation with relevant industries, the GOJ plans to deal with dissemination and promotion of the OECD Guidance. At present, the above-mentioned ICGLR-OECD-UN GoE multi-stakeholder forum is discussing consistency between the OECD Guidance and other international instruments on conflict minerals and Japan will actively participate in such discussions.



88. Promoting action to minimize commodity price volatility(WP-E/#20/EJ to EJ)

BRT Recommendation

Japan and the EU should strive to reduce excessive price volatility in commodity markets and should accordingly identify common actions to take in international fora.

Action taken so far

In international conferences such as the International Energy Forum (IEF), the Asian Ministerial Energy Roundtable Meeting, G20, price volatility of fossil fuels has been discussed. In the IEF Special Ministerial Meeting held on February 2011, the Government of Japan (GOJ) commented that: 1) since excessive oil price volatility negatively affect not only energy market but also the world economy, producing and consuming countries should make their effort to hold down such volatility, 2) as countermeasures against oil price volatility, preparing statistical data and developing a common awareness of improvement of supply-demand situation is necessary. Additionally, the GOJ, in the International Organization of Securities Commissions (IOSCO), set out “the Principles for the Regulation and Supervision of Commodity Derivatives Markets” to help ensuring the fundamental function of the commodity derivatives markets, that is, price discovery and hedging, and further to reduce excessive price volatility in commodity markets.

Future outlook

The GOJ continues to tackle for stabilizing fossil fuel price through various international conferences. Additionally, the GOJ will join in working in IOSCO to conclude a report on the implementation of “the Principles for the Regulation and Supervision of Commodity Derivatives Markets” by the end of 2012.

89. Supporting R&D for recycling and material substitution (WP-E/#21/EJ to EJ)

**BRT Recommendation**

Japan and the EU should encourage the recycling of raw materials in developed countries through R&D, industrial policy, and international cooperation as well as promote research aimed at the substitution of critical raw materials.

**Action taken so far**

Following the large-scale reduction of the export quotas of Chinese rare earth, the Government of Japan promotes cooperation with consuming countries such as the EU, in order to secure raw materials including rare metals.

The Trilateral Japan-EU-U.S. Conference on Critical Materials for a Clean Energy Future was held in Washington DC on October 4-5, 2011. At this conference, Japan, the EU and the U.S. shared the recognition of importance of the cooperation among consuming countries in developing alternative materials, technologies for the reducing usage and recycling. .

**Future outlook**

The 2nd Trilateral Japan-EU-U.S. Conference will be held in Tokyo in the spring of 2012. “Recycling of rare metals” will be proposed as one of the themes of the conference.

## 90. Establishing new, fair, and effective international framework (WP-E/#22/EJ to EJ)

### BRT Recommendation

The EU and Japan should promote a post-Kyoto framework that engages all major emitters of greenhouse gases to take a fair share of the burden of global  $CO_2$  emission stabilization and reduction.

### Action taken so far

Japan has actively been contributing to negotiations toward the ultimate goal of adopting expeditiously a new single and comprehensive legal document which will establish a fair and effective international framework in which all major economies participate. Japan urged other Parties at various levels to establish expeditiously the future framework, through negotiations under the UNFCCC, frequent bilateral meetings with many countries and organizations including the EU and various international conferences. Moreover, Japan proposed a roadmap for a comprehensive framework on climate change before COP17, as well as establishment of a new working group to discuss a future framework during COP17. These proposals contributed significantly to fostering the momentum, and Japan's idea resulted in establishment of "an Ad Hoc Working Group on the Durban Platform for Enhanced Action" as one of the outcomes of the COP17.

### Future outlook

Japan will continuously contribute to negotiations, through UNFCCC process, various international conferences and bilateral meetings, so as to establish "an Ad Hoc Working Group on the Durban Platform for Enhanced Action", a new process agreed in Durban to develop a future framework, and to complete its work as early as possible but no later than 2015 in order to adopt a protocol, another legal instrument or an agreed outcome with legal force applicable to all Parties and to enable the outcome to come into effect and be implemented from 2020.

91. Setting CO2 emission targets in a fair and transparent way(WP-E/#23/EJ to EJ)

BRT Recommendation

The EU and Japan, when setting national targets, should take into account their international fairness, feasibility, and social impact on citizens. The setting of such targets should be done with a high level of transparency and in consultation with stakeholders.

Action taken so far

In October 2011, the Energy and Environment Council started to review domestic Global Warming Measures as well as energy and environment strategies as a part of the Strategy for Rebirth of Japan. In December 2011, the Council formulated the basic policy for presenting choices regarding the innovative energy and environment strategies which is supposed to be announced in spring 2012.

Future outlook

Based on the basic policy adopted by the Energy and Environment Council in December 2011, related council bodies such as the Japan Atomic Energy Commission, the Advisory Committee for Natural Resources and Energy, and the Central Environment Policy Council plan to prepare drafts of choices of nuclear policy, energy mix, and global warming measures around in the spring of 2012.

Against this background, the Council will present options regarding the energy and environment strategies.

Through this process, national discussion is expected to be promoted. The Council is scheduled to formulate strategy around summer 2012.

## 92. Facilitating transfers of green technologies(WP-E/#24/EJ to EJ)

### BRT Recommendation

The EU and Japan should assist emerging economies in developing the necessary human resources and infrastructure so that they can smoothly absorb advanced technologies. To facilitate the transfer of technologies on a commercial basis, the EU and Japan should support the recipient countries in putting in place an appropriate regulatory framework and enforcement tools to ensure the protection of intellectual property rights.

