

(Tentative Translation)

Report from the Government of Japan

Concerning the Recommendations

from the EU-Japan Business Round Table (BRT)

April 2016

Note: The content of this report is based on the situation as of December 31, 2015.

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Working Party A : Trade Relations, Investment and Regulatory Cooperation

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

BRT Recommendation

The BRT welcomes and supports the Authorities' determination to work for agreement in principle on a comprehensive and ambitious EU-Japan FTA/EPA during 2015. The BRT restates its longstanding conviction that an EU-Japan FTA/EPA will boost trade and investment, promote job creation and accelerate growth in both economies, and that it will also help create new opportunities for global economic growth. The BRT reiterates its call for the EU and Japanese

Authorities to step up their efforts to tackle and resolve the substance of outstanding issues and to conclude a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA as soon as possible, and reaffirms its commitment to making efforts to achieve this objective, such as making industry expertise available.

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.

< 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

On May 29th, on the occasion of the 23rd Japan-European Union (EU) Summit Meeting in Tokyo, both leaders shared the view that they attach importance to both speed and quality in the Japan-EU FTA/EPA, and will further accelerate the negotiations, aiming to reach agreement in principle during 2015.

On November 15th, on the occasion of the Japan-EU Summit Meeting on the sideline of the G20 Antalya Summit, both leaders shared the view that they would continue to make their utmost efforts to reach agreement in principle during 2015, and, if not, to achieve such agreement at the earliest possible time in the course of 2016.

Based on the leaders' commitment above, 6 negotiations rounds were held in total, and vigorous discussions were conducted on areas such as trade in goods, trade in services, intellectual property rights, non-tariff measures, government procurement, and investment.

Future outlook

The Government of Japan (GOJ) will, maintaining dialogue with the business community, continue to move forward the negotiations further in order to pursue a comprehensive and high level agreement, with a view to reaching agreement in principle at the earliest possible time during 2016.

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

BRT Recommendation

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 calls upon the authorities of the EU and Japan, together with other WTO members to quickly implement the Trade Facilitation Agreement.

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 Information Technology Agreement (ITA) and Trade in Services Agreement (TiSA).

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.

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, the 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 BRT welcomes the adoption of the Protocol of Amendment to insert the Agreement on Trade Facilitation (TFA) into the WTO Agreement (Protocol amending the WTO Agreement) at the Special Session of the General Council of the World Trade Organization (WTO) held in Geneva in November 2014. The BRT welcomes the advancement in the DDA negotiation.

The informal WTO Ministerial gathering held in Davos on 24 January 2015 was

furthermore 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.

< 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 agreement of the 9th WTO Ministerial Conference (MC9) in December 2013 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 government's efforts, in June 2015, Japan accepted the Trade Facilitation Agreement sixth earliest among the member countries, and has encouraged the other member countries to ratify it in order to make the Agreement enter into force early. In addition, the 10th WTO Ministerial Conference (MC10) in December 2015 saw some results as the agreement was reached with Japan and European and other countries in cooperation on certain fields such as export competition in agriculture including export subsidy and LDC matters. Furthermore, at the MC10, the Expansion of Trade in Information Technology Products Agreement (ITA), which would be of benefit for the IT industry in the deepening global value chains, was concluded under the chairmanship of Japan in cooperation with the EU.

Future outlook

As to the way a ahead on the negotiations in the WTO, including whether or not the Doha Development Agenda (DDA) should be continued, there is no prospect because of the lack of convergence of opinions between developed countries and developing countries. Although it is important to discuss the eight specific issues which have been the subjects of DDA, it is necessary to consider a new approach by exceeding the framework of DDA, continuing to cooperate with WTO members including the EU, in order to handle the issues that reflect the needs of the times. From now on, Japan will continue to cooperate with WTO members, including the EU, analyze the reasons why consensus was not reached, and then, advance the discussion constructively.

3. Applying international standards and enhancing regulatory cooperation (WP-A / # 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 provides a solid and comprehensive framework for regulatory cooperation to address the sector-specific concerns of the business community. In addition, the BRT welcomes 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 Regulatory Reform Council 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 and June 2015, taking

approaches such as “Test for Most Internationally Reasonable Regulation” 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 and June 2015 respectively.

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 Regulatory Reform Council, items for regulatory reform are expected to be compiled into report by around June 2016.

(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, the EU and Japan exchanged information on the progress of chemicals regulations and discussed transferring information of chemicals in products, risk assessment approach of existing chemicals, in the expert meeting for EU-Japan regulatory cooperation in July 2014 and in the 2nd Chemical WG of EU-Japan Industrial Policy Dialogue in October 2014. At the same time, Japan received comments on the information transfer scheme (later named chemSHERPA) for chemicals in products, from not only the authority but also the industry of the EU. In 2015, both regulatory authorities held the preparation meeting for next Chemical WG to exchange their views.

Japan has shared information and discussed 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 members including the EU. In addition, Japan has dialogues with ASEAN countries and shares the

achievement with the regulatory authorities of the EU.

Future outlook

The EU and Japan are going to hold the 3rd Chemical WG of EU-Japan industrial policy dialogue in February 2016 in order for continuous information and views exchange with regard to chemical management. Japan will keep discussion on emerging issues and cooperation with regulatory authorities including the EU, utilizing the opportunities such as 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

'Energy Saving Labeling Program' introduced by the GOJ is mainly applicable to household products (covering 21 items at present).

Also, the government operates 'Integrated Energy Saving Labeling Program' specifying multistage evaluation in the 'Retailers Labelling System' which is a labelling system for retailers (covering 6 items at present).

The Carbon Footprint of Products (CFP) Pilot Project, which had been in effect since 2009 was completed in March, 2012 as scheduled, after 73 Product Category Rules (PCR) and CFPs for 469 products were verified. After the transitional period, it has been operated as a private project since July 2012.

Future outlook

The GOJ continues to review the 'Energy Saving Labeling Program'. In addition, in order to enhance the degree of recognition of the label, The GOJ will distribute publicity matters regarding the program.

With regard to the Carbon Footprint of Products Pilot Project, the rule was formulated on the occasion of transition to private sector reflecting the discussion at ISO at the time. The government will make the program consistent

with international guidelines such as ISO.

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

BRT Recommendation

Following the agreement on the mutual recognition of the AEOs in June 2010 between the EU and Japan, the Authorities of the EU and Japan should aim at introducing further regulatory cooperation in order to give more concrete benefits to AEOs. The BRT would in this regard like to put emphasis on simplifications of import procedures where companies are given greater freedom while also taking greater responsibility for their imports without an excessive administrative burden. Authorities should also establish closer contacts to learn from each other in order to improve and further facilitate trade between the EU and Japan. The BRT is aware that the two authorities are engaged in regular discussion, but no concrete benefits have emerged for operators.

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 that can be granted by the mutual recognition of the AEOs.

Future outlook

With respect to the mutual recognition of the AEOs between Japan and the 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.

(5) Fight against counterfeited, pirated and contraband goods

BRT Recommendation

The BRT would like to see the EU and Japan to 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 which allows individuals to bring in or import counterfeits for personal consumption.

The BRT reiterates its support for 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 procedures. 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 an increased cooperation by the manufacturers and importers of the authentic goods, including the provision of more information on their products, the on-site training of officials and the training of officials on the more effective use of the WCO's IPM (Interface Public Members), the customs authorities should make inspection more efficient and increase the rate of its coverage.

Actions taken so far

Japan has made efforts, including through various training programs, to develop human resources of local authorities such as customs agents of the countries where IPR infringement matters have occurred.

As countermeasures against the websites where counterfeit and pirated goods are traded, Japan provides information on such websites to foreign governments such as the Chinese Government and requests them to close the websites. In

addition, Japan continues to implement measures for prevention of consumer damage by collaborating with antivirus software vendors, etc.

Japan also advances countermeasures against IPR infringements on the Internet through activities such as support for establishing a scheme leading users to genuine contents, and deletion of pirated copies from video distribution websites.

In order to prevent import and domestic distribution of goods that violate IPRs, nationwide customs agencies and the police strengthen control by such activities as intensive crackdowns. Moreover, Japan Patent Office conducted anti-counterfeit annual campaign to raise public awareness of IPR issues.

Future outlook

The GOJ will continue discussions and share information with foreign governments and related agencies on damages caused by counterfeit and pirated goods traded on the Internet, etc., and will request them to strictly enforce law on IPR infringements on the Internet.

Furthermore, to combat counterfeit and pirated goods traded on the Internet, Japan will enhance cooperation, part of which started already, with parties involved in the Internet trading, such as banks, credit card companies and anti-virus software vendors, and will actively take necessary and appropriate measures collaborating among related government agencies.

(6) Adoption of UN Regulations

BRT Recommendation

In the automobile sector, the Japanese and EU 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 Japanese and EU 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 35 of the 47 areas included in Japanese type approval.

< 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 GOJ adopts UN/ECE 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/WP29. The GOJ, in cooperation with the EU, has been actively contributing to promoting IWVTA, inter alia, through acting as co-vice-chair of an expert meeting on IWVTA in WP29.

Future outlook

The GOJ will continue to adopt the UN/ECE Regulations which have not been adopted 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/WP29, as a part of its efforts toward the realization of IWVTA.

4. Supporting timely development of business (WP-A / # 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 10 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. 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 a limited progress in the past year.

< Background >

As individual EU Member States and Japan conclude a bilateral social security agreement, it will lessen 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, Italy and Luxembourg have been signed. Furthermore, negotiations are underway between Japan and Sweden, and are at the preparatory stage between Japan, and the Slovak Republic, Austria and Finland.

Actions taken so far

(a) The Government of Japan (GOJ) has been making efforts to conclude social security agreements with EU member states. The social security agreements with Germany, the UK, Belgium, France, the Netherlands, the Czech Republic, Spain, Ireland and Hungary have already entered into force. In addition, the GOJ signed the agreement with Luxembourg in October 2014. Furthermore, the GOJ is forwarding inter-governmental negotiations with Sweden and Slovakia, and exchange of information and opinions with the authorities of Austria and Finland,

with the aim of concluding social security agreements.

(b) With regard to an interim measure, the Japanese pension system provides benefit of the “lump-sum payments withdrawal” according to the insured periods in case that foreign nationals return to their countries after their short stay in Japan.

Future outlook

The GOJ intends to continue negotiations as well as exchanges of information and opinions with a view to concluding social security agreements with more European countries.

5. Support for SMEs (WP-A/#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. Helping graduates with international backgrounds find local jobs with the other side's SMEs.
5. A study of the feasibility of creating a joint investment fund for both Japanese and European SMEs.
6. Exchanging best practices and tested solutions in industrial policy for SMEs.
7. 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 GOJ, 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 GOJ 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 GOJ 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 GOJ also has been providing assistance through the multi-layered measures including fund-raising etc. In addition, the GOJ has contributed to SME cooperation through sharing Japan's best practices on SME policy in international fora such as OECD.

Future outlook

The GOJ will steadily execute the above policies and initiatives and continue to support SMEs through related institutions. In addition, the GOJ will continue carefully cooperation in international fora and consider the possibility of bilateral

cooperation if specifically requested by a foreign country.

6. Harmonisation & mutual recognition of standards and product certifications; acceptance of international standards where applicable (WP-A/#06**/E to J)

(1) Automobiles

BRT Recommendation

Reluctance of the GOJ 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 GOJ to place particular emphasis on:

Automobiles

The GOJ 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 GOJ 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.

Action taken so far

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

Future outlook

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

(2) Construction Products

BRT Recommendation

The GOJ should work together with the EU Authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials. Such efforts are unfortunately still needed 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 GOJ should, furthermore, better support local and regional authorities to ensure transparent and consequent interpretations in regards to technical regulations and guidelines.

< Recent progress >

While some progress has been made, much work still remains. We furthermore note that the GOJ did not respond to the issue of discrepancy between ISO and JIS/JAS in its progress report 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 their 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 GOJ 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 GOJ 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 reported to be discussed in the FTA/EPA negotiations. Additionally, there are signs of movement in regards to the standard of use for fluoride in toothpaste and mouthwash.

< 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

The GOJ has developed and published positive lists of active ingredients and excipients/additives used in the so-called “medicated cosmetics,” which are classified as quasi-drugs prescribed by the Pharmaceutical and Medical Device Act in Japan. The Pharmaceutical and Medical Devices Agency (PMDA), regulatory authority responsible for reviewing quasi-drugs, has already set the goal of the average duration of processing time for approval of quasi-drugs 5.5 months.

The periodical meetings among the Ministry of Health, Labour and Welfare (MHLW), the PMDA and the industry have been held to exchange views and opinions on rapid review process of quasi-drugs. As part of an approach to accelerate the review process of quasi-drugs, the government published the amendment of the standards for marketing approval of 5 sorts of quasi-drugs on

March 25th, 2015. Moreover, the government is translating these standards into English and some of them have already been published.

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

Future outlook

The GOJ will continue to hold the periodical meetings with the industry for the purpose of ensuring the transparency of the approval process and the rapid review of “medicated cosmetics.”

Also, when other specific alternative methods for animal tests that the OECD has not adopted are requested based on appropriate data, the government will consider their validation through the activities at JaCVAM.

(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 GOJ 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 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 that all operators adhere to.

< 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 of Japan and the EU have been developed reflecting their respective 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 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.

As well, even where Japanese suppliers' goods have been found conformity to the technical standards in Japan, conformity assessment in the EU is required for the EU market. In addition, the GOJ is aware that in both Japan and the EU that railway operators is able to test whether the goods satisfy their request.

