(Tentative Translation)

Report from the Government of Japan

Concerning the Recommendations

from the EU-Japan Business Round Table (BRT)

April 2017

Note: The content of this report is based on the situation as of December 31, 2016.

Contents

Working Party 1 : Trade Relations, Investment and Regulatory Cooperation

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

BRT Recommendation

The BRT recognizes and welcomes the progress that the negotiators have made in many areas under discussion, but is concerned that momentum will be lost as time passes without an agreement. In view of the political calendar in 2017, the BRT considers it difficult to maintain momentum beyond the end of 2016. The BRT stresses that 2016 represents the best window of opportunity to conclude the negotiations of the EU-Japan FTA/EPA.

For this reason, the BRT reiterates its call from last year, that “The BRT believes that an aim of a speedy conclusion must come together with a high level of ambition. Should a sufficiently high level of ambition seem difficult to achieve on the basis of the technical negotiations, the BRT urges, for the sake of our economies, political leaders at the highest level to intervene to resolve the deadlocks and bring the negotiations to a timely and ambitious conclusion” .

The BRT is strongly convinced that the EU-Japan FTA/EPA will lead to an expansion of trade and investments, job creation and acceleration of growth in both economies, as well as contributing to the creation of new opportunities for global growth. The BRT highlights its request to the highest Authorities of the EU and Japan to focus on addressing the remaining obstacles to the conclusion of a comprehensive, ambitious, high-level, and mutually beneficial FTA/EPA as early as possible.

< Background >

As major advanced economies and major global traders and investors, the EU and Japan can do more to unlock the enormous growth potential which their bilateral economic relations can offer. They are now working on enhancing bilateral trade, investment and cooperation and building a closer relationship. As both strive to overcome global financial instability and economic uncertainties, it is crucial that they join forces in tackling common challenges in order to attain a long-term, sound and stronger growth. The EU-Japan relationship should not be

left behind

Actions taken so far

Leaders concerned reaffirmed their strong commitment on the Japan-EU EPA/FTA negotiations in the Joint Statement issued on the occasion of the G7 Ise-Shima Summit in May, as well as in the Japan-EU leaders' meetings in May and July.
Based on those leaders' commitments above, in addition to 3 negotiations rounds in total in 2016, Japan and the EU negotiated continuously and incessantly in the various levels, including that of chief negotiators, and vigorously discussed areas such as trade in goods, trade in services, intellectual property rights, government procurement, and investment.
In December 2016, Foreign Minister Kishida and Dr. Malmström, European Commissioner for Trade, shared the view to hold negotiations in early January, 2017, maintaining momentum of the negotiations, so as to aim at an agreement on fundamental elements as early as possible.

Future outlook

The Government of Japan (GOJ) will, maintaining dialogues with the business community, continue to move forward the negotiations vigorously in order to pursue a comprehensive, high-level and balanced agreement, with a view to reaching an agreement on fundamental elements of the negotiations as early as possible.

2. Call for effective and quick implementation of WTO ‘Bali Package’ and work on a future WTO work program (WP-1/# 02**/EJ to EJ)

BRT Recommendation

It is evident that the WTO is to maintain its core role as the forum to create multilateral trade rules, the EU and Japan should lead the member countries of the WTO and adapt the organisation to the changing global trade environment better, for instance, by re-evaluating its negotiating processes to make them more efficient, by facilitating the delivery on the remaining DDA mandate and by agreeing to create new sets of rules on issues beyond the DDA.

The agreement on Trade Facilitation signed in November 2014 can serve as a boost to global trade by reducing costs of trade by 10-15%. Its objectives are to speed up customs procedures, make trade easier, faster and cheaper, provide clarity, efficiency and transparency, reduce bureaucracy and corruption, and use technological advances. The BRT therefore calls upon the authorities of the EU and Japan, together with other WTO members to quickly ratify and implement the Trade Facilitation Agreement.

Additionally, the BRT suggests that the authorities of the EU and Japan should, together with other WTO members, explore further topics that are essential for the smooth functioning of global value chains. These could include, for example, competition, investment, subsidies, the reduction of export restrictions and data flows. Exploring these topics could reinforce the interest in the multilateral trading system and underline the central role of the WTO in rule making.

The BRT strongly supports the progress in these issues, and requests the authorities of the EU and Japan to further make efforts to vitalize and earn momentum in order to move the DDA negotiations forward, as well as to facilitate timely conclusion of plurilateral agreements such as expansion of the Trade in Services Agreement (TiSA).

Furthermore, the BRT requests the authorities of the EU and Japan to exert their utmost efforts to realise global free trade in goods and services under the

auspices of the WTO, including environmental goods, so long as it does not discriminate unfairly between products and sectors.

However, tariff liberalisation should not be limited to finished goods but include goods over the whole value chain to have a real impact and to take into account the globalisation of the value chains.

< Recent Progress >

The informal WTO Ministerial gathering held in Davos on 24 January 2015 was a good opportunity for WTO members to discuss the future work programme on the remaining issues of the DDA. A number of WTO members expressed the following views:

- it is important to steadily and gradually operationalise the agreed items, based on the MC9 outcome;
- for the remaining DDA items, the discussion of a work program to address such items should commence as soon as possible;
- and the WTO must not refrain from discussing potentially contentious issues such as agriculture and market access for non-agricultural goods and services.

The BRT hopes the negotiation on other agenda items such as non-agricultural market access (NAMA), agriculture, non-tariff barriers (NTBs) and export subsidies will make progress now that the TFA has been passed.

The BRT welcomes the conclusion of the expansion of the Information Technology Agreement (ITA) and the Agreement on export subsidies and export competition elements at the WTO Ministerial Meeting in Nairobi in December 2015. For the future course of DDA negotiation, however, two courses of its continuation and termination have been set forth in parallel. The BRT expects further progress in WTO's DDA negotiation to reach a new stage in negotiation, which should result in mutually beneficial outcome for both developed and developing countries.

< Background >

The BRT is a strong supporter of the multilateral trading system, whose core

functions are trade liberalisation, rule-making and dispute settlement. However, to liberalize multilateral trade, the initial high-level ambition of the Doha Round, launched in 2001, has not been maintained, resulting in the current deadlock of negotiations which continue due to the lack of political will and the inability to bridge the gap in the market access commitments between OECD and emerging country members.

Especially given the great and increasing uncertainty in the world economy, the WTO must demonstrate its ability to deliver results for the business community. As the only international organisation creating rules and setting standards on trade at the multilateral level, the WTO must remain a leader in this area and take more and stronger action. The existing legal framework provides an excellent basis for such action. However, it needs to be updated in order to respond to a changing global economic landscape.

WTO members made partial progress in the DDA at the 9th WTO Ministerial Conference in Bali in December 2013. The so-called"Bali Package" that was agreed consists of three main components: (1) a trade facilitation agreement; (2) an agreement on the agriculture sector; and (3) agreements on development (a package for least developed countries and flexibilities for public food stockholding programmes).

Actions taken so far

Following up with the agreements of the 9th WTO Ministerial Conference (MC9) in December 2013 the 10th WTO Ministerial Conference (MC10) in December 2015, and the outcome of the Special Session of the General Council in November 2014, Japan has actively worked on the implementation of the Bali package. As part of the governments' efforts, G20 members including Japan and EU committed to accept the Trade Facilitation Agreement by the end of 2016 and called other WTO members to do the same at G20 Hangzhou Summit in September 2016. G20 members also welcomed the landing zone achieved in the WTO EGA negotiations, and reaffirmed their aim to redouble efforts to conclude an ambitious, future-oriented EGA by the end of 2016 at the Summit. In December of the same year, based on the G20 Hangzhou Summit Declaration, the EGA ministerial meeting was held with the aim to conclude the negotiation by

the end of the year. At the ministerial meeting, while the gap between the positions of members on covered products remained and they could not reach an agreement, they shared the same recognition that all members should continue to negotiate, aiming at an for early conclusion of the negotiations.

Future outlook

Although each of eight areas covered by Doha Round (DDA) remains important, it is also necessary to consider new approaches including dealing with the issues that reflect the needs of the times, such as electronic commerce, by exceeding the framework of DDA, in continued cooperation with WTO members including the EU. We will work for achieving positive outcomes in the 11th Ministerial Conference (MC11) in December 2017 and beyond.

3. Applying international standards and enhancing regulatory cooperation (WP-1 /# 03**/EJ to EJ)

(1) General recommendations

BRT Recommendation

The BRT strongly supports the joint development and application of internationally harmonised technical requirements and procedures for the testing and approval of products that are traded internationally.

The BRT recommends the authorities of the EU and Japan to enhance their regulatory cooperation. The aim is to eliminate barriers to trade and investment in order to promote business and to disseminate the experience of the EU and Japan to the rest of the world.

To this end, the BRT encourages the authorities of the EU and Japan to work together in the relevant fora to develop international product standards and certification procedures. The BRT recommends that the authorities of the EU and Japan should apply such standards in as many sectors as possible.

Where international standards have not yet been developed, the BRT urges the authorities of the EU and Japan, when possible, and appropriate, to accept the mutual approval of the import, sale or use of products that have been approved on the basis of functionally equivalent requirements.

Taking into account the benefit of common regulatory environment, the BRT recommends that the EU-Japan FTA/EPA should include a framework to promote regulatory cooperation and to ensure that the authorities of the EU and Japan not take unnecessary measures which act as an impediment to trade and investment.

The BRT recommends that the policy-makers of the EU and Japan should increase their understanding of existing and upcoming regulations of the other side. Where a harmonised regulatory framework between the EU and Japan has not yet been developed, the regulatory authorities of the EU and Japan should review their domestic technical regulations and conformity assessment

procedures at regular intervals to determine the scope for further regulatory harmonisation. The outcome of these reviews, including scientific and technical evidence used, shall be exchanged between the regulatory authorities and provided to industry upon request.

The BRT recommends that the regulators of the EU and Japan should study the possible impact of new regulatory developments on domestic and foreign business to avoid taking initiatives that might unwittingly create barriers to trade and investment. They should exchange annual legislative work programmes at the earliest stage to prevent regulatory divergence and the creation of new trade barriers. In addition, they should agree to an early warning system for draft legislation to facilitate an effective bilateral dialogue.

The policy-makers of the EU and Japan should develop a joint strategy to promote better regulation by learning from each other's experience and adopting a common system of good governance. Throughout the process, the two authorities should have close dialogue with businesses.

The BRT calls on the Leaders of the EU-Japan Summit to ensure that the FTA/EPA will be a living agreement and will provide a solid and comprehensive framework for regulatory cooperation to address the sector-specific concerns of the business community. In the recommendations of last year, the BRT welcomed the adoption of a Joint Document for Regulatory Cooperation at the EU-Japan Industrial Policy Dialogue between METI and DG GROW on 17 March 2015. As a long-standing advocate of regulatory cooperation, and recognising that this is a key issue for the future, the BRT hopes that this joint initiative will reinforce and complement the upcoming FTA/EPA and set the frame for a solid, forward-looking and long-lasting regulatory cooperation. The BRT is willing to support the EU and Japanese Authorities on regulatory cooperation matters.

<Background>
The BRT believes that regulatory cooperation will be a key to the economic prosperity of the two economies. Once an FTA/EPA is concluded, it will be important not only to ensure that new regulations do not nullify or impair the market access benefits accruing to either party under the agreement or create new barriers to bilateral trade, but also to expand and strengthen the relations

between the two economies so that the benefits of their cooperation will further increase and so that they will eventually be able to expand such regulatory cooperation to other bilateral and multilateral relations.

In the meetings of the BRT on 8-9 April 2014, the Japanese side proposed that the authorities of the EU and Japan together with key players such as the BRT should look at future issues coming out of a long-range vision for the relationship for, say, the next three decades.

Action taken so far

The Ministry of Economy, Trade and Industry (METI) and the European Commission (EC) DG for Internal Market, Industry, Entrepreneurship and SMEs (DG Growth) have been propelling regulatory cooperation from an early stage in order to avoid future misalignments of regulations between Japan and the EU and facilitate the commercialization of new technologies.

*The METI and the EC DG Growth agreed to enhance regulatory cooperation in 13 areas of including chemicals and robotics areas at the Japan-EU Industrial Policy Dialogue in Brussels in March, 2015.

At the 23rd EU-Japan Summit in May, 2015, two leaders expressed their great expectations for further progress in the EU-Japan regulatory cooperation. Japan together with the EU has actively participated in standardization in international institutions such as ISO and IEC.

In accordance with the WTO's TBT Agreement, measures have been taken to harmonize Japanese Industrial Standards, also known as JIS, with international standards which led to 97% of JISs harmonized with corresponding international standards when there are relevant international standards.

In addition, accreditation of certification bodies is open to both domestic and international organizations.

Furthermore, since 2002, the Agreement on Mutual Recognition between Japan and the EU, covering the sectors of telecommunications equipment, electrical

products, good laboratory practice (GLP) for chemicals and good manufacturing practice (GMP) for medicinal products, has been in effect.

In addition, the Council for Regulatory Reform was established as an organ investigating and discussing on regulatory reforms in January 2013 in order to remove impediments to the revitalization of Japanese economy and to realize private-sector-demand-led growth. The council compiled the items for regulatory reform into reports respectively in June 2013, June 2014, June 2015 and May 2016, taking approaches such as “International Best Practice Tests” that examines the necessity and rationality of regulations based on international comparisons. In order to realize progress in regulatory reform items steadily “Implementation Plan for Regulatory Reform” was endorsed by the Cabinet in June 2013, June 2014, June 2015, and June 2016 respectively. Since the Council reached the limit of its mandate in July 2016, the Council for Promotion of Regulatory Reform was established as a new organ investigating and discussing regulatory reforms in September 2016.

Future outlook

The METI and the EC DG Growth will continue to promote discussions on regulatory cooperation.

Japan has intention to take part in the standardization activities in international standardizing bodies. In accordance with the WTO’s TBT Agreement, Japan will make further efforts to harmonize JIS with international standards.

At the Council for Promotion of Regulatory Reform, items for regulatory reform are expected to be compiled into report by around June 2017.

(2) Create a common chemicals regulation

BRT Recommendation

Policies on the control of chemicals such as the EU's REACH and RoHS and Japan's Chemical Control Law have a significant impact on global supply chains. The two Authorities should not only implement effective regulations, but also establish a common list of restricted substances and a common approach to the evaluation of risks and sharing of data. Such a common regulatory environment will not only benefit industries through cost mitigation but also benefit users and consumers through lower prices and consistent protection.

Furthermore, the two Authorities should develop a common policy on emerging issues such as endocrine disruptor and nano materials. The two authorities should also support supply chain management in developing countries in cooperation with businesses.

Actions taken so far

The regulatory authorities of the EU and Japan have shared information on the current situation of each regulation and have exchanged views on regulatory cooperation through the Chemical WG of EU-Japan Industrial Policy Dialogue. Specifically, at the 3rd meeting of the Chemical WG in February 2016, the EU and Japan exchanged information on the progress of chemicals regulations and discussed information transfer of chemicals in products and risk assessment approach of existing chemicals, followed by a seminar on chemSHERPA, an information transfer scheme regarding chemicals in products, where Japanese industry demonstrated its performance to the industry of the EU.
In addition, in February 2016, the regulatory authorities of the EU and Japan agreed on a work plan valid until 2018 to share information on the implementation of REACH and Japan's Chemical Substances Control Law, with each other.
Japan has shared its information and has exchanged views on emerging issues such as endocrine disruptors and nanomaterials, in the OECD Joint Meeting of the Chemicals Committee and Working Party on Chemicals, Pesticides and Biotechnology, with the regulatory authorities of the OECD members including

the EU.
Furthermore, Japan has dialogues with ASEAN countries and shares the achievement with the regulatory authorities of the EU.

Future outlook

The regulatory authorities of the EU and Japan are going to exchange information continuously with regards to chemical management. Japan will continue discussion on emerging issues with regulatory authorities including those of the EU, utilizing appropriate fora such as the OECD.

(3) Create a common resource efficiency policy

BRT Recommendation

The authorities of the EU and Japan should promote the concept of energy efficiency including resource efficiency, using the right incentives, standardised methodology, criteria and the format of environmental product declaration between the EU and Japan and cooperate with each other so that such a policy will be internationally shared.

The two authorities should work together at the multilateral level to promote international harmonisation of energy conservation regulations, relevant labelling rules, and environmental and carbon footprint schemes.

Action taken so far

The "Energy Saving Labelling Program" that the Government of Japan introduced is applied mainly to household products (21 items today).
The government also operates ‘Uniform Energy Saving Label’ specifying multistage rating in the ‘Retailers Label Display Program’ which is a labelling program for retailers (6 items today).
The Government of Japan implemented an empirical research project of the Type III Environmental Product Declarations (EPDs) from 1998 to 2001. After the transitional period, the project was transferred to a private organization in 2002, and it has been certifying EPDs since then. By the end of 2016, a total of 83 PCRs and 1,844 EDPs were certified and released.
In addition, a government’s pilot program for the Carbon Footprint of Products, which had started in 2009, certified 73 product category rules (PCRs) and 469 carbon footprints of product (CFPs), and was completed in March 2012, as scheduled. After the transitional period, the program was transferred to a private organization and it started as the “CFP Communication Program” in July 2012. When the program was transferred, its rules were modified by reflecting ISO discussions at that time. By the end of 2016, a total of 107 PCRs and 1,319 CFPs have been certified and released.

Future outlook

The Government of Japan will continue to review "Energy Saving Labelling Program." In addition, in order to enhance the degree of recognition of the label, the Government of Japan will distribute publicity materials regarding the program.

The Government of Japan will regularly communicate with private businesses involved in the CFP communication program, so as to keep the program consistent with international guidelines including ISO.

(4) Expand the benefits of AEOs (Authorized Economic Operators)

BRT Recommendation

The authorities of the EU and Japan should aim at introducing further regulatory cooperation in order to give more concrete benefits to AEOs. The BRT is aware that the two authorities are engaged in regular discussion following the agreement on the mutual recognition of the AEOs in June 2010 between the EU and Japan, but that no concrete benefits have emerged for operators. According to the progress report of the EU in 2015, the scope of this agreement is restricted to 'security and safety' only. The BRT would like in this regard to put emphasis on the simplification of import procedures where companies are given greater freedom while taking greater responsibility for their imports without an excessive administrative burden. The BRT recommends that the two authorities should consider expanding the legal base if it is necessary to realise the simplification of import procedures.

Action taken so far

The mutual recognition of the AEOs between Japan and the EU has been steadily implemented since May 2011. Based on the mutual recognition, the AEOs in Japan and the EU have received benefits in customs procedures of the other side. With a view to enhancing regulatory cooperation on AEOs between Japan and the EU, their Customs Authorities held the Japan-EU Joint Customs Cooperation Committee in June 2015 and discussed the possibility for expansion of benefits by the mutual recognition of the AEOs.
To further simplify customs procedure for AEOs, the Government of Japan considers the possible measures to improve it on particular issues of private sectors by exchanging opinions and information with them.
As for “broadening the choice of customs office for declaration”, Japan amended the Customs Law and the Customs Brokerage Law to allow AEOs to lodge import/export declarations to a customs office other than a customs office, where the goods are located, as a special case, and to repeal restriction on area of service of customs brokers, while maintaining general rule that import/export declarations need to be lodged to a customs office where the goods are located.

Future outlook

With respect to the mutual recognition of the AEOs between Japan and EU, in addition to the continuous review of its implementation, the Customs Authorities of Japan and the EU will continue to discuss the additional benefits to be granted to the AEOs.

To further simplify Customs procedure for the AEOs, the Government of Japan will consider possible measures to improve it on particular issues of private sectors by exchanging opinions and information with them.

The Government of Japan intends to take necessary steps to implement measures for “broadening the choice of customs office for declaration” by the end of FY 2017.

(5) Fight against counterfeited, pirated and contraband goods

BRT Recommendation

The BRT would like to see the EU and Japan step up efforts to fight against counterfeited, pirated and contraband goods, both inside and outside the EU and Japan. For example, they should better cooperate with each other and with the third country authorities to secure the closure of sites trading in fake goods.
The BRT requests that the authorities of Japan should make all trade with fake goods illegal by closing the loophole by which individuals are allowed to bring in or import counterfeits for personal consumption.
The BRT reiterates its support of Regulation (EU) 608/2013 of the EP and Council of 12 June 2013 on Customs enforcement of Intellectual Property rights which reflects to some extent the BRT's key recommendations such as simplifying the procedure. However, the BRT requests the authorities of the EU that they should seek ways to mitigate the financial burden of the importers of the authentic goods.
The BRT would like to see an enhanced role of the Observatory on Counterfeiting and Piracy in line with the Regulation adopted by the European Parliament and Council on 19 April 2012.
The BRT suggests that with increased cooperation by the manufacturers and importers of authentic goods, including the provision of more information on their products, on-site training of officials and training of officials on more effective use of the WCO's IPM (Interface Public Members), the customs authorities should make inspection more efficient and raise the rate of its coverage.

Actions taken so far

The Government of Japan has made efforts, including various training programs, in order to develop human resources of local authorities such as customs agents of the countries where infringements of Intellectual Property have occurred. As countermeasures against websites where counterfeited and pirated goods have been traded, Japan has provided information on such websites to foreign governments, including the Government of China, and has requested them to delete those websites. In addition, Japan has continuously implemented measures for prevention of consumer damage by collaborating with internet

service providers, Intellectual Property right holders and others.
Japan has also reinforced countermeasures against infringements of Intellectual Property on the internet, including the deletion of pirated contents in video streaming websites and the provision of supports to establish a scheme in which users of those websites are guided to authorized contents.
In order to prevent import and domestic distribution of goods that violate Intellectual Property, nationwide customs agencies and the police strengthen control through such activities as intensive crackdowns. Moreover, Japan Patent Office has conducted anti-counterfeit annual campaign to raise public awareness of Intellectual Property issues.

Future outlook

The Government of Japan will continuously have discussions and share information with foreign government and related organizations regarding the situation of damage, for example, caused by counterfeited and pirated goods on the Internet, and will strongly request them to take rigorous measures against infringement of Intellectual Property on the Internet.
Furthermore, in order to combat counterfeited and pirated goods on the Internet, Japan will enhance cooperation with parties involved in the Internet trading, such as Internet service providers and Intellectual Property right holders, and will actively take necessary and appropriate measures collaborating with related government ministries and agencies.

(6) Adoption of UN Regulations

BRT Recommendation

In the automobile sector, the EU and Japanese Authorities should accelerate their adoption of UN Regulations to lower the cost of regulatory compliance for both European and Japanese automobile exporters by extending the benefits of mutual recognition. Also the EU and Japanese Authorities should work together to establish internationally harmonised technical requirements and testing procedures that will encourage the smooth market adoption of new environmentally friendly power-train technologies – clean diesel, electric vehicles, hybrid vehicles and fuel-cell vehicles.

< Background for 6 >
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 UN Regulations in one contracting country are exempt from testing in any other signatory country where those regulations have been adopted. Japan has now adopted UN-ECE Regulations in 41 of the 47 areas included in Japanese type approval for passenger cars.

< General Background for 1-6 >
Implementation of these recommendations will lead to a significant improvement in the business environments of both the EU and Japan.

Action taken so far

The Government of Japan applies UN Regulations, having made relevant revisions to them taking into consideration the ensuring of safety and environmental protection in Japan, as a part of its efforts toward the realization of an International Whole Vehicle Type Approval (IWVTA), which is currently ongoing at the UN/ECE/WP.29. The Government of Japan, in cooperation with the European Commission, has been actively contributing to promoting IWVTA, inter alia, through acting as Co-chair of an expert meeting on IWVTA in WP.29.

Future outlook

The Government of Japan will continue to apply the UN Regulations which have not been applied by Japan, taking into consideration the ensuring of safety and environmental protection in Japan, after the assessment of their validity and the necessary revisions of those regulations at the UN/ECE/WP.29, as a part of its efforts toward the realization of IWVTA.

4. Supporting timely development of business (WP-1/# 04*/EJ to EJ)
(1) Social security contributions (avoiding double contributions)

BRT Recommendation

The BRT welcomes the conclusion of social security agreements between Japan and 11 EU Member States. Negotiations or preliminary talks are under way between Japan and 4 EU Member States. The BRT requests that, Japan and the Member States of the EU should make further efforts to expand the network of Social Security Agreements.

The BRT takes note that no new preliminary talks have been started since 2012 between EU Member States and Japan. The BRT is concerned that Japan and the remaining 13 EU Member States, with whom talks have not commenced, could be left without a social security agreement. The BRT recommends that the authorities of the EU and Japan should explore the possibility to make a common EU-Japan agreement on social security to cover the remaining Member States.

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, not only partially, when expatriates return to their home country.

< Recent progress >
There has been limited progress in the past year

< Background >
When an individual EU Member States and Japan conclude a bilateral social security agreement, it lessens the burden both on companies as well as their employees. So far, social security agreements between Japan, and Germany, the United Kingdom, Belgium, France, the Netherlands, Czech Republic, Spain, Ireland and Hungary have entered into force. The agreements between Japan, and Italy and Luxembourg have been signed. Furthermore, negotiations are underway between Japan, and Sweden and Slovak Republic, and are at the preparatory stage between Japan, and Austria and Finland.