### Action taken so far

METI conducted training programs for trainees from developing countries. Technical trainings were conducted for engineers and managers invited to Japan from developing countries as trainees. Its programs included practical training offered by private-sector companies, which allowed trainees to acquire skills or techniques in specific fields. In 2010, about 3,000 trainees from developing countries were trained through the programs.

The Japan Patent Office (JPO) has made contributions to various projects, such as enhancing intellectual property (IP) systems, supporting human resources development and raising awareness, for developing countries in the Asia-Pacific and Africa regions through the schemes of the Japan International Cooperation Agency (JICA) and the WIPO Funds-in-Trust/Japan. In 2011, the JPO accepted about 200 trainees in Tokyo from developing countries in the Asia-Pacific and Africa regions, and provided them with various training courses on examination practices, enforcement, computerization of IP offices and so forth.

In addition, the JPO sent about 20 experts/lecturers, who consisted mainly of JPO officials, for IP-related on-site seminars or workshops held in developing countries in the areas, on the agenda of university-industry collaboration and enforcement. Through such efforts, the JPO actively engaged in human resources development for intellectual property rights (IPR) and reinforcing IPR protection in developing countries.

### Future outlook

The training program for engineers and managers from developing countries will continue beyond 2011 through cooperation between METI and private-sector companies.

The JPO intends to continue taking various efforts for the purpose of enhancing IP systems in developing countries. During the first quarter of 2012, the JPO will hold in Tokyo two workshops, for government officials involved in IP in developing countries in the Asia-Pacific and Africa regions, regarding formulating a national IP strategy and promoting accession to the Madrid system respectively. Furthermore, the JPO will actively continue conducting IP-related technical training courses and on-site seminars or workshops on examination practices and other technical fields.

93. Continuously improving incentives and regulations to promote adoption of energy-efficient technologies and processes(WP-E/#25/EJ to EJ)

**BRT Recommendation**

The EU and Japan should continue to refine their regulations and incentives to promote the efficient use of energy (energy efficiency as well as energy savings). Setting norms for building and house insulation plays a major role in achieving a significant reduction in CO<sub>2</sub> emissions. Japan and the EU should also share best practices for eco-labelling.

**Action taken so far**

Japan's energy conservation policy is categorized into three sectors, the industrial sector, commercial/residential sector, and the transportation sector. Both regulative measures through implementation of the Energy Conservation Law and supportive measures through budgets, tax incentive, the introduction of energy-efficient equipment are implemented in these sectors. Furthermore, the Energy Conservation Law ordained standards of the thermal insulation of houses and buildings, and the efficient utilization of energy for equipment, enforcing its standards step-by-step.

**Future outlook**

Having experienced the March 11 earthquake with Fukushima nuclear power plant severely damaged, Japan now faces a new challenge and strives to establish a new energy policy that should be based on the ensured safety and the sectoral confidence of the people. To draw up a scenario of bold shift in the energy mix, the Government of Japan (GOJ) will set new strategy and plans of Japan's mid, long-term energy systems by the summer of 2012. The GOJ strengthens the Energy Conservation Law by restraining demand of electricity usage during the peak period and by re-evaluating standards of the buildings and its materials.

94. Cooperation on long-term innovative R&D projects to reduce GHG emissions(WP-E/#26/EJ to EJ)

**BRT Recommendation**

The EU and Japan should cooperate on joint R&D efforts by industry, academia, and government to develop innovative technologies to reduce greenhouse gas emissions. They should also allow access by their industries to their domestic pre-competitive, government-funded research projects because highly innovative technologies require lengthy timelines and very large budgets for basic research and development,

**Action taken so far**

The Ministry of Economy, Trade and Industry (METI) and the Directorate-General for Research of the European Commission held a meeting on Japan-EU energy technology R&D cooperation in March 2011.

Experts from the governments, research, business, sectors from both sides discussed ways of cooperating on research and development in the fields of photovoltaics, power storage, carbon dioxide capture and storage (CCS) in the meeting.

**Future outlook**

The Government of Japan will continue to promote international public-private cooperation through expert or working-level meetings on Japan-EU energy technology R&D cooperation that are held among METI, NEDO, and the DG for research of the European Commission.

(Attachment)

Tax-system-related proposals

Decisions on changes in the tax system are made every year following deliberations by relevant bodies such as the government's Tax Commission that focus on requests and opinions submitted by government ministries and agencies to the tax authorities, taking into account the economic climate and fiscal situation. In addition, opinions from various sectors, 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:

7. Harmonization & mutual recognition of standards and product certifications; acceptance of international standards where applicable.

(7)Automobiles

9. Promoting foreign direct investment

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

Working Party C:

43. Incentive to drive innovation at private sectors

(3) Tax credit for R & D

Working Party D:

65. Tax issue proposal for the EU and Japan

(2). Corporate accounting and tax practice

(3). Transparent and fair taxation

(4). Introducing participation exemption

68. Tax issue proposal for Japan

(1). Review of transfer-price taxation

(2). Reducing corporate tax rates

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

Proposals have been presented concerning each of the above issues and the Government of Japan would refer to reasonable ones from the standpoint of whether it can contribute to improving the business environment.