2) The GOJ 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, 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 websites.

http://www.mlit.go.jp/english/2006/h_railway_bureau/Laws_concerning/index.html)

3) Japan, with the Japanese Railway International Standards Center (J-RISC) playing the central role, proactively engages in its standardization activities, 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 ISO/IEC etc. standards, including testing methods, based on its active cooperation extended to development of international standards.

4) The GOJ understands that Japanese railways operators seek safe and

reliable products and that they are ready to continue to proactively procure such qualified and conforming products including from the EU.

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

Future outlook

Japan and the EU are currently conducting discussions on further enhancement of mutual market access with regards to the railways sector, and it is the GOJ's expectation that Japan and the EU will continue to hold constructive discussions. Furthermore, the GOJ 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 controls and unnecessary tests before being approved in Japan, which increases costs and causes delays. Accordingly, the BRT:

- a) urges the GOJ to take all measures available to speed up product approvals.
- b) requests Japan and EU to work towards mutual recognition of European and Japanese marketing authorisations for veterinary products. This should start with mutual recognition of GMP certification for veterinary medicines. MAFF and European agencies should accept GMP certification of the other party where the GMP requirements are similar or equivalent.

< Recent progress >

In recent years, MAFF has implemented various measures to improve the predictability, quality and speed of the registration process leading to a significant improvement. Furthermore, on 25 December MAFF revised regulations presented, both in Japanese and English, on the issuance of accreditation licenses. This change accommodated a request by JVPA. However, since harmonisation is still not complete and non-recognition of GMP certificates is common, improvement is still needed.

< Background >

Japan participates in the VICH, which aims to harmonise registration requirements for animal health products at the international level. This has helped to some extent to reduce the registration cost for globally developed products. However, there are still requirements that are unique to Japan.

Actions taken so far

MAFF works positively to accelerate approvals of veterinary medicinal products (VMPs), exchanging opinions with Japan Veterinary Products Association (JVPA) and Marketing Authorization Holders of VMPs. (Please see Attachment #1. MAFF has held relevant meetings 11 times during 2013 and 2015.)

Of 21 action items related to accelerator of approvals of VMPs including the 10

action items for change which MAFF presented to the JVPA in December 2012, MAFF has already implemented 17 items. Of the remaining 4 items, MAFF will implement 2 items by the end of March 2016, and is actively working on the remainder. (Please see Attachment #2. Showing timelines for the 21 action items related to accelerate approvals of VMPs. Preparing to implement ii and iii in ongoing actions by the end of March 2016.)

Moreover, MAFF prepared the documents on the progress of the action plan in English to provide branches of foreign manufacturers in Japan and encouraged them to communicate with their head offices. MAFF has been proactively providing 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 already implemented 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 obtained only in foreign countries in accordance with VICH guidelines (Good Clinical Practice (GCP) of participants to VICH (ie, 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. To our knowledge, only Japan accepts such application among VICH participants (i.e. Japan, the US, the EU and Australia), which is expected to considerably contribute to the acceleration of approvals of VMPs.

As stated above, Japan has been actively working for harmonization through VICH, and there seems to be a misunderstanding in the statement in "Background".

We are confident that MAFF has been working aggressively to accelerate approval procedures and making significant progress. Furthermore, MAFF will keep working on this issue and is ready to consider reasonable and concrete proposals based on thorough research on actual situation in Japan.

VMPs approved and distributed in Japan need to comply with the Japanese

GMP 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 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 are already approved in the EU.

Therefore, there is no strong necessity to establish mutual recognition of GMP certification for veterinary medicines.

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 addresses the remaining 4 items of the 21 action items related to accelerated approvals of VMPs, and is ready to examine other possibilities that are beneficial to the acceleration of the approvals of VMPs.

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. We request EU businesses to make a concrete proposal on this issue if it has any reasonable and feasible methods to standardize evaluations of technical dossiers.

Attachment #1

As of Dec 31, 2015

Explanation and Opinion Exchange on the MAFF's Actions
for the Acceleration of the Approval Review Processes

2013

July 17: Opinion Exchange with JVPA Members

July 21: Opinion Exchange with JVPA Members and Medical Device
Makers

July 25: Opinion Exchange with the JVPA Members of Foreign AH Makers

October 3: Opinion Exchange with JVPA Members

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

2014

February 27: Opinion Exchange 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: Opinion Exchange 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

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)

2. Ongoing Actions

- i. Change of management of animals for clinical trials, and introduction of simultaneous review process by MAFF, MHLW and FSC (List No. 9)
- ii. Change of requirements of data needed for application (general pharmacological testing, toxicity testing and ADME testing of drugs for pet animals) (List No. 10)
- iii. Review of the regulatory framework for veterinary drugs for minor animal species (List No. 4)
- iv. Improvement of efficiency of review on live vaccines for non-zoonotic diseases by MHLW

(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 processes
- b) introducing mutual recognition of conformity assessment procedures to eliminate the duplicate costs of evaluations.
- c) introducing deadlines for all parts of the application processes. While there are guidelines on timelines these only cover part of the application processes. Accordingly, it is difficult for an applicant to know how long the application procedures 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 GOJ 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 Food Safety 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 GOJ 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 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 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 GOJ, 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 GOJ 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 GOJ recognises that the EU also restricts the use of them.

c) The GOJ is considering the possibility of setting a standard time frame for approval procedure by the MHLW, upon the establishment of the above mentioned Food Additive Designation Consultation Center.

Future outlook

For the remaining four substances, which are under review by the FSC's Experts Committee, 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 GOJ 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 GOJ will follow the ordinary process for designation of substances other than these 45, such as the substances 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 for LED luminaries 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 GOJ 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 IEC test report can be used (“appendix 12”). This list does not include LED lamps and some LED 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 established by the IEC (International Electrotechnical Commission) (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 already, as a technical standard with a few additional requirements.

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 GOJ should issue clarifying orders to provide retailers with flexible alternatives for providing Japanese consumers with globally sourced products while taking full responsibility for the quality and safety of the products. A simple example of an inflexible labelling rule that has substantial labelling cost implications for European companies is that the dimensions of furniture must be expressed in millimetres and not centimetres, although use of the latter is common practice in other countries using the metric system. 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 GOJ progress report of April 2013. In parallel to this, Japan has announced that it will align its regulation on washing instruction with the ISO standards.

< 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 a total of 90 items of goods in the following categories: textile products, electrical appliances and apparatus, plastic goods and miscellaneous manufactured goods. The rules stipulate the minimum information which must be included in labels that are useful to consumers, as well as those matters to be

complied with by manufacturers, sellers and labelling contractors concerning methods of labelling. In 2014, it was decided by the cabinet to review the labelling requirements etc. in order to respond to social changes, to require minimum but comprehensible information for consumers and to cope with global harmonisation. The labelling requirements are currently being reviewed. Furthermore, the GOJ 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 it is scheduled to enter 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 Labelling Act is also increasing. Therefore the GOJ 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 GOJ will also continue to facilitate understanding of the Household Goods Quality Labelling Act among business operators including overseas business operators by publishing information on the web and other media.

7. Fuel Cell Vehicles (WP-A/#08/E to J)

BRT Recommendation

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

< Background >

Phase I of the UN Regulation for HFCVs is expected to go into force in the summer of 2015. Both the EU and Japan intend to implement this regulation. But 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

UN-R134 (HFCV), known as "Phase 1", stipulates that any Contracting Parties may introduce appropriate measures in order to address hydrogen embrittlement in the materials of containers. There is a significant risk of hydrogen embrittlement for onboard hydrogen storage containers of fuel cell vehicles especially under the high pressure (70 MPa) and low temperature (-40 degree) conditions of hydrogen storage.

Under Japan's current safety regulation scheme, the METI's Notice pursuant to the High Pressure Gas Safety Act lists examples of certain materials, such as specific types of stainless steel and aluminum alloys which have been proven safe in terms of Hydrogen Embrittlement. However, HFCVs equipped with the containers made of the materials other than above-mentioned two metals may be utilized in Japan once the safety of the containers is demonstrated by the manufactures and importers and the containers are authorized by the expert

committee established by the High Pressure Gas Safety Institute of Japan (KHK).

The EU side mentions that METI is “limiting the choice of materials to very few specific types of stainless steel and aluminum” in the safety regulations for storage containers for HFCVs. However, this description is misleading because, as mentioned above, Japan’s regulations are flexible in terms of the material composition of the containers. In order to correct such misunderstanding, the regulatory authorities of Japan and the EU have started to cooperate by exchanging information and views on respective regulatory systems.

Future outlook

Japan and the EU will continue to have the expert level meetings between authorities to exchange information. Furthermore, in order to accelerate the development of “Phase 2” of UN-R134 and gtr-No.13 (HFCV), Japan will promote cooperation with the members of WP29, *inter alia*, the EU and the US.

8. Ensuring free and open competition in services (WP-A/#09/E to J)

BRT Recommendation

The BRT urges the GOJ 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 GOJ. 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 private-sector life insurance companies, which ensures the consistency with international agreements such as WTO agreements.

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

In accordance with the provisions of the Insurance Business Act, the application for new products filed by JPI involves the examination as to whether it is secured that the applying service will be provided in a sound and efficient manner as well as 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 (hereinafter referred to as "FSA") and the 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 22th.

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.

(Kyosai)

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

(Japan Post and private delivery operators)

BRT's recommendation is not necessarily correct since Japan's services market is extremely open, and GOJ believes that European companies also enjoy benefits under such circumstances.

The international postal services of Japan Post Co., Ltd. are responsible for the exchanging of postal items among the postal operators 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 that has its own global-wide network. There is naturally a difference in characteristics between these two kinds of services, and therefore, the rules for Japan Post and those for private delivery operators are not always 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 16, 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, in 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 not suitable. We understand that other countries including the U.S. are also applying the official assessment system at least to a part of postal items.

Future outlook

(Japan Post Insurance)

The GOJ, maintaining the consistency with international obligations such as WTO agreements, will continue to provide appropriate supervision over JPI in the same manner as other life insurance companies, based on the Insurance Business Act, etc. and will regulate JPI appropriately under the frameworks based on the Postal Services Privatization Act, etc.

(Kyosai)

N/A.

(Japan Post and Private delivery operators)

N/A.

9. Freight and logistics (WP-A /#10/E to J)

BRT Recommendation

1. Further to the WP-A / # 03 / EJ to EJ, the BRT recommends Japan to revise 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 for companies 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 >

There has been no progress.

< 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.

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 area 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, ie. the license given by Tokyo Customs is not valid in Yokohama.

Action taken so far

To further simplify Customs procedure for AEOs, Japan Customs considers possible measures to address particular issues of private sectors by exchanging opinions and information with each other. From April 2015, Japan Customs improved the export procedure so that exporters do not need to report the change of the declared value to the Customs once they have obtained export permission except in the cases of miscalculation etc.

Japan Customs play a central administrative function to harmonize interpretations and applications of laws and regulations and thus ensures uniform operations among the regional customs authorities in different regions. The GOJ is now considering reforms to allow AEOs to lodge import/export declarations to customs offices other than the customs office where the goods are located, and to abolish restriction on area of services of customs brokers so that customs brokers can conduct their businesses nationwide by obtaining a single permission, while maintaining general rule to lodge import/export declarations to the customs office where the goods are located.

Future outlook

To further simplify customs procedure for the AEOs, Japan Customs will consider possible measures to address for particular issues of private sectors by exchanging opinions and information with each other.

The GOJ continues to ensure uniform interpretations and applications of laws

and regulations through Centers. In addition, the GOJ intends to take necessary steps for implementation of “broadening the choice of customs office for declaration” by FY 2017.

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

BRT Recommendation

The GOJ should create a business environment that will foster investment of foreign firms in the domestic economy. To this end, and in line with the treatment applied to stock swaps involving purely domestic companies, it should consider allowing tax deferrals for capital gains stemming from direct cross-border mergers and re-organisations.

The 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 makes foreigners liable for inheritance tax covering all global assets from day one of being registered in Japan. While many countries have removed the inheritance tax Japan is moving in the opposite direction.

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

< 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 shorting 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 UNCTAD in 2012 inward stocks was only 3.5 % of GDP.

Action taken so far

The Council for Promotion of Foreign Direct Investment in Japan, as the leading organ in the field, determines that it will promote activities to identify and attract investment projects, seek opinions from the top management of foreign enterprises, and cooperate with bodies such as the Council on Economic and Fiscal Policy, the Council for Industrial Competitiveness, and the Council for Regulatory Reform, so as to continuously implement additional measures, such as regulatory system reforms that contribute to the improvement of the investment environment and support measures effective in expanding investment.

The second round of the Council for Promotion of Foreign Direct Investment in Japan, which was held in March 2015, adopted the "Five Promises for Attracting Foreign Businesses to Japan" to improve what have been requested by foreign companies to enhance the convenience of business and life in Japan.

Future outlook

For further vitalization of the Japanese economy, the GOJ, with the Council for Promotion of Foreign Direct Investment in Japan as the leading organ in the field, continues to conduct activities focused on identifying and attracting investment projects, carrying out the necessary institutional reforms and implement additional measures, such as regulatory system reforms that contribute to the improvement of the investment environment and support measures effective in expanding investment, and taking foreign companies' needs into consideration. Moreover, ministries/agencies in charge will promptly and steadily implement the

measures in the “Five Promises for Attracting Foreign Businesses to Japan”.

11. Procurement (WP-A / # 12** / E to J)

BRT Recommendation

< General Recommendations >

The GOJ 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 cities are included.