Actions taken so far

The Government of Japan has been constantly making efforts to conclude social security agreements with EU Member States. The Government of Japan has already concluded social security agreements with Germany, the UK, Belgium, France, the Netherlands, the Czech Republic, Spain, Ireland and Hungary. In addition, the Government of Japan has already signed the agreement with Italy and Luxembourg. Furthermore, the Government of Japan is conducting intergovernmental negotiations with Sweden and Slovakia, and exchanges of information and of opinions with the authorities of Finland and Austria, with the aim of concluding social security agreements with those countries.

Future outlook

The Government of Japan will continue to have negotiations and exchanges of information and opinions with a view to concluding more social security agreements with EU Member States.

(2) Liberalisation of the movement of intra-corporate transferees in the framework of an FTA/EPA

BRT Recommendation

The EU and Japan should realise far-reaching liberalisation of the movement of intra-corporate transferees within the framework of an FTA/EPA. Such liberalisation should aim at the following system:

- A framework agreement between the mother company, sending expatriates, and the host country, stipulates the maximum number of expatriates. Within the agreed limit, the mother company is free to send intra-corporate transferees to that country without further obtaining individual work permits.
- When the mother company concludes such an agreement with several Member States in which its subsidiaries or branches have operations, movement of intra-corporate transferees between those countries does not require a new work permit as long as the total number in each agreement is respected.
- Both sides should facilitate access to the labour market for accompanying family members without any limitations in regard to regular working hours.

< Background >

For the smooth and efficient running of international businesses, it is essential that companies are able to dispatch key personnel, including directors without going through red tape. Such transfers do not have any negative impact on the labour market of the host country. On the contrary, they will expand employment in the host country through the development of the business concerned. In addition, expatriates themselves tend to pay high income taxes to the host country. The requirement to obtain work and residence permits for intra-corporate transferees between the EU Member States and Japan is usually a formality. However, the burden on companies as well as employees and their family members is substantial, and it constitutes an obstacle to the swift development of business.

The EU has adopted Directive 2014/66/EU of the European Parliament ad of the Council of the 15 May 2014 on the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer. By 29

November 2016, the directive should be transposed in the Member States. The directive will prove very useful for Japanese companies sending their employees to the EU because, for example, it will facilitate an assignment that involves several Member States and allow accompanying family members to have access to the labour market. However, unfortunately, the new Directive will not be applied in the UK, Ireland and Denmark due to the opt-out of those Member States. Japanese nationals in the UK, where their number is the highest among the EU Member States, will not benefit from this Directive. It is therefore imperative that such liberalisation is realised within the framework of an EPA/FTA so that it will be applicable to all intra-corporate transferees between the Member States of the EU and Japan.

Actions taken so far

Japan does not require work permits of intra-corporate transferees in its immigration system nor does it apply any numerical restrictions such as a cap, a quota or a labour market test with regards to their entry.
Even accompanying family members of intra-corporate transferees are allowed to engage in working activities without any restrictions regarding working hours if they fulfil the requirements under Immigration Control and Refugee Recognition Act and are granted in advance the status of residence for the purpose of engaging in working activities.

Future outlook

Japan will further work on the negotiations of JP-EU EPA to achieve high level of liberalisation, while taking into consideration respective legal frameworks of both sides.

5. Support for SMEs（WP-1/#05*/EJ to EJ）

BRT Recommendation

The BRT calls on the EU and Japanese Authorities to develop measures to promote and assist each other's SMEs within their own jurisdictions. Specific consideration should be made to include such cross-support in FTA/EPA negotiations.
This would include:

1. Providing each other's SMEs the same general support and privileges as provided to one's own SMEs.
2. Establishing permanent local assistance in language, paperwork, hiring local personnel, legal and regulatory matters, as well as advice on financing and banking, etc.
3. Providing tax breaks and incentives, tax deduction for total research expenses, income tax breaks for foreign experts, tax exemption for doctoral students, tax relief for R&D, tax deduction for joint and entrusted researches based on industry-academic-government cooperation, as well as tax and other facilities and incentives for investors.
4. Assisting and supporting SMEs with participation in local “Requests for Proposals”, especially for renewable energy projects. This could include streamlining and extending the proposal submission time frames which in many cases are too short for foreign SMEs to respond.
5. Helping graduates with international backgrounds find local jobs with the other side's SMEs.
6. Conducting a feasibility study on creating a joint investment fund for both Japanese and European SMEs.
7. Exchanging best practices and tested solutions in industrial policy for SMEs.
8. Expanding the SME-related programmes already run by the EU-Japan Centre for Industrial Cooperation.

< Recent progress >

The BRT welcomes the willingness of both Authorities to increase cooperation on cross-support for SMEs.

< Background >

SMEs are the most promising sources of growth and jobs in both Europe and Japan. Their success in bilateral trade is a major factor in their development and also helps to revitalise both Japanese and EU industries by disseminating new products and technologies. However, market access problems and various impediments noted in other BRT recommendations are even harder to tackle or manage for SMEs. While the Japanese government, the European Commission and most EU Member States have internationalisation programmes for their own SMEs, existing help programmes for foreign companies are mostly geared towards large foreign direct investments in established industries and are inadequate for SMEs. Once a European SME has established a footing in Japan, or a Japanese in the EU, using already available government support programmes, it should continue to receive support from the host region. Such support cannot be expected as a unilateral measure but would only be possible if agreed in a formal bilateral agreement. The BRT is aware of the major work being done for both Japanese and European SMEs by the European Commission and the Government of Japan through the programmes run by EU-Japan Centre for Industrial Cooperation.

Actions taken so far

With a view to supporting foreign SMEs which are considering investing in Japan as well as Japanese SMEs which seek to expand their business in the EU, the Government of Japan has been providing various forms of assistance such as improvement in the provision of necessary business information, introduction of corporate activities, support for business-matching and consultation with experts through related organizations such as the Japanese diplomatic missions overseas, EU-Japan Centre for Industrial Cooperation, the Japan External Trade Organization(JETRO), the Organization for Small & Medium Enterprises and Regional Innovation, JAPAN (SMRJ). The Government of Japan also has been providing assistance through the multi-layered measures including fund-raising etc. In addition, the Government of Japan has contributed to SME cooperation through sharing Japan’s best practices on SME policy in international fora such as OECD.

Future outlook

The Government of Japan will steadily execute the above policies and initiatives and continue to support SMEs through related institutions. In addition, the Government of Japan will continue carefully cooperation in international fora and consider the possibility of bilateral cooperation if specifically requested by a foreign country

6. Recommendation on BEPS Action Plan and Other Tax Issues (WP-1/#06**/ EJ to EJ)

(1) General

BRT Recommendation

The BRT supports the creation of an internationally fair taxation framework and level playing field. At the same time, the BRT urges that authorities of the EU and Japan to ensure that the implementation of the BEPS Actions should not create additional administrative burden on businesses.

The BRT welcomes the agreement by OECD/G20 countries to implement the master file-local files system in the transfer pricing documentation in BEPS Action 13. The BRT eagerly awaits coherent and successful implementation in the bilateral and multilateral relations between the EU Member States and Japan in a way that will reduce the compliance costs and uncertainty significantly.

The BRT recommends that the authorities of the EU, its Member States and Japan to also aim at facilitating the conclusion of bilateral and multilateral APAs.

The BRT emphasises that it is important that the scope of information required for disclosure through Country-by-Country Reporting to be internationally coherent and in accordance with BEPS Action 13 in order to realise a level playing field.

The BRT also would like to point out that information concerning a tax payer should be kept confidential by the tax authorities as BEPS Action 13 demands.

As was agreed by OECD/G20 countries in 2013, introduction of the measures developed by the BEPS Action Plan should not lead to unnecessary uncertainty for compliant taxpayers and to unintended double taxation.

The BRT welcomes the commitment made by 20 countries including Japan and 13 EU Member States (Austria, Belgium, France, Germany, Ireland, Italy, Luxembourg, the Netherlands, Poland, Slovenia, Spain, Sweden and the UK) to

provide for mandatory binding MAP arbitration in their bilateral tax treaties as a mechanism to guarantee the resolution of treaty-related disputes within a specified timeframe. The BRT recommends that this mechanism should be extended to between all the EU Member States and Japan.

<Recent Progress>
There was a progress as the final package of measures was presented by the OECD and endorsed by G20 leaders.

<Background>
The BEPS Action Plan was proposed by the OECD and endorsed by G20 Finance Ministers and Central Bank Governors in July 2013. The OECD presented the final package of measures (the 2015 Final Reports) to G20 Finance Ministers and they endorsed the final package on 9 October 2015. The G20 leaders endorsed the BEPS and committed to its implementation on 15 November 2015.

Action taken so far

In the BEPS Project, OECD had several public consultations to reflect opinions of business sectors to the international tax rules.
The Government of Japan takes into account potential compliance costs of companies based on discussions with business sectors and relevant authorities in designing its tax systems in accordance with the recommendations of the project. For example, in revising “transfer pricing documentation” rules in the 2016 tax reform, the Government of Japan introduced measures to exempt multinational enterprise groups whose total revenue for the ultimate parent entity’s preceding fiscal year is less than 100 billion yen from the obligation to submit the “country-by-country reportings” and “master files” to the tax authority.
The Government of Japan has vigorously made negotiations with EU Member States, through the mutual agreement procedures (MAP) based on tax treaties, to resolve Advance Pricing Arrangement(APA) cases for the purpose of avoiding international double taxation.
Japan’s National Tax Agency (NTA) has made every effort to resolve MAP cases flexibly and efficiently, deploying appropriate number of staff members and

strengthening the cooperative relationship with the tax authorities of EU Member States.

Future outlook

The Government of Japan has already moved into the implementation phase of the BEPS Project. The Government of Japan will steadily continue to implement the agreed measures, including through relevant law amendment as necessary.
The Government of Japan will continue to design tax systems that can prevent aggressive tax planning by global companies, while taking into account opinions from business sectors.
The Government of Japan will continue to make every effort to resolve APA cases promptly through flexible and efficient MAP negotiations, in order to avoid double taxation between Japan and EU Member States.

(2) Pursue simpler, lighter and sensible tax systems that will lead to growth and innovation.

BRT Recommendation

1. Pursue simpler, lighter and sensible tax systems that will lead to growth and innovation. A simple, light and sensible tax system will reduce the incentive to avoid or reduce taxation. It should include participation exemptions that will exempt dividends and capital gains received from business investment above a certain holding threshold from further corporate taxation.

Action taken so far

Corporate tax reform in the FY2015 and FY2016 Tax Reforms aimed to reform the structure so that the burdens of corporate tax will be shared more broadly by 'expanding the tax base while reducing the tax rate', through revision of special tax measures etc.
The Government of Japan promoted the corporate tax reform further from the viewpoint of securing the realization of the virtuous economic cycle and reduced the percentage level of the effective corporate tax rate down to the twenties in FY2016 Tax Reform, realizing the internationally-comparable level,.

Future outlook

The Government of Japan has realized the aimed reduction of the percentage level of the effective corporate tax rate down to the twenties in FY 2016 Tax Reform, and will consider the effects hereafter.

(3) Reduce administrative burden.

BRT Recommendation

2. Reduce administrative burden. The more complex a tax system and the heavier the tax burden, the more time and money both businesses and tax authorities spend merely to comply or enforce.

Action taken so far

Refer to the response to WP-1 / # 06** / EJ to EJ, (1). above.

Future outlook

Refer to the response to WP-1 / # 06** / EJ to EJ, (1). above.

(4) Promote healthy competition in attracting investments.

BRT Recommendation

3. Promote healthy competition in attracting investments. In the majority of investment decisions, a combination of tax, human resources and infrastructure plays the decisive role. The authorities of the EU and Japan should promote and compete on the three factors in a healthy way in order to attract investments.

Action taken so far

The Government of Japan aims to increase the amount of inward foreign direct investment (FDI) stock to ¥ 35 trillion by 2020. The actions taken so far have improved business and living environment, the issues of which foreign businesses had requested, and Japan's reputation as an investment destination by foreign companies has been steadily improving.
In addition to this improvement, the Council for Promotion of Foreign Direct Investment in Japan adopted the "Policy Package for Promoting Foreign Direct Investment into Japan to Make Japan a Global Hub" to promote more FDI to make Japan a global hub for trade and investment. In accordance with the policy package, the Government of Japan has implemented, amongst others, measures such as simplifying regulations and administrative procedures relevant to investments by foreign companies, and others.
In terms of taxation, the Government of Japan participated to the review of potentially harmful intellectual property regimes such as patent boxes in light of the new criteria developed in the context of BEPS Project to review such regimes that erodes tax bases of other countries.

Future outlook

For the purpose of increasing the amount of inward foreign direct investment (FDI) stock to ¥ 35 trillion by 2020, in accordance with the "Policy Package for Promoting Foreign Direct Investment into Japan to Make Japan a Global Hub", by steadily promoting growth strategy including discussion and reaching conclusions on simplifying regulations and administrative procedures relevant to

investments by foreign companies and others, the Government of Japan will work on the improvement actively Japan's business environment to attract foreign investments.

In terms of taxation, the Government of Japan will contribute to the discussions over the review of preferential regimes of countries, including emerging countries, that have recently participated in the Forum on Harmful Tax Practice of OECD.

(5) Eliminate double taxation.

BRT Recommendation

4. Eliminate double taxation. Double taxation still weighs heavily on cross-border business activities. The EU Member States and Japan should modernise the tax treaties between them and ensure, to the greatest possible extent, that dividend, royalty and interest payments are exempted from withholdings taxes.

Action taken so far

From the viewpoint of further promoting investment and economic exchanges between Japan and the EU, by reducing the source country taxation on investment income and introducing arbitration proceedings, the Government of Japan has been actively expanding its tax treaty network between Japan and EU Member States. In 2016, five new or wholly revised tax treaties were signed or agreed in principle with EU Member States as follows:

(1) Slovenia (new, signed in September)
(2) Belgium (revision, signed in October)
(3) Latvia (new, agreed in principle in June)
(4) Austria (revision, agreed in principle in October)
(5) Lithuania (new, agreed in principle in December)

Future outlook

Based on the “Japan Revitalization Strategy 2016”(Cabinet Decision, June 2nd 2016), the Government of Japan will actively continue to expand its tax treaty network with the EU Member States for further promoting investments and economic ties between Japan and the EU in a globalized business environment.

7. Harmonisation & mutual recognition of standards and product certifications; acceptance of international standards where applicable（WP-1/#08**/E to J）

(1) Automobiles

BRT Recommendation

Reluctance of the Government of Japan to accept imported products approved in accordance with EN and ISO standards or CE marking delays the introduction of innovative new products to the market and increases import costs. While accepting the need to safeguard consumer health and safety, the BRT urges Japan to promote the harmonisation of standards and certification procedures, the mutual recognition of product certification and, in areas where harmonised standards do not exist, the mutual approval of the import, sale or use of products that have been approved on the basis of functionally equivalent requirements, so that products certified for one market are automatically accepted in the other market. The BRT recommends the Japanese Government to place particular emphasis on:

Automobiles

The Government of Japan should adopt the relevant UN Regulations in all areas where Japan requires certification for passenger cars but does not currently accept a UN approval as demonstrating compliance with Japan's national requirements, so that a vehicle certificated in the EU can be sold in Japan without modification or further testing. The Government of Japan should also work towards the international harmonisation of Japan's technical requirements for commercial vehicles which should be included within the scope of the provision of any FTA/EPA.

< Recent progress >

There are still seven areas where Japan does not accept a UN approval as demonstrating compliance with its national type approval requirements. The reference to commercial vehicles is a new recommendation.

Action taken so far

Refer to the response to WP-1 / # 03 / EJ to EJ, (6). above.

Future outlook

Refer to the response to WP-1 / # 03 / EJ to EJ, (6). above.

(2) 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. This is unfortunately still rather common with non-recognition of standards in the flooring sector as well as for roofing sheets. Mere reference to ISO standards within JAS/JIS, has not proved to be adequately helpful in facilitating the process.
The Government of Japan should, furthermore, better support local and regional authorities to ensure that transparent and consequent interpretations are made in regards to technical regulations and guidelines.

< Recent progress >

There has been some progress, however much work still remains. We furthermore note that the Japanese government did not respond to the issue of discrepancy between ISO and JIS/JAS in its progress reports of April 2013, April 2014 and April 2015.

< Background >

The Japanese construction sector has long been a very "domestic" market. Even in the aftermath of the 2011 Tohoku earthquake and tsunami, there is little evidence that this situation is changing.

Actions taken so far

Japan has been developing JAS/JIS complying with WTO/TBT Agreement while JAS/JIS and its marking system are not mandatory.
Under JAS/JIS marking system, a foreign institute can be registered as a Registered Overseas Certifying Body (JAS) or a Foreign Accredited Certification Body (JIS) following a review of the required documentation and an on-site inspection. Some certifying bodies of the EU are indeed registered as the Registered Overseas Certifying Body (JAS).
Moreover, registration is based on ISO/IEC 17065, an internationally recognized accreditation standard. In other words, the Government of Japan does not

believe that it is imposing particularly complicated requirements for registration. Therefore, conformity assessment bodies in Europe can operate, with necessary resistance, as conformity assessment bodies of JAS and JIS without an intergovernmental mutual recognition agreement in these fields.

Future outlook

The Government of Japan continues to ensure the appropriate management of the accreditation system, while explaining its system to relevant institutes it necessary.

(3) Cosmetics

BRT Recommendation

The BRT 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.

< Recent progress >
While very little has been confirmed or decided, the BRT is pleased to see that the issue is reportedly under discussion in the FTA/EPA negotiations. Additionally, Japan has taken the first step to revise the levels of fluoride in toothpaste and mouthwash. The BRT views this in a positive light.

< Background >
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.

Actions taken so far

As for medicinal cosmetics, which is categorized into quasi-drug, the lists of its active ingredients and excipients have been prepared and published. Pharmaceuticals and Medical Devices Agency (PMDA), which conducts review of medical cosmetics, sets the goal of the review period by the regulatory side as 5.5 months on quasi-drug (including medicinal cosmetic).
Opinions regarding measures to accelerate review for quasi-drug pre-market application have been regularly exchanged among MHLW, PMDA and the industry.
Regarding the acceleration measures taken in Japan, the Government of Japan published the lists of excipients for hair dye and permanent wave on 27th January 2016 and issued the compilation of frequent asked questions and answers regarding the cosmetic standards and quasi-drug pre-market

application on 30 March 2016.
As for the alternative to animal testing, Japan has accepted not only the alternatives adopted by OECD, but also the test methods verified by Japanese Center for the Validation of Alternative Methods (JaCVAM) in cooperation with each assessment institute in EU, USA, Canada and South Korea under International Cooperation on Alternative Test Methods (ICATM).

Future outlook

Japan will continue to address transparency and acceleration of medicinal cosmetic pre-market application review, and consider necessary assessment or actions through activities of JaCVAM, should a specific alternative to animal testing which is not adopted by OECD should be proposed on the basis of appropriate data.

(4) Railways

BRT Recommendation

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. This has repeatedly been communicated by one operator. 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.
The BRT furthermore recommends Japan to establish a system whereby standards and requirements are available openly so that European companies will have a better understanding of what is needed in order to offer goods and services that meet or exceed the safety measures in the Japanese market. While the BRT understands that operators might have different performance requirements, the same safety requirements and standards should preferably be used by all operators in Japan, which currently is not the case as each individual operator can choose its own standards and requirements. As a first step, test results and approvals by one operator should be accepted by other domestic operators.
The BRT, however, recognises the latest development and positively views the first call for tender by a Japanese operator The BRT recommends Japan to make better use of the tendering system as this leads to more competition and better transparency, while not negatively affecting safety.

< Recent progress >
While some progress has been made, the core issue still remains that there is no common conformity assessment scheme in Japan to which all operators adhere. The BRT takes note of the efforts of some operators in publishing a list of potential future procurements, and views this as a good first step to improved market access.

< Background >
Japanese safety standards and regulations are not publically available. There is,

therefore, no possibility for foreign manufacturers to know exactly what requirements must be fulfilled. Furthermore each operator can in principle have their own testing requirements as there is no legislation on exactly what safety requirements need to be fulfilled.

Actions taken so far

1) Railway safety standards have been developed in each country, reflecting its own specific situations relating to transportation and past experience of rail accidents as well as other considerations. Accordingly, measures to be taken to ensure conformity with safety standards are different between Japan and the EU. In Japan, the Government of Japan conducts conformity assessment with respect to Technical Regulatory Standards, and thus, unlike the EU, Japan has not established any particular regulations with respect to compliance for product safety based on third-party certification systems.
   Besides, even when Japanese suppliers' goods have conformed to the technical standards in Japan, conformity assessment procedure of the EU is applied to those goods exported from Japan to EU. In addition, the Government of Japan recognizes that, both in Japan and the EU, railway operators have a right to test whether the goods conform to their requirement.

2) The Government of Japan establishes a legally-binding ministerial ordinance on "Technical Regulatory Standards" and also sets out a non-binding guideline on "Approved Model Specifications", which stipulates definitive and interpretative standards with indication of precise figures, in a manner consistent with the above "Technical Regulatory Standards". These standards are published in English at the following website.
   (http://www.mlit.go.jp/english/2006/h_railway_bureau/Laws_concerning/index.html)

3) Japan proactively engages in its standardization activities, with the Japanese Railway International Standards Center (J-RISC) playing its central role, as exemplified in information exchange sessions held on a regular basis with the EU, including JISC-CEN/CENELEC meetings. Japan also promotes harmonization between JIS and such international standards as ISO/IEC, with respect to those relating to testing methods, based on its active cooperation

extended to development of international standards.

4) It is recognized that Japanese railways operators continue to seek safe and reliable products and that they are ready to continue to proactively procure qualified and conforming products including those from the EU.

5) The Government of Japan recently composed the comparing list between TSI (Technical Specification for Interoperability) in the EU and Technical Regulatory Standards in Japan, and instructed related railway operators to apply testing and demonstrating obligations on a non-discriminatory basis. The Government of Japan understands that such railway operators take concrete measures. The Government of Japan expects the EU suppliers to take concrete approach to Japanese operators.

Future outlook

Japan and the EU are currently conducting discussions on further enhancing mutual market access with regards to the railways sector, and it is the Government of Japan's expectation that Japan and the EU will continue to hold constructive discussions.
Furthermore, the Government of Japan intends to promote cooperation in the field of standardization activities as well as to foster dialogues between Japanese and EU railways-related experts and industries with a view to deepening their mutual understandings.

(5) Veterinary Products

BRT Recommendation

Animal health products already approved in the EU have to undergo further rigorous reviews on market authorisation application dossiers and Japan-specific tests before being approved in Japan, which increases costs and causes delays. Accordingly, the BRT:

a) The BRT requests the Government of Japan to take all measures available to speed up product approvals, particularly for veterinary products intended for use in food producing animals.

b) The BRT requests the Ministry of Agriculture, Forestry and Fisheries to minimise Japan-specific tests for market authorisation, such as the serological potency test for live vaccines, which is a unique requirement in Japan.

< Recent progress >

On August 3, 2015, MAFF announced a drastic change in the review process under discussion for veterinary products intended for food producing animals. The current step-by-step or sequential flow of reviews among MAFF, Food Safety Commission, and MHLW will shift to a parallel review process among those government bodies. According to MAFF, this has the potential to shorten the review process toward MA by one to two years when compared to the current process.

< Background >

Japan is part of the Trans-Pacific Partnership (TPP), which is shaping up to become the largest trade deal in history. If it passes, Japan may face more competition in certain meat categories, such as the low- to middle-price range of beef and pork imported from abroad. Therefore, the availability of innovative veterinary products for both pharmaceuticals and biologicals for Japanese livestock producers are considered critical to ensure their competitiveness.

Actions taken so far

MAFF works positively to accelerate approvals of veterinary medicinal products

(VMPs) including those for animals used for food, exchanging views with Japan Veterinary Products Association (JVPA) and Marketing Authorization Holders of VMPs. (Please see Attachment #1. MAFF has held relevant meetings 13 times between 2013 and 2016.)

Of 23 action items related to the acceleration of VMPs approvals including the 10 action items for change which MAFF presented to the JVPA in December 2012, MAFF has already implemented 22 items with the remaining 1 item to be implemented 1 by the end of March 2017 (Please see Attachment #2 which shows timelines for 22 action items related to the acceleration of VMPs approvals. MAFF is preparing to implement it in ongoing action by the end of March 2017.).

Moreover, MAFF prepared the documents in English regarding the progress of the action planto provide branches of foreign manufacturers in Japan and encouraged them to communicate with their head offices. MAFF has been proactively provided such information.

MAFF has been actively participating in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and making a considerable contribution to its activities. MAFF has been implementing all relevant VICH guidelines in Japan, and accelerated approval procedures of VMPs developed in foreign countries.

For instance, in October 2013, MAFF decided to accept an application with clinical trial data conducted only in foreign countries in accordance with VICH guidelines (Good Clinical Practice (GCP) of countries participating VICH (i.e., the EU, the US and Australia)) with the exception of biologicals and antimicrobials containing active ingredients such as fluoroquinolones and 3rd and 4th generation cephalosporins which are considered to be very important in terms of human healthcare. As far as known, only Japan accepts such application among VICH countries (i.e., Japan, the US, the EU and Australia), which is expected to make considerable contribution to the acceleration of approvals of VMPs.