Japan should, furthermore, make more information available in English. The BRT is aware of the recent initiatives by JETRO, but the complete information is rarely available in English. In addition the BRT requests the use of English when submitting tender proposals to be 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.
- Making certain that the recent changes to the Operation Safety Clause indeed leads 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 the changes in the OSC will bring.

< Background >

Studies have shown that over 80% of the total procurement market in Japan is not covered by the GPA. 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

(Improvements in government procurement market access)

With the entry into force of the “Protocol Amending the Agreement on Government Procurement” on 16 April 2014, Japan expanded its government procurement market access in accordance with its commitment under the revised GPA. For example, it lowered its thresholds for goods and services procured by Central Government Entities (excluding construction services and engineering services) from 130,000 SDR to 100,000 SDR. Seven designated cities were newly added to the covered Sub-Central Government Entities. Also, seven services were newly added to the covered services of all covered entities, and nine more services were added to the covered services of Central Government Entities.

(Operational safety clause)

In the view of the GOJ, the “operational safety clause” of the WTO Agreement on Government Procurement applies to the following five categories. Furthermore, since 28 October 2014, the GOJ has taken measures to identify the scope of the operational safety clause thereby increasing its transparency, 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 third Japan-EU Railway Industrial Dialogue was held in Brussels in May 2015 and the fourth Dialogue took place in Tokyo in November 2015, 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 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, fulfillment place and fulfillment period. In order to streamline the requirements for pre-registration, the GOJ takes measures for the implementation of the unified qualification procedures in terms of central-government entities.

Future outlook

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

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

1. Sensitive handling of ratification / implementation of CBD / the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing (WP-B / # 01** / EJ to EJ)

BRT Recommendation

The EU government has already ratified the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their utilization to the Convention on Biological Diversity. EU-J BRT members strongly call for the re-examination of several issues in the regulation (EU) No. 511/2014 and/or the Implementing Acts draft, as these will become serious impediments to the business operations including international trade of a wide range of products and activities for research and developments. In particular, the requirement to provide a due diligence declaration at the time of market launch in the EU for products developed or manufactured outside of the EU and utilizing genetic resources must be removed.

The GOJ should not ratify the Nagoya Protocol until (1) the sufficient encouragement for denial of the retroactive application to genetic resource is made, (2) the benefit sharing scheme of the genetic resources is determined that it will not be applicable for the genetic resources, which companies and institutes have already held, (3) utilization stage is reached where it can be determined that the retroactive application to genetic resource utilization will be denied for Japan, and (4) the appearance of clear feasible measures, which could be implemented by utilizers of genetic resources such as companies and research institutions without unreasonable costs. Furthermore, when discussions are held on feasible measures toward ratification of the Protocol, the GOJ must not proceed in a hasty manner, but reach a conclusion only after conducting sufficient coordination with the industry.

<Yearly status report>
New recommendation.

<Background>

The Nagoya Protocol, annexed to the Convention of Biological Diversity (CBD), went into effect on October 12, 2014. The Nagoya Protocol is a multilateral arrangement, in which the economic scheme for benefit sharing between providers and utilizers of genetic resources is defined, and it possibly influences the widely related industries such as the food manufacturers, the forestry, the pharmaceutical, the seeds, the cosmetics, the bio fuel and others, which are utilizing genetic resources. However, the Nagoya Protocol had been adopted at the 10th Conference of the parties of CBD (COP10) in 2010 without sufficient coordination with the industries.

EU-Japan BRT members are especially concerned about the structural problem, of which the genetic-resource-providing countries may unilaterally legislate the obligations of the resource utilizing countries in accordance with the Provision 1 of Article 15 in the Nagoya Protocol. This structure may also impose the utilizers such as companies in the EU and Japan to obligate for compliance of the legislations of the resource providing countries, even though the contents of the legislation is favourable to the provider's side. Besides, we have another concern that the unreasonable burden for monitoring the proper usage of the genetic resources may be imposed for utilizing companies.

In addition, it is also a risk that the time of acquisition of the resources may be retroactively determined to the time before the effect of the CBD or the Nagoya Protocol, because (1) there are opinions claiming that the time of acquisition of the genetic resources should be retroactively applied for the period after which the CBD was enacted, or (2) negotiations are underway so that the genetic resources which were utilized in the past should be in the scope of the benefit sharing.

Furthermore, considerations with research and development (R&D) activities are not sufficiently defined in the Nagoya Protocol. This may increase the legal instability and the risk to widely hinder or delay the applications of the innovative outcomes from R&D activities utilizing genetic resources, unless the clearer position of each country concerned with regard to the scheme of the benefit sharing is developed.

On the other hand, the EU government has already adopted the Nagoya Protocol. The Regulation (EU) No 511/2014 of the European Parliament and the European Council (adopted in March 2014 and April 2014, respectively, became effective as of June 9, 2014) defines the intraregional procedures with regard to the Nagoya Protocol. The EU government has drafted the Implementing Act and

they are preparing for the finalization within the first half of 2015 followed by the effect as of October 2015. The industries have concern about the specific contents, such as “Due diligence declaration at the stage of the final development of a product” in the Article 7, which may cause significant barriers to the business operations. Different industry sectors including the European Crop Protection Association (ECPA), the European Federation of Pharmaceutical Industries and Associations (EFPIA), the European Seed Association (ESA) and Europa BIO submitted comments to the EU Commission on 9th of Jan. 2015 addressing issues and areas of uncertainty associated with the Regulation and the Implementing Acts. With regards to the particular concern on the requirement for due diligence declaration for the products developed outside of the EU, it’s addressed in the ECPA letter to the Commission “ECPA believes that no declaration should be made where the utilization has taken place outside of the Union. There is no legal basis in these paragraphs to extend the geographical scope of the basic Regulation and such a broad geographical raises questions as to compliance with WTO rules.”

For the companies in both EU and Japan, it is expected that the financial and operational burdens to access to the genetic resources in the outside of the region or country may increase whereas business predictability may be limited by adoption of the implementing measures from the Nagoya Protocol, unless these many problematic issues such as unclear scope of the rules are resolved. Furthermore, there is another concern that it may widen the gap in terms of the business competitiveness against the United States, which is not a member of the CBD.

Actions taken so far

The GOJ 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 of the GOJ, taking into account the opinions from various stakeholders including the private sector.

In this connection, the GOJ understands and has been stressing that, according to the international law, the provisions of the Protocol are not applied retroactively.

Future outlook

The GOJ will further promote the consideration by its relevant ministries of domestic measures necessary for concluding the Nagoya Protocol, taking into account the opinions from various stakeholders. Based on the results of such consideration, the Government aims to conclude the Protocol at the earliest possible time.

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

BRT Recommendation

Further extension of “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 Bio products are being requested to apply to the MRA. Full support is requested to expand the MRA of GMP to liquids, and sterile forms, API and bio products 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 EU-Japan economics 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>

Harmonization:

- Safety measures from surveillance to vigilance should be harmonized with international standards.
- Clinical development guideline and biological preparation standards for vaccine.

- Minimum requirements for biological products.

Actions taken so far

MHLW, PMDA and the prefectural-level authorities in each prefectures joined PIC/S on July 1, 2014. The GOJ has been discussing with the EU to expand the EU-Japan MRA, focusing on inclusion of all EU Member States that are members to the PIC/S and Bulgaria to the Annex on GMP for Medicinal Products, and it is at final stages of the procedure.

Guidelines for clinical development of vaccines were published on May 27, 2013, after considering the comments from the pharmaceutical industry including the European Federation of Pharmaceutical Industries and Associations (EFPIA).

The revision of the Minimum Requirements for Biological Products (MRBP) went into effect on September 12, 2013 after the consideration by the experts on the comments from the industry including the EFPIA.

Future outlook

Having joined PIC/S, the GOJ will continue to make efforts to ensure further harmonisation of the Japanese GMP regulations with PIC/S GMP guidelines. The GOJ and the EU will amend the Annex on GMP for Medicinal Products to include all EU Member States and continue technical/scientific discussions on expansion of specific types of pharmaceutical products.

The GOJ will continue the discussions on a revision of the MRBP, while, as necessary, listening to comments from the industry including the EFPIA.

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

BRT Recommendation

Improve mutual recognition of Quality Management System (QMS) audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical and Medical Device Act (J-PMD Act).

All industry-related manufacturers request PMDA and MHLW to further harmonize and streamline the QMS audit results. MHLW has notified that RCBs can accept non-Japanese QMS audit results. However, ISO13485 continues to be only one part of the Japanese QMS ministerial ordinance. In addition, the recognition system of “Application for Accreditation of Foreign Manufacturers” should be considered. Even if QMS is evaluated on ISO13485, all industry-related manufacturers have to be registered and are obliged to stick to the additional Japanese requirements.

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 are also to be harmonized. Therefore, 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 grace period.

About the cost of QMS audit, there is a test calculation that the cost will increase depending on the number of medical devices under the same “State of conformity”. We request to review the price of QMS audit after a certain period.

<Yearly status report>

Good progress has been seen for this recommendation with the acceptance of ISO 13485.

<Background>

Based on Medical Devices Directive (MDD) of the EU and 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

The revision of the Pharmaceutical Affairs Law came into effect on November 25, 2014, and, accordingly, MHLW harmonised Japanese QMS standard for medical devices with the international standard (ISO13485), which is also adopted by the EU.

With the revision of the Pharmaceutical Affairs Law made in November 2014, the registration system that replaced the former accreditation system has become applicable to foreign manufacturers. In addition, the scope of manufacturing site to be registered has been revised.

Future outlook

Since the global harmonization of QMS regulations is necessary for the mutual recognition of QMS audit, the GOJ will continue to discuss not only with the EU but also with the U.S. and other countries through activities such as those in the IMDRF (International Medical Device Regulators Forum).

4. Mutual recognition of regulation and approval of medical devices (WP-B/ #4*/ EJ to EJ)

BRT Recommendation

Introduce a mutual recognition of medical device product licenses between the EU and Japan. PMDA and MHLW should introduce a 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 will be solved quickly. Level difference between NBs should also be considered. It should be recognized that the regulatory approval scheme of class II medical devices in Japan is far from that in the EU, i.e. no need to be reviewed by NBs for Conformance Européenne (CE) marking of class II medical device in the EU but reviewed by NBs in Japan.

<Yearly Status Report>

No progress / no dialogue has been seen, however, some improvements through the implementation of the new pharmaceutical and medical device law, which makes Japan accept the audit report ISO13485 issued by the countries. Improvements are required to accept ISO14155 for clinical trials. Based on the new pharmaceutical and medical device law, some of Class II and Class III products will move to “ninsyo” application. As a result, no progress on “mutual recognition” discussions, but improvement on the speed of approvals for medical devices.

<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 time frame and with one process.

As mentioned before, it could be possible to start with lower risk, class II 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, a 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, the GOJ basically accepts the international standards of the ISO and the IEC.

Future outlook

The global harmonization of medical device regulations needs to be discussed with not only between Japan and the EU, but also jointly with the U.S. and other countries. For this reason, the GOJ will achieve the global harmonization of medical device regulations through activities such as in the IMDRF (International Medical Device Regulators Forum).

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

BRT Recommendation

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

Foreign clinical trial data have been accepted as a part of application dossier when:

(1) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, (2) the standards are equivalent or surpass the Japanese medical device GCP, and (3) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality.

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

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. In this regard, the ordinance was released in December 2012 by MHLW and some improvements has been seen but in our opinion further improvements are required in the actual operation to accelerate mutual recognition of clinical trial results for medical devices. 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, GOJ should prepare a clear definition of accepting / preparing clinical trial reports.

<Yearly Status Report>

Some progress has been seen but more progress is required as described above.

<Background>

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 time frame and through one process, ensuring high level of quality while reducing the burden on manufacturers.

Action taken so far

Foreign clinical trial data has been accepted as a part of application dossier when: i) standards for conducting medical device clinical trials are set out in regulations of the country or region where the trial was performed, ii) the standards are equivalent or above the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or those considered to have equivalent level in quality.

Future outlook

The GOJ encourages applicants to take advantage of consultation service provided by the Pharmaceuticals and Medical Devices Agency (PMDA) on utilisation of foreign clinical trial data for application of individual medical devices.

6. Shortening review period of plant protection & biotechnology products (WP-B/#06/EJ to EJ)

BRT Recommendation

Shorten review times for new applications / registrations.

<Yearly Status Report>

Some progress has been seen for this recommendation.

<Background>

Research and development of innovative and beneficial Plant Protection & Biotechnology products require high input costs. Therefore, timely access to the markets is crucial for R&D-intensive companies in order to successfully market their products and recover their initial R&D investments, which then again are used to finance further innovations.

Establishment and maintenance of science-based, predictable and timely regulatory systems free from undue political influence and the appropriate protection of proprietary data are therefore key requirements for sustainable and innovative research.

Due to the introduction of new risk assessments on humans and environment, which are necessary to secure safety and should be well-harmonized with other countries, the required investment and time for preparation of dossiers on new products are increasing. It is crucial for R&D-intensive companies to secure the time to market in a reasonable timeline in order to continue with innovations. Though the ministries might be working for improvement of their resources as shown in the recent change of the guideline for import tolerance application, the process in the risk assessment might be further improvable to shorten overall time for review, like a parallel review in toxicology and residue chemistry, which are currently sequentially conducted. Increase of resources both in administrative and technical reviewers is also crucial in order to achieve a shortening of the review time under growing requirements on safety.

Actions taken so far

In December 2014, MAFF and Ministry of Environment amended Director's Notice on application procedure for environmental risk assessment of GM plants. With this amendment, it is not necessary any more now to conduct confined field trials in Japan for a GM corn meeting certain requirements with respect to scientific knowledge of functions of the inserted gene(s)/DNA.

Future outlook

MAFF will continuously conduct consistent environmental risk assessment of GM 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 sectors (WP-B / # 07* / EJ to EJ)

BRT Recommendation

The governments and the private sector should speed up research in Plant Protection & Biotechnology and inform consumers regularly and accurately about the state of play on GMOs, based on sound scientific knowledge. To that effect 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>

A stable supply of food is an urgent requirement. While world population keeps growing, the enhancement of conventional culture on existing farmlands is reaching its limit. GMOs offer the hope of breaking these limits, but remaining doubts about their safety hamper the development of their utilisation. Considering this situation, it is an urgent matter to speed up research on GMOs and inform consumers regularly and accurately about the state of play of that research.

Actions taken so far

The GOJ has provided information on Japan's plant biotechnology researches in the related symposiums held by bio-industry associations in Japan and also exchanged information with researchers from Europe. In addition, the government has co-operated for the harmonization of GMO (Genetically Modified Organism) regulation at OECD Working Group on the Harmonization of Regulatory Oversight in Biotechnology.

Future outlook

We will continue the above-mentioned efforts.

8. Mutual recognition of GMP and marketing authorization for animal health products (WP-B / # 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.

<Background>

Any 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. The 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

Refer to the response to WP-A / # 06 / E to J (5) above.

Future outlook

Refer to the response to WP-A / # 06 / E to J (5) above.

9. The revision of the rules for the pricing and prescription of innovative new medical drugs (WP-B / # 11** / 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 drug will be continued until March 2016. It is welcomed as it supports incentives for innovative drug development; however, it is only the continuation of a trial scheme.

The GOJ 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>

No 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 GOJ is willing to reward innovation in the medical field. The premium for new drugs will be continued until 2016. 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 developments of many unapproved / off-label use drugs and forwarded those constructively. Furthermore, companies received additional requests on developments of another hundreds of unapproved / off label use drugs for several times.

However, in the FY 2014 drug pricing system reform, Chuikyo concluded to postpone full-fledged implementation of the premium for new drug creation to

FY2016 revision, even though the industry strongly requested. The conclusion brings the industry deep concerns about sustainability for evaluation of innovations. The GOJ should implement the new premium system for innovative new drugs at the FY 2016 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

As a result of the drug pricing system reform in FY 2016, the premium for new drug creation and elimination of unapproved / off-label use drug (the premium for new drug creation is expected to continue until March 2018).

Future outlook

The drug pricing system will be reviewed and discussed continuously in the Chuikyo (the Central Social Insurance Medical Council), taking into account opinions of the industry.

(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>

No progress has been seen for this recommendation.

<Background>

The abolishment of the market expansion re-pricing was not accepted by Chuikyo even though industries insisted to eliminate the system. While the agenda for the 2014 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 “abolishment of market expansion re-pricing”. Therefore, we urge to discuss this topic to abolish the repricing rule by market expansion in the next pricing system reform in 2016, 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, including, example when their actual sales significantly exceed their original estimations. With the severe fiscal situation of the NHI system, this scheme functions as an appropriate apportionment mechanism for pharmaceutical expenditures of public health insurance system with limited resources, and the Chuikyo itself recognizes this scheme as essential in the discussions on the drug system reform in FY 2016.

Future outlook

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

(3) Abolishment of the 14-day prescription rule

BRT Recommendation

EU-Japan BRT members call on the GOJ to revise the 14-day prescription rule for all new drugs.

<Yearly Status Report>

New recommendation

<Background>

Despite government's policies to promote new drug development, patient access to innovative drug is hindered by the 14-day prescription rule, which restricts the prescription lengths 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 GOJ to revise the prescription length for all new drugs.

Actions taken so far

In June, 2015, the Cabinet has decided that the government would review the 14-day prescription restriction on new drugs in FY 2015, while ensuring drug safety.

Future outlook

The 14-day prescription restriction on new drugs will be reviewed and discussed in the Chuikyo, while taking into account opinions of the industry.

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

BRT Recommendation

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

<Yearly Status Report>

New recommendation

<Background>

The methods of HTA for drugs and medical devices have been discussed in Chuikyo. Although the GOJ intends to determine the introduction of HTA system for drugs and medical devices until the medical service fee revision in 2016, the hasty and insufficient discussions may lead to the inappropriate conclusion.

For instance, some countries have caused the limited patients access to innovative new drugs.

Furthermore, HTA may hinder the companies' willingness to the research and development activities for the innovative new drugs in the country. The GOJ should consider these possible risks and discuss with all stakeholders so that HTA may not hinder the improvement of public health.

Actions taken so far

The government made a final report as to trial introduction of cost effectiveness analysis on drugs and medical devices on December 2015 in Chuikyo.

Future outlook

The government will introduce cost effectiveness analysis on a trial basis for the FY2016 revision of remunerations for medical treatment. Subsequently, it will continue to discuss in Chuikyo to seek to introduce cost effectiveness analysis on a full-fledged scale.

10. Appropriate assessment in prices of innovative values of medical devices (WP-B / # 12** / EJ to J)

BRT Recommendation

Promote sub-dividing of the current functional classification, enhance the premiums for C1 or C2 products (class-C products) and introduce a product-based listing system for new products in order to move towards a product-based, market-oriented reimbursement pricing system in the future.

<Yearly Status Report>

In 2014, no major progress has been seen in general and major progress was made in the revision of reimbursement. More detailed division of functions into subcategories, introduction of multiple prices for medical devices of the same category as well as the abolition of the reprising system and innovation in home healthcare medical devices should be assessed appropriately.

<Background>

Different from pharmaceutical brand-oriented pricing systems, about 300,000 medical devices are classified into about 800 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 old and new products, having various realized prices, have the same reimbursement price within one functional class, which means that the price drop of old products influences the reimbursement price of new ones on the revision of the reimbursement price. This is the reason why the introduction of a productbased reimbursement pricing system is desired. In Japan's 2014 price revisions, the government's efforts to progress forward the assessment of innovative values can be seen, such as making exception of functional class rule for the excellent and innovative class-C products to keep the independent functional class within the twice price revisions. On the other hand, they strengthened the influence of foreign reference pricing. We hope the Japanese government will make further efforts to promote medical device development.

Actions taken so far

In the revision of medical fee in FY 2014, the GOJ took steps to evaluate the value of innovation for medical devices more appropriately through various measures such as reviewing requirements for the premiums and introducing the exceptional functional class at the price revisions.

Future outlook

For the medical fee revision in FY2016, the GOJ will consider evaluating value of innovation of medical devices appropriately and promoting establishment of new functional classifications or sub-dividing the current functional classifications of medical devices.

11. Support research in crop breeding (WP-B / # 13* / EJ to J)

BRT Recommendation

Support research in crop breeding.

<Yearly Status Report>

No progress has been seen for this recommendation.

<Background>

Overall, research cooperation between governmental institutes and MNC is limited in Japan. Applied science researches are widely conducted for instance by the Plant Protection Stations (PPS) in all prefectures, but these are not meant for basic researches, while researches at agricultural universities are undertaken on an individual basis. In the past, MAFF has spent around 400 million yen for residue trials on substances used for rice to confirm the level of the residue in rice for feed and the transfer into livestock (cow and chicken) but under the initiative of the government or some independent institutes. The project is motivated by the policy to increase food sufficiency rate. The current target of the government is a revitalization of the agriculture in general. To achieve this, a more offensive action in regard to new technologies (like application technology) is necessary.

In the future, MAFF should spend more money on basic research / fundamental technologies in order to facilitate research activities in general. In biotechnology, considerable money is spent on plant molecular biological research but the budget is recently decreasing and no genetically modified (GM) products are developed in Japan. It should be taken into consideration to develop GM rice in order to increase yield and decrease production costs. In the past, the rice genome project was supported by the government and it has been concluded, but only a smaller post genome project is running currently. The outcome of the project is only contribution to develop a marker assisting the breeding of rice. From such research where a considerable amount of Japanese tax payers' money is invested, yielding practical applications is desirable through cooperation among governmental institutes, universities, Japanese companies and MNC. Recently, MAFF and governmental institutes are developing new breeding technologies in order to improve crop cultivars.

Actions taken so far

In 2015, the Ministry of Agriculture, Forestry and Fisheries (MAFF) is advancing the following research initiatives in order to establish the breeding base to enhance agricultural productivity using the latest innovations in genomics: 1. Development of DNA markers in rice, wheat, soybean, horticultural crops etc., and proliferation of marker-assisted selection (MAS) to plant breeding institutions nationwide; 2. Development of new breeding technology for complex quantitative traits such as yield which are difficult to be bred by MAS, and a system for efficient management of genetically modified organisms and to evaluate their impact on biological diversity; 3. Development of the tools and strategies for efficient identification of useful genes from genetic resources to facilitate the breeding of new cultivars adaptable to specific regions, and for the conservation of genetic resources. In addition, advanced and innovative breeding strategies using genome editing, acceleration of flowering, and ionizing radiation etc., and the development of lines with modified genomes (cultivar prototype) are being pursued by Cabinet Office.

Future outlook

The MAFF will continuously promote the above-mentioned research projects.

12. Responsible use of antibiotics in animal health (WP-B / # 14* / E to EJ)

BRT Recommendation

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

<Yearly Status Report>

Progress has been seen in that the product list for 2nd line treatment has been updated on the web site of NVAL/MAFF.

<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 (FQs) 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

We appreciate further clarifications to understand the how proposal above would serve the objectives of BRT to facilitate trade and investment.

Concerning “anti microbial resistance” issues, in accordance with the existing international standards such as the Codex Guidelines and the Codex Code of Practice, MAFF has been developing and implementing appropriate risk

management measures based on risk assessment with scientific evidence and promoting the responsible and prudent use of antimicrobials.

We recommend that the EU also implement risk management measures based on the result of risk assessment.

Moreover, Japan has been actively participating in and contributing to international standard setting activities in WHO, OIE and Codex, including WHO's global action plan on antimicrobial resistance.

Future outlook

From FY 2016, MAFF will review current monitoring system on antimicrobial resistance in order to improve effectiveness of collecting appropriate data.

MAFF will continuously implement appropriate risk management measures based on risk assessment, in accordance with procedures of risk analysis.

13. Regulatory harmonization for animal health products (WP-B / # 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 of 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>

Significant progress was made by MAFF, FSC and MHLW in shortening the withdrawal period for inactivated oil-adjuvant vaccines based on FSC's scientific assessment of dietary health impact.

<Background>

Restrictions on withdrawal period for innovative oil-adjuvant vaccines are especially stringent in Japan. Implementing scientific health risk assessment approach in establishing the withdrawal period and increased collaboration of different ministries involved in food safety would certainly improve access of animals and animal owners to innovative animal health products which are readily available in Europe. While such global new veterinary medicinal products go already 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 aspect 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 actively been addressing the issue of harmonization of technical requirements for registration of veterinary products through VICH, and has already accepted overseas data which was compiled in accordance with VICH guidelines. Therefore, there seems to be a misunderstanding in the comment of paragraph 2 of “background”.

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

For instance, certain inactivated vaccines which meet specific conditions have been exempted from the FSC assessment. In addition, the FSC assessment procedures for certain veterinary attenuated live vaccines and combined vaccines have been decided to be simplified. Besides, MAFF, MHLW and FSC have been considering introduction of parallel procedures including deliberation among the authorities and MAFF has actively been considering allowing the companies to submit the data on clinical studies after application to MAFF for approval, so that the procedures for approval will be streamlined.

In addition, MAFF reviewed the principles to establish the withdrawal period in December 2014, and since then the withdrawal period of vaccine has not been required if each excipient of the vaccine has been assessed by FSC 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 respond to the comment from the EU sides as we cannot confirm its appropriateness. Regarding the effectiveness of the approval procedures, parallel approval procedures at the three ministries and submission of clinical trials data after approval are being considered.

Concerning MAFF’s basic stance related to acceleration of approvals of VMPs,

please refer to “Action taken so far” in WP-A/#06/E to J.

14. Shortening review period for animal health products (WP-B / # 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>

In 2014, it has been recognized that MAFF is trying to shorten the review timeline among three ministries, but it seems that MAFF is struggling to negotiate with the other two ministries. It would be appreciated if this recommendation could accelerate MAFF's initiative to deal with MHLW and FSC on this matter. It was confirmed that MAFF established the guideline to develop veterinary GMO products or products containing GMOs, however it is not clear how this guideline would affect a shortening of the review timeline.

<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 efficiency of review and assessment process for approval of new product.

For instance, certain inactivated vaccines which meet specific conditions have been exempted from the FSC assessment. In addition, the FSC assessment procedures for certain veterinary attenuated live vaccines and combined vaccines have been decided to be simplified.

Besides, MAFF, MHLW and FSC have been considering introduction of parallel procedures including deliberation among the authorities and MAFF has actively been considering allowing the companies to submit the data on clinical studies after application to MAFF for approval, so that the procedures for approval will be streamlined. In this regard, MAFF has already held hearings from the Advisory Committee and explained the draft of new policies to the industry.

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.

We could find 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”.