MAFF, MHLW and FSC have been cooperating to improve efficiency of review and assessment process for approval of new products. For instance, certain inactivated vaccines which meet specific conditions have been exempted from the FSC assessment. In addition, the FSC assessment procedures for certain attenuated live vaccines have been simplified. Furthermore, parallel deliberation among MAFF, MHLW and FSC was introduced and started to operate on 30th

September, 2016.
Serological potency test of live vaccine is conducted to assure the efficacy of the product. Rationalization of batch release testing would be possible if the scientific validity is proven. MAFF will consider it as needed.
MAFF is confident that it has been working positively to accelerate approval procedures and making significant progress. Furthermore, MAFF will keep working on this issue and is ready to honestly consider reasonable and concrete proposals based on thorough research on actual situation in Japan.

Future outlook

Regarding VICH activity, approximately 20 guidelines are now under development. Japan will implement VICH guidelines in accordance with VICH rules on harmonization. MAFF actively tackles the remaining 1 item of the 23 action items related to the acceleration of approvals of VMPs, and is ready to consider new plan for the acceleration of the approvals of VMPs. The three relevant authorities will endeavour to properly operate the procedures such as approvals of VMPs of the respective authorities.
In order to enable the FSC to conduct its risk assessment in a timely manner, Japan appreciates the cooperation of EU industries and the European Commission in providing data and information necessary for the risk assessment.

Attachment #1
As of Dec. 31, 2016

Explanation and Exchanging views on the MAFF's Actions

for the Acceleration of the Approval Review Processes

2013

July 17: Exchanging views with JVPA Members

July 21: Exchanging views with JVPA Members and Medical Device Makers

July 25: Exchanging views with the JVPA Members of Foreign AH Makers

October 3: Exchanging views with JVPA Members

December 24: The JVPA's 24th Regular Council Meeting on Veterinary Medicine Regulatory Issues

2014

February 27: Exchanging views with Technical Issue Committee of JVPA and the JVPA Members of Foreign AH Makers

March 13: The 3rd Board Member Meeting of JVPA in the Fiscal Year of 2013

May 12: The 1st Board Member Meeting of JVPA in the Fiscal Year of 2014

May 30: Exchanging views with the JVPA Members of Foreign AH Makers

November 21: The JVPA's 25th Regular Council Meeting on Veterinary Medicine Regulatory Issues

2015

August 3: Briefing session related to speed up approvals of VMPs

2016

April 5: Briefing session concerning expanded application of Seed-Lot System

to whole Veterinary Biologics

August 31: Briefing Session concerning change of management of animals for clinical trials, and introduction of simultaneous review process by MAFF, MHLW and FSC

Attachment #2

Major MAFF's actions for the acceleration of the Approval Review Processes, and their timelines for practice

1. Completed Actions

i. Change of requirement of data on clinical trials for newly developed veterinary medicinal products except for vaccines etc. (Data on clinical trials conducted in Japan is not required, if it is collected in accordance with GCP of the EU, the US and Australia.) (List No. 6. October, 2013)

ii. Improvement of efficiency of review and assessment on live vaccines for non-zoonotic diseases by the Food Safety Commission (FSC) (August, 2013)

iii. GLP is no longer required for the data on animal experiments to set withdrawal periods for vaccines which contain adjuvants (List No. 8. July, 2013)

iv. Change of requirement of data sets for application of medical devices for veterinary use (July, 2013)

v. Review of procedure to change vaccine seeds of products approved in Japan (List No. 2. December, 2013)

vi. Enhancement of pre-filing consultation and post-filing review by the consistent team review (List No. 1. February, 2013)

vii. Establishment of guidelines to develop veterinary products containing genetically engineered substances (List No.3. November, 2014)

viii. Establishment of guidelines to develop veterinary products which are radiation-ionized in the manufacturing process (November, 2014)

ix. Change of requirement of data sets for application of *in vitro* diagnostics (List No.5. November, 2014)

x. Establishment of guidelines on capability testing and clinical trials for the development of *in vitro* diagnostics for veterinary use (List No.5. November, 2014)

xi. Establishment of guidelines on clinical trials for the development of antimicrobials such as fluoroquinolones and 3rd and 4th generation cephalosporins (November, 2014)

xii. Establishment of standard of procedure for the preparation of the package insert (November, 2014)

xiii. Promote applications for the human drugs approved in Japan which have experiences of use in cats and/or dogs by diverting to animal drugs (for companion animals) (List No.7. August, 2014)

xiv. Change of approach to set withdrawal periods of vaccines containing adjuvants for food-producing animals (December, 2014)

xv. Reclassification of medical devices for veterinary use (April, 2015)

xvi. Reduction of paper documents for the consultation steps by the Council (April, 2015)

xvii. Review of requirement of data sets for application of combined vaccine (April, 2015)

xviii. Change of requirements of data needed for application (general pharmacological testing, toxicity testing and ADME testing of drugs for pet animals) (List No. 10)

xix. Review of the regulatory framework for veterinary drugs for minor animal species (List No. 4)

xx. Improvement of efficiency of review on live vaccines for non-zoonotic diseases by MHLW

xxi. Review of procedure to approve veterinary recombinant vaccines pursuant to the Cartagena protocol

xxii. Change of management of animals for clinical trials, and introduction of simultaneous review process by MAFF, MHLW and FSC (List No. 9)

2. Ongoing Actions

i. Introduction of Marketing Notification system for in-vitro diagnostic

(6) 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. High conformity costs are incurred because Japanese authorities do not accept evaluations made by the EU or international bodies, and the FSC is constantly asking for tests to be carried out in Japan. The market potential for European exporters would be greatly enhanced by:

a) Substantially increasing the list of permitted additives and enzymes, in addition to speeding up and fundamentally revising the approval process
b) Introducing mutual recognition of conformity assessment procedures to eliminate the duplicate costs of evaluations.
c) Introduce deadlines for all parts of the application process. While there are guidelines on timelines these only cover part of the application process. Accordingly, it is difficult for an applicant to know how long the application will take.

< Recent progress >

There has been no concrete progress, although the issue is under discussion in the EU-Japan FTA/EPA negotiations. We note that the progress report of 2014 mentions that the Government of Japan is considering setting “a standard time frame” for approval procedure upon establishment of the Food Additive Design Consultation Center. We are very much looking forward to know more about this.

< Background >

The limited number of permitted food additives in Japan and unaligned standards between the EU and Japan increases costs and prevent EU exporters from utilising scale effects.

Actions taken so far

a, b) The Food Sanitation Act prohibits the use of food additives in Japan except when they are designated under the Act by the Minister of Health, Labour and

Welfare (MHLW) as substances that are unlikely to pose a risk to people's health. The procedure of designation of food additives, as described above, is initiated based on an application filed by an applicant such as a business operator. The Government of Japan understands that the EU adopts a similar system for authorization of food additives.
The MHLW has made utmost efforts to streamline the designation process for food additives, which the EU is concerned with. Specifically, the MHLW has facilitated communication with the Food Safety Commission (FSC), a risk assessment body, efficiently handled clerical work needed before the MHLW requests the FSC to carry out safety assessments, and cooperated with the FSC so that assessment can be carried out in a more speedy manner. In June 2014, the MHLW established the Food Additive Designation Consultation Center in the National Institute of Health Sciences to give advices on the approval procedure for food additives.

Since 2002, the Government of Japan, on its own initiative, has been proceeding with designation of the 45 food additives (excluding flavorings) which are confirmed safe and used internationally, including substances requested by the EU.
In September 2012, the Government of Japan drafted and published the roadmap for the designation of the 15 non-approved substances among above-mentioned 45 additives based on the Cabinet decision made in July 2012 to designate them within around one year, excluding time required for collecting additional information requested by the FSC.

Consequently, eleven substances have been designated by December 2015. The remaining four substances are under review by the Experts Committee of the FSC. However these substances are aluminum-containing additives and the Government of Japan recognizes that the EU also restricts the use of them.

c) In June 2016, the MHLW announced that the standard period of time for process by the MHLW, including the establishment of standards period for food addtives, is one year from the date when the FSC notifies the MHLW the results of the assessment by the FSC.

Future outlook

For the remaining four substances, which are under review by the Experts Committee of the FSC, the MHLW will initiate formalities for designation as soon as assessment by the FSC is completed. The MHLW will continue the swift designation process that has been carried out until now.

In 2002 the MHLW listed the 45 substances with the intention to designate them. At that time, these substances were already proven safe by the JECFA and being widely used as food additives in many countries including the EU Member States and the United States. The MHLW took the views of the EU and the US into consideration in the listing work. The Government of Japan believes that the designation of the 45 substances mostly cover the food additives whose needs are globally recognized.

Japan‘s action for the 45 substances is a special measure taken to ensure international consistency.

The Government of Japan will follow the ordinary process for designation of substances other than these 45, such as the substance certified by JECFA and the substances of whose uses have been approved by the EU, the USA etc. since 2002, based on applications from businesses, as other major countries, including the EU and the U.S., do.

(7) LED lamps and lightings

BRT Recommendation

Lack of harmonisation of international electrical safety standards, such as IEC, and Japanese standards and technical requirements, such as PSE/JIS/JET results in high costs and effectively prohibits entry to the Japanese market for EU companies.

- The current standard issued by the Japanese ministry (i.e. METI) is not compatible with standards used by manufacturers of other countries

The BRT requests Japan without delay to harmonise with international standards and safety/technical requirements in order for Japan to avoid being left behind in the global market. The market for LED lamps and luminaries is rapidly expanding and these products are expected to play an important role in saving energy on a global basis.

< Recent progress >
While the Japanese Government has agreed to harmonise JIS with IEC, the authorities have also said that this will take more than five years. Needless to say this is not acceptable. Japan has issued a list of products where an IEC test report can be used ("appendix 12"). However, updating of the list is slow and does not cover all LED lamps and luminaries.

< Background >
Japan has its own standards and technical requirements, such as PSE and JIS, and delays in setting standards such as J-deviation increases costs and prohibits EU companies and exporters from entering the Japanese market. In addition, lack of harmonisation of standards of remote control prohibits EU companies from entering the Japanese market.

Actions taken so far

The Electrical Appliances and Materials Safety Act (DENAN law) has two technical requirements: the Japanese original technical requirements (Requirements in Appendix Tables 1 to 11) and the requirements harmonized

with international standards (Requirements in Appendix Table 12). Manufactures and Importers in Japan shall comply with either of them.
Ten JIS standards in line with IEC standards have been incorporated in DENAN law, as a technical standard with a few added.
There is no international standard (ISO, IEC) for the remote control devices of LED lamps and luminaries. Therefore, they are defined in Requirements in Appendix Table 8 of Interpretation of the Ministerial Ordinance Specifying Technical Standards for Electrical Appliances and Materials in Japan.

Future outlook

With regard to the standards and technical requirements, Japan will cooperate with the European industry in the context of the IEC.

(8) Labelling rules

BRT Recommendation

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. There are also examples where the information required on the labels is too technical for the consumer to understand.

< Recent progress >
This issue was brought up in the Regulatory Reform Council where both representatives for European companies as well as domestic companies argued for a revision of the Household Labelling Law. The CAA is said to be working on a revision, but has so far not presented anything concrete. This issue was not touched upon in the Government of Japan progress report of April 2013.

< Background >
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.

Actions taken so far

The labelling rules prescribed in the Household Goods Quality Labeling Act currently cover the following categories: textile products, plastic goods, electrical appliances and apparatuses, and miscellaneous manufactured goods. The scope of goods under these categories had been specified in the Cabinet Order. However, in order to respond swiftly to social changes, the Cabinet Order and the Cabinet Office Ordinance were amended in April 2016 to allow some of these goods to be specified in the Cabinet Office Ordinance. The rules stipulate the minimum information which must be included in labels that are useful to

consumers or a product-by-product basis, as well as the matters that needto be complied with. Based on the Cabinet Decision in 2014, the Government of Japan has been reviewing the labelling requirements to respond to social changes, while requiring minimally necessary and comprehensible information for consumers and coping with global harmonisation. Furthermore, the Government of Japan amended a notification in March 2015 to incorporate a new standard on textiles care instructions on home laundry which is in line with the relevant ISO standard and the notification entered into force in December 2016.

Future outlook

With growing importance of consumer protection as well as diversification, complication and globalisation of products, the importance of the labelling as provided for in the Household Goods Quality Labeling Act is also increasing. Therefore the Government of Japan will continue to review the scope of product coverage as well as what to be included in labels, while taking into account the Cabinet Decision in 2014. The Government of Japan will also continue to facilitate understanding of the Household Goods Quality Labeling Act among business operators including overseas business operators by publishing information on the web and other media.

8. Fuel Cell Vehicles（WP-1/#10**/E to J）

BRT Recommendation

Pending agreement and implementation of Phase II of the UN Regulation for HFCV's concerning the material requirements for hydrogen storage systems, the Japanese and EU Authorities should introduce flexible arrangements to allow manufacturers/importers to demonstrate that HFCV's meet each other's requirements and approval procedures

< Background >
UNR 134: Hydrogen and Fuel Cell Vehicles, Phase I of the UN Regulation for HFCVs, entered into force in June 2015 and has been adopted by the EU, but not yet by Japan. Even when Japan has implemented Phase I, HFCV tanks imported into Japan would still need to meet Japanese unique national requirements concerning metal materials. Whereas the EU uses a performance-based approach to approve hydrogen compatible materials, Japan's approach is more prescriptive, in effect limiting the choice of materials to very few specific types of stainless steel and aluminium.

Actions taken so far

The UN Regulation on HPCV, known as "Phase 1", stipulates that any Contracting Parties may introduce appropriate measures in order to address hydrogen embrittlement of metals a significant risk in dealing with hydrogen especially under the low temperature (-40 degree) and high pressure (70 MPa) conditions.
Under Japan's current safety regulation scheme, METI's Notice pursuant to the High Pressure Gas Safety Act lists examples of certain materials, such as specific types of stainless steel and aluminium alloys which have been proven safe in terms of Hydrogen Embrittlement. HFCVs equipped with the containers made of the materials other than above-mentioned, however, may be utilized in Japan once the safety of the containers is demonstrated and the containers are authorized by the expert committee established within the High Pressure Gas Safety Institute of Japan (KHK).
It is misleading that Japan is limiting the choice of materials to very few specific

types of stainless steel and aluminium and the regulatory authorities and experts of Japan and the EU have started sharing information and views on respective regulations.

Future outlook

Japan and the EU will continue to share information between regulatory authorities and experts on respective regulations.. Furthermore, in order to accelerate the development of “Phase 2” of UN Regulation on HFCV, Japan will promote cooperation with the EU and the US among others.

9. Ensuring free and open competition in services（WP-1/#11**/E to J）

BRT Recommendation

The BRT urges the Government of Japan to tackle the lack of free and open competition in Japan's services markets.
On the matter on postal reform, the BRT is disappointed with the decisions taken so far by the Japanese Government. Japan has a duty to abide by its WTO obligations, including the national treatment provision of the 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:

a) Kampo insurance business should be subject to the same capital, solvency margin, tax and policyholder protection funding requirements as private sector insurers. Limits are needed on expansion of Japan Post's services, including the introduction of new products as well as caps on postal life insurance, until competitive safeguards have been established to prevent cross-subsidies from its existing dominant position. The BRT is particularly concerned by the recent approval of the new or modified products offered by Japan Post Insurance. It is also imperative that Japan Post remains under the jurisdiction of the FSA. The above requests are well within the realm of the GPA. Similarly, the insurance business of cooperative societies (kyosai) should be subject to the same requirements as private sector insurers.
b) Japan Post and private postal delivery operators should be subject to the same customs procedures and formalities. A level playing field for both Japan Post and private postal operators should be ensured in the requirements for dedicated airway bills, obligatory customs, quarantine and security clearance and the funding of these services, as well as in the issuance of parking tickets for delivery vehicle parking infringements.

< Recent progress >
While the issue is being discussed in the FTA/EPA negotiations, the WP A is not aware of any concrete improvements. Furthermore, on issues directly related to Japan Post very little change in either direction has been seen during the last year.

< Background >

Since the Big Bang in the late 1990's, Tokyo has seen its role diminish in the global arena. This is partially due to the very few changes undertaken since that time. The preferential treatment extended to Japan Post and its subsidiaries still exists, and has unfortunately been expanded without private companies having access to the same benefits.

Actions taken so far

(Japan Post Insurance)

Japan Post Insurance (hereinafter referred to as "JPI"), as a life insurance company under the Insurance Business Act, has been subject to the same laws and regulations as other life insurance companies, which ensures the consistency with international obligations such as WTO agreements.

In addition to the Insurance Business Act, etc., the regulations under the Postal Services Privatization Act apply to JPI as "add-on regulations" in the course of privatization.

The application for new products filed by JPI shall be examined on whether it is secured that the applying service will be provided in a sound and efficient manner, etc., in accordance with the provisions of the Insurance Business Act. Moreover, it shall also be examined on whether there is a possibility that the implementation of the business applied for approval will impede the equivalent conditions of competition between JPI and other life insurance companies, and the appropriate provision of the services to users, in accordance with the provisions of the Postal Services Privatization Act.

The application for renewal of education endowment insurance product filed by JPI on September 3rd, 2012, was approved by the Financial Services Agency of Japan (hereinafter referred to as "FSA") and Ministry of Internal Affairs and Communications (hereinafter referred to as "MIC") with conditions to be fulfilled before the provision of the service based on the Postal Services Privatization Act, on November 30th of that year. On January 24th, 2014, it was confirmed by FSA and MIC that the conditions were fulfilled. At the same time, the application was approved by FSA based on the Insurance Business Act. JPI launched the renewed education endowment insurance product on April 2nd, 2014. In addition, the application for consignment sales of Aflac's cancer insurance products filed by JPI on April 16th, was approved on June 27th, based on the Postal Services

Privatization Act and the Insurance Business Act, and JPI has begun to sell the products since July 22nd.
The application for consignment sales of both the Dai-ichi Life's and MetLife's term insurance products filed by JPI on July 1st 2015 was approved based on the Postal Services Privatization Act and the Insurance Business Act on September 30th 2015. JPI has begun to sell the products since November 30th.
In addition, JPI has been listed on the first section of the Tokyo Stock Exchange since November 4th.
The application for the underwriting reinsurance and its ancillary services by JPI dated January 19th, 2016 was approved based on the Postal Services Privatization Act and the Insurance Business Act on March 11th, 2016.
Unlike the other life insurance companies, the government limited the maximum amount of postal life insurance of a single policyholder to 13 million yen under certain conditions based on the Postal Services Privatization Act and Order for Enforcement of the Postal Services Privatization Act. FSA and MIC amended the order to change the maximum amount of postal life insurance from a maximum of 13 million yen to that of 20 million yen, which was entered into force on April 1st, 2016.

(Kyosai)
Kyosai or Japan's Mutual aid funds are mutual assistance organizations among those who have close relationship in certain regions or workplaces. These are the funds organized as a part of broad mutual assistance activities among them, such as joint co-operation project, mutual loaning, and social welfare provision, and by the investment from their own union members.
There are many kinds of mutual aid funds and each of them is organized in accordance with the character of each organization on which the fund is based. Due to the distinct character of each fund, it would be inappropriate to supervise them in the same manner as being done to the private insurance companies. It is also worth noting that the mutual aid funds are managed under the legal control and supervision of the responsible ministries and agencies, which assure the sound management including respective contractor's protection through the screening on the calculating method of the premiums and liability reserves.
(Japan Post and private delivery operators)
BRT's recommendation is not necessarily correct since Japan's services market is extremely open and it is believed that European companies also enjoy

benefits therein.

The international postal services of Japan Post Co., Ltd. are responsible for the exchanging of postal items among the postal operators which are designated by each member country of the Universal Postal Union based on the Universal Postal Convention. On the other hand, the international delivery services of private operators are provided by each operator with its own global-wide network. There is naturally a difference in characteristics between these two services, and therefore, the rules for Japan Post and those for private delivery operators are need not to be the same.
As for customs procedures, international postal items whose assessment value exceeds 200,000 yen have been subject to the self-assessment system since February 16th, 2009 as a result of the revision of the Customs Act in 2007. Currently, general import items are subject to the self-assessment system, and only international postal items with an assessment value of 200,000 yen or less are subject to the official assessment system under which customs officials assess and specify the amount of duty.

Since a recipient does not necessarily know the content of a postal item beforehand, the self-assessment system is necessarily not suitable to postal item. We understand that other countries including the U.S. also apply the official assessment system to, at least, a part of postal items.

Future outlook

(Japan Post Insurance)
The Government of Japan, maintaining the consistency with international agreements such as WTO agreements, will continue to provide appropriate supervision over JPI in the same manner as other life insurance companies, based on legal instruments including the Insurance Business Act and will regulate JPI appropriately under the provisions in such frameworks as the Postal Services Privatization Act, etc.

(Kyosai)
N/A.

(Japan Post and Private delivery operators)
N/A.

10. Freight and logistics（WP-1/#12**/E to J）

BRT Recommendation

1. Further to the WP-A / # 03 / EJ to EJ, the BRT recommends that Japan revises its AEO system to introduce real benefits for operators regardless of whether they are forwarders, customs brokers or importers.
   Furthermore, the administrative load needs to be lessened if companies are to be truly attracted to the AEO status.

The AEO concept should focus more on offering simplifications if the operator meets the agreed criteria for traceability and adheres to the agreed process flow. Examples of this could be:

- Deregulated customs clearance beyond the local customs jurisdiction territories
- Reducing the physical examination of shipments
- Being able to use alternative documentation for showing “direct shipment” under free trade arrangements

< Recent progress >

Japan Customs have announced a plan to deregulate customs clearance beyond the local customs jurisdiction territory by 2017. The BRT looks forward to this change which will be perceived by industry as a significant improvement.

< Background >

The current system of AEO has unfortunately not led to the simplifications that many operators had hoped for. On the contrary, in many cases the administrative burden has increased.

Action taken so far

To further simplify Customs procedure for AEOs, the Government of Japan considers possible measures to improve the situation regarding the specific cases of operators by exchanging opinions and gathering information among the Government of Japan and private sectors.

Future outlook

To further simplify Customs procedure for the AEOs, the Government of Japan will consider possible measures to improve the situation regarding the specific cases of operators by exchanging opinions and gathering information among the Government of Japan and private sectors.

BRT Recommendation

2. The BRT recommends that Japan introduces a comprehensive system of remote filing and at the same time, strengthens alignment of the various customs areas to avoid discrepancies between the regional customs authorities. This would improve the situation not only for European companies, but also for small- and medium-sized Japanese companies,

A long-term solution could be to consolidate the various jurisdictions. A first step would be to consolidate Tokyo and Yokohama, and Osaka and Kobe.

< Recent progress >
This is a new recommendation.

< Background >
Currently Japan has nine separate customs areas and no real central customs authority. This leads to discrepancies between the treatments of imported goods depending on the port of entry. The different interpretations of customs law in addition to different HS code classification create costs for the importer This also makes it difficult for European logistics companies, which lack multiple regional offices in Japan to expand their regional coverage as licensing is per region, i.e. the license given by Tokyo Customs is not valid in Yokohama.

Action taken so far

Japan has centers for uniform interpretation and application of its laws and regulations to ensure that there is no disparity in treatment among regional customs offices.
As for “broadening the choice of customs office for declaration”, the Government of Japan amended the Customs Law and the Customs Brokerage Law to allow AEOs to exceptionally lodge import/export declarations to a customs office other than customs offices where the goods are located, and to repeal restriction on area of service of customs brokers, while maintaining the general rule that import/export declarations need to be lodged to a customs office where the goods are located.

Future outlook

The Government of Japan continues to ensure uniform interpretation and application of its laws and regulations through the centers. In addition, the Government of Japan intends to take necessary steps for implementation of “broadening the choice of customs office for declaration” by FY 2017.

11. Promoting foreign direct investment（WP-1/# 13*/E to J）

BRT Recommendation

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 BRT furthermore would like to point out the disadvantageous rules for Net Operation Loss (NOL). With the upcoming changes, companies in Japan will be able to carry forward 50% (from 2017) of their losses for ten years. This is well behind the NOL in neighbouring countries, countries with which Japan competes for investments.
In addition, Japanese rules on inheritance tax make foreigners liable for inheritance tax covering all global assets from day one of registration as a resident in Japan. This differs from the application of both global income taxation, which applies only after five years, and the recently introduced exit tax which will only apply to persons with either permanent residence visas or spouse visa. This will serve as a disincentive to foreign direct investments. 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 automotive 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.

< Recent progress >
While Japan has established incentive programmes for FDI, they are often

limited in scope and application procedures are very inflexible. There are also some indications that Japan is contemplating shortening of the period.

< Background >
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. Even with the reorganisation of JETRO and the efforts starting with former Prime Minister Koizumi to increase FDI to Japan, only very small improvements have been seen. According to OECD in 2013 inward FDI stocks was accounted for only 3.5 % of GDP.

Action taken so far

Regarding the disadvantageous rules for Net Operation Loss (NOL), in Tax Reform 2015 and 2016, the introduction of the tax deferral system allowing for the carrying-over of the loss by a large company is limited to the 50% of the income of the company, which will be applied from the fiscal year 2018. This reform was made to give an incentive for the companies to improve profits without the implementation of the limitation regarding the tax deferral system.
Regarding the small and medium sized companies, consisting large majority of the companies in Japan, they can be allowed to deduct up to 100% of the income to the extent that the limitation on tax deferral does not apply to them.
Regarding the rule on the inheritance tax, it is decided that in the case of inheritance between foreign nationals with temporary resident status, Japanese inheritance tax will not be imposed on their foreign assets, corresponding to the increase of foreign nationals working in Japan due to economic globalization.
Regarding the regulatory reform on the financial and medical fields in general, measures for the regulatory reform to be taken in the medical fields and financial services fields has been mentioned in the Implementation Plan for Regulatory Reform, which is authorized by the Cabinet on June 2nd, 2016.

Future outlook

Regarding the rules or the inheritance tax, tax reform bill which includes the revision of the tax obligation on inheritance tax will be submitted to the 193th Diet Session (2017.

The Government of Japan will take steps for the regulatory reforms in the medical field and financial services field in general based on the aforementioned Implementation Plan for Regulatory Reform decided by the Cabinet on June 2nd, 2016.

12. Procurement (WP-1/#14**/E to J)

BRT Recommendation

< General Recommendations >

The Government of Japan should increase its efforts to facilitate better access to the procurement market in Japan. This could be achieved by lowering the threshold for public tenders and better defining or removing the “operational safety clause” within the transport sector. Japan should also include more cities in the GPA as currently only nineteen are included.

Japan should, furthermore, make more information available in English. The BRT is aware of the recent initiatives by JETRO, but complete information is rarely available in English. In addition the BRT requests that the use of English when submitting tender proposals to allowed or at least partially allowed, especially for the technical specifications.

In addition the BRT asks that Japan streamlines the requirements on pre-registration and also recognises overseas experience and qualifications when setting up requirements for the bidders.

< Specific Recommendations >

- In the bidding process in public tenders for helicopters>

  a. More balanced competition should be ensured by comprehensive evaluation systems that also take aircraft performance into account.

  b. Single year budget procurement constraints should be relaxed.

- Procurement of integrated systems of space ground equipment should be encouraged.

- The share of open tendering as a means for procurement by the Japanese utilities should be increased substantially.

- The recent changes to the Operation Safety Clause should indeed lead to more open calls for tenders in accordance with the WTO agreement on government procurement.

< Recent progress >

The BRT has seen some changes in particular for the three JR Honshu companies and is therefore looking forward to see what impact the changes in the OSC will have.

< Background >

Studies have shown that over 80% of the total procurement market in Japan is not covered by the GPA.[1] Currently some sectors are exempted from the threshold of 5 million SDR. Some changes have been seen, such as the establishment of a national data base on calls for tenders, and the first ever open call for tender in the railway sector. However, significant improvements are required to bring Japanese procurement closer to the levels of the EU.

Actions taken so far

(Operational safety clause)

In the view of the Government of Japan, the "operational safety clause" of the WTO Agreement on Government Procurement applies to the following five categories. Furthermore, since October 28th, 2014, the Government of Japan has taken measures to increase transparency of the scope of the operational safety clause by identifying it, based on the result of talks with the EU.

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

The fifth Japan-EU Railway Industrial Dialogue was held in Brussels in May 2016, with the participation of railway operators and suppliers from Japan and the EU, with a view to further deepening the mutual understandings between Japan and the EU.

(English information and streamlined requirements for pre-registration)

As the voluntary measures on government procurement, which are applied only

1 Copenhagen Economics, *"Assessment of barriers to trade and investment between the EU and Japan"*, 2009

to Central Government Entities and Other Entities, stipulating non-discriminate, fair and transparent procurement procedures in addition to the GPA rules, with a view to increasing access opportunities for foreign suppliers, each notice of intended procurement includes such information in English as contact point for the notice, qualification for participating in the tendering procedures, fulfilment place and fulfilment restrictions. In order to streamline the requirements for pre-registration, the Government of Japan has taken measures for the implementation of the unified qualification procedures in terms of central-government entities.

Furthermore, the statement, referred to in the above < Background >, “Studies have shown that over 80% of the total procurement market in Japan is not covered by the GPA.”, is not officially recognized by the Government of Japan.

Future outlook

The Government of Japan will continue to discuss areas of government procurement, making use of various platforms.

Working Party 2: Life Sciences and Biotechnologies, Healthcare and Well-being

1. Implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing under coordination with industries (WP-2/# 01**/EJ to EJ)

BRT Recommendation

EU-Japan BRT members fully support the objectives of the Convention on Biological Diversity (CBD) and of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their Utilization.
The European Parliament and the Council adopted the Regulation (EU) No 511/2014 on 16 April 2014 as a compliance measure for users under the Nagoya Protocol. Although the Regulation entered into force on 9 June 2014 and all of its provisions have been applied since 12 October 2015, there are still unclear issues regarding implementation. The BRT members call for detailed and clear guidance on the scope of the regulation under full coordination with industries.
The Japanese government is proceeding to develop domestic measures towards ratification of the Nagoya Protocol. The BRT members call for open discussion to set up a framework to implement the measures with sufficient coordination with industries.

<Yearly status report>
Some progress in our recommendation in 2015 has been seen. Namely, the requirement to make a due diligence declaration at the time of market launch in the EU for products developed outside the EU via utilizing genetic resources has been removed. The Japanese government has not ratified the Nagoya protocol and is carefully preparing domestic measures for its implementation.
<Background>
The Nagoya Protocol was adopted at the 10th Conference of the Parties to the CBD (COP10) in 2010 and went into force on October 12, 2014. It is an international agreement, which aims at sharing the benefits arising from the utilization of genetic resources in a fair and equitable way. However, it has the possibility to influence a wide range of industries, such as the pharmaceutical, plant-breeding, seeds and horticulture, animal-breeding, food and beverage,

biotechnology, cosmetic, bio-control and other industries, which are utilizing genetic resources. EU-Japan BRT members are concerned that implementation of the Nagoya Protocol presents many challenges and areas of uncertainty.

We are especially concerned about the structural problem, namely the obscure scope of the Protocol based on the ambiguous definitions of some terms, such as "genetic resource" and "utilization of genetic resources". Therefore, providing countries of genetic resources may unilaterally and separately take measures for access to genetic resources and benefit-sharing. This may impose an excessive burden on the users of genetic resources, such as companies in the EU and Japan, to fulfil different access requirements in each country.
Furthermore, the users would be required to comply with the legislations of the resource providing countries, even though the contents of the legislation might be overly favourable to the provider's side. We are concerned about compliance measures for users from the EU or Japan that may impose unreasonable burden on the users of genetic resources because the terms of "research and development", related to "utilization of genetic resources", are not clearly defined in the Nagoya Protocol. This may increase the legal instability and may widely impede or delay the R&D activities of utilizing genetic resources.

In addition, we are concerned that the benefit-sharing may be required for the genetic resources accessed before entry into force of the CBD or the Nagoya Protocol, because the negotiations of Article 10 of the Nagoya Protocol are underway and there are opinions claiming that the obligation of benefit-sharing should be retroactively applied for the genetic resources which were accessed before the CBD entered into force.

The European Parliament and the Council adopted the Regulation (EU) No 511/2014 on 16 April 2014 as a compliance measure for users under the Nagoya Protocol. It entered into force on 9 June 2014 and all of its provisions have been applied since 12 October 2015. At present, each EU member state is developing domestic measures for implementation of the Regulation, and the European Commission is preparing guidance on the scope of the Regulation, as well as guidance on the utilization of genetic resources in several industry sectors.

The Japanese government has not ratified the Nagoya protocol yet and is

internally preparing domestic measures for ratification and implementation of the Nagoya Protocol. EU-Japan BRT members are concerned that unreasonable financial and operational burdens may increase in relation to access to genetic resources and in implementation of the compliance measures, unless the problematic issues such as the obscure scope of the Protocol and of the compliance measures are resolved.

Furthermore, we have another concern that it may widen the gap in terms of the business competitiveness against the United States, which is not a Party of the CBD.

Actions taken so far

The Government of Japan signed the Nagoya Protocol in May 2011. Since the utilization of genetic resources relates to a wide range of business and research activities, domestic measures necessary for Japan to conclude the Protocol have been considered by relevant ministries in the Government, taking into account the opinions from various stakeholders including the private sector.

Future outlook

The Government of Japan aims to conclude the Nagoya Protocol at the earliest possible time by furthering the consideration by its relevant ministries on domestic measures necessary for concluding the Protocol, taking into account the opinions from various stakeholders.

2. MRA of GMP for Pharmaceuticals (WP-2/# 02*/EJ to EJ)

BRT Recommendation

Further extension of the “Mutual Recognition Agreement” (MRA) of GMP should be proceeded in order to avoid redundant inspections of manufacturing facilities. In addition to oral dosage forms, API, Sterile and Biotechnology products are being requested to apply to the MRA. Full support is requested to expand the MRA of GMP to liquids, sterile forms and API, as well as biotech products in order to avoid redundant inspections and testing.

<Yearly Status Report>
Japan’s application was approved in May 2014 and Japan officially joined PIC/S on July 1st 2014. As the guideline enforces the harmonization of the inspections among PIC/S countries, this issue might be advanced by starting negotiations between both governments.

<Background>
In March 2012, MHLW applied for PIC/S and the practical inspection by the global team was completed. However, as currently only oral solid dosage forms are included within the MRA between Japan and the EU, there are still a lot of redundant inspections of manufacturing facilities. This is not only a costly process but it also slows down the launching of new drugs in Japan, creating a significant disadvantage for Japanese patients. In order to eliminate this problem and integrate the EU and Japan economies more efficiently, harmonization of standards / guidelines and expansion of MRA should be conducted under mutual agreements. Below-mentioned are highly prioritized items for harmonization. Also, the MRA issue is one of the items of the EPA negotiation between EU and Japan.

<Other prioritized items for harmonization and MRA>
- *Safety measures from surveillance to vigilance should be harmonized with international standards.*
- *Clinical development guidelines and biological preparation standards for vaccine.*
- *Minimum requirements for biological products.*

Actions taken so far

MHLW and the Pharmaceutical and Medical Device Agency(PMDA) confirmed the equivalence of GMP requirements and their implementation by competent authorities of the EU Member States. Based on that confirmation, Diplomatic Notes were exchanged on April 22nd, 2016 to amend the Sectoral Annex on GMP for medicinal products of the Japan-EU Mutual Recognition Agreement.. With this amendment, the coverage of the Sectoral Annex was expanded to the all EU Member States.
In addition to the expansion of the Member States, MHLW and PMDA, along with the EU's authority, European Medicine Agency, have been conducting technical and scientific consideration for expanding product coverage of the Sectoral Annex.

Future outlook

The Government of Japan will continue dialogues with the EU side for the expansion of the product coverage of the Sectoral Annex, with a view to finalising it at the earliest possible time.

3. Mutual recognition of quality management audit results for medical devices between EU and Japan (WP-2/#03*/EJ to EJ)

BRT Recommendation

The EU and Japanese governments should establish a mutual recognition scheme for Quality Management System (QMS) audit results. In June 2015, the Japanese government announced it would officially join the Medical Device Single Audit Program Pilot (MDSAP) to share QMS audit results between United States, Canada, Australia and Brazil. improvement in efficiency and reduction of workloads for both authorities and the industry are expected. We call for a similar regulatory harmonisation approach between the EU and Japan for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical and Medical Device Act (J-PMD Act).

As a result of the implementation of the J-PMD Act in November 2014, the ISO13485 audit report is accepted for the QMS process in Japan. However, the Japanese original requirement still remains. For a real regulatory harmonization, submission related formats / standards also need to be harmonized. We would like to request a clear direction towards a product-based and rationalized annual audit.

The EU side requests a complete harmonization by eliminating Japan's deviations on top of ISO13485. As a next step, mutual recognition of medical device products for lower risk classes should be introduced as soon as possible. Further improvements are desirable when introducing a new ISO revision. If the ISO revision differs per country (for example: ISO 60601 rev2 and rev3), the workload for manufacturers is very heavy. Therefore, the introduction schedule of new ISO standards should be harmonized, including a grace period. The EU side would also like to suggest the necessity of disseminating information on QMS ministerial ordinances in English, for the purpose of MDSAP rationalization of investigation pursuant to Chapter 3, Production and Marketing.

<Yearly Status Report>

Under the Japanese Pharmaceutical and Medical Device Act enforced in November 2014, QMS of medical devices in Japan has proceeded to be aligned

to international standards. In addition, Japan announced it would join MDSAP to ensure its internationalization. Good progress has been seen for this recommendation after the J-PMD Act was implemented in November 2014.

<Background>
In June 2015, the Japanese government announced it would officially join MDSAP.
MDSAP is an international cooperation programme for quality assurance of medical devices by the United States, Canada, Australia and Brazil as members, established in January 2014. Regulatory authorities of the member countries cooperatively evaluate QMS audit agencies and share audit results among member countries. Medical device companies normally have to get a QMS audit in each country. However, under MDSAP a single QMS audit results will be valid among member countries. This programme will reduce the burdens on both companies and authorities. Although there are issues to be solved to implement this programme, distribution of medical devices will be stimulated between the member countries of MDSAP. Similar scheme between the EU and Japan should be considered.

Based on the Medical Devices Directive (MDD) of the EU and the J-PMD Act, QMS audit results are required for each application for a license to introduce new medical devices into the market. In Europe, the regular annual ISO audit results can be used for all applications during the period in which the ISO audit is valid. Although Japan has started to accept QMS audit results at a specific manufacturing site for products with the same generic name under certain conditions, a number of RCBs still require submitting QMS audit results for each application. Further alignment is necessary.

Actions taken so far

With the implementation of the revised Pharmaceutical Affairs Act on November 25th, 2014, MHLW harmonised the Japanese QMS standard for medical devices with the international standard (ISO13485), which was adopted by the EU.
With this revision of the Pharmaceutical Affairs Act, foreign manufacturers are now under the registration system, instead of the accreditation system. In addition, the scope of manufacturing sites to be registered was also revised.

Furthermore, MHLW and PMDA have been promoting MDSAP , which is an international collaboration project on QMS reports, and, working toward the reduction of the manufacturers' burden by sharing the QMS reports made by the audit bodies which are recognized among all participating counties.

Future outlook

The global harmonisation of QMS regulations needs to be discussed in order to achieve the mutual recognition of QMS audit. The Government of Japan will move forward with the global harmonisation of QMS regulations through the activities such as in the International Medical Device Regulators Forum (IMDRF) together not only with the EU but also with the U.S. and others.

4. Mutual recognition of medical devices product licenses (WP-2/#4*/EJ to EJ)

BRT Recommendation

Mutual recognition of medical device product licenses between the EU and Japan should be introduced. Regulations of low risk class II devices are similar in the EU and Japan. Therefore, mutual recognition of this category of products may be realized earlier. After a basic agreement on the Trans Pacific Partnership (TPP), the Japanese government is revising the law proceeding convergence of approval conditions of medical devices. A similar approach is needed between the EU and Japan. PMDA and MHLW should introduce mutual recognition of medical device product licenses with low risk of class II devices by taking the difference of classification of medical devices between Japan and the EU into account. By harmonizing QMS and classification it should be possible to introduce new products within the same time frame and in one process. It is desirable that this issue is solved quickly.

The EU will pursue MDR, but not enough information is communicated to Japan. We would like to suggest that the EU communicates with the Japanese government about the new MDR implementation.

<Yearly Status Report>
No progress / no dialogue has been seen. However, there have been some improvements through the implementation of the Pharmaceutical and Medical Device Act, which makes Japan accept the audit report ISO13485 issued by the countries. The PMDA's performance has been improved to shorten approval times for medical devices. ISO14155 has been accepted but we request further improvement.
Based on the Pharmaceutical and Medical Device Act, some Class II and Class III products will move to "Ninsho" application. As a result, there has been no progress on "mutual recognition" discussions, but improvement on the speed of approvals for medical devices has been seen.

<Background>
Mutual recognition of licenses for medical devices in Japan and the EU would make it possible to introduce new products in both the Japanese and European

markets within the same timeframe and with one process.

The Japanese government is preparing the amendment of the Pharmaceutical and Medical Device Act in response to the TTP agreement. The proposed amendment says companies in TTP countries can use certified Notified Bodies in any TTP country in order to obtain Ninsho approval, which will be valid to distribute approved Medical Devices in Japan. This can be one step for mutual recognition but it would negatively impact on the distribution of Medical Devices between the EU and Japan.

As mentioned before, it could be possible to start with lower risk devices.

The evaluation scheme between the Medical Devices Directive of the EU and J-PMD Act are quite similar, with

- Evaluation schemes based on registered 3rd party bodies (Notified Bodies)
- Essentially quite similar requirements
- Based on ISO/IEC or JIS standard compliance

With these similarities, mutual recognition should be easy to implement.

Action taken so far

With regard to the establishment of Certification Standards or Standards for Quality Management Systems, Japan basically accepts the international standards of the ISO and the IEC.
In order to conclude the Trans Pacific Partnership (TPP), Japan made a decision to start a process to amend the Pharmaceutical and Medical Device Act, which would make it clear the equal treatment of domestic and foreign certification bodies under the Act is ensured.

Future outlook

The global harmonization of medical device regulations needs to be discussed.
The Government of Japan will work toward the global harmonization of medical device regulations through activities such as in the IMDRF (International Medical

Device Regulators Forum together not only with the EU but also with the U.S. and others).

5. Mutual recognition of clinical trial results for medical devices (WP-2/# 05*/EJ to EJ)

BRT Recommendation

Mutual recognition of clinical trial results for the development of new medical devices should be accelerated. At present, the standards of clinical trials in the United States, EU and Japan are seen to be almost equivalent and there are several cases where clinical trial results are mutually recognized between EU and Japan. EU Japan BRT members request to both governments in the EU and Japan to accelerate mutual recognition of clinical trial results by increasing such cases and showing clinical trial conductors implementing guidelines.

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

Foreign clinical trial data have been accepted as a part of the 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. The Japanese government encourages active use of consultation service on individual medical device applications in advance provided by the Pharmaceuticals and Medical Devices Agency (PMDA) to address the use of foreign clinical trial data for the application of a device.

At present, clinical data are often accepted because the standards of clinical trials in the United States or the EU are seen to be equivalent or sometimes more sophisticated than those required by the Japanese medical device GCP. However, then additional data are required with unclear reasons.

Japan GCP (J-GCP) has been harmonized with ISO14155, but the EU side requests Japan to improve the actual operation of J-GCP. The clinical trials performed in EU countries according to ISO 14155 should be easily accepted and if not accepted, an explanation with a scientific background is a must. In addition, the Japanese government should prepare a clear definition for accepting/preparing clinical trial reports.

While the harmonization between GCP and ISO14155 for medical devices in Japan has made progress, we hope for early disclosure of a clear guidance for judgment on the need for clinical studies, conditions for acceptance, etc. in order

to make the actual operation of GCP smoother. Regarding the guidance for the preparation of the Clinical Evaluation Report, we request the Japanese Government to issue the guidance as early as possible.
We expect that the standard for deciding whether clinical trials are necessary or not will be clearly established. The Government should publish guidelines for creating clinical evaluation reports as soon as possible.

<Yearly Status Report>
A certain level of progress has been seen for this recommendation. We expect that the Japanese Government will publish guidelines for creating clinical evaluation reports as soon as possible.

<Background>
For the new medical device applications in Japan, the clinical trial results acquired in the EU could not be accepted so far. However, several cases can be seen where the Japanese medical device companies submit new medical device applications with clinical trial results in the EU and obtain regulatory approval in Japan. Also, there are some cases reported where the clinical trial results acquired in Japan are applied to the new medical device applications in the EU. However, environmental improvement such as showing regulatory authorities in the EU and Japan an implementing guideline in order to lessen the burden of development costs and to ensure patient access to the innovative new medical devices is very limited today.

With regards to the procedure between the United States and Japan, mutual recognition of clinical trial results is already being practiced under the clinical trials by comprehensive and simultaneous processes, such as "Harmonization By Doing (HBD)" by both regulatory authorities in the United States and Japan.

Differences in the definition of GCP between Japan and the EU currently prevents the use of non-Japanese clinical trial results in the application for new medical devices in Japan. Mutual recognition of clinical trial results would make it possible to make new products available to patients in Japan and the EU within the same timeframe and through one process, ensuring a high level of quality while reducing the burden on manufacturers. Early disclosure of clinical trial-related guidance will promote the entry of overseas companies to the

Japanese market.

Action taken so far

As pointed out above, foreign clinical trial data has been accepted as a part of application dossier when: i) standards for conducting clinical trials of medical device 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 the equivalent level of quality.
Furthermore, MHLW is working on establishing a guidance regarding clinical trials of medical devices by facilitating basic understanding concerning the number of clinical cases required and the necessity of the clinical trials.

Future outlook

For the use of foreign clinical trial data in individual medical device applications, Japan encourages active use of the consultation service provided by the Pharmaceuticals and Medical Devices Agency (PMDA) in advance of their respective applications.

6. Shortening review times of plant protection & biotechnology products (WP-2/ # 06*/EJ to EJ)

BRT Recommendation

Shorten review times for authorization to place novel plant protection products in the market and approval of importation of commodities treated with novel plant protection products and/or derived from biotechnology by the harmonization of safety dossier and risk assessment as well as streamlining the review process.

Possible area for improvement to shorten times might be:

- Further harmonization of the dossier on human safety and acceptance of summaries in English.
- Opportunistic use of the evaluation results from foreign countries in order to reduce the resource burden in authorities.
- MAFF, MHLW and FSC should start harmonization to shorten review times. Realization of parallel review for human dietary risk assessment within competent authorities, which is currently undertaken in a sequential manner, MAFF => MHLW => FSC => MHLW => MAFF.
- Association and synchronization of review for domestic registration with that for import MRLs.

<Yearly Status Report>
Some progress has been seen in the introduction and harmonization of safety dossiers (J-MAFF) and in the revision on the application timing for import MRLs (J-MHLW).

<Background>
Delivering novel and safe plant protection products and seeds has utmost importance for the plant protection & biotechnology companies in order to meet the needs of the growing world population requiring high quality foods and feeds. While R&D-intensive companies are continuously and heavily investing in research & development of technologies, the innovation will not contribute to the food production without governmental approval. Therefore, early market access of novel plant protection products is crucially important not only for R&D

companies but also for farmers who have to be competitive on their agricultural production, as well as consumers whose living is dependent on the sustainability of food production. The delay of market access of novel products will cause technology gaps resulting in unnecessary disadvantage to farmers due to the limited access to innovative products which are safer and more effective. In addition, the delay of review for import approval on agricultural commodities, including the establishment of import MRLs, may limit the access to innovative technology in exporting markets due to trade barriers in the importing countries.

Though Japanese ministries have taken measures to shorten review times of human safety studies of plant protection products and some further measures like the harmonization of dossier format for registration application with the OECD dossier format (J-MAFF) and the revision of the guideline for import tolerance application (J-MHLW), the time-to-approval is still lagging behind other countries, e.g. the US and Canada. This kind of technology gap should be avoided to give competitiveness in food production.

Actions taken so far

MAFF, MHLW and FSC started parallel review to shorten the review times for new applications/product registrations in plant protection.
In Japan, genetically modified plants are required to be evaluated scientifically on their food safety, feed safety and biosafety before the authorization of use, in accordance with the following three Acts; Food Sanitation Act, Feed Safety Act and Act on the Conservation and Sustainable Use of Biological Diversity through Regulations on the Use of Living Modified Organisms ("Cartagena Act") respectively.
Streamlining of the review process regarding biosafety is already undertaking.

Future outlook

Regarding biosafety of genetically modified plants, MAFF will continuously conduct consistent environmental risk assessment of Genetically Modified crops, in accordance with the Standard Operating Procedures Regarding Environmental Risk Assessment and Management of Genetically Modified

Plants Based on the Cartagena Act.
(http://www.maff.go.jp/j/syouan/nouan/carta/about/sop_eng.html)

7. Acceleration and dissemination of scientific knowledge on GMOs by both the governments and the private sector (WP-2/# 07*/EJ to EJ)

BRT Recommendation

The governments and the private sector should implement concrete actions in order to increase public awareness and societal acceptance on the benefit and contribution of Plant Protection & Biotechnology to the sustainable supply of safety foods.

To achieve these objectives the Japanese and European biotechnology and bio-industry associations should work closely with other sectorial organisations and their respective authorities.

<Yearly Status Report>
No progress has been seen for this recommendation.

<Background>
While plant protection and biotechnology significantly contribute to the sustainable food production for an ever growing population, the contribution of new technologies has never been well recognized. Moreover, the benefit of improved quality traits on imported seeds has not been fully addressed. Considering the possible limitation of future access on foods and feeds as a consequence of limited arable land and global competition on limited foods, new technologies bringing higher productivity are required.

It is necessary to increase the societal acceptance of GMO as an option to increase and sustain the agricultural productivity in the world through awareness-building on the benefit of this technology to better life.