Future outlook

With close cooperation among MAFF, FSC, and MHLW, we will continuously consider the following measures to improve efficiency:

- Application of provisions exempting the FSC assessment
- Development of a way to perform each procedure of the three bodies as simultaneously as possible; and
- Allowing the companies to submit the data on clinical trials after application to MAFF for approval (which enables MAFF to begin earlier the review of the data on the trials except for clinical trials)

In order to enable the FSC to conduct its risk assessment in a timely manner, GOJ appreciates the cooperation of the EU industry and government in providing data and information necessary for the risk assessment.

15. Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan (WP-B / # 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 noticed to medical gas suppliers to obey voluntary standard by the industry. This standard is almost compatible to GMP standard. PMDA / MHLW will reinforce the GMP for medicinal gases through the PIC/S, Japan officially joined in July 2014.

<Background>

Medicinal gases are drugs or medicinal devices and have to be compliant with governmental regulations. Main regulations are national Pharmacopeia, GMP (Good Manufacturing Practices), and GDP (Good Delivery Practice). Annex 6 describes GMP and GDP for medical gases: production and distribution. The currently loose interpretation of GMP in Japan along with relatively low standards of Japanese Pharmacopeia is of lower standards as 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.

Action taken so far

With regard to the medical gas in Japan, MHLW discussed the establishment of the industry standard with industry group and then made public “The Standard on Manufacturing Practice for Medical Gases (hereinafter “The Standard”)” n February 13, 2012.

Future outlook

MHLW provides medical gas manufacturers with information on The Standard through prefectures and promotes manufacturing and quality control systems in accordance with The Standard.

16. Requirement of Japanese version of the clinical trial protocol and investigators brochure (WP-B/#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 available to patients earlier in Japan. MAFF, MHLW and FSC should start harmonized ways to shorten review times.

<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 for delay of the start for patients' enrolment in Japan.

Action taken so far

Most of the materials attached to a new product application are not required to be translated into Japanese, and the documents in English may be attached.

Future outlook

For example, some of the materials attached to an application are open to the public for the proper use of a medical product, partly masked for the trade secret protection. In addition, documents related to clinical trials are not only used in

regulatory authorities, but also given as important information to clinical trial facilities (doctors, nurses and other medical professionals) including subjects. Considering this situation, the level/type of documents or materials to be submitted in Japanese needs to maintain their current level.

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

BRT Recommendation

For imported vaccines, national tests in both Japan and manufacturing sites have been conducted (for more than 20 years in some cases). 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 done according to GMP (Good Manufacturing Practice) and PMDA (Pharmaceuticals and Medical Devices Agency) 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 vary considerably in quality, manufacturers and the National Regulatory Authority need to double-check the conformity to the specifications of product, before the products are released. It is the national lot release operated by MHLW that plays the administrative part of this system. We recognize that EU countries also have similar systems of the national lot release in Japan.

MHLW has been reviewing and amending items as the tests during the national lot release for vaccines, as necessary, on a regular basis.

Future outlook

MHLW continuously attempts to operate properly the national lot release system for vaccine products.

Working Party C : Innovation, Information & Communication Technologies

1. Cybersecurity of Critical Infrastructure (WP-C / # 01** / EJ to EJ)

BRT Recommendation

Trust, safety and robustness are key pillars expected of cyberspace and physical infrastructure supported by ICT. The BRT appreciates that both sides' Authorities are already working on joint initiatives on cybersecurity issues, and also encourages further cooperation between the EU and Japan on safe and robust infrastructure based on ICT.

Security of data and, preventing damaging leaks from public or private organizations is a key growing issue, as more and more data go into clouds and are processed from it. A common frame of best practices related to protection from and adequate response to cyber-attacks should be established by both Authorities. Cooperation between critical infrastructure operators and ICT service providers is a must in order to address cyber threats. The BRT considers that security notification reporting should be applied only to critical infrastructure operators and that such a requirement should not be applied to enablers of internet services. The BRT requests that both sides' Authorities enhance the quality and volume of human talent in the cybersecurity area.

Finally, due to the sometimes crucial role played by ICT in supporting and developing key lifelines (energy, transportation, etc.), a robust ICT sector is especially important. Considering the development and smartening of the infrastructures including Electricity Grid Transmission, the BRT recommends the Authorities to encourage the private sector to construct resilient and safe ICT infrastructures in order to both promote the development of new technologies and guarantee an adequate level of protection for critical infrastructures.

< Yearly Status Report >

There has been good progress on this recommendation. In the joint statement of the 22nd EU-Japan Summit held in May 2014, the EU and Japan shared their recognition of risks in cyberspace and agreed to launch a Cyberspace Dialogue. Based on the agreement at the Summit, In October 2014, the 1st Meeting of the Japan-EU Cyber Dialogue was held in Tokyo.

In November 2014, Japan adopted the Basic Law for Cybersecurity. Based on

this basic law, a Cybersecurity Strategy Headquarters was established and is in the process of formulating a new Cybersecurity Strategy.

In March 2014, the European Parliament voted to give mandate to negotiate with the Council on the NIS Directive. Several informal trilogues are conducted among the European Commission, the European Parliament and the EU Council.

< Background >

Risks surrounding Cyberspace are increasing. Cyber-attacks against critical infrastructure are serious threats to society. The operations of critical infrastructure such as energy, transportation, water, etc., are highly dependent on ICT. It means that defending critical infrastructure from cyber threat is indispensable for maintaining the business operations and a stable civil society. Addressing these serious issues requires a close international cooperation of the public and private sectors.

Action taken so far

At the 23rd Japan-EU summit in May 2015, Japan and the EU announced a joint statement which emphasizes the importance of ensuring the rule of law in cyberspace.

After the enactment of the “Basic Act on Cybersecurity” (November 2014), the Cybersecurity Strategic Headquarters, which was given mandates such as formulating cybersecurity strategy and conducting supervision over relevant governmental bodies, was established and as its secretariat, National center of Incident readiness and Strategy for Cybersecurity (NISC), was also established in January 2015.

In September 2015, the “Cybersecurity Strategy” was adopted as a cabinet decision, the aims of which are to ensure a free, fair and secure cyberspace, and subsequently contribute to improving socio-economic vitality and sustainable development, building a society where the people can live safe and secure lives, and ensuring peace and stability of the international community as well as national security.

Future outlook

Japan will, with the Tokyo 2020 Olympic and Paralympic Games in its view, endeavor to ensure cyberspace with trust, safety, and robustness including critical information infrastructure based on the “Cybersecurity Strategy” and other policy documents.

Through the existing frameworks such as the Japan-EU Cyber Dialogue, both Japan and the EU will cooperate to further develop the Japan-EU relations in the field of cybersecurity.

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

BRT Recommendation

The responsible collection and use of personal data is important not only for the ICT industry but also for the entire society. The BRT requests both sides' Authorities to set clear rules for the use of each category of data, thus enabling data transfers and creating an environment that facilitates the utilisation of "big data" in a responsible way that also protects privacy. The BRT also requests both sides' Authorities to adopt laws and regulations on data protection which are compatible with each other, so that there is no gap in data protection and enterprises can conduct business without concern about different data protection regimes. The BRT welcomes Japan's decision to revise its personal data protection regime.

The BRT also welcomes that the European Commission prioritized the Digital Single Market as its policy agenda and positioned the single data protection rule as important pillar for Digital Single Market in the EU.

The BRT recommends that Japan's new law consolidate the currently fragmented authorities over personal data protection to one independent data protection authority and ensure transparency and foreseeability for both domestic and foreign-based companies.

The BRT also strongly recommends the authorities of Japan make sure that the amended law will satisfy the adequacy-finding procedure under the EU system. The BRT suggests that a reasonable and equitable 'safe harbour' agreement between the EU and Japan or an adequacy-finding procedure under the EU system be explored after or during the completion of the reforms of the two regimes.

Concerning the draft EU General Data Protection Regulation, the BRT thinks that the authorities of the EU should balance privacy protection and innovation, and recommends an active use of recognised certification schemes in international data transfers, a clearer definition of extraterritorial applicability, a flexible notification period in case of a breach, simplified rules for the cross border transfer of employee data within multinational companies, and the maximum fines to be proportionate and equitable. The BRT expects the adoption of EU General Data Protection Regulation by the end of 2015 to the extent possible.

Furthermore, both sides' Authorities should launch a dialogue to seek an international framework by enhancing cooperation with third countries and international organisations. It should eventually lead to the closer alignment of data protection regimes around the world that would enable global businesses to transfer personal data by complying with one regime.

< Yearly Status Report >

There has been good progress on this recommendation. The draft EU Regulation is in the process of deliberations and might be adopted by the end of 2015.

A revision of Japan's personal data protection law is under discussion at the Diet. The draft law includes the establishment of an independent authority responsible for personal data protection.

< Background >

The European Parliament voted in its plenary session in March 2014 and adopted the amendments proposed by the committee on Civil Liberties, Justice and Home Affairs (LIBE), the committee responsible for the proposal. The amendments by the EP keep harsh conditions on business entities such as potential fines up to 5% of an enterprise's annual worldwide turnover or 100 million Euros (whichever is greater) for data breach or complicated requirements on consent and erasure, although it introduces a definition of pseudonymous data and the certification program that would be favourable for business enterprises considering the use of personal data.

Paving the way for a more comprehensive agreement in 2015 at a Council level, agreements on key aspects of a data protection were reached in June, October and December 2014 and in March 2015 by the Justice Ministers of the Member States (rules in case of non-EU entities involvement, rules of territoriality, rules on processing data, and partial rules for the public sector).

Action taken so far

The Bill to amend the Act on the Protection of Personal Information passed the Diet on 3 September 2015 and the amendments were promulgated on 9 September 2015. The amendments are aiming for the protection of the rights

and interests of individuals, while taking into consideration usefulness of personal information.

In addition, based on the amendments, the Personal Information Protection Commission, which is a highly independent authority, will be established on 1 January 2016.

Future outlook

The amended Act comes into force within 2 years from the promulgation, whereby the Commission sets the Cabinet Orders and rules. For instance, the Commission establishes the Cabinet Orders and rules in relation to the definition of personal information, de-identification of personal information and cross-border data transfer. After the amended Act comes into force, the Commission will exercise authorities in accordance with the amended Act, Cabinet Orders and rules independently to develop the circumstances under which both utilization and protection of personal information will be promoted. The Commission will also be committed to facilitating international cooperation and sharing information about the amended Act with foreign states in order to develop mutual understanding of legal frameworks respectively.

3. Cooperation to Maintain an Open and Transparent Internet (Internet Governance)(WP-C/#03/EJ to EJ)

BRT Recommendation

The BRT supports the past coordinated efforts on Internet Governance by both sides' Authorities and expresses its utmost gratitude to the Leaders and Authorities of the EU and Japan for the leadership and efforts they have shown in relation to this issue. 2015 is an important year as the UN General Assembly will review the WSIS (World Summit on the Information Society) activities therefore we request both sides' Authorities to continue cooperating in order to maintain an open and transparent online environment involving multi-stakeholders.

< Yearly Status Report >

In February 2014, The European Commission released its communication "Internet Policy and Governance" on the EU's role in shaping the future of Internet Governance.

In March 2015, DG CONNECT and the Ministry of Internal Affairs and Communication (MIC) held 21st EU-Japan ICT Policy Dialogue and discussed Internet Governance among others.

< Background >

Internet has become an indispensable social infrastructure to sustain citizens' life, innovation, and economic growth. The BRT acknowledges that several innovative services using internet have emerged under the multi-stakeholders / international governance mechanism. At WCIT 2012, revisions of ITRs were discussed by ITU (International Telecommunication Union) member states. Different positions on governance among countries became obvious, and international governance remains a key topic in current discussions.

Several top level international meetings on Internet governance have been held in 2014 (Global Multistakeholder Meeting on the Future of Internet Governance in April in Brazil and the ITU Plenipotentiary Conference in October in the Republic of Korea) , advocating for a global Digital governance and some more are planned for 2015 (including the General Assembly's special high-level meeting in December). Reflecting a global trend regarding global governance, it

is to be noted that ICANN (Internet Corporation for Assigned Names and Numbers) should transition to international governance in September 2015.

Actions taken so far

In March 2015, the Ministry of Internal Affairs and Communications (MIC) and the Directorate General for Communications Network, Content & Technology (DG CNCT) of the European Commission held the 21st EU-Japan ICT Policy Dialogue in Tokyo and shared their views on the importance of Internet Governance by a multi-stakeholder approach so as to ensure the free flow of information and maintain an open and transparent Internet. At the same time, MIC and DG CNCT affirmed that they would continue to cooperate at various international conferences in the field of Internet Governance.

Future outlook

The GOJ will continue to cooperate with the EU in order to maintain an open and transparent online environment, in conformity with principles such as ensuring the free flow of information on the Internet and the multi-stakeholder approach.

4. Concerns on Emerging FLMs and Market Access Improvement in Third Countries (WP-C/#04/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

In cooperation with the European Committee and the Government of the United States, the GOJ has continuously requested for improvement of market access in third countries at the WTO/TBT committee by raising FLMs-related issues and other opportunities including bilateral dialogues with governments thereof. The GOJ worked actively on international trade negotiations such as the TiSA which was committed at the Japan-EU summit held in May 2015 to achieve concrete results.

Future outlook

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

5. Continued Efforts for Conclusion of ITA Expansion (WP-C/#05/EJ to EJ)

BRT Recommendation

The BRT requests that both sides' Authorities set a near-term deadline for WTO talks and try to bring the current negotiations to expand the ITA to a successful conclusion. To enjoy the outcome of ITA expansion, we urge zero or shorter staging periods for the majority of negotiated products.