Actions taken so far

The Government of Japan has worked forward with the harmonization of GMO regulation at OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology. Moreover, the Government of Japan has conducted activities, such as science communication by officials and researchers, to inform

consumers and consumer organizations about plant biotechnology including its benefits and contributions.

Future outlook

The Government of Japan will continue conducting the harmonization of GMO regulation and the activities to inform about biotechnology including its benefits and contribution.

8. Mutual recognition of GMP and marketing authorization for animal health products (WP-2/#08*/EJ to EJ)

BRT Recommendation

With regard to the mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products, MAFF and the European agency should accept GMP certification of the other party where the GMP requirements are similar or equivalent.

<Yearly Status Report>

MAFF revised regulations to issue accreditation licenses written in both Japanese and English on 25 December 2014. This change accommodated a request from JVPA. However, there is no example of mutual recognition at product level as of December 2015.

<Background>

Overseas production facilities that are involved in manufacturing veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative work. An EU-Japan Economic Partnership Agreement should aim for mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines where the GMP requirements are similar or equivalent.

Actions taken so far

Veterinary Medicinal Products (VMP) that are approved and distributed in Japan must comply with the GMP provided by the Japanese competent authority to ensure that those products are consistently produced and controlled under the quality standards appropriate to their intended use. However, the requirements of Japanese GMP similar to and are not more stringent than those of EU, and we are confident that the absence of mutual recognition scheme on GMP does not create an obstacle in acquiring Japanese approval for VMPs which have already been approved in the EU.

Therefore, the comment of paragraph 2 of “background” is not necessarily correct.

Future outlook

Japan recognizes that mutual recognition for human medicine and VMPs has never been implemented among major countries including the EU. Although it is possible to share technical data on VMPs, it is not practical to standardize evaluations of technical data, due to the differences in the biological characteristics of pathogenic microorganisms, antimicrobial susceptibilities, and situation, in livestock production. The Government of Japan requests EU businesses to make a concrete proposal on this issue if the EU has reasonable and feasible methods to standardize evaluations of technical dossiers.

9. The revision of the rules for the pricing and prescription of innovative new drugs (WP-2/#12**/EJ to J)

(1) Full-fledged implementation of the new drug pricing system

BRT Recommendation

The premium for new drug creation and elimination of unapproved / off-label use drugs will be continued until March 2018. This is welcome as it supports incentives for innovative drug development, however, it is only the continuation of a trial scheme. The Japanese government should finalize the implementation of the new, internationally competitive drug pricing system in Japan based on the industry proposal, since in addition to innovation rewards it is also protecting public health. Furthermore, it adds an element of predictability and stability so that the industry can adequately plan, forecast product requirements and effectively manages inventory as well as the distribution of products across Japan.

<Yearly Status Report>

Although the "new" drug pricing system will be continued until March 2018, it is only the continuation of a trial scheme. No practical progress has been seen for this recommendation.

<Background>

The National Health Insurance (NHI) price reform proposed by the industry has been positively reviewed by the Central Social Insurance Medical Council (Chuikyo) in December 2009 and the government decided to start a pilot implementation in April 2010. This represented a significant improvement, as it provides price stability for innovative drugs and was seen as a positive signal that the Japanese government is willing to reward innovation in the medical field. The premium for new drugs will be continued until 2018. As a compensation for this new scheme, the government will attach a system that fosters the registration of "unapproved/off-label use drugs". Companies have received requests on development of many unapproved/off-label use drugs and proceeded with those constructively. Furthermore, on several occasions companies have received additional requests on development of hundreds more unapproved/off label use drugs.

However, in the FY2016 drug pricing system reform, Chuikyo concluded to postpone full-fledged implementation of the premium for new drug creation to FY2018 revision, even though the industry strongly requested this. The conclusion brings the industry deep concerns about sustainability for evaluation of innovations. The Japanese government should implement the new premium system for innovative new drugs at the FY2018 drug pricing system revision to evaluate the companies' efforts for elimination of the so-called drug lag in Japan and research and development of innovative new drugs.

Actions taken so far

It was decided in the FY2016 drug pricing system reform that the premium for new drug creation and elimination of unapproved / off-label use drug (the premium for new drug creation) will continue.
The modality of the premium for new drug creation will continue to be considered in the *Chuikyo* by reviewing the progress of unapproved/off-label use drugs development and the results of R&D for new drug creation.

Future outlook

The drug pricing system will be reviewed and discussed continuously in the *Chuikyo*, taking into account the industry's opinions.

(2) Abolishment of the market expansion re-pricing

BRT Recommendation

The re-pricing system rule by market expansion can adversely affect innovation in Japan and therefore, should be abolished.

<Yearly Status Report>
The situation has deteriorated, with a proposed revision of the re-pricing rule targeting "huge selling" drugs with price cuts of up to 50%.

<Background>
The abolition of the market expansion re-pricing was not accepted by Chuikyo even though industries strongly requested the elimination of the system. While the agenda for the 2016 NHI pricing discussion between Chuikyo and the industry included topics such as "NHI pricing for long-listed products" and "continuation vs. discontinuation of incentives for innovative drug development", it did not include "abolition of market expansion re-pricing". Furthermore, the government additionally introduced a new extra (huge sales) market expansion re-pricing at FY2016 revision. Therefore, we urge to discuss this topic to abolish both re-pricing rules by market expansion in the next pricing system reform in 2018, which is contrary to the policy of evaluating pharmaceutical innovation.

Actions taken so far

The market expansion re-pricing is a scheme to reduce new drug prices based on the ratio of their sales expansion when their premise on pricing changes, for example when their actual sales far exceeded their original estimations. In the drug pricing system reform in FY2016, a special provision was introduced for drugs, the market size of which is extremely large. With the extremely limited resources for financing healthcare and insurance systems, these schemes, which reconcile for both promoting innovations and ensuring the sustainability of the NHI, function as an appropriate apportion mechanism for pharmaceutical expenditures under the public health insurance system.

Future outlook

The drug pricing system will be reviewed and discussed continuously in the *Chuikyo*, taking into account the industry's opinions.

(3) Abolishment of the 14-day prescription rule

BRT Recommendation

EU-Japan BRT members call on the Japanese government to abolish the 14-day prescription rule for all new drugs in line with the recommendation of the government's Regulatory Reform Council in 2015.

<Yearly Status Repot>
No major progress has been seen for this recommendation.

<Background>
Despite the government's policies to promote new drug development, patient access to innovative drugs is hindered by the 14-day prescription rule, which restricts the prescription length to a maximum of 14 days for all new drugs in the first year after their launch. This practically means a delay of one year in patient access to drugs which are already in extensive use abroad. The safety of new drugs in Japan is now underpinned by the post-marketing surveillance system, and by the introduction of a Risk Management Plan (RMP) in 2013. Accordingly, EU-Japan BRT members call on the Japanese government to revise the prescription length for all new drugs.

Actions taken so far

As a result of the review by the *Chuikyo* in FY2015, the Government of Japan has decided to continue the 14-day prescription restriction on new drugs in order to ensure their safety.

Future outlook

The rule regarding the prescription of drugs will be reviewed, taking into account stakeholders' opinions.

(4) Sufficient discussion with stakeholders on introduction of HTA for the drug pricing system

BRT Recommendation

EU-Japan BRT members urge the Japanese government to sufficiently discuss with all stakeholders the introduction of HTA for the drug pricing system in Japan.

<Yearly Status Report>
No major progress has been seen for this recommendation.

<Background>
The methods of HTA for drugs and medical devices have been discussed in Chuikyo. The government decided implementation of HTA evaluation for certain approved products as a trial basis since April 2016. And also Chuikyo intends to ask companies to submit HTA results on new drugs at the time of reimbursement price applications in future. We strongly ask the Japanese government to sufficiently discuss the process of making appropriate framework with the industry, academia, patients and all stakeholders. We have seen that some countries have caused the limited patients access to innovative new drugs.
Furthermore, HTA may hinder the companies' willingness to conduct research and development activities for the innovative new drugs in the country. The Japanese government should consider these possible risks and discuss with all stakeholders so that HTA may not hinder the patient access to the innovative treatments and the improvement of public health.

Actions taken so far

From FY2016, the health technology assessment (HTA) has been introduced for innovative 13 drugs and devices.

Future outlook

The Government of Japan will introduce HTA on a trial basis for the selected 13 drugs and devices through data submission by companies and review by a third party, the result of which will be put into the overall appraisal for price adjustment

in FY2018.

(5) Maintain biennial drug price revision and appropriately reflect the increase of consumption tax ratio into the NHI prices

BRT Recommendation

A) Maintain biennial price revision

EU and Japan BRT members strongly believe that the R&D-based pharmaceutical industry is a leading industry of the Japanese economy. From the viewpoint of Japan being an innovation leader, annual NHI price revision for pharmaceutical and medical device products would be inconsistent with the government's growth strategy, and would damage the companies' competitiveness. EU and Japan BRT members strongly request to the Japanese government that comprehensive discussions, including the viewpoint of evaluation and support for new drug discovery and further growth of the industry should be initiated.

B) Reflect appropriately the increase of consumption tax into the price

Also, following the medical service fee revision in 2016, there will be an irregular price revision for pharmaceuticals in April 2017 due to increase of the consumption tax ratio in Japan. This price revision in April 2017 should not be based on the actual market price from a price survey, but only on the increase of the consumption tax ratio. That is, adding a certain percentage on to the reimbursement prices, which is the same procedure as in the price revision in 1989, is the preferable option.

<Yearly Status Report>

This is a new recommendation.

<Background>

The R&D-based pharmaceutical industry is anticipated to contribute to the growth of the Japanese economy as an innovation leader. Several promotion policies, focusing on the development of the pharmaceutical industry are included in the "Japan Revitalization Strategy" and "Healthcare Policy" documents, announced by the government last year. On the other hand, the new introduction of annual price revisions for pharmaceutical products and medical devices as a medical expenditure containment policy have been discussed in

the government's councils, such as the Council on Economic and Fiscal Policy, chaired by the Prime Minister of Japan.

Current rules for NHI price revision are developed with biennial medical service fee revision. Therefore, it is highly inappropriate to discuss only the "frequency" of the price revision for only pharmaceutical and medical device products, without consideration about consistency with medical service fee or other NHI pricing rules.
Significant difficulty in annual price revision is anticipated due to the following reasons, i) market price survey for drugs is not feasible in such a short period, ii) the accuracy is not secured if the market price survey is conducted in a short period, and iii) annual price revision hinder companies' incentive for the investment in innovative products. Also, from the distribution point of view, significant disorders will occur in the market such as re-writing price data in the system of hospitals or wholesalers due to annual price revision for pharmaceutical and medical device products. EU and Japan BRT members have concerns that this unbalanced medical expenditure containment policy by the Japanese government could damage industry's competitiveness and growth capability.

As for the consumption tax ratio, it will be raised in April 2017. From the viewpoint that this price revision is clearly different from the regular biennial price revision, the price revision in April 2017 should not be based on the actual market price from a price survey, but on only the increase of the consumption tax ratio.

Actions taken so far

A) Regarding the drug price revision, which has been basically conducted every 2 years, the Government of Japan recognizes that there are some challenges concerning incentives to create innovative new drugs, and drug distribution.
B) Since the increase of the consumption tax rate has been postponed, there are no plans for drug price revision in April 2017 coincided with the increase of the consumption tax rate.

Future outlook

A) In accordance with “Basic Policy 2015,” the Government of Japan will discuss the drug price revision including its frequency based on the past record of the revision until FY2018 in consideration of the above-mentioned challenges as well as effects on the medical service fee.
B) As necessary, the price drug revision due to increase of the consumption tax rate will be discussed in the *Chuikyo*, considering the industry’s opinions.

10. Appropriate assessment of innovative values of medical devices in prices (WP-2/#13**/EJ to J)

1. Sub-dividing the current functional classification

BRT Recommendation

Promote sub-dividing of the current functional classification in the special treatment material system in order to accelerate appropriate evaluation of the innovativeness.

<Yearly Status Report>
No major progress has been seen in 2015 for this recommendation.

<Background>
Different from pharmaceutical product-oriented pricing systems, about 280,000 medical devices are classified into about 900 functional classes in Japan and one reimbursement price is set for one functional class based on structure, intended use, effectiveness and so on.

Currently, various products, having various market prices, have the same reimbursement price within one functional class. For the revision of reimbursement prices the price reduction of old products influences the reimbursement price of new products. In order to realize the appropriate evaluation of the innovativeness in medical devices, the reimbursement price of new products should be set separately from the price of old product. It is desired that the reimbursement pricing system should be revised closer to a product-oriented system.

Actions taken so far

In the revision of the medical service fee in FY2016, the Government of Japan took measures to evaluate the value of innovation for medical devices more appropriately through such measures as the application of the subdivision of functional categories (from 844 in FY2014 to 852 in FY2016 for medical materials) and the continuous application of the special provision of functional

categories for the price revisions.

Future outlook

For the medical fee revision in FY2018, the Government of Japan will evaluate the value of innovation of medical devices appropriately and consider the most appropriate system for functional categories of medical devices, including the establishment of new functional categories or of sub-dividing the current functional categories.

2. Careful introduction of HTA based on characteristics of medical devices

BRT Recommendation

EU and Japan BRT members request both governments in EU and Japan to examine carefully the appropriate HTA system design by considering the factors:

i) QALY, a sort of HTA evaluation index for pharmaceutical products, cannot be applied for evaluation about medical devices

ii) users' skills and techniques of each medical device must affect the evaluation and

iii) medical devices have a shorter improvement cycle.

In addition, we ask both governments for their consideration in order not to hinder the creation of innovative products nor delay the listing to the medical insurance reimbursement and not to impose an excess burden on the industry for developments of databases or human resources for HTA.

<Yearly Status Report>
This is a new recommendation.

<Background>
Following several EU member states, the Japanese government determined to introduce HTA into approval processes for the medical insurance reimbursement of medical devices on a trial basis at the medical service fee revision in 2016. QALY cannot be applied to the evaluation of medical devices, which is different to pharmaceutical products as the users' skills and techniques significantly influence the outcome of the treatment. Similar issues can be seen in the EU where HTA procedures are already introduced prior to Japan. Considering this, both governments in the EU and Japan should carefully examine an appropriate HTA system design by considering such special characteristics for medical devices.

Furthermore, both governments in the EU and Japan should be careful about

HTA not to hinder innovative quality improvements in medicine and patient access to cutting-edge medical technologies.

Actions taken so far

From FY 2016, the health technology assessment (HTA) has been introduced as a trial basis for innovative 13 drugs and devices. The Government of Japan considers that the QALY is the basic method, while other measures can be also applied depending on the situations such as characteristics of diseases, medicines and medical devices.

Future outlook

The Government of Japan will introduce HTA as a trial basis for selected 13 devices through data submission by companies and review by a third party, the result of which will be put into the overall appraisal for price adjustment in FY2018.

3. Abolishment of the foreign price reference system in Japan

BRT Recommendation

The foreign price reference system in Japan should be abolished because the average price in Japan is already only 80% of foreign prices according to MHLW documents and the upper limit of the price variance between foreign countries and Japan no longer makes sense in reality.

<Yearly Status Report>
At the medical service fee revision in 2016, the government determined to lower the upper limit of reimbursement price variance between foreign countries and Japan from the current level 1.5 times to 1.3 times.

<Background>
As one of a series of medical expenditure containment policies, at the medical service fee revision in 2016 the Japanese government determined to lower the upper limit of reimbursement price variance between foreign countries and Japan to 1.3 times so that the shrinkage of the price variance of medical devices can be achieved. It is required that the reimbursement pricing system should be revised by considering the special characteristics in Japan, such as the necessity to support wholesalers' distribution costs (a very important role was played by wholesalers when disaster hit Japan) and medical institutions because the patients are decentralized in Japan.

Actions taken so far

In the revision of the medical service fee in FY2016, the Government of Japan lowered the upper limit of reimbursement price gap of newly listed medical devices between foreign countries and Japan from the current level of 1.5 times to 1.3 times in order to solve the disparity between domestic and foreign prices.

Future outlook

The Government of Japan has been considering measures for setting more appropriate reimbursement prices of medical devices since the disparity of the

prices between foreign countries and Japan has been pointed out. The foreign price reference system, which started in FY2002, has been implemented while receiving the opinions from the medical devices industry. In the revision of the medical service fee in FY2016, the Government of Japan reduced the ratio regarding the foreign price adjustment related to new listed medical devices to the compatible level to the foreign states for eliminating the reimbursement price variance between foreign countries and Japan. Toward the medical service fee revision in FY2018, the reimbursement price of medical devices will be discussed in the *Chuikyo* with the situations surrounding individual medical devices under consideration.

4. Maintain biennial price revision

BRT Recommendation

EU and Japan BRT members strongly oppose yearly revisions of reimbursement prices and support maintenance of the current biennial revision scheme.

<Yearly Status Report>
New recommendation

<Background>
Same as the recommendation #12-5

Actions taken so far

Regarding the medical device price revision, which has been basically conducted every 2 years, the Government of Japan recognizes that there are some challenges concerning incentives to create innovative new medical devices and medical devices distribution.

Future outlook

The Government of Japan will discuss the medical device price revision including its frequency based on the past record of the revision until FY2018 with the above-mentioned challenges as well as the effects on medical service fee under consideration.

11. Prudent use of antibiotics in animal health (WP-2/#14*/E to EJ)

BRT Recommendation

The establishment of a cascading system prioritizing use of approved drugs and formulations where they exist, rather than other available products lacking such claims, would promote responsible use of all drugs in animal health.

<Yearly Status Report>
MAFF continues to promote prudent use of antibiotics in animal health.

<Background>
In common with the rest of the world, Europeans and Japanese are concerned by the development of resistance to antibiotic medicines used in human health and the potential threat that the use of antibiotics in animal health will accelerate this process. The use of antibiotics as growth promoters has been prohibited in the EU since 2006. As a responsible industry, the animal health industry seeks to work with veterinarians, farmers and the feed industry to dispel the myths about the use of antibiotics in animals and promote their responsible use.

MAFF requested Marketing Authorization Holders of fluoroquinolones, 3rd and 4th generation of Cephems, 15-membered ring macrolide to indicate the "2nd choice drug" on their packages and to specify precautions such as "Veterinarians should change a medication based on their judgment about the efficacy of the drug within 3 days after the initial administration" on the labelling of products for food animals in November 2014.

Actions taken so far

The Government of Japan would like to request further clarifications on whether the proposal meets the objectives of BRT to facilitate trade and investment between Japan and the EU.
Concerning Antimicrobial Resistance (AMR) issues, in accordance with the international standards such as the Codex Guidelines and the Codex Code of Practice, MAFF has been developing and implementing appropriate risk management measures such as promotion of the responsible and prudent use

of antimicrobials and monitoring of antimicrobial resistant bacteria from livestock animals, based on risk assessment with scientific evidence.
The Government of Japan recommends that the EU also implements risk management measures based on the result of risk assessment.
Furthermore, in April 2016, the Government of Japan developed “National Action Plan on Antimicrobial Resistance” including actions to be implemented in the coming 5 years (2016 to 2020).
Moreover, Japan has been actively participating in and contributing to the effort for international standard setting by WHO, OIE and Codex, including WHO’s global action plan on antimicrobial resistance.

Future outlook

MAFF will continuously implement appropriate risk management measures based on the result of risk assessment, in accordance with the treatments of risk analysis.
Also, based on the “National Action Plan on Antimicrobial Resistance”, MAFF will continuously strengthen the current activities to ensure responsible and prudent use of antimicrobials and will be actively committed to actions in the animal health sector in line with the WHO global action plan.

12. Regulatory harmonization for animal health products (WP-2/#15*/E to J)

BRT Recommendation

The food animal product registration process is particularly cumbersome, involving a sequential review by MAFF followed by the FSC and the MHLW. Decision criteria and timelines for the following stages of the review process are not provided, resulting in extended review times.

In 2014, MAFF held a series of explanatory meetings to update the J-PMD Act and their approaches for shortening the review time for animal health products. It is recognized that MAFF, FSC and MHLW started discussions on how to shorten review times for livestock products (i.e. introduction of parallel deliberation among the authorities.) Discussions among the authorities are ongoing.

<Yearly Status Report>
MAFF did a tremendous job to align the Japanese regulations with that of the EU by shortening the withdrawal period following the administration of oil adjuvant vaccines.

<Background>
Restrictions on the withdrawal period for innovative oil-adjuvant vaccines are especially stringent in Japan. Implementing a scientific health risk assessment approach in establishing the withdrawal period and the increased collaboration of different ministries involved in food safety would certainly improve the access of animals and animal owners to innovative animal health products which are readily available in Europe. While such global new veterinary medicinal products already go through rigorous review processes in Europe and the USA prior to registration, it requires substantial additional testing in J-PMD Act before an approval is granted.

An additional important aspect is the negative impact on animal welfare: since the regulatory requirements are not harmonized, the companies are required to repeat some tests on animals in Japan even though results of identical tests are already available and are fully compliant with stringent frameworks like GLP or VICH. Recognition of animal welfare aspects is not yet optimal in the

administration of animal health products in Japan. Japan should minimize the use of animals by accepting more overseas data and alternative approach.

Actions taken so far

Japan has been actively working toward the harmonization of technical requirements for registration of veterinary products through VICH, and has accepted overseas data which are performed in accordance with VICH guidelines. Therefore, there seems to be a misunderstanding in the comment of paragraph 2 of “Background”.
Concerning cooperation among MAFF, MHLW and FSC to improve the efficiency of the review and assessment process for approval of new products, please refer to “Action taken so far” in WP-A/#08**/E to J.
In addition to that, MAFF reviewed the principles to establish the withdrawal period in December 2014, and since then the withdrawal period of vaccine is not required if each excipient of the vaccine has been assessed as “the risk to human health from the intake of the substance is negligible as long as it is used as excipient of vaccine”.

Future outlook

At this point, it is difficult to make response to the comment as its appropriateness is not confirmed.
Concerning MAFF’s basic stance related to the acceleration of approvals of VMPs, please refer to “Action taken so far” in WP-A/#08/E to J.

13. Shortening review times for animal health products (WP-2/# 16*/E to J)

BRT Recommendation

Shorten review times for new product applications for food animals. MAFF, MHLW and FSC should start harmonization to shorten review times. The process is complicated in addition to a review period that already for pet animal products (not requiring Acceptable Daily Intake (ADI) and Maximum Residue Limits (MRL)) is among the longest in the world. A lot of questions are asked in the process that might be academically interesting but are not necessarily safety- or efficacy-related. Clarifying registration requirements and shortening review times for the import of recombinant vaccines from Europe should also be implemented.

<Yearly Status Report>
Significant progress was made by MAFF. They explained to the industry in August 2015 that a new review process will be introduced to shorten the overall review period for veterinary medicinal products for food-producing animals by allowing MAFF, MHLW and FSC to review in parallel in the near future.

<Background>
In Japan, marketing authorization of a veterinary medicinal product is granted by MAFF. For an animal drug intended for use in food-producing animals, FSC and MHLW are also involved in establishing the acceptable daily intake and maximum residue limit respectively. The review process, involving three different authorities, is rather complex and certainly has some room for efficiency improvement. Also, the review can take an extremely long time until completion. Hence, it delays the access of animal owners and animals to innovative animal health products. This is also true with the introduction of recombinant vaccines from Europe due to lengthy processes of implementing the Cartagena protocol even if the vaccine has already been extensively used in Europe.

Actions taken so far

MAFF, MHLW and FSC have been cooperating to improve the efficiency of the review and assessment process for approval of new products.

For instance, certain inactivated vaccines which meet specific conditions have been exempted from the FSC assessment. In addition, the FSC assessment procedures for certain attenuated live vaccines and combined vaccines have been simplified.
Furthermore, on September 30th, 2016, MAFF has completed the process for allowing the companies to submit the data on clinical studies after application to MAFF for approval and the three relevant ministries started the implementation of the procedure for approach, so that the procedures for approval will be streamlined.
In addition, it should be noted that, with regard to questions to applicants in the process of the approval, only necessary questions for scientific evaluation of quality, safety and efficacy of drugs are requested to answer.
The Government of Japan found no rational basis to the comment, “a review period that already for pet animal products (not requiring ADI and MRL) is among the longest in the world”.
MAFF has been promoting the efficiency of the review and assessment process of veterinary recombinant vaccines in accordance with the Cartagena Protocol, and the process was simplified in June 2016.

Future outlook

The three relevant ministries will operate parallel deliberation of the procedures for approval properly. For the FSC to conduct its risk assessment in a timely manner, the cooperation of the EU industry and government is required in providing data and information necessary for the risk assessment.

14. Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan (WP-2/#17*/E to J)

BRT Recommendation

Reinforce the regulation for GMP on medicinal gases in Japan. MHLW has started these initiatives along with industries. But industries are protective to non-GMP facilities because of financial implications.

<Yearly Status Report>
Some progress has been seen for this recommendation. In February 2012, MHLW notified medical gas suppliers that they should voluntarily obey the industry standard. This standard, called the JIMGA standard, was almost compatible to GMP standard but a little looser. PMDA/MHLW reinforced the GMP for medicinal gases through the PIC/S. Japan officially joined in July 2014. MHLW has announced the GMP standard only to the JIMGA core team, which is an updated JIMGA standard and almost equivalent to PIC/S Annex 6. The formal announcement will be made in a couple of months.

<Background>
Medicinal gases are drugs or medicinal devices and have to be compliant with governmental regulations. The main regulations are the national Pharmacopeia, GMP (Good Manufacturing Practices) and GDP (Good Delivery Practice). Annex 6 describes GMP and GDP for production and distribution of medical gases. The currently loose interpretation of GMP in Japan, along with relatively low standards of the Japanese Pharmacopeia, is at a lower level compared to those applicable in Europe or the US. We would like to suggest a reinforcement of regulations on GMP for medical gases in Japan.

Actions taken so far

With regard to medical gases in Japan, the MHLW discussed the establishment of the guidelines with industry and made public “The Standard on Manufacturing Practice for Medical Gases (*hereinafter* “the standard”)” on February 13th, 2012. The standard was reviewed afterward taking into account the revised Annex 6 of PIC/S GMP guide, and the MHLW made public the revised standard, on March

22nd, 2016.

Future outlook

The MHLW provides medical gas manufacturers with information on the standard through prefectural government and promotes manufacturing and quality controling systems in accordance with the standard.

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15. Requirement of Japanese version of the clinical trial protocol and investigators brochure (WP-2/# 18*/E to J)

BRT Recommendation

The Japanese health authority requires a clinical trial protocol and investigator's brochure in Japanese. Translation from English is required for clinical trial notification in Japan. The acceptance of English-only materials for global clinical trials performed in Japan requires further English language education of Japanese regulators. However, if applications could be made in English-only, it would substantially accelerate the process and make innovative drugs earlier available to patients in Japan.

<Yearly Status Report>
No progress has been seen for this recommendation but currently, an English application format is being positively discussed.

<Background>
The Japanese health authority requires a clinical trial protocol and investigator's brochure in Japanese. Translation from the original English version is required for clinical trial notification of global trials in Japan. Therefore, the requirement is considered to be a cause of delay to the start of patients' enrolment in Japan.

Action taken so far

The Government of Japan already implements internationally standardized pre-market review of drug and medical device by reflecting the contents of ICH-E6 guidelines in the Ministerial Ordinance of Good Clinical Practice (GCP). The Pharmaceuticals and Medical Devices Agency (PMDA) shares information with regulatory authorities in the U.S. and Europe such as the Food and Drug Administration(FDA) and European Medicine Agency(EMA), aiming at standardization of review operations, by sending its review staff to FDA and EMA and giving training of FDA and EMA. These efforts are contributing to the resolution of review period gap with the U.S. and the EU, in comparison with the review period in the U.S. and the EU.

Future outlook

The Government of Japan will continue its efforts in international standardization of pre-market application review.

16. Shorten or eliminate national tests for vaccines（WP-2/#19*/E to J）

BRT Recommendation

For imported vaccines, national tests in Japan and manufacturing sites have been conducted (for more than 20 years in some instances). National tests for vaccines should be eliminated or reduced to an absolute minimum.

<Yearly Status Report>
Some progress has been seen for this recommendation.

<Background>
Vaccine production is conducted according to GMP and PMDA periodical audits of production sites. However, the higher quality assurance of vaccines is strongly demanded by society. The GMP of manufacturing countries should be accepted by the Japanese authority and the national tests for vaccines in Japan should be eliminated or reduced to an absolute minimum.

Action taken so far

Since vaccine products tend to vary considerably in quality, the manufacturer and the National Regulatory Authority need to double-check the conformity to the specifications of products, before the products are released. The national lot release operated by MHLW is one of the systems for such a checking process. We recognize that the countries in the EU countries also have similar systems of the national lot release as the system Japan has.
The MHLW has been reviewing and amending items to be tested in the national lot release for vaccines, as necessary, on a regular basis.

Future outlook

The MHLW continue to operate properly the national lot release system for vaccine products.

Working Party 3 : Innovation, Information & Communication Technologies

1. Concerns on Emerging FLMs and Market Access Improvement in Third Countries (WP-3/#01**/EJ to EJ)

BRT Recommendation

The BRT has serious concerns that some countries are implementing Forced Localization Measures (FLMs). Those measures could become a real threat to digital trade. Maintaining the business environment to realize adequate "cross-border data flows" is imperative for multinational companies and for citizens who consume services offered by global players.
The BRT requests both sides' Authorities to lead global rule making by incorporating provisions to restrict digital protectionism such as FLMs into EPA negotiations respective parties are engaged or TiSA negotiation, and jointly approach the abolishment of such regulations.

< Yearly Status Report >
In May 2015, the 23rd Japan EU Summit was held in Tokyo. The EU and Japan emphasized their determination to combat all forms of protectionism.

In October 2015, the European Commission released a trade strategy "Trade for All", where it addressed digital protectionism and sought to use FTA and the TiSA to set rules on e-commerce and cross-border data flows.

The TPP agreement, in which Japan is participating, also specifies provisions to prevent Forced Localization Measures in the e-commerce chapter.

< Background >
The ITA facilitated the global trade of IT products and contributed substantially to the global economy. In the ICT sector, services are an important component of business in addition to products. Global rules on digital services need modernization reflecting technology development and emerging business models.

Actions taken so far

In cooperation with the European Commission and the Government of the United States, the Government of Japan has continuously called for improvement of market access in third countries at the WTO/TBT committee by raising FLMs-related measures and at other opportunities including bilateral dialogues with governments thereof. The G7 leaders recognized the importance of promoting digital economy and endorsed the G7 Principles and Actions on Cyber at the G7 Summit Meeting in May 2016. Furthermore, the Government of Japan worked actively on international trade negotiations such as the TPP and the WTO/TiSA.

Future outlook

Working together with the European Commission and the Government of the United States, the Government of Japan continues to call for improvement of market access in third countries including FLMs-related issues through international conferences (including the WTO), international trade negotiations and bilateral dialogues with the governments thereof.

2. Balancing Privacy Protection and Innovation（WP-3/# 02**/EJ to EJ）

BRT Recommendation

The BRT welcomes the fact that revisions of the data protection regulations are underway both in the EU and Japan.

The BRT requests the EU and Japan that regulations create a balanced, harmonized and future-proof set of data protection rules both for the EU and Japan as we believe that adoption of a modern and flexible regulation has the potential to act as a catalyst for growth and innovation both in the EU and Japan.
(Concerns on EU GDPR)
The BRT understands that some of the provisions will be specified in delegated acts and implementation acts.
The BRT also requests the EU to carry out a public consultation as early as possible before the release of the draft delegated act, the implementation act and/or guidelines so that the views of business may be taken into consideration.
Furthermore, the BRT is concerned that the amount of sanctions up to 4% of the total global turnover or 20 million Euros could have too much of an impact on the concerned businesses. The BRT would like to urge, therefore, that sanctions should be transparently applied with careful consideration of the risk that disproportionately large sanctions might have on the industries and economy in the EU and beyond its border.

(Concerns on the amended Act on the Protection of Personal Information in Japan)
The development of provisions on extraterritorial application and transfer of personal information to a third party in a foreign state is expected in Japan's amended Act on the Protection of Personal Information. The BRT requests transparent implementation, while the EU and Japanese companies strive to comply with the Act.

(Rulemaking for facilitation of cross border transfer of personal data)
The BRT appreciates that the codes of conduct and certification mechanisms are included in the EU Regulation in addition to the standard contract clause and the binding corporate rules.

Both sides' Authorities are requested to start substantial discussions on the establishment of a mechanism that will lead to free flows of personal data between the EU and Japan. Especially, it should be possible to transfer personal data between the EU and Japan without a specific procedure. The BRT requests that the EU and Japan mutually certify that each side insure an adequate level of personal data protection.
Furthermore, both sides' Authorities should strengthen their dialogue to realize consistent personal data protection regimes around the world, to assure interoperability and to address digital protectionism through enhanced cooperation with third countries and international organizations.

< Yearly Status Report >
There has been good progress on this recommendation.

On 14 April 2016, the European Parliament adopted the General Data Protection Regulation.

Japan's revised Act on the Protection of Personal Information was established in September 2015. Based on this law, the Personal Information Protection Commission was established on 1 January 2016.

< Background>
The original personal data protection laws were adopted before the technical advancement of internet and cloud computing. Since then, citizens have become more concerned about privacy protection, and the differences in regulations by countries in various jurisdictions have caused an increase in compliance costs. Those differences have become obstacles to efficient global operation and innovation utilising data. Reviewing the regulations is thus needed.

Action taken so far

At the Japan-EU Leaders' Meeting in May 2016, Prime Minister Abe stated on the importance of promoting smooth cross-border transfers of personal information and Japan's intention to accelerate Japan-EU dialogue in this area. The Personal Information Protection Commission(PPC) adopted two commissionary decisions in 2016: "New Initiatives for Ensuring Smooth

Cross-Border Personal Data Flows" on July 29th and "Concerning the International Efforts" on November 8th, 2016, and the PPC Secretariat held cooperative dialogues with the Directorate-General for Justice and Consumers of the European Commission five times in 2016 with a view to possible establishment of a framework to promote reciprocal and smooth personal data transfer between Japan and the EU. The PPC has also made efforts to foster mutual understanding with the foreign enforcement authorities.

On a domestic front, with the amended Act on the Protection of Personal Information (APPI) put partially into force on January 1st, 2016, the PPC has been established as an independent administrative organization. The PPC has amended the enforcement order issued according to the APPI, and set out the PPC rules, guidelines, etc. in preparation for the full enforcement of the amended act scheduled on May 30th, 2017.

Future outlook

The PPC will continue to vigorously hold cooperative dialogues with the EU and other authorities based on the above-mentioned commissionary decisions on July 29th and November 8th, 2016, and the Government of Japan as a whole will keep efforts to establish a framework to enhance reciprocal and smooth personal data transfer between Japan and the EU. The PPC will also actively contribute to international frameworks such as GPEN (Global Privacy Enforcement Network) and APPA (Asia Pacific Privacy Authorities) and make efforts toward global harmonization of personal information protection legislations across the nations including through promoting the APEC CBPRs (APEC Cross Border Privacy Rules System).

After the full enforcement of the amended APPI on 30 May, 2017, the PPC will become the single authority to equitably and fairly enforce supervision over business operators' handling of personal information.

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3. Cybersecurity of Critical Infrastructure（WP-3/#03**/EJ to EJ）

BRT Recommendation

The BRT welcomes the EU's adoption of the Network Information Security Directive. The Cybersecurity Basic Act was adopted in Japan, and the GoJ established the Cybersecurity Strategy Headquarters and National centre of Incident readiness and Strategy for Cybersecurity. The EU and Japan share their views on the importance of cybersecurity measures for critical infrastructure.

Cloud computing services, being digital services, are under the scope of the NIS Directive. Detailed provisions will be specified by EU Member States. As there are several types of service provision of cloud operators, the BRT asks the Commission to encourage EU Member States to release obligations for operators.

International cooperation is effective in coping with high-level attacks. The BRT requests to actively conduct educational activities such as public-private joint seminars. A sharing scheme should be created between the national contact points designated in each Member States based on the NIS directive on the one hand and Japan on the other hand.

The BRT also requests that both sides' Authorities enhance the quality and volume of human talent in the cybersecurity area.

< Yearly Status Report >
There has been good progress on this recommendation.

At a trilogue held in December 2015, the EU institutions agreed on a first EU level cyber security law "Network Information Security Directive".

This Directive stipulates EU Member States to specify a competent authority responsible for cybersecurity, and to establish CSIRT (Computer Security Incident Response Team), and cooperation mechanism between Member States.

The GoJ adopted its Cybersecurity Basic Act in November 2014. Based on this basic act, a Cybersecurity Strategy Headquarters was established. In September 2015, the Cabinet decided a Cybersecurity Strategy.

< Background >
With the diffusion of IoT, the fusion of real space and cyberspace is accelerating. Risks surrounding cyberspace are increasing. Critical infrastructures sustain citizen's life and economic activities. The impediments of their operations because of cyber-attacks, etc., are serious threats to society. It means that defending critical infrastructures from cyber threats is indispensable for maintaining the business operations and a stable civil society.
As the entities conducting cyber-attacks act globally, and their attacks become more and more advanced, addressing these serious issues requires a sustained and close international cooperation between the public and private sectors.

Action taken so far

In April 2016, the GOJ revised the "Basic Act on Cybersecurity" to further strengthen cybersecurity measures of government agencies and related organizations.
For advocacy purposes, the GOJ designated every February as the "Cybersecurity Awareness Raising Month" and every October as the "International Cybersecurity Campaign Month," in which it actively conducts advocacy for cybersecurity, including public-private joint seminars.
As for human resources development in the cybersecurity area, the Cybersecurity Strategic Headquarters decided the "Comprehensive Policy for Cybersecurity Human Resources Development" in March 2016 to strengthen various policy measures in this area, and to facilitate effective collaboration among them. Furthermore the Headquarters decided the "Roadmap for Critical Information Infrastructure Protection policy update" in March 2016, which aims to review the third edition of the "Basic Policy of Critical Information Infrastructure Protection," and is taking measures based on the roadmap.
As for the bilateral relationship between Japan and the EU, the Japan-EU Cyber Dialogue and other bilateral cyber dialogues between Japan and several EU Member States are being held. Through these dialogues, both sides exchange their contact points and their information on both sides' policy efforts,

governmental framework and strategies, and discuss collaborative issues on cybersecurities between Japan and the EU.

Future outlook

Looking toward the 2020 Olympic and Paralympic Games in Tokyo, the Government of Japan is working on ensuring security at cyberspace including critical information infrastructure protection, based on the “Cybersecurity Strategy” and other policies. For the success of these Games, the Government of Japan will further conduct advocacy for cybersecurity, and enhance various policies for human resources development in this area based on the “Comprehensive Policy for Cybersecurity Human Resources Development.” In addition, the Government of Japan will review the third edition of “Basic Policy of Critical Information Infrastructure Protection,” based on its roadmap, and revise the policy by the end of March 2017.
Japan and the EU will continue to work on enhancing their cooperative relationship in the field of cybersecurity through the frameworks such as the Japan-EU Cyber Dialogue.

4. Expansion of membership of Expanded ITA(WP-3/#05/EJ to EJ)

The BRT highly welcomes the conclusion of the Information Technology Agreement (ITA) Expansion negotiation at the 10th WTO Ministers conference in Nairobi, Kenya in December 2015. With this agreement, the tariffs of 201 products will be eliminated. The BRT also highly welcomes that periodical review mechanisms are included in the agreement. The original ITA is supported by 82 members, while the expanded ITA was negotiated by 53 members.

The BRT recommends that both authorities work together in order to convince additional members to sign up to the expanded ITA.

The BRT would like to emphasise to both sides' authorities the importance of the punctual implementation of tariff elimination starting on 1st July 2016. The BRT also recommends both sides' authorities to consider an accelerated implementation.

< Yearly Status Report >
The expanded Information Technology Agreement (ITA) was concluded by 53 WTO members at 10th Ministers Conference of WTO held in Nairobi, Kenya in December 2015.
In July 2015, the negotiators of the ITA agreed to eliminate tariffs of 201 products.

< Background >
No product review had been conducted after the agreement on the original ITA in 1996. Business associations requested an expansion of product coverage. Based on this request, an ITA expansion negotiation was conducted from May 2012 onwards.

Action taken so far

The members participating in the expanded ITA periodically convene their meetings for stocktaking in Geneva, review their implementation status and exchange information on issues such as newly added members.

Future outlook

The Government of Japan will surely implement the tariff elimination on the ITA expansion, and will cooperate with the EU's relevant organs and industries both in Japan and in the EU on the expansion of the membership in the future.

5. Work towards International Standardisation in Joint R&D Programmes (WP-3/#07*/EJ to EJ)

BRT Recommendation

Both sides' Authorities should specifically favour joint R&D programmes that are geared towards international standardisation such as standardisation in advanced manufacturing, the Internet of Things and Cybersecurity. Regulatory cooperation between the EU and Japan for facilitating digitalization will accelerate creation of innovation through the deployment of new services and products in both regions.

< Yearly Status Report >
In May 2015, The EU and Japan signed a joint declaration concerning R&D and cooperation for standardization called "A strategic cooperation on the future generation of communication network (5G)". In February 2015, the GoJ adopted Japan's Robot Strategy. The Robot Revolution Initiative was established as the execution body of this strategy. The IoT Acceleration Consortium was established with the support of METI and MIC.

< Background >
The EU and Japan share common societal challenges such as aging population, climate change, resources constraints, etc. Enhancing cooperation between EU and Japan expertise will increase possibilities to create new products and services addressing complex issues. However, a real breakthrough is possible if both economies and Authorities use the same standards, so that double certification will not be needed. As this is more difficult to achieve for incumbent technologies and markets, at least new standards should be developed jointly as much as possible. It is well known that the seeds for standards are already defined at the R&D level, thus joint R&D programs should encourage joint standardisation activities.

In March 2015, DG GROW and METI held the 18th Annual Meeting of the EU Japan Industrial Policy Dialogue in Brussels and adopted a joint document regarding the regulatory cooperation between the EU and Japan.

Action taken so far

The Ministry of Internal Affairs and Communication (MIC) instituted joint calls with the EU since FY2012 under the programme of “Strategic Information and Communications R&D Promotion Programme (International Standards Acquisition Type),” which aims at accelerating international standardisation and commercial application of the research findings. The MIC launched joint calls in FY2015 together with the European Commission in two areas of “5G – Next Generation Communication Networks” and “EU-Japan Novel ICT Robotics based solutions for active healthy aging at home or in care.” The MIC adopted two proposals in the former area and one proposal in the latter area after the domestic evaluation by external reviewers and the joint evaluation with EU.
Moreover, National Institute of Information and Communication Technology (NICT) instituted joint calls with the EU since FY2012 for the same purpose as the MIC launched joint calls. Following the joint calls launched in FY2015 together with the European Commission in the areas of “IoT/Cloud/Big Data platforms in social application contexts” and “Experimental testbeds on Information-Centric Networking,” the European Commission and NICT adopted two proposals in the former area and one in the latter. In addition, in FY 2016, the NICT launched a new joint call with the European Commission in the area of “EU-Japan cooperation on research and development on network platform technology for active and healthy ageing at home or in care facilities” and adopted one proposal.
Furthermore, in October 2016, MIC and NICT co-hosted “the 6th Japan-EU Symposium on ICT Research and Innovation” together with the European Commission, where they broadly shared the products and future direction of the Japan-EU joint research and development in the ICT area. They also organized a special session during the symposium with the participation of promoting groups and standardization organization in the area of IoT/ smart city, where they renewed their recognition of the value of Japan-EU joint research and confirmed to strengthen collaboration between Japan and Europe towards further development of the area of ICT research, with a core of this framework.

Future outlook

The Government of Japan continues to seek the possibility of wider cooperation, with consideration on international standardization, following up progress of the joint research and the dialogues which has been launched so far.

6. Sharing Vision and Roadmaps for a Better Coordination of R&D Projects/Programmes (WP-3/#08*/EJ to EJ)

BRT Recommendation

To make the programmes even more effective to manage and accessible from the industry, the procedure for preparation, launch and evaluation of coordinated calls should be well discussed by both parties and standardised. Especially, transparency should be enhanced throughout the application and evaluation processes. Clearly mentioning correspondences between European and Japanese calls would greatly facilitate the identification of opportunities for cooperation. If possible, synchronized publication of such calls would be desirable. Both sides' Authorities should increase matchmaking activities between European and Japanese industry to find out common themes. The role of National Contact Points (NCP) should be reinforced. Japanese NCP should work more closely with European NCPs and both should coordinate their efforts. For sharing the vision and working on the common roadmaps, the industry-led activities of European Technology Platforms (ETPs) can be a model.

To increase participation in the respective R&D projects of each region, the BRT recommends authorities to promote the services offered by the National Contact Point in Japan for Horizon 2020 and other relevant instruments (including the EEN) to widely circulate R&D call notifications and support the formation of partnerships. The BRT hopes that initiatives under Horizon 2020 and Japan's 5th Science and Technology Basic Plan will lead to further EU-Japan strategic R&D cooperation.

< Yearly Status Report >
A few joint calls for proposals under Horizon 2020 were released in the fields of aeronautics and ICT, health and advanced materials.

On 18 May 2015 in Brussels, the 3rd Joint Committee on Scientific and Technological Cooperation between the EU and Japan was held. The Committee adopted a Joint Vision on the new strategic partnership in Research and Innovation between the European Commission and the Government of Japan. In addition to the current joint areas of cooperation (ICT, Advanced

Materials/CRM, Aeronautics), both sides' authorities have a common view on the strategic significance of increasing cooperation in the fields of health/medical research, environment, energy, and high-energy physics.

To further enhance EU-Japan cooperation in research and innovation, the JEUPISTE project has continued its activities, reinforced by Japan's National Contact Point for Horizon 2020. The EU-Japan Centre for Industrial Cooperation conducted several activities to facilitate R&D collaboration between the EU and Japan: a major seminar on Horizon 2020 (October 2015), a Power Electronics Symposium (December 2015) and several activities in Europe (such as an innovation workshop in Barcelona on healthy ageing and smart cities in November 2015). Various seminars/workshops/trainings were also organized in cooperation with local hosts in Japan, tailored to specific needs or the organisations.

France has also given a European dimension to its activities under the France-Japan Innovation Year, such as the EU-Japan 5G Symposium (February 2016).

Japan's Cabinet Office has adopted its 5th Science and Technology Basic Plan in late January 2016. It outlines Japan's science and technology approach for the next 5 years.

< Background >
Science, Technology and Innovation are engines for growth. Ideas cannot be prevented from crossing borders. Consolidating expertise from both regions will be an effective way to address current complex global issues. Countries can make more effective use of human resources and financial funds if their R&D programmes are coordinated and if mutual access to R&D programmes is easier for participants from both regions. Coordination should also be promoted at local/regional levels (e.g. Smart Specialisation). A similar coordination should be promoted by coordinating the work of Chambers of Commerce, Industrial Associations and Universities.

Action taken so far

The Government of Japan designated the EU-Japan Centre for Industrial Cooperation as the National Contact Point (NCP) in Japan on November 2013, and has allocated a budget necessary for the activities of the NCP from FY2014. This Centre has been providing counsel to facilitate application procedures and search for partners under the Horizon2020 programmes, in response to inquiries from universities and private enterprises. The Centre also has been conducting comprehensive support activities including translation of the Horizon2020 official documents released by the European Commission, such as online manual and model grant agreement, and dissemination of the Horizon2020 programmes through holding seminars and workshops.
In April 2015, this Centre launched the NCP Japan Portal Site, which the Centre provides the latest call information on the website and started to operate its one-stop service system consistently supporting from searching European partners to draft proposal documents.
In October 2016, the increase of activities of the NCP was confirmed at the meeting on Science and Technology Cooperation between Japan and the EU.

Future outlook

The Government of Japan will support for reinforcing the organisational system of the NCP, with a view to further facilitating the activities of the NCP to announce calls for R&D proposals under the Horizon2020 and to formulate partnerships of entities of Japan and the EU.

7. Government-Led Industrial Cooperation in Aeronautics (WP-3/#9**/EJ to EJ)

BRT Recommendation

The Authorities of Japan and the EU should establish a permanent dialogue aiming to significantly upgrade the scale of EU-Japan industrial cooperation in aeronautics based upon mutual trust, equality and mutual benefits, and stimulated by government funding. This should include a broad cooperation on environmental issues.

<Yearly Status Report>

Some progress has been made on this recommendation.

<Background>

Europe's aeronautics industry has long been a major supplier to the world market. Japan also has many advanced technologies. Both are challenged by new entrants. In this context, joint technology and project development are necessary for both sides' companies to maintain technological leadership and competitiveness, and for governments faced with severe budgetary constraints. Some Europe-Japan industrial cooperation exists in helicopters and aeroengines but the potential is much greater

EU-Japan industrial cooperation in civil airliners has stagnated since the early 2000s, when 15 Japanese suppliers joined the A380 programme. The situation is better for Japanese participation in engine programmes and as suppliers of carbon fibre materials. The aerospace industries of other countries have improved significantly in recent years and price competitiveness has become a key decision criterion.

Europe and Japan support mostly separate research programmes on environmental issues, from noise to emissions. We believe that the eco-technology at all aircraft speeds is one of the fields where further cooperation between Europe and Japan could yield significant cooperation and business opportunities.

Actions taken so far

A director-level meeting on the Sustainable Network for Japan-Europe aerospace research and Technology cooperation II (SUNJET II), a joint project to make a roadmap for technology development, was held in June 2016, based on the framework on civilian aeronautical cooperation in accordance with the Terms of Reference of the European-Japanese Working Group on Civilian Aeronautics Research between the Ministry of Economy, Trade and Industry (METI) and the Director-General Research & Innovation of the European Commission(EC), signed in 2013. In July 2016, the METI and the EC held the meeting of the working group meeting on civilian aeronautics research.