The BRT also requests that, in the expanded ITA, compulsory and periodical review mechanisms be built in order to ensure that the ITA will always be kept up-to-date and reflect technological developments.

< Yearly Status Report >

Negotiators of ITA expansion participated in the WTO meeting in December 2014 to conclude the negotiation. But unfortunately, they could not finalize the negotiation. WTO Director General Roberto Azevêdo urged members to remain actively and constructively engaged to bridge the gaps in the negotiations.

< Background >

An ITA expansion would boost trade, remove uncertainties relating to product classification, and ensure technological developments across all economic sectors and public services. Both Japan and Europe will benefit from the development of a major industrial sector that is a driver, in virtually all other sectors and in public services, of productivity, innovation, job creation, improved competitiveness, and service quality.

Unlike the current ITA, which has not been updated since 1996, a built-in periodical review mechanism will enable additional categories of ICT goods to be traded duty free and will minimize the risk of current and future innovative technological developments giving rise to product classification uncertainties.

Action taken so far

After the launch of ITA expansion negotiations in May 2012, after the negotiation rounds in Geneva, the negotiations reached an agreement on a product list in July 2015. The ITA expansion negotiations were continued to discuss the

staging period for each product, and concluded at the WTO's 10th Ministerial Conference in Nairobi, Kenya in December 2015.

As a result of the conclusion, around 65% of tariffs lines will be eliminated in 2016 (accounting for around 88% of imports). By 2019 this share will increase to 89% of the tariff lines (and 95% of imports), and all customs duties will be eliminated within 7 years. Moreover, a paragraph related to the review of the product coverage was added to the declaration agreed in July 2015 (WT/L/956).

Future outlook

Japan will eliminate tariffs as agreed in the ITA expansion negotiations, and closely cooperate with the EU government and industries to review the product coverage in the future.

6. Work towards International Standardisation in Joint R&D Programmes (WP-C / # 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 and in the Internet of Things. Regulatory cooperation for emerging technologies between the EU and Japan will facilitate the deployment of new services and products in both regions.

< Yearly Status Report >

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.

< 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.

Action taken so far

The Ministry of Internal Affairs and Communication (MIC) has instituted joint calls with the EU since FY 2012 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. In the fiscal year 2015, MIC and

the European Commission launched new joint calls in two areas, namely, “5G – Next Generation Communication Networks” and “EU-Japan cooperation on Novel ICT Robotics based solutions for active and healthy ageing at home or in care facilities..”

Moreover, for the same purpose as the projects above, National Institute of Information and Communication Technology (NICT) has instituted joint calls with the EU. In the fiscal year 2015, NICT and the European Commission launched two new joint calls which are “IoT/Cloud/Big Data platforms in social application” and “Experimental testbeds on Information-Centric Networking.”

At the 18th Japan-EU Industrial Policy Dialogue held in Brussels in March, 2015, Ministry of Economy, Trade and Industry (METI) and the Directorate-General for Internal Market, Industry, Entrepreneurship and SMEs (DG-GROW) discussed cooperation on their legislative processes at earlier stage, and released a joint document regarding Japan-EU regulatory cooperation overseeing the progress in 13 subjects in 12 areas such as robotics, chemicals and automobile.

Future outlook

The GOJ continues to seek the possibility of wider cooperation with the EU, with a view to establishing international standardization, by following up progress of the joint research and the dialogues which have been launched so far.

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

BRT Recommendation

To make the programmes even more effective to manage and accessible from the industry, the procedure for preparation and launch 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 EU and Japanese industry to find out common themes. 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 newly established National Contact Point in Japan for Horizon 2020 and other relevant instruments (including EEN) to widely circulate R&D call notifications and support the formation of partnerships. The BRT hopes that initiatives under Horizon 2020 and the forthcoming 5th Science and Technology Basic Plan in Japan will lead to further EU-Japan strategic R&D cooperation.

The BRT welcomes the successful outcome of the EU-Japan ICT Policy Dialogue held in March, 2015 between MIC and DG CONNECT. It confirmed the importance of policy coordination and R&D cooperation in the ICT field to promote growth and competitiveness. In particular, the BRT welcomes their announcement of the forthcoming signature of the EU-Japan 5G (5th Generation mobile communication systems) Ministerial Joint Declaration.

< Yearly Status Report >

A few joint calls for proposals under Horizon 2020 were released in the fields of aeronautics and ICT.

In October 2014, the European Commission, Japan's MIC and NICT held the 5th EU-Japan Symposium in ICT Research and Innovation in Brussels to discuss updates on Joint R&D ICT projects between the EU and Japan.

In March 2015, a Horizon 2020 project, SUNJET II organized in Tokyo the “Europe- Japan Symposium Electrical Technologies for the Aviation of the Future”.

To further enhance EU-Japan cooperation in research and innovation, a new project called JEUISTE was launched in Sep. 2013 under FP7. Since its nomination as NCP of Japan, the EU-Japan Centre for Industrial Cooperation conducted several activities to facilitate R&D collaboration between the EU and Japan (translation of key Horizon 2020 contractual documents, organization of seminars on ICT (December 2014) and Renewable Energy (February 2015), organization of seminars/workshops in cooperation with local hosts (grass-root approach, tailored to specific needs), establishing the Horizon 2020 portal site for Japan and networking and exchanging information with other NCPs.

The GOJ is developing its 5th Science and Technology Basic Plan.

< 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 GOJ and the European Commission adopted the “Joint Vision on the new strategic partnership in research and innovation between the GOJ and the European Commission” at the 3rd Japan-EU Joint Committee on Science and Technology Cooperation held on 18 May, 2015. The strategic partnership includes frequent consultation at multiple levels for deepening the strategic cooperation; promoting joint research activities in key strategic thematic areas, such as Information and Communication Technology (ICT), Aeronautics and Materials (including Critical Raw Materials), health/medical research,

environment, energy and high-energy physics; establishing a mechanism for the joint funding of research and innovation projects; enhancing the mobility of researchers between Japan and the EU; enhancing consultation and collaboration on Science, Technology and Innovation policy development; and promoting public engagement to give further visibility to Japan-EU cooperation in research and innovation. This Joint Vision was endorsed by the leaders of Japan and the EU at the 23rd Japan-EU Summit on 29 May 2015.

In the field of ICT, building in the outcome of Japan-EU ICT dialogue held on March, 2015, Ministry of Internal Affairs and Communication (MIC) and the Directorate-General for Communications Networks, Content and Technology (DG-CONNECT) signed the “Joint Declaration on a Strategic Cooperation on the Future Generation of Communication Networks (5G).”

Future outlook

The GOJ will implement research cooperation with the EU in a steady manner, in accordance with the “Joint Vision on the new strategic partnership in research and innovation between the GOJ and the European Commission” and the “Joint Declaration on a Strategic Cooperation on the Future Generation of Communication Networks (5G).”

8. Tax credits and other incentives for R&D (WP-C/#09/EJ to EJ)

BRT Recommendation

The BRT recommends further enhancement of tax credits for R&D, public-private cooperation in the procurement of R&D results, etc., in particular for SMEs. The authorities should not change the laws and rules too often, otherwise companies will be reluctant to plan long-term R&D.

< Yearly Status Report >

The GOJ extended and expanded special treatment of R&D tax credit in the FY2014 Tax Reform.

< Background >

R&D presents in itself a high risk for companies. Authorities should help to reduce the cost of such risks and apart from subsidies, tax credits present another effective solution. Particularly SMEs, with limited access to funding, will benefit from tax credits as the simplest and least bureaucratic form of R&D subsidy. Tax credits should take into account the long-term nature of R&D, which requires long-term planning of funds and expense management. Tax credits should therefore be established for a prolonged period, so that companies can plan their R&D expenditures effectively.

Actions taken so far

The GOJ has amended the R&D tax system in the FY 2015 Tax Reform. From the perspective of promoting open innovation, while increasing the tax credit rates (from 12% to 20-30%) for “special experiment and research expenses” such as expenditures for joint research and contract research with national research institutions, universities, and corporations, the GOJ has set the upper limit on the tax credit amount (5% of the corporation tax) separated from that for “general experiment and research expenses”. Also, the scope of “special experiment and research expenses” has been expanded. For example, the license fees for intellectual property rights of the small-medium enterprises have been included in this category.

Future outlook

The GOJ would like to continue considering the R&D Tax system for the next Tax Reform.

9. Government-Led Industrial Cooperation in Aeronautics (WP-C/#10/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

In March 2015, METI and the European Commission(DG Research & Innovation) held a director-level meeting on SUNJET-2, the project to jointly make a roadmap for technology development, based on the Terms of Reference of the European-Japanese Working Group on Civilian Aeronautics Research (made by METI and EC(DG Research & Innovation) in 2013). In June, METI and the European Commission (DG Research & Innovation) held the third working group on civilian aeronautics research.

As to the joint research projects, in addition to the ones that are already carried out, four proposals on 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 to EC and EC adopted the projects for which it would budget. Contracts of the cooperation projects will be signed between the project participants and EC in December. The GOJ is preparing for putting budget into the same projects from FY 2016.

In October 2015, METI and DGAC (Directorate General for Civil Aviation) of France held the third Working Group in Tokyo, based on the Memorandum of Cooperation (MoC) in Civil Aeronautical Industry, signed in June 2013. In conjunction with the Working Group, METI and DGAC also held a workshop in Tokyo aimed at finding future cooperation between Japanese and French companies.

Future outlook

With respect to efforts to develop environmentally-enhancing aircraft technologies, the cooperation between Japanese civil aeronautics industry and those of other countries including the EU 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 Japanese government will continue to support the further collaboration between the Japanese and European civil aeronautics industry, such as finding and supporting new cooperation projects, utilizing the Japan-EU and Japan-French cooperation framework.

10. Weight Restrictions on Haneda Airport D Runway (WP-C / # 17/ 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. This will prevent Japan from realising its objective to grow the number of visitors from 13 million per annum today to 20 million by 2020, when the Tokyo Olympics will take place. 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. 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 line-up 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 ensuring safe operations, hence, it is extremely difficult to ease the restrictions which are required for ensuring the durability of structures. This is why Runway D, which is only 2,500 meters long, has weight restrictions. Meanwhile, Haneda Airport does not reject larger airplanes including A380 and A350, and they are allowed to make landings if being operated with the acceptable weight (for instance, reduce fuel and cargo unless it affects operations that are in accordance with the weight requirements).

In relation to this, Runway C at Haneda Airport has been extended to 3,000 meters in December 2014. With the permission from JCAB (Japan Civil Aviation Bureau), larger aircraft including A380 are allowed to make landings on this runway during 23:00PM to 6:00AM.

Future outlook

JCAB has no specific plans over the next year.

11. Approval of Satellite Launch Service Providers (WP-C/#18*/E to J)

BRT Recommendation

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

< Yearly Status Report >

We have no new information.

< Background >

Japanese Authorities contemplate Space Operations legislation that would require Japanese users of satellite launch services to obtain an official approval before they contract for launch, and that would also require them to only use reliable launch service providers approved by Japanese Authorities. We have no issue with such legislation if it cannot be used to make competition in Japan difficult for EU launch service providers.

Actions taken so far

The GOJ is internally considering the formulation of “an act on space activities” taking into account practices including the US and European third party liability systems for damages caused by space objects and legal frameworks on governmental authorization and supervision for space activities by non-governmental entities.

Future outlook

The GOJ continues the consideration mentioned above.

Working Party D : Financial Services, Accounting and Tax Issues

1. Recommendation regarding Financial Reform and Regulation (WP-D / # 01** / EJ to EJ)

BRT Recommendation

The BRT requests that regulating bodies continue to address the impact of reforms and new regulations on the real economy and take a co-ordinated approach to reduce extraterritorial impact of rules introduced in one jurisdiction on other locations and to recognise substituted compliance.

<Recent Progress>

Numerous consultations are taking place. Notably, the International Organization of Securities Commissions (IOSCO) Task Force on Cross-Border Regulation has launched a consultation on regulatory tools and challenges in November 2014 after extensive discussions with a variety of stakeholders. The European Parliament (EP) has adopted equivalence decisions for Japan concerning the regulatory regimes of central counterparties in October 2014 and the banking supervisory and regulatory arrangements in December 2014. The European Commission published its delegated decision on the Solvency II equivalence assessment of Japan's solvency regime with respect to reinsurance and group solvency in November 2015.

<Background>

Both the European and Japanese authorities have expressed their commitment to implementing the measures designed to protect the real economy and to ensure economic growth and stability of the financial system. The authorities are pursuing regulatory dialogues and believe equivalence would serve to prevent double or overlapping requirements to operators.

Actions taken so far

As to the OTC derivative market in Japan, in order to resolve cross-border conflicts, inconsistencies, gaps and duplicate requirements, we have been

engaged in discussions proactively with the EU on the equivalence assessments. EC adopted equivalence decisions on Japan concerning the regulatory regimes of central counterparties in October 2014 followed by conclusion of Memorandum of Cooperation with ESMA (European Securities and Markets Authority) in February 2015. In April 2015, ESMA recognized Japan Securities Clearing Corporation and Tokyo Financial Exchange Inc as a third-country CCP. EC published the equivalent assessment which is requested by CRR (Capital Requirements Regulation). It states Japanese regulation and supervision to credit institutions and exchanges are equivalent to the EU's in December 2014. As to reinsurance and group solvency, the EC published its decision on the Solvency II equivalence assessment of Japan's solvency regime with respect to reinsurance and group solvency in November 2015. It states that the Japan's solvency regime has respectively temporary equivalence and provisional equivalence to EU's. In addition, IOSCO published final report of the IOSCO Task Force on Cross-Border Regulation in September 2015, providing toolkits of cross-border regulatory options.