As to the cooperation projects between Japan and the EU in aeronautics, following the joint researches in the first phase that had been already carried out, four proposals for the joint researches in the second phase, namely, future passenger-friendly cabin architecture and system, lighter integrated heat exchanger systems, efficient composite structure manufacturing and monitoring, and smarter flight control technologies for enhanced safety, were submitted, and the EC adopted the projects for which it will allocate its budget. Japan also adopted these four projects for which it will allocate its budget as well. These cooperation projects started in 2016.

In November 2016, the fourth Working Group and a workshop aimed at finding future cooperation between Japanese and French companies in Paris, based on the framework on civil aeronautical cooperation between Japanese and French industries in accordance with the Memorandum on Cooperation (MoC) in Civil Aeronautical Industry concluded between the METI and the Directorate General for Civil Aviation of France (DGAC) in June 2013.

Future outlook

With respect to efforts on aircraft technologies related to environment, the cooperation between Japanese civil aeronautics industry and those of other countries including Europe is vital from the viewpoint of improvement of Japanese companies' technological capability and competitiveness. In addition to steadily carrying out the adopted Japan-EU cooperation projects, the Government of Japan will continue to support the further collaboration between

the Japanese and European civil aeronautics industries, such as finding and supporting new cooperation projects, utilizing the Japan-EU and the Japan-French cooperation framework.

8. Cooperation in Aircraft Certification(WP-3/#10 */EJ to EJ)

BRT Recommendation

Cooperation between Japanese and European aircraft certification authorities should be upgraded. Specifically, the BRT recommends the signature of a Bilateral Aviation Safety Agreement (BASA) between the JCAB and the EASA that would cover both type certification and maintenance activities.

< Recent Progress >

Significant progress is made towards a BASA between Japan and the EU.

< Background >

There is a bilateral agreement between US and Japanese civil aviation authorities that facilitates the mutual acceptance of the other party's certification basis, while there is only a working arrangement between Europe (EASA) and Japan (JCAB) that proves extremely difficult to work with. Validation by JCAB of European Type certified aircraft is a very lengthy process. In particular, validation of EASA-certified new optional equipments for helicopters whose Type Certificates are already validated by JCAB should be almost automatic, but instead the Japanese authority requires a review of all the technical documentation before approval. This is often the cause of delivery delays of the products to Japan and may at times preclude European manufacturers from fairly competing in public tenders, due to stringent delivery requirements. Moreover, Japan is probably the only country in the world where the Rotorcraft Flight Manuals must be translated into the local language and approved by the local authority, again representing an obstacle to helicopter imports.

Actions taken so far

On March 7th, 2016, the EU Council conferred the European Commission (EC) the mandate to open negotiations with Japan in view of concluding a Bilateral Aviation Safety Agreement (BASA)

On May 3rd, 2016, at the Japan-EU Leaders Meeting, Prime Minister Abe welcomed the start of official negotiations on Japan-EU BASA.

Based on the above, the Government of Japan and the EC have been coordinating to hold the first meeting of official negotiations on a BASA at an early timing.

Future outlook

The Government of Japan will actively move forward with the negotiations with an aim to conclude a BASA, while conducting a survey of regulations and systems by the Japanese Aviation Authority and the European Aviation Authority.

9. Weight Restrictions on Haneda Airport D Runway (WP-3/#16**/E to EJ)

BRT Recommendation

Haneda D runway weight restrictions are an obstacle to the use of European-made aeroplanes and an obstacle to further development of international traffic at Haneda. These weight restrictions should be re-examined to allow the operations of new and larger airplanes such as Airbus-made A380 and A350. We request both sides' Authorities in charge to cooperate in making the necessary verifications. Additionally, for the newest mid-size A350 aircraft, operation could be possible with the re-verification of the withstand load with regards to part of the construction.

< Yearly Status Report >

No progress has been seen on this recommendation. However, the recent approval of the 747-8i (Code F aircraft) for day-time operations in Haneda offers hope that the A380 (also a Code F aircraft) will be approved soon for day-time operation as there are some airlines looking at operating the A380 into Haneda.

< Background >

With the purpose of expanding airport capacity in response to the increase in air travel demand as well as to reduce congestion, a fourth runway (D runway) and an international terminal were opened in Haneda in October 2010. So far focusing on flights to and from Asian countries, its use for long-haul international routes will increase in the future. The number of flights will grow together with the demand but will be limited in the end by the capacity in terms of slots. The recent dramatic increase in the number of foreign visitors to Japan, just under 20 million in 2015 has caused the GoJ to revise the target upwards to 40 million for 2020. The average size of aircraft departing Haneda (230 seats) is now lower than it was in 1980 (240 seats) when 747s were used domestically. To see traffic grow at Tokyo's airports and more specifically Haneda, work needs to be done to ensure larger aircraft can be used at Haneda. In this regard, the use of new and larger aircraft will be an important part of the airlines' strategies. Under such circumstances, aircraft weight restrictions on the D runway could impede the conversion of Haneda Airport to larger and newer aircraft. New aircraft such as the A350 and A380 are significantly quieter and environmentally friendly than

older aircraft now in use at Haneda airport and, with plans to overfly the city to increase flights to and from Haneda, it is essential that quiet aircraft are used as much as possible. In order to avoid disturbing the flow of the Tama River, the D runway was overhauled using a pier-like structure instead of a conventional landfill. Due to this, weight restrictions have been placed upon the aircraft in use, and with the entire lineup of Airbus' newest A380 and A350 series exceeding the weight limit, these aircraft could no longer be used as they currently are (cf. chart below).

Unit: tons	Weight limit	A380	A350-1000	A350-900	B747-400	B777 -200ER
Total weight	400	**571**	308.9	268.9	396.0	286.9
Main gear load, t/gear	139.5	**161.6**	**146.9**	126.0	92.8	134.9
Wheel load	26.2	**26.9**	24.5	**31.5**	23.2	22.5

Actions taken so far

Weight restrictions at Runway D were placed for the purpose of safe operations; hence, it is extremely difficult to ease the restrictions which are based on the computation of the durability of structures. This is why Runway D, which is only 2,500 meters long, has weight restrictions. Meanwhile, Haneda Airport never rejects larger airplanes including A380 and A350, and they are allowed to make landings if being operated within the acceptable weight (by, for instance, reducing fuel or cargo within a scope which does not affect its operation, meeting the weight requirements).
Runway C in Haneda Airport has been extended in December 2014. With the permission from Japan Civil Aviation Bureau (JCAB), larger aircrafts including A380 are able to use the runway C which is 3,000 meters in length from 23:00PM to 06:00AM.

Future outlook

JCAB has no specific plans over the next year.

Working Party 4 : Energy, Environment, and Sustainable Development

1. Changes and harmonization in the areas of energy and environment
（WP-4/#01*/EJ to EJ）

BRT Recommendation

Diversification and destabilization of resource- and energy-supplying regions:

While the diversification of energy and resource supply sources through the full-scale export of shale gas by the U.S., the lifting of sanctions on Iran, and other circumstances is contributing to stable energy supplies and the leveling of abrupt and erratic price fluctuations, the Middle East still plays a major role in the supply of energy to the world, and breeding grounds for civil war and terrorist activities exist within the region due to the continued fragility of some governments there.

We have also begun to see signs of sectarian violence and terrorism even in Middle Eastern regions that have been comparatively stable up until now. Moreover, in light of piracy issues off the coast of Somalia, it remains important for us to ensure the safety of sea lanes, including the Suez Canal and the Strait of Hormuz. The governments of Japan and EU countries will continue their efforts to strengthen cooperation among members of the international community to improve energy security.

The significant impact of the destabilization of energy prices on Japan and EU countries that import energy:

There are both positive and negative aspects to the fall in oil prices for consuming countries.

Growing dependence on oil from the Middle East, the world's low-cost resource superpower, means that the risk of a sharp rebound in price in the event of shrinking oil investment would offset the economic benefits. And if the price drops to such a level that it does not bring investment to the supply sector, there will also be growing concern over the stable supply of natural gas. Furthermore, incentives for the use of bio fuels do not seem to be working, and there has been a major impact on investment in energy efficient technologies and energy conservation measures. Also, in the unlikely event that a resource-rich country was to fall into a national financial crisis, it could lead to

growing geopolitical risks and the preservation of terrorist organizations.

Although declining resource prices have contributed to the short-term improvement of trade deficits in Japan and EU countries, it is important for these countries to fully understand the impact that the stabilization of resource prices can have on energy security, energy conservation, and energy efficiency, and to act accordingly.

The impact of rising energy demand in newly developing countries on national energy policy changes and resource prices:

At COP21, expectations were high for efforts toward the introduction of energy systems that are not only more low carbon but also more efficient. However, as was also introduced in IEA WEO-2015, world energy consumption in the future will be driven primarily by India, China, Africa, the Middle East, and Southeast Asia. It is predicted that energy consumption will increase by one-third of present consumption by 2040, and that the entire increase will be due to consumption in non-OECD countries. The reduction of energy consumption in OECD countries is the result of demographic changes, economic structure changes, and growing efficiency. By 2040, energy consumption is expected to decrease by 15% in Europe, 12% in Japan, and 3% in the U.S. With the world population expected to continue growing in the future, the center of energy consumption is shifting from developed countries to newly developing countries. While the export of shale gas by the U.S. is expected in the long run, aggressive resource development by state-owned companies in newly developing countries is currently being witnessed and competition for resources is becoming fierce.

Japan and the EU are committed to working together to stabilize resource prices and implement energy mix policies suitable for regional needs that will enable companies to continue their business activities in a stable manner.

Actions taken so far

The Government of Japan hosted the G7 Kitakyushu Energy Ministerial Meeting on May 1st-2nd, 2016, where Mr. Hayashi, then Minister of Economy, Trade and Industry, chaired the meeting under the main theme of "Energy Security for Global Growth." During the meeting, the ministers deepened discussions on promoting energy investment including upstream projects, which would contribute to the stabilization of energy prices, and on strengthening energy

security, under the circumstances of the recent changes in the energy market and geopolitical situations. Their specific messages and action plans were contained in the joint statement.
Further, during the G7 Ise-Shima Summit on May 26th-27th, 2016, the leaders expressed their commitment to (1) promoting investment on upstream developments, high quality infrastructures, and clean energy technologies, (2) strengthening security for the natural gas market, and (3) the promotion of innovative energy technologies and improved energy efficiency, and also shared (4) the recognition on the importance of nuclear safety.
In July 2015, the Government of Japan developed the energy mix as a vision of a desired energy demand and supply structure for FY2030 in accordance with the Strategic Energy Plan, which was approved by the Cabinet in April 2014.

Future outlook

The Government of Japan will continue to work on the specific actions adopted in the "Kitakyushu Initiative on Energy Security for Global Growth" at the G7 Kitakyushu Energy Ministerial Meeting and endorsed by the leaders.
Toward the realization of our energy mix, we are taking various measures such as taking through energy saving efforts, maximizing the introduction of renewable energy, improving the efficiency of thermal power generation, securing the stable supply of natural resources, and restarting nuclear power plants after their safety is confirmed.

2. Basic energy policy (WP-4/#02**/EJ to EJ)

BRT Recommendation

Harmonization of supply stability, economic efficiency, the environment, and safety standards:

Energy forms the foundation of economic activities. Efforts to reduce energy demand while at the same time ensuring the stable supply of energy and proper electricity rates are not only critical to business operations but also have a profound impact on the creation of new business opportunities. It is also important to give due consideration to environmental load. Based on this perspective, the governments of Japan and EU countries should carefully consider the resumption of nuclear power generation, which can be an effective measure for reducing greenhouse gas emissions.

Cooperation with other countries from a global point of view:

In regard to the energy demand and supply structure of the world, changes in demand are occurring primarily in Asia, and the diversification of energy sources such as natural gas, renewable energy, and nuclear power is becoming more pronounced. Meanwhile, the impact on the global environment is being exacerbated, and energy issues are becoming even more complex.

Amid these circumstances, Japan and the EU must promote a framework for a more comprehensive collaborative alliance from the viewpoints of energy and the environment.

As such, it will be imperative to not only deepen our relationship with the IEA and IAEA but also strengthen cooperation by exchanging information with our European counterparts in various international committees.

Short-, medium-, and long-term energy strategies:

All of the countries participating in COP21 have affirmed their commitment to controlling carbon dioxide emissions as a countermeasure against global warming.

The key to this will be to balance economic growth with the reduction of CO_2 emissions. And while the decision to engage in global efforts to cut CO_2 emissions was made at COP21, it will be essential to ensure that these efforts are paired with economic growth to make it possible to move forward with them

in a sustainable manner.

Going forward, it will be important for governments, industries, and citizens to develop a solid understanding of the current energy situation and consider which changes are temporary or cyclical, and which are permanent. In addition, it will be necessary to determine what kinds of risks and chances are conceivable for the future, identify what can be done to make our energy systems more secure, reliable, and sustainable, and consider short-, medium-, and long-term energy strategies.

Achieving a stable supply of energy through a multi-layered energy supply structure:

There are invariably advantages and disadvantages to the adoption of every energy source, and there is no form of energy that provides complete satisfaction from both a stability and economic standpoint. In view of this, a multi-layered energy supply structure capable of functioning not only during times of peace but also in emergencies should be established.

Maintenance and upgrading of energy infrastructure:

To ensure the stable and adequate supply of energy, Japan and the EU must share best practices for the construction of an energy value chain capable of achieving the prescribed energy mix and consider the upgrading of old equipment and facilities to improve their safety.

Actions taken so far

The energy mix developed in July 2015 was the result of examination aiming at achieving the following three goals at the same time on the premise of secured safety: (1) stable supply, (2) reduced electricity costs, and (3) CO2 emission control. In the energy mix, nuclear power is planned to be utilized to the extent of about 20 to 22% in the total power supply. As nothing is more important than secured safety for nuclear power plants, only after the Nuclear Regulation Authority confirms that a nuclear power plant meets the new regulatory requirements, which is at the world's highest level at present, the power plant will be allowed to restart, respecting the judgment made by the Authority.

At the same time, the Government of Japan has proactively contributed to the activities of international and regional fora, such as IEA, IRENA and IAEA, G8/G7, Asia-Pacific Economic Cooperation (APEC), and ASEAN+3. For

example, Japan chaired the G7 Kitakyushu Energy Ministerial Meeting, the G7 Ise-Shima Summit, and the Energy Charter Conference in 2016. In addition, the Government of Japan worked on broadening and deepening its international collaboration network by inviting IEA's Executive Director and other key figures to Japan to deliver speeches at several international conferences in Japan. With respect to international cooperation from international perspective, particularly on renewable energy, the Government of Japan carried out the study tour inviting diplomatic coups in Tokyo to Koriyama City in Fukushima Prefecture for visiting facilities related to renewable energy and assistance for reconstruction from the earthquake. The diplomatic coups participating in the study tour including those from Europe deepened their understanding on the outcomes of the most advanced technologies and research and development regarding the utilization of solar power, wind power, hydrogen and geothermy.

Future outlook

To realize the energy mix developed in July 2015, the Government of Japan is taking measures such as taking thorough energy saving efforts, maximizing the introduction of renewable energy, improving the efficiency of thermal power generation, securing the stable supply of natural resources, and restarting nuclear power plants once their safety is confirmed. As to the restarting of nuclear power generations, the Ikata Nuclear Power Plant's No. 3 reactor started operation on August 12th, 2016 and had started generating electricity from August 15th. The Nuclear Regulation Authority will continue to examine whether the other nuclear plants meet the new regulatory requirements.
At the same time, we will continue to proactively contribute to the international/regional forums, such as IEA, IRENA and IAEA, G8/G7, G20, and APEC.

3. Fossil fuels（WP-4/#03*/EJ to EJ）

BRT Recommendation

Advantages and disadvantages of coal, oil, natural gas, and LP gas:

Although fossil fuels are known to emit greenhouse gases, they do excel in terms of economic efficiency and output stability. Progress is currently being made toward the development and commercialization of highly efficient low-carbon alternatives, and governments should be providing support for these development and commercialization efforts, as well promoting the use of these alternatives in developing countries.

Still valued today as an important base-loaded power supply, coal-fired thermal power poses little geopolitical risk. It should also be noted that fossil fuels remain low in price as a form of thermal energy in developing countries.

Japan and the EU should contribute to countermeasures against global warming by supporting the introduction of coal-fired thermal power characterized by high efficiency and low CO_2 emissions, such as ultra-supercritical coal-fired power, and the development of new technologies, such as carbon capture and storage (CCS).

Actions taken so far

In its energy mix target developed in July 2015, the Government of Japan decided to promote utilizing high efficiency coal- and LNG-fired thermal power generation while reducing environmental burdens at the same time. In addition, based on the Paris Agreement adopted in December 2015, the "Technology Road Map for Next-Generation (Super-Advanced) Thermal Power Generation" was developed by a public-private council in June 2016 in order to realize high efficiency thermal power generation and the reduction of CO2 emissions. Toward the practical use of carbon dioxide capture and storage (CCS) technologies we are conducting large-scale demonstration tests, research and development and environmental impact assessment among and many efforts whereby the government of Japan contributes to taking measures against global warming. Furthermore, through energy policy talks with our relevant countries and cooperations with private companies, we are supporting the dissemination

of high-efficiency and low-carbon technologies to developing countries and helping the reduction of CO2 emissions on a global scale.

Future outlook

Regarding the introduction of high-efficiency, low-carbon coal-fired power generation, the Government of Japan will promote the introduction of its world-class high- efficiency power generation technologies such as ultra super critical coal-fired power generation overseas. Aiming at the earlier introduction of next-generation (super-advanced) coal-fired power generation technologies, such as oxygen-blown integrated coal gasification combined cycle (IGCC) with higher performance than ultra super critical coal-fired power generation, the Government of Japan is carrying out necessary technical development and demonstration tests based on the "Technology Road Map for Next-Generation (Super-Advanced) Thermal Power Generation," which was developed in 2016. Regarding the practical use of CCS technologies, the Government of Japan will continue to conduct necessary demonstration tests, research and development and environmental impact assessment amongst other efforts.
Through these activities, the Government of Japan will endevour to reduce environmental burdens on a global scale.

4. Nuclear power (WP-4/#04**/EJ to EJ)

BRT Recommendation

There is keen interest in nuclear power generation from the viewpoints of promoting measures against global warming and stably securing energy that is less susceptible to fluctuations in fossil fuel prices.

Nuclear power generation is also expected to play a major role in keeping the global temperature rise this century below two degrees Celsius, which is the long-term aim of the Paris Agreement reached at COP21. However, if we attempt to achieve this without nuclear power, the cost of doing so will increase dramatically. At the same time, it would lower the feasibility of achieving this aim, and we therefore believe it will be impossible to accomplish without the inclusion of nuclear power generation.

A critical and competitive base-loaded power supply in regions without energy resources:

Safe nuclear power generation plays an important role in the energy mix for Japan and the EU. Moreover, it contributes to giving Japan and the EU a competitive edge, securing a low-cost base-load power source, ensuring grid stability, achieving economic growth, and creating jobs.

Rising expectations for nuclear energy and the importance of education and training on ensuring safety:

Japan and the EU must cooperate to universalize lessons learned from the Fukushima nuclear accident, as well as provide education and training in order to ensure the safety of nuclear power generation.

Promotion of the resumption of operations at nuclear power plants in Japan where safety checks have been completed:

The rising cost of coal-fired thermal power generation due to the shutdown of nuclear power plants in Japan in 2013 has not only led to the destabilization of electricity prices and increases in greenhouse gas emissions but also caused a decrease in the competitiveness of both Japanese and European companies in the Japanese market.

Taking into account economic reasons and greenhouse gas emissions, we must proceed with resuming the operation of power plants where safety has been confirmed by the Nuclear Regulatory Commission, as well as promote the stable

supply of electricity in conformance with the energy mix the government aims to achieve.

Replacement of current nuclear reactors with safer ones:

The latest nuclear reactors provide a technologically high level of safety, are being explored as a possibility for inclusion in the energy mix of the future, and should be considered for use in replacing aging nuclear reactors in Japan and the EU. The construction of nuclear reactors in Japan and the EU utilizing the latest models should be used as a reference for the export of nuclear power technology by Japan and European countries to third countries.

Recycling and disposal of nuclear fuel:

In regard to spent nuclear fuel, Japan and the EU must take sweeping measures and make comprehensive decisions to solve the issue of how spent nuclear fuel should be managed, recycled, and discarded.

Japan and the EU should therefore promote an R&D program for collaboration on the development of methods for nuclear waste disposal.

Developing decommissioning technologies and methodologies:

Japan and the EU hold a large part of the worldwide inventory of the aged nuclear reactors which subject to decommissioning. Establishing decommissioning technologies and methodologies for safety and minimum environmental impact is an obligation of Japan and EU and precondition to promote nuclear power technology to third countries. Japan and EU should therefore promote an R&D program for collaboration on the development of method for nuclear power plant decommissioning.

Finance & Support:

To achieve the highest possible safety standards, we would like to request that Japan and the EU not only promote investment in nuclear energy but also request that the World Bank, European Bank for Reconstruction and Development (EBRD), European Investment Bank (EIB), and JBIC provide financing to support programs dedicated to ensuring the safety of nuclear power.

Security measures:

Japan and the EU should cooperate in facilitating the effective implementation of international nuclear safety standards and security measures at bilateral meetings and multilateral meetings on nuclear power.

In addition, discussions between specialists from both Japan and the EU on information and technology related to nuclear power plant decommissioning projects, decontamination, and waste disposal should continue to be promoted.

(Meanwhile, interest in nuclear power development is on the rise in Asia and the Middle East. Viewing nuclear power as a great opportunity for the future of international business, there are also countries emerging with plans to attempt to maximize the impact on share expansion first. Since there are fragile states and areas where terrorism runs rampant in conflict zones within the region for which construction is planned, it will be crucial for the international community to proceed with caution and carefully consider how to reduce risks through nuclear non-proliferation and other measures.)

Actions taken so far

In the Strategic Energy Plan on which a cabinet decision was made in April 2014, nuclear power is positioned as an "important baseload electricity source that will contribute to the stability of our energy demand and supply structure on the premise of secured safety." Having said that, the Government of Japan gives top priority to safety for nuclear power generation under any circumstance. For this reason, only when the Nuclear Regulation Authority confirms that a nuclear power plant meets the new regulatory requirements, the power plant will be allowed to restart, respecting the judgment made by the Authority.
In accordance with this policy, the Ikata Nuclear Power Plant's No. 3 reactor restarted operation on August 12th, 2016 and started generating electricity on August 15th.
Meanwhile, Japan's basic policies call for the effective use of resources and the promotion of a closed nuclear fuel cycle that will be conducive to reducing the volume and hazardousness of high-level radioactive wastes. In order to steadily and efficiently implement spent nuclear fuel reprocessing projects under the new business circumstances, such as the deregulation of the electric power industry, an amendment bill to the Spent Nuclear Fuel Reprocessing Fund Act was approved. As a result, NuRO (Nuclear Reprocessing Organization of Japan) has been established as a primary operator responsible for carrying out spent nuclear fuel reprocessing in an organized manner.

Future outlook

The details of issues over nuclear power projects will continue to be discussed at the Advisory Committee for Natural Resources and Energy.

Toward the realization of closed nuclear fuel cycle policy, the Government of Japan will continue to strengthen tis cooperative relationship through frameworks for exchanges of views, such as the Japan-France Committee on Nuclear Energy and the Annual Japan-UK Nuclear Dialogue.

5. Renewable energies（WP-4/#05**/EJ to EJ）

BRT Recommendation

Renewable energy is expected to play a major role in countermeasures against global warming, and there have been recent signs of improvement in the cost aspect, which had been considered an issue against the use of renewable energy. At the same time, thorough discussions regarding the economic, efficiency, and stability aspects must also be continued.

Advantages of renewable energy:

Although the role of renewable energy in the reduction of CO_2 emissions and achievement of energy security cannot be denied, integration into the grid and stability of supply remain major issues to address. Despite its potential to complement traditional energy, it will require a robust and integrated power distribution network.

Currently there are various options for renewable energy, including wind, solar, hydro, geothermal, tidal, and biomass. However, other than hydroelectric power, which can provide a certain level of base power, these power sources are affected by regional appropriations. Thus, there are remaining economic, efficiency, and stability issues that need to be addressed, pointing to the need for further discussions before their uptake can be realized.

To overcome these instability factors, it is imperative to:

- Comprehensively discuss how the adoption of renewable energy sources can be realized
- Evaluate the total costs for renewable energy, including the supply chain components
- Promote research on immature renewable energy technologies towards their commercialization

Energy storage batteries:

Storage batteries contribute to the stabilization of the energy supply-and-demand structure through the storage of convenient power and the ability to use it anytime, anywhere. As a technology for long-term and large-scale storage of power, the hydrogen energy storage system should be more widely utilized for the efficient utilization of power.

Due to the development of the smart grid, storage battery applications are expected to expand further to include vehicles, residences, buildings, and commercial establishments. Japan and the EU must continue to work together toward lowering costs and increasing efficiency through technological development and standardization.

On the other hand, the uptake of renewable energy has led to instability of the power grid due to the increase in distributed power sources. Systems for maintaining stability, however, are prohibitively expensive. Recently, the use of cloud and ICT has made it possible to intensively gather data and carry out control at lower costs. Also, in regard to storage batteries, technologies to prevent imbalances that prevent further charging due to having one battery depleted and another fully charged are being developed. It is imperative to proactively make use of the microgrid and ICT that enable handling efficient power sources, such as solar power generation.