Future outlook

Japan and EC continue to discuss the part which is still not assessed in relation to CRR(the equivalence decision on Japanese regulation and supervision to investment firms) to finalize it. Moreover, Japan and the EC are aiming at establishing a regulatory cooperation framework within the context of the EU-Japan EPA negotiation to achieve more harmonized rules and supervision. In addition, Japan will contribute to IOSCO work to monitor progress on the implementation of the final report's recommendations.

2. Recommendation on BEPS Action Plan and Other Tax Issues (WP-D/#02/EJ to EJ)

BRT Recommendation

The BRT maintains the following recommendations:

BEPS (base erosion and profit shifting) Action Plan

The authorities should carefully consider the risks of excessive disclosure requirements and anti-tax avoidance measures so as not to hamper multinational enterprises' business activities.

Furthermore, in order to realise fair taxation and to enhance direct investment between the EU and Japan, the following measures should be adopted:

Tax Treaties

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 and that corresponding adjustments and arbitration in case of transfer pricing taxation are provided.

Transfer Pricing

The BRT requests the harmonisation and simplification of documentary requirements in transfer pricing taxation and the facilitation of the conclusion of bilateral and multilateral APAs (Advance Pricing Arrangements).

Participation Exemption

The BRT recommends further introduction of participation exemption that will exempt dividends and capital gains received from business investment from further corporate taxation.

<Recent Progress>

The BRT understands the Commission Services are giving consideration to a balanced approach to disclosure between effective tax collection, transparency and legitimate business interest. The OECD released its first recommendations for a co-ordinated international approach to combat tax avoidance by multinational enterprises in September 2014, causing some concerns.

Some progress has been seen for the recommendation on the modernisation of tax treaties. No progress has been seen on transfer pricing and participation exemptions.

<Background>

The BEPS Action Plan was proposed by the OECD and endorsed by G20 Finance Ministers and Central Bank Governors in July 2013. The BRT supports the idea of modernising international taxation rules that would include non-OECD countries to cope with the globalisation and digitalisation of economy. However, the BRT is concerned that the requirement of BEPS Action Plan for multinational enterprises to disclose information on their global allocation of income, economic activity and country-by-country taxes paid to all relevant governments would lead to an increase of administrative burden on enterprises and of a risk of double taxation. The BRT recommends that the introduction of excessive disclosure and anti-tax avoidance rules should be avoided so that legitimate business activities would not be hampered. In order to enhance direct investment between the EU and Japan, measures to reward for taking risks associated with cross-border investment are essential. In particular, the measures to avoid double taxation of the same profit should be regarded as *sine qua non*.

While there is a convergence of policies on transfer pricing taxation among major countries according to the OECD Guidelines, companies find it costly and complicated to comply with the transfer pricing requirements of various countries.

In addition, compliance costs associated with the transfer pricing taxation requirements are potentially very high. Although APAs are increasingly used in the EU Member States as well as in Japan, the conditions differ country by country and companies have to satisfy the requirements of each country. An EU-Japan transaction often involves three countries or more. For such businesses, multiple APAs are necessary to obtain sufficient assurance. However, multiple APAs are still its infancy even within the EU and the implications for costs and managerial resources are often prohibitive.

Participation exemption, by which dividends and capital gains received from business investment above certain holding threshold are exempted from further corporate taxation, is one measure to encourage mutual direct investment.

Actions taken so far

(BEPS Action Plan)

The purpose of the BEPS project led by the OECD's Committee on Fiscal Affairs is to avoid excessive tax planning and tax avoidance by multinational enterprises and ensure the level playing field between enterprises.

The first set of the reports was published in September 2014 and the final reports of the BEPS project were published in October 2015. During the process of finalization of those reports, the OECD held public consultations and received comments on discussion drafts from many stakeholders including business and civil society. At the same time, the GOJ collaborated with business sectors through opportunities to exchange views and reflect ideas on discussion at the OECD.

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

(Tax Treaties)

From the view point of promoting investment and economic exchanges between Japan and the EU member states, the GOJ is actively expanding and enhancing the tax treaty network with the EU member states. The new agreement between Japan and Germany was signed in December 2015, which wholly amended the contents of the current Agreement. The new Agreement reduces taxes withheld at source on investment income (dividends, interest and royalties) so as to further promote the investment exchanges between the two countries, updates the article concerning taxation on business profits, and introduces the arbitration process to the mutual agreement procedure. Corresponding adjustment in case of transfer pricing taxation is also provided.

(Transfer Pricing, Participation Exemption)

Transfer pricing documentation requirements are defined by laws and the National Tax Agency operates its administration in consideration of taxpayers' burdens.

APAs with the EU Member states overall are being smoothly implemented based on common understanding of the OECD transfer pricing guidelines.

For the GOJ's overall position on tax-system reform of Japan, please refer to the

attachment in the Appendix of this report.

Future outlook

(BEPS Action Plan)

With the endorsement of the BEPS project, we are now moving to the implementation stage which requires each country to consider the necessary domestic legislation and amendments to tax treaties.

The GOJ will continue to take appropriate steps toward proper implementation in cooperation with other countries and international organizations, taking opinions from business sectors and academia into consideration.

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

(Tax Treaties)

The new Agreement will enter into force after the completion of the approval process on both sides. The GOJ will continue to work on the expansion and enhancement of the tax treaty network with the EU member states as necessary, which contributes to further strengthening investment and economic ties between Japan and the EU in a globalized business environment.

(Transfer Pricing, Participation Exemption)

The GOJ will continue to clarify the NTA's operations by Administrative Guidelines with reference to the international trends.

With regard to APAs with EU member states, the GOJ will continue to implement them appropriately based on the provisions of tax treaties and the OECD transfer pricing guidelines.

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

(Attachment)

Tax-system-related proposals

In 17th EU-Japan Business Round Table, the followings were proposed with respect to Japanese tax system:

Working Party D:

Recommendation on BEPS Action Plan and Other Tax Issues

Changes to the Japanese tax system are made every year, and the decisions on what changes to make are made following deliberations by bodies such as the Tax Commission. These deliberations focus on requests and opinions submitted by government ministries and agencies to the tax authorities, and take into account the economic climate, and fiscal situation. Opinions from various levels, including proposals from the Business Round Table, are referred to by ministries and agencies when they prepare their requests for changes to the tax system, and accordingly reflected in the tax reform process.

3. Recommendation on Japanese Fiscal Soundness (WP-D / # 04** / EJ to J)

BRT Recommendation

The BRT urges the Japanese Government devise a detailed roadmap towards its goal of primary-balance surplus by fiscal 2020.

<Background>

Fiscal soundness is a fundamental issue for regaining trust in the Japanese economy. Primary-balance deficit risks leading to jump in interest rate and abrupt retrenchment in budget, and resulting in serious impact to the Japanese economy. Reforms of Japan's social security and taxation systems are keys for both economic growth and the realisation of fiscal soundness.

Actions taken so far

Through reform efforts aiming at achieving both economic revitalization and fiscal consolidation, the primary deficit to GDP ratio is expected to halve in FY 2015 compared to FY 2010. Under this situation, the GOJ formulated "The plan to Advance Economic and Fiscal Revitalization" toward realizing both economic revitalization and fiscal consolidation in an integrated manner. Based on this plan, the GOJ aims at achieving a primary surplus by FY 2020 through the following three pillars: overcoming deflation and revitalizing the economy, expenditure reforms, and revenue reforms.

The GOJ formulated "The Economic and Fiscal Revitalization Action Program", identifying a roadmap and KPIs to clarify details and timeline of reform implementation on December 2015 including main 80 reform items in each expenditure area, and manage the reform progress, assessing the effect of the reforms, and will steadily proceed with the reforms.

Future outlook

The GOJ will surely implement the consumption tax increase to 10% in April 2017. In addition, the GOJ firmly maintains the FY 2020 target of achieving

primary surplus. To achieve this, the GOJ will have the FY2016 budget, which is the first year of “The Plan to Advance Economic and Fiscal Revitalization” enacted and then proceed with steadily implement it.

The Council on Fiscal and Economic Policy will manage and review the progress of reform measures described in the roadmap in order to advance those as scheduled.

4. Recommendation on Japanese Tax system (WP-D / # 05* / EJ to J)

BRT Recommendation

Attracting and encouraging foreign direct investment to Japan would induce Japanese economic growth with jobs and technological innovation by inviting prominent technologies and individuals. Reduction of effective corporate tax rate and abolition or reduction fixed asset tax on depreciable assets are necessary measures for providing a globally competitive business environment.

<Recent Progress>

The Cabinet decided Fiscal Year 2015 Tax Reform (Main Points) which mentions the reduction of effective corporate tax rate in January 2015.

<Background>

There is expectation that in addition to revitalisation of Japanese corporations, foreign direct investment to Japan will contribute to Japanese economic growth. So as to encourage foreign direct investment to Japan as one of the attractive markets in Asia, a globally competitive corporate tax system should be adopted.

Actions taken so far

The GOJ promotes more boldly the corporate tax reform that was embarked from FY 2015. While a revenue source will be secured through such measures as broadening the tax base, the GOJ decided to reduce the effective corporate tax rate (32.11% in FY 2015) to 29.97% in FY 2016 and 29.74% in FY 2018.

In addition, the GOJ decided to introduce a special measure which will reduce the property tax temporarily for small and medium enterprises (SMEs) when they obtain certain machinery, aiming to promote capital investments by local SMEs. The GOJ will keep the property tax on depreciable assets, considering that the property tax is a stable and basic tax revenue for the municipalities..

Future outlook

The GOJ will submit to the FY 2016 ordinary session of the Diet the amendments to the tax law including the corporate tax reform and SMEs related acts including the special property tax measures.

Working Party E : Energy, Environment, and Sustainable Development

1. Changes and harmonization in energy and environment (WP-E/#01*/EJ to EJ)

BRT Recommendation

Significant geopolitical risks in energy-supply areas

Political and social instability remain in the Middle East, a region that supplies a large portion of the world's energy. The road to stability in oil producing countries such as Iraq, Libya, Algeria, and Iran remains unclear. For Japan, a country that imports more than 80% of its oil from the Middle East, securing the energy required to support the country's economic activities is an issue of vital importance. This applies also to EU, whose average oil import dependency is 83%.

Recent events in Ukraine and Russia also raise concerns over security of gas supplies as the EU-28 imports more than 60% of its energy needs in gas, a quarter of which from Russia.

Energy importers also continue to face security issues such as combating piracy off the coast of Somalia and maintaining access to sea lanes such as the Suez Canal and the Strait of Hormuz. Japan and the EU should therefore enhance international collaboration to preserve energy security.

Energy price volatility strongly impacts importing countries such as Japan and the EU

Oil prices have halved in less than 6 months since June 2014, with mixed consequences worldwide: sizable revenue losses for energy exporters such as Russia and Venezuela, cheaper energy and improvement of trade deficit in Japan and the EU. However, this situation negatively affected the effort by the EU and Japan to end long periods of deflation.

Increased energy demand from emerging countries affects the energy policies of other countries and price stability

As the world's population continues to increase, the main consumption of energy is shifting from developed to emerging countries. In the long term, exports of shale gas from the United States may help stabilizing both energy prices and

supply; however, the development of resources by state-owned enterprises in emerging countries will lead to severe competition to secure stable supply at affordable prices .

Japan and the EU should cooperate to stabilize natural resource prices and establish an energy mix policy that reflects the actual energy situation in each country so that private-sector corporations can continue to carry out stable business activities.

Increase in greenhouse gas emissions and its impact on the environment

Global warming causes increase in the acidity of the oceans, raises sea levels, and severely affects many aspects of human life such as agriculture, forestry and fishing, ecosystems, water resources, and human health. Governments, industries, and academia in Japan and EU should deepen their dialogue on measures to mitigate global warming.

Japan and EU should accelerate developing the next generation of technically advanced and competitive renewable energies and promote the technologies globally.

In Japan, in order to reduce greenhouse emissions, restarting the nuclear power plants that are verified as being safe needs to be seriously considered.

Actions taken so far

With regard to the collaboration on energy security, the 5th Energy Dialogue was held in Tokyo on 17 September, 2015 between the Japanese Ministry of Economy, Trade and Industry and the European Commission. At this dialogue, both organizations discussed present and future policy trends including the strategic framework of EU's Energy Union, the review of Japanese energy policy, the reformation of electricity market and the energy mix in the future. In addition, gas security and emergency response principles were discussed and the necessity of intense collaboration concerning this issue within the framework of G7 was reaffirmed.

Following the Strategic Energy Plan, which the Cabinet approved in April 2014, the Long-term Energy Supply and Demand Outlook (energy mix) was decided in July 2015. This is a forecast and also a vision of a desired future energy

supply-demand structure to be realized.

Future outlook

With regard to the collaboration on energy security, Japan and the EU will continuously cooperate to ensure the flexibility, liquidity and transparency of LNG markets through the G7 Kitakyusyu Energy Ministerial Meeting (May 1 and 2, 2016), the LNG Producer-Consumer Conference, and the 6th EU-Japan Energy Dialogue.

Japan will go ahead with a comprehensive approach to realise its energy mix, such as; 1) promotion of thorough energy efficiency and conservation; 2) review of the system so as to allow compatibility between the maximum introduction of renewable energy and the inhibition of public burden; 3) enhancement of efficiency of thermal power generation; and 4) establishment of appropriate business environment for nuclear operation.