Feed-in tariff system in Japan

There have been many cases wherein permits have been secured under the renewable energy feed-in tariff system (FIT) in Japan but the project did not actually become operational, leading to concerns regarding the high burden on citizens and the prevention of entry of latecomer energy producers that offer lower costs and higher performance. In particular, in regard to the FIT for solar power systems, which are being introduced at a rapidly increasing rate, there is a need to formulate schemes to encourage producers to find ways to lower costs from the perspective of lowering the burden on citizens. And also, hydro, geothermal, and wind power, which are cheaper to generate but have longer lead times for commercialization, and biomass power, which contributes to “local production for local consumption” initiatives should be more encouraged to be adopted.

Actions taken so far

The Government of Japan's basic policy on renewable energy is to maximize the introduction of renewable energy while reducing the public financial burden. Under the revised Feed-in Tariff (FIT) Act enacted in May 2016, the equipment accreditation system has been reviewed to resolve the problem of existing non-operating renewable energy projects and to prevent similar projects from

being accredited in the future. This Act encourages more cost-effective introduction of renewable energy, such as introducing a bidding system for large-scale solar power projects. At the same time, for power sources that require a longer lead time such as geothermal power, a new scheme has been introduced to increase business predictability for energy producers by providing energy purchase prices in several years ahead of time, which will encourage more participation in this field.
Regarding storage batteries for electric power conditioning applications, the Government of Japan supported demonstration tests for a possible virtual power industrial plant, developed cost reduction technologies, and demonstrated large-scale storage batteries. The international standard was established based on the joint proposal between Japan and France regarding the performance of industrial (stationary) lithium secondary batteries at the International Electrotechnical Commission (IEC).

Future outlook

In order to achieve the targeted level of introduction of renewable energy in the best energy mix developed in July 2015 (22 to 24% of the total power generation in 2030), the Government of Japan will properly implement the revised Feed-in Tariff (FIT) System and work on further development of technologies and the rationalization of regulations.
Regarding storage batteries for electric power conditioning applications, the Government of Japan will continue the research and development and demonstration tests for cost reductions and early installation. In addition, the Government of Japan will make sure the precise integrated control of those storage batteries can be managed by third parties..

6. Effective use of biomass resources(WP-4/#06**/EJ to EJ)

BRT Recommendation

In order to make the shift from fossil to biomass resources as raw materials for a wide range of uses and therefore achieve significant reduction in greenhouse gas emissions, technologies and processes to convert biomass into fuel or useful chemicals must be developed and become widely adopted.

Fast-tracking the practical utilization of technologies that convert agricultural waste products, wood-based biomass, and other non-edible plant resources into fuel or useful chemicals requires strengthening of government support for collaborative R&D and technical trials between private-sector companies and academic institutions in Japan and the EU. Further, promoting the uptake of products manufactured using the above technologies requires the implementation of a sustainable, effective, and transparent framework for providing subsidies and tax incentives for biomass-derived fuels and chemicals.

International standardization of evaluation methods, classification schemes, and labeling procedures are also necessary to enable a stable and profitable uptake of biomass-derived products at the global level. In labeling for example, although there are internationally defined environmental labels (Type I, II, and III), compliance standards vary among different countries.

Standardization of the certification criteria for labels will make it possible to have universal labels that can be used worldwide. This will lead to the establishment of market reliability of biomass-derived products and pave the way for their stable and profitable uptake. Also, linking environmental labels with requirements/conditions for tax incentives and public procurement can serve as an impetus for the further spread of the use of biomass-derived products. To enable Japan and the EU to agree on and lead the way in establishing international standards for evaluation and labeling systems, both governments must pursue the harmonization and mutual recognition of their respective regulations.

Actions taken so far

Regarding technical development efforts, the Government of Japan is currently

carrying out research and development to produce bioethanol from cellulosic materials and biojet fuel from microalga-derived oil and biomass-gasification/liquefaction. In addition, the Government of Japan is working on development of technologies to produce alternatives to petrochemicals from non-edible woody biomass and to separate and utilize cellulose nanofiber and on demonstration tests aiming at the social implementation of measures against global warming.
In order for the widespread use of such products, the Government of Japan also sets a specific target for the introduction of biomass-derived fuels to have oil wholesale companies take further actions. At the same time, the Government of Japan is providing tax incentives and import duty exemptions for the purpose of facilitating the introduction of biofuel. The Government of Japan is also developing international standards for the assessment of the performance of cellulose nanofiber products.
The "Fourth Basic Environmental Plan" calls for "the creation of a framework for globally common environmental labels using cross-certification, universal standards, and other mechanisms." Based on this plan, the Government of Japan is surveying and analyzing the consistency of the current systems and standards of environmental labels in Japan and in foreign countries.

Future outlook

The Government of Japan will continue to implement research and development on production technology to produce biojet fuel from cellulosic ethanol and microalga, aiming at practical use around 2030. Also, the Government of Japan will also carry out research and development on production technologies for biomass-derived chemicals, aiming at practical use around 2030 with the assistance of chemicals and paper manufacturers.
Regarding the expansion of cross-certification for environmental labels, the Government of Japan will continue to survey and analyze how the existing systems and standards of Japanese and overseas environmental labels have been harmonized in the past.

7. Energy conservation and energy efficiency（WP-4/#07**/EJ to EJ）

BRT Recommendation

Energy conservation is an initiative aimed at fulfilling the need for economic efficiency, environmental compatibility, and energy security, and industries in Japan and the EU should make every possible effort to develop and promote the use of energy conservation technologies.

At the same time, it is also important to ensure that excessive investment burden is not placed on companies nor that production suppression is imposed on them for the sake of achieving excessive energy conservation effects.

The promotion of energy conservation will require the strengthening of research and development and improvement of public awareness of energy conservation.

Strengthening of energy conservation in each field:
One area in which energy conservation effects are foreseen in the residential and business fields is the use insulation materials and high-performance windows as energy conservation measures in houses and buildings.

Energy conservation technology for electric appliances and equipment, such as refrigerators, air conditioners, servers, and LED lighting, is also evolving. In the transportation field, advancements are being made in the energy efficiency of automobiles through the development of EV, PHEV, clean diesel, and hydrogen fuel. Japan and the EU should collaborate on standards to take the lead in promoting market introduction of these technologies.

One commonality among all fields is that the introduction of energy management is also an effective means to increase energy efficiency.

To increase the efficiency of energy, Japan and the EU must revise laws and regulations, develop advanced technologies that boost energy efficiency through best practices, and implement stimulus measures such as investment in methodologies. At the same time, these actions should be complemented by aggressive measures that will have an impact on technologies for soundproofing of buildings and stabilization of room temperature.

Prompt implementation of mandatory regulations for building standards and insulation of houses will make it possible for the resulting highly energy efficient buildings and homes to contribute to the lowering of energy consumption and

expenditures, the reduction of CO_2 emissions, and the maintenance of good health at both a household and national level.

Action taken so far

The Japanese policy systems on energy efficiency Japan are classified largely into three sectors: "industrial," "consumer (business and households)," and "transportation" and each sector has taken both regulatory measures under the Act on the Rational Use of Energy and assistant measures utilizing such as budget and tax systems.

With respect to regulatory measures, in order to improve the energy efficiency performance of buildings, the Government of Japan made public in July 2015 a law requiring that new non-residential buildings of over a certain size comply with energy efficiency performance standards (the Act on the Improvement of Energy Consumption Performance of Buildings).
With respect to assistant measures, on the other hand, the Government of Japan is trying to promote energy efficient buildings by supporting the construction of such facilities, which is expected to encourage private companies to invest more on energy-efficient and low cost facilities. At the same time, the Government of Japan offers energy efficiency and energy saving diagnosis free of charge to medium- and small-sized enterprises, and supports the dissemination of efforts on energy efficiency by sharing best practices such as through introducing examples of possible energy efficiency approaches and technologies.

Future outlook

Toward the realization of thorough energy efficient society, the Government of Japan will enhance its energy efficiency measures in each sector through both regulatory and assistant measures.

8. Energy research and international cooperation（WP-4/#08*/EJ to EJ）

BRT Recommendation

The reduction of greenhouse gas emissions and energy technology development focused on the mid and long-term

Greenhouse gas emissions are impacting climate change and the environment, thereby making this an issue facing all of mankind that requires international insight. As such, the development of technologies capable of reducing greenhouse gas emissions with the use of electricity produced using fossil fuels, non-fossil-fuel renewable energy, and nuclear power deemed safe is becoming necessary on a global scale, and it is imperative that the development framework be reinforced through cooperation among industry, government, and academia.

Human resource development

To promote sustainable efforts aimed at achieving the goal set by all ratifying nations of the Paris Agreement to reduce CO_2, both Japan and the EU—as leaders in the fields of energy and environmental technology—must forge ahead with ground-breaking innovation.

In addition to contributing to the international society, sustainable innovation activities like these are also conducive to economic growth. This is why a system for continuously training technical experts in energy-related fields through personnel exchanges should be considered.

Actions taken so far

Regarding research and development in the energy field, the Government of Japan continues its efforts on the development of technologies, aiming at the promotion of low-cost and high efficiency production of all types of renewable energy including solar power. The Government of Japan also carries out the development of technologies to further improve the safety level such as the sophistication of comprehensive risk assessment measures on nuclear power plants.

Regarding human resource development, during the G7 Energy Ministerial Meeting, Japan, as the host country, proposed the efforts toward exchanging

researchers among the G7 countries, including through encouraging international collaboration among relevant research institutes, in order to promote the development of innovative clean energy technologies.

Future outlook

Regarding renewable energy, the Government of Japan will continue its efforts to reduce the cost of introducing renewable energy through research and development project, such as those on high efficiency and low-cost solar panels and technical improvements in wind turbine maintenance. On the other hand, regarding nuclear power, the Government of Japan will continue to carry out technical development to meet enhanced safety requirements for nuclear power, such as the sophistication of comprehensive risk assessment measures on nuclear power plants.
Regarding human resource development, taking an opportunity of international conferences such as Innovation for Cool Earth Forum (ICEF), the Government of Japan will first provide places where research organizations and researchers can build relationships to promote the development of innovative clean energy technologies. Based on such relationships this will be followed by exchanges of researchers in each specific field of technology.

9. Efforts toward the prevention of global warming following the Paris Agreement reached at COP 21(WP-4/#09**/EJ to EJ)

BRT Recommendation

The prevention of global warming is an issue facing all of mankind.

Since much of the world's greenhouse gas emissions have already shifted from developed countries to newly developing countries, it will be impossible to prevent global warming if only developed countries set targets for reduction.

We welcome the Paris Agreement as a framework through which all major emitting countries, including the U.S. and China, are able to participate, and view it as an extremely important and historical first step that enabled all countries participating in COP21 to set their own targets.

Going forward, it will be necessary to not only ensure that all major emitting countries ratify this agreement but also establish a system with which the fulfillment of the promises made by each country can be reviewed internationally from the perspective of enhancing fairness and effectiveness.

Japan and the EU will need to undertake the tasks of developing low-carbon technologies and transferring technology to developing countries with significant potential for making reductions.

Actions taken so far

At the COP21 in December 2015, the Parties adopted the Paris Agreement applicable to all Parties, which the Government of Japan has long called for. Japan signed the Agreement at the high-level signature ceremony for the Agreement in April 2016 and concluded it in November 2016.

Japan has been actively contributing to the negotiations on modalities, procedures, guidelines or guidance towards fair and effective implementation of the Paris Agreement. The negotiations include building of the reporting and reviewing mechanism which provides clarity on each Party's action and support, and facilitates its efforts.

Japan has also been strengthening efforts for development and dissemination of

low-carbon technologies based on the Plan for Global Warming Countermeasures and the Energy & Environment Innovation Strategy towards 2050. As for technology transfer, Japan has been actively promoting both bilateral approaches including emission reductions in developing countries by JCM and multilateral approaches under UNFCCC.

Future outlook

Japan will continue to actively contribute to negotiations toward the fair and effective implementation of the Agreement. Japan will also continuously undertake the efforts for the development of technologies and the technology transfer.

Visualization of emission reduction effects

BRT Recommendation

Public and private sectors must work together to specifically promote efforts to demonstrate the validity of energy-saving effects of low-carbon technologies and products used to visualize CO_2 emission reduction effects.

[Public and private sectors must work together to specifically promote efforts to visualize emission reduction targets and validate the energy-saving effects of low-carbon technologies and products?]

LCA is a technology that can be used to evaluate the environmental impact made by a product at every stage of the product life cycle from the cradle to the grave. The visualization of products and technologies capable of determining CO_2 reduction effects through LCA analysis should be promoted through public-private collaboration.

Actions taken so far

Regarding visualization of CO2 emissions reduction, the Government of Japan carried out a pilot program for the Carbon Footprint of Products (CFP), which started in FY2009 and completed in FY2011. After the completion of the pilot program, a private initiative replaced over it, and has been operating as the CFP Communication Program.
The Government of Japan launched the pilot project of carbon offset products making use of carbon footprint program called as “DONGURI (Acorn) Project” in November 2012. This program puts marks on goods and services whose CO2 emissions calculated by measures such as the CFP Communication Program are offset. Also, the “DONGURI Point Project,” which adds points to the DONGURI Project goods and services, was started by the government in November 2013.
The Government of Japan, amongst others, has also been working on a guideline development for corporate emissions accounting throughout the supply chain

Future outlook

As previously mentioned, a private association has already taken over the “CFP Communication Program”. In addition, the “DONGURI Point Project” is to be a purely private program in 2016. In order to keep on promoting visualization of emissions reduction, the Government of Japan will continue to examine toward the expansion of dissemination of the existing “DONGURI Project” and regularly communicate with private organizations carrying out the “CFP Communication Program” and the “DONGURI Point Project”. The Government of Japan will also continue to develop the basis for supply chain emissions accounting.

Contributions to global warming measures in Japan and the EU

BRT Recommendation

The creation of a framework through which both developed and developing countries can work together to achieve low-carbon growth will play a critical role in addressing climate change issues. The outstanding technologies, products, and know-how possessed by Japan and the EU will not only lead to the strengthening of innovation and sustainable development in both countries but also contribute to global warming countermeasures on a global scale.

In particular, contributions utilizing ICT should also be considered. These include continuous observation of the global environment using artificial satellites, radars, sensors, and other equipment to monitor climate change, the use of supercomputers and other means for climate change prediction and research on the mechanisms behind climate change, and the construction of a global earth observation system.

It will also be imperative to conduct research and development of technologies for calculation and verification of greenhouse gas emissions and carbon dioxide capture and storage (CCS) in order to alleviate climate change.

Moreover, a bilateral offset mechanism will be an effective means for achieving greenhouse gas reductions in newly emerging and developing countries where a sharp rise in energy demand is becoming apparent. Japan and the EU must not only work together with industry to design such a system but also clarify support measures.

In conjunction with measures like these to alleviate climate change, the governments of Japan and EU countries must open their doors to industry, provide easy-to-understand explanations of adaptive planning, technology needs, and financial assistance, and create an environment in which industry can easily participate. Governments in Japan and the EU must also set high standard regulations, as well as a share a common interest in making efforts toward market liberalization that would include third countries in addition to Japan and the EU.

Actions taken so far

Japan has established and been implementing the JCM (Joint Crediting Mechanism) in order both to appropriately evaluate contributions from Japan to greenhouse gas (GHG) emission reductions and removals in a quantitative manner achieved through the diffusion of low carbon technologies, etc. as well as implementation of mitigation actions in developing countries, and to use them to achieve Japan's emission reduction target. So far 9 demonstration projects and 91 JCM Financing Programs are implemented out of which 15 projects have been registered as JCM projects.

GOSAT has been monitoring GHGs from space for over 7 years and detected the whole-atmospheric monthly mean CO2 concentration which was exceeded 400 ppm in December 2015. Furthermore, anthropogenic CO2 concentrations over the world's mega-cities were analyzed by GOSAT, which showed that GOSAT has the potential for verifying CO2 emissions.

In May 2016, Japan announced that the CO2 concentration around Japan was the highest on record. In October of the same year, the Japan Meteorological Agency (JMA) published 'Annual Greenhouse Gas Bulletin' as one of the roles for the World Data Centre for Greenhouse Gases (WDCGG) of the World Meteorological Organization (WMO).

As to a methodology for estimating GHG emissions, an expert group was established to elaborate it every year. Also, research and development on the carbon dioxide capture and storage (CCS) technology are being promoted.

Future outlook

In the global warming prevention measures plan, apart from contributions made by the projects on private basis, accumulated emission reductions or removals by FY 2030 through governmental JCM programs to be undertaken within the government's annual budget are estimated to be ranging from 50 to 100 million t-CO2. Japan will continue to support further implementation of JCM projects.

The Ministry of the Environment of Japan, the Japan Aerospace Exploration

Agency, and the National Institute for Environmental Studies have been jointly developing the successor of GOSAT (GOSAT-2) to continue GHG monitoring from space.
Japan will also continue to monitor global environment through the in-situ observations of GHG to contribute to measures against climate change and promote Earth Observation data sharing globally by connecting Data Integration & Analysis System (DIAS) to Global Earth Observation System of Systems (GEOSS). In addition, Japan is going to publish ‘Global Warming Projection Vol. 9’ which outlines the global warming projections for the area around Japan based on the results of numerical experiments using a supercomputer.

Japan will continue to work on an elaboration of methodologies for estimating GHG emissions, and promote research and development on CCS technology.

Establishment of IPR protection

BRT Recommendation

To promote commercial technology transfer, Japan and the EU must take measures to ensure the creation of appropriate regulatory frameworks in countries to which technology transfers are to be made and the protection of intellectual property rights. It will be necessary to create appropriate regulatory frameworks to establish IPR protection in newly emerging and developing countries, and governments in Japan and the EU should introduce monitoring systems for the protection of IPR, provide patenting assistance, and establish technology partnerships.

Actions taken so far

The Government of Japan, in order to ensure that intellectual property rights are adequately protected in emerging and developing countries, has carried out bilateral and regional cooperative activities according to the particular needs and circumstances of countries and regions. Also, Japan has assisted developing countries through its cooperative efforts with the World Intellectual Property Organization (WIPO).

In 2016, the Japan Patent Office (JPO), as in previous years, supported emerging and developing countries to develop human resources and improve their intellectual property systems. More specifically, the JPO conducted its training programs for them in Japan in the areas of, for example, enhancement of examination practices, effective management of intellectual property, and anti-counterfeiting measures. Also, the JPO conducted its experts to these countries to assist in their needs.

In particular, the JPO carried out a variety of assistance activities for countries in the Association of Southeast Asian Nations (ASEAN) region. The JPO's activities include support for drafting and updating patent manuals and sharing JPO's expertise and experiences in terms of managing operations for speeding up the patent examination process, and support for modernization of IP Offices. Also for India, the JPO sent patent examiners to provide a training program designed for around 460 new examiners employed by the Controller General of Patents, Designs and Trade Marks (CGPDTM) of India. For Latin American

countries, the JPO held the dialogues between examiners of Japan and Latin American countries in Examiner Exchange Programs and conducted training courses in Japan. In addition, for African countries, by using the Japan Funds-in-Trust for Africa at the WIPO, the JPO provided support for digitizing filing documents and developing human resources.

Future outlook

The JPO will continue to advance its support activities, through bilateral and regional cooperation and collaboration with the WIPO, in order to ensure adequate and effective protection of intellectual property rights in emerging and developing countries. More specifically, the JPO will provide assistance in terms of sharing the JPO's examination practices and methods, improving the operational practices of the Madrid Protocol (the Protocol Relating to the Madrid Agreement Concerning the International Registration of Marks), and enforcement field of intellectual property rights. To achieve these objectives, the JPO will conduct training programs in 2017 by inviting trainees from emerging and developing countries. In addition, the JPO plans to send its experts and examiners to various countries in order to share their expertise and experiences as well as to give technical advice on intellectual property issues in such countries.

10. Promotion of resource efficiency and the circular economy(WP-4/#10*/EJ to EJ)

BRT Recommendation

Although resource prices are declining in the short term, resource constraints are likely to inhibit economic growth over the medium to long term. This is why it is imperative to improve the efficiency of resource use. In this light, Japan and the EU welcome the progress being made through international-level discussions on resource efficiency and the circular economy, including the establishment of the G7 Alliance on Resource Efficiency at the G7 Summit at Schloss Elmau held last year. The announcement of the EU's adoption of a Circular Economy Package and the promotion of efforts to improve resource efficiency are also welcomed.

Discussions on resource efficiency and the circular economy go beyond recycling and other aspects of the venous industry to cover a wide range of concepts impacting manufacturers, service providers, and other companies to be recognized as arterial industry, including the extension of product life, the sharing of services, and the goods and services through operational billing. The discussion holds the potential to create business opportunities that will lead to additional economic growth and the job creation in the future.

On the other hand, the pursuit of resource efficiency through exceedingly regulatory approaches could inhibit economic growth. Therefore it is desirable to choose an approach that will lead to economic growth, such as promotion through voluntary efforts by stakeholders. It will also be imperative to pursue resource efficiency from the viewpoint of international circulation system based on the fact that movement of secondary raw materials across borders is now the norm.

In view of the above, Japan and the EU should not only move forward with efforts aimed at improving resource efficiency but also work together to formulate consistent rules. In addition, Japan and the EU are expected to take advantage of the advanced innovation and competitive edge in international market, which they possess in regard to the institutional and technical aspects of resource efficiency and the circular economy, deepen their cooperation and collaboration, and take the lead in international discussions on the future

direction of the circular economy and resource recycling, as well as on the creation of institutions and systems. In this regard, we are looking forward to active discussions on resource efficiency and the circular economy during coming G7 Summit chaired by Japan in 2016.

Actions taken so far

Under the framework of Japan-EU Industrial Policy Dialogue, the discussion of regulatory cooperation on the resource efficiency has taken place. Specifically, the Government of Japan conducted the sharing of information and exchange of views on the legislation system of both side related to resource efficiency including eco-design requirements, at the Climate Change and Environment WG held in February. On the occasion of the Climate Change WG, Ministry of Economy, Trade and Industry and EU-Japan Center for Industrial Cooperation jointly held a seminar for promoting the discussion with stakeholders including the industrial sector.
At G7, “Toyama Framework on Material Cycle”, which includes the common vision of G7, ambitious actions by G7 and the follow-up process, was adopted at the Toyama Environment Ministers’ Meeting. Resource efficiency and the 3Rs was included in the agenda of G7 Ise-Shima Summit, and the leaders endorsed the above framework and agreed to work with business and other stakeholders to improve resource efficiency. Moreover, Japan hosted a Work Shop under the G7 Alliance on Resource Efficiency on February 2016 and December 2016, and US hosted a Work Shop in March 2016. Through the discussion in these Work Shops, the Government of Japan promoted the sharing of information among stakeholders.

Future outlook

Japan and the EU continue the discussion on regulatory cooperation under the framework of Japan-EU Industrial Policy Dialogue, and cooperate towards developing the harmonized common rules to improve resource efficiency. The Government of Japan further promotes discussion and information sharing with industry and other stakeholders through holding seminars etc. such as the WS on G7 Alliance for Resource Efficiency.

11. Promotion of global investments and nurturing of long-term relationships(WP-4/#11*/EJ to EJ)

BRT Recommendation

Amidst sharp fluctuations in the price of oil and other resources, continued investment and strong economic collaboration in a wide range of fields will be necessary to secure stable and inexpensive resources in response to global risks.

When it comes to long-term sustainable energy policy, it is important to make the necessary investments and ensure strong cross-border collaboration in order to achieve ambitious targets. Japan and Europe should therefore encourage direct investment from a transparent, open, and long-term perspective living up to the commitments all parties made in the Energy Charter Treaty.

To promote the spread of energy conservation technologies and the like, it will be important to promote high-efficiency, low-cost renewable energies and conduct research and development of hydrogen, energy storage, geothermal, and other new energies. In addition, research that will contribute to the highly efficient utilization of fossil fuels and both the safety and security of nuclear power should also be considered.

Actions taken so far

At the G7 Kitakyushu Energy Ministerial Meeting, G7 countries agreed to lead the promotion of energy investment to bolster the growth of the world economy. Japan is the chair of the Meeting of the Energy Charter Conference 2016 and is dealing with international issues such as the protection and liberalization of investment in the energy field.
As part of the specific international cooperation related to the promotion of investment, Japan carried out overseas projects that demonstrate Japan's advanced energy saving and renewable energy technologies and systems, and discussed such issues as nuclear safety through frameworks for exchanges of views, such as the Japan-France Committee on Nuclear Energy and the Annual Japan-UK Nuclear Dialogue.

Future outlook

The Government of Japan will continue to work on the "promotion of energy investment" for global growth.
In order to thoroughly promote the energy efficiency initiative, the Government of Japan will encourage investment in energy efficiency through both assistance and regulatory measures. Japan will also continue to properly operate the Feed-in Tariff (FIT) scheme, which helps ensure investment recovery from renewable energy projects.
Regarding the nuclear energy field, Japan will continue to strengthen cooperation with France and the U.K..