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

BRT Recommendation

It is crucial for the EU and Japan to secure stable energy supply and to reduce their energy needs while supporting the development of their economic infrastructure in an affordable manner.

Striking a balance among stable energy supply, economic efficiency, environmental issues, and safety regulation

Energy is the basis of all economic activities. Securing stable energy supply at reasonable prices, developing the necessary infrastructure as well as reducing energy needs are crucial not only for sustainable business activities but also for the creation of new business opportunities. At the same time, it is important to consider the environmental impact of energy use. Paying utmost attention to safety, Japan and EU should establish energy policies which preserve a role for nuclear power, one of the effective means of reducing greenhouse gas emissions.

International coordination

The acceleration of the global demand for energy, particularly in Asia, combined with an increase in the diversity of available energy sources such as natural gas, renewable energy, and nuclear energy, is transforming the global pattern of energy supply and demand. At the same time, the negative impact on the environment caused by human energy use makes the adoption of rational energy policies more urgent and complex.

Japan and EU should create a comprehensive and collaborative framework to handle the inter-relationship between energy and environment issues. Japan and EU should also deepen their cooperation through their participation in the IEA and IAEA, as well as through information exchanges at other relevant international meetings in which they participate.

Actions taken so far

In July 2015, the Long-term Energy Supply and Demand Outlook (energy mix)

was decided. In forwarding the energy mix, the basic principle is to simultaneously achieve specific policy goals: on the major premise of ensuring safety, 1) to improve self-sufficiency rate to the level higher than before the Great East Japan Earthquake (approx.25%), 2) to lower the electric power costs than the present, and 3) to set the energy mix that contributes to a greenhouse gas reduction target comparable to the EU and the U.S.. The energy mix provides that the dependence on the nuclear power plants will be approx. 20 to 22 % in FY 2030. On the major premise of safety, in case that the Nuclear Regulation Authority confirms the conformity of nuclear power plants with the new regulatory requirements, which are of the most stringent level in the world, the GOJ will follow the judgment and will proceed with the resuming operations of such nuclear power plants.

Japan has been actively contributing to the international and regional forums such as IEA, IRENA, IAEA, G8/G7, Asia Pacific Economic Cooperation (APEC) and ASEAN+3. For example, by organizing lectures by the executive director of IEA on the occasion of an international conference in Japan as well as at the governmental committees, it attempts to realize the expansion and deepening of international cooperation have been made. In addition, Japan chaired the Fifth Session of the Assembly of IRENA in 2015 and demonstrated its intention to lead the world in the field of renewable energy.

Future outlook

In order to achieve the realistic and well-balanced energy mix, Japan will go ahead with comprehensive efforts such as promotion of thorough energy efficiency and conservation and review of the system so as to allow compatibility between maximum introduction of renewable energy and inhibition of public burden.

No.1 unit at Sendai nuclear power plant restarted on August 11 and entered commercial operation on September 10. No.2 unit at the same plant also restarted on October 15 and entered commercial operation on November 17. The Nuclear Regulation Authority will continue to implement the examination regarding the conformity to the new regulatory standards.

Moreover, Japan will actively contribute to the international and local forums such as IEA, IRENA, IAEA, G8/G7, G20 and APEC.

3. Energy policy timeline, energy mix policies and integrated energy market (WP-E/#03*/EJ to EJ)

BRT Recommendation

Short, medium and long-term energy policies

Large-scale natural disasters, such as the Great East Japan Earthquake, underscore the challenge of providing energy in an emergency. The earthquake also demonstrated that, in order to maintain an uninterrupted supply of energy logistics issues such as the repair of roads and ports, securing tank lorries, tankers and other appropriate means of transport, and setting up supply bases, must be solved. Geopolitical instability can also contribute to fluctuations in resource prices as a result of speculative purchases. The EU and Japan should establish both a short-term energy strategy for handling crisis situations, such as the immediate aftermath of a natural disaster, and a long-term energy mix strategy that will provide a stable supply of energy in the face of inevitable changes in geopolitics.

Promoting supply stability through a multi-layered energy policy

All sources of energy have their strengths and vulnerabilities; no energy source can meet all demands for stability and affordability. Therefore, it is necessary to build a multi-layered energy supply system supported by an adequate power transmission infrastructure that can function both in normal times and during crises.

Creating an energy mix considering regional variations and cost

In Japan and the EU, there are some regions blessed with abundant energy resources, and some that are not.

While some regions have already established an inter-dependent power exchange system, with other countries, some countries have no close neighbours and have therefore had to build an independent supply system. Deliberations by Japan and EU concerning the stable and safe supply of energy, economic efficiency, and environmental issues should take into account these regional variations.

Creating and maintaining a resilient and effective energy infrastructure

To secure a stable and affordable supply of energy, Japan and the EU should share best practice on how to build an energy value chain, including a resilient and reliable energy infrastructure, capable of executing their chosen energy mix policies and consider measures to replace outdated equipment and facilities to improve safety.

Developing an integrated and safe energy market

Japan and EU should actively exchange best practices on the design and market mechanism necessary to ensure a well-functioning integrated Energy market, allowing the chosen energy mix at an affordable cost.

Actions taken so far

Following the Strategic Energy Plan, which the Cabinet approved in April 2014, the Long-term Energy Supply and Demand Outlook (energy mix) were decided upon in July 2015. In formulating the energy mix, the basic principle is to simultaneously achieve specific policy goals: on the major premise of ensuring safety, 1) to improve self-sufficiency rate to the level higher than before the Great East Japan Earthquake (approx.25%), 2) to lower the electric power costs than the present, and 3) to set the energy mix that contributes to a greenhouse gas reduction target compatible to the EU and the U.S.

Integrated reform in the domestic energy fields of electricity, gas, and heat supply is advancing and a comprehensive energy market is expected to be created. In April 2015, the Organization for Cross-regional Coordination of Transmission Operators which is to develop the transmission and distribution systems that are necessary for the cross-regional utilization of power sources was inaugurated. In September, 2015, the Electricity Market Surveillance Commission which is responsible for an appropriate monitoring in the electricity, gas and heat markets was established.

Future outlook

In order to realize the realistic and well-balanced energy mix, Japan will go ahead with comprehensive effort such as promotion of thorough energy

efficiency and conservation and review of the system so as to allow compatibility between maximum introduction of renewable energy and inhibition of public burden.

For the steady implementation of integrated reform in the energy fields, entry into the electricity retail market will be fully liberalized in April, 2016. In addition, the current market entry regulation for heat supply businesses will be changed from the permission system to the registration system, and regulations such as tariff restraints and supply obligation will be abolished.

4. Fossil fuels (WP-E/#04*/EJ to EJ)

BRT Recommendation

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

Fossil fuels emit greenhouse gases, but have a relative advantage in terms of cost and stable supply. Research into making the use of fossil fuels more efficient and reducing CO₂ emissions is ongoing. Japan and EU should support this research and developing countries' use of the resulting technologies.

Coal is still being evaluated as an important base power supply because it involves the lowest geopolitical risk and has the lowest price per unit of heat energy among fossil fuels especially in developing countries. Japan and EU should contribute to reduction of greenhouse gas emission by adopting highly efficient power generation systems, and promoting the development of new technologies such as carbon dioxide capture and storage (CCS).

Actions taken so far

In the energy mix policies approved in July 2015, the government has declared its intention to enhance the efficiency of coal fired power plant and LNG power plant and to promote their effective use while balancing it with the reduction of environmental burden. Based on this decision, 'Technical Roadmap for Next-generation Power Generation Technologies' was formulated by a public-private joint conference in the same month, in order to realize the enhanced efficiency of thermal power plant as well as the reduction of carbon dioxide. As for the carbon dioxide capture and storage (CCS) technology, large-scale demonstration project, research and development aiming at its practical use are being conducted, which are contributing to the countermeasure for global warming. Through energy policy dialogues with the countries concerned and collaboration with private sector, Japan supports the diffusion of high-efficiency, low-carbon technology in developing countries and contributes to the reduction of carbon dioxide in the world.

Future outlook

As for the introduction of high-efficiency and low-emission dioxide emitting coal fired plant, the demonstration test facilitying constructed in order to start the oxygen blow IGCC (Integrated coal Gasification Combined Cycle) demonstration test in 2017. As for the CCS technology, demonstration programs, research and development, aiming at its practical use, will be continued.

In addition, by promoting the introduction of the world's most efficient Japanese power generation technology overseas, Japan will contribute to global-scale reduction of environmental burden.

5. Nuclear power (WP-E/#05**/EJ to EJ)

BRT Recommendation

Nuclear power is an important and competitive source of energy, in particular for regions with no other economically extractable energy resources.

The accident at the Fukushima Daiichi nuclear power plant demonstrated the need for failsafe systems, based on a thorough analysis of the causes of the accident, to restore public confidence in nuclear power.

Safe nuclear power generation can play an important role in the energy mix of the EU and Japan. It could be a valuable asset supporting EU and Japanese competitiveness, supplying base load electricity at low cost and contributing to grid stability, reduction of CO₂ emissions, and economic growth.

Rising global expectations for nuclear energy and the necessity for education and training to assure safety

Many countries throughout the world are looking to nuclear energy to release them from their dependency on fossil fuels, and are evaluating schemes to adopt nuclear power. The EU and Japan should cooperate to provide education and training to assure the safety of nuclear power generation.

In Japan, accelerating the restart of nuclear power plants in areas verified as safe

The lack of nuclear power generation has caused a rise in electricity prices, affecting the competitiveness of the activities of both the EU and the Japanese industries in Japan, as well as increased GHG emissions. In terms of both economical reasons and reducing greenhouse gas emissions, it is necessary to restart as soon as practically possible those nuclear power plants that are verified as being safe by the Nuclear Regulation Authority.

Replacing ageing nuclear reactors with safer models

The latest nuclear reactors such as Gen III and Gen III+ are designed to meet very high safety standards. It is therefore necessary to explore the possibility of using these state-of-the-art reactors in future energy mixes, and also consider replacing some ageing reactors, in both the EU and Japan.

Construction of latest generation of reactor models in both Japan and the EU can also serve as reference for export of European and Japanese nuclear technologies to third countries.

Nuclear fuel recycling and waste disposal

Regarding the situation of spent nuclear fuels, Japan and EU should drastically reinforce and comprehensively promote efforts to resolve the challenge of how to manage, recycle and dispose of spent fuels. Japan and EU should also promote collaborative R&D programs on the disposal of waste.

Financial support

To assure the highest level of safety, Japan and the EU should promote investment in nuclear energy, and at the same time, encourage financial institutions such as the World Bank, the European Bank for Reconstruction and Development (EBRD), the European Investment Bank (EIB), and the Japan Bank for International Cooperation (JBIC) to provide finance for projects that promote the safety of nuclear power.

Safety measures

Japan and EU should cooperate bilaterally and in the relevant multilateral fora on all aspects of nuclear energy, in particular the development and effective implementation of harmonized international nuclear power safety standards.

Japan and the EU should continue their specialist consultations concerning technologies related to decommissioning nuclear reactors, decontamination, and radioactive waste treatment at nuclear power plants.

Actions taken so far

In the Basic Energy Plan approved by the Cabinet in April 2014, nuclear power was given the status of important base load power source which excels at energy security, economical efficiency and carbon dioxide emission. On that basis, as for the nuclear plant, the safety is given top priority under any circumstances and, when it is approved by the Nuclear Regulation Authority to be conforming to the new requirements, the assessment will be respected and

the restart of such nuclear plants will be pursued.

On that basis, No. 1 reactor of Sendai Nuclear Plant was resumed on 11 August 2015, and then normal operation has been conducted since 10 September. Moreover, No.2 reactor of Sendai Nuclear Plant was resumed on 15 October, and then normal operation has been conducted since 17 November. It is recognized as an important step in terms of the establishment of well-balanced power sources and further stable supply of electric power.

In Japan, promotion of the nuclear fuel cycle which contributes to the efficient use of resources as well as to the reduction of volume and toxicity of high-level radioactive waste is adopted as the basic policy. Through the cooperation between the civil nuclear power departments of Japan and the EU, such as the Fifth meeting of Japan-France Nuclear Energy Committee in November 2015, and the Fourth Annual Japan-UK Nuclear Dialogue in the same month, efforts for better understanding towards the nuclear fuel cycle policy has been continued.

Future outlook

As for the issues on the nuclear power, the Advisory Committee for Natural Resources and Energy will continue to examine it in detail.

According to the law, the steps of the processes required to restart a nuclear power plant are alteration in the installment license for nuclear reactor, construction plan approval, pre-service inspection and so on. When these steps are completed, the operator is allowed to restart the generator.

In order to execute and realize the nuclear fuel cycle policy, cooperation between Japan and the EU Member-States will be reinforced in the framework of opinion exchange such as the Japan-France Nuclear Energy Committee and Japan-UK Nuclear Dialogue.

6. Renewable energies (WP-E/#06**/EJ to EJ)

BRT Recommendation

Advantages of renewable energies

Renewable energies can reduce carbon emissions and increase the security of supply, but it also poses huge challenges in terms of grid integration and stability of supply. Realizing its potential to complement conventional energy requires a robust and fully-integrated distribution network.

Renewable energy sources are available in many forms, including wind, solar, hydro, geothermal, tidal, biomass, etc. However, with the exception of hydro, which is already a power supply source to a certain degree, renewable energy remains unclear in terms of economic potential, efficiency, and stable supply due to variations in availability to different regions. To answer these uncertainties, it is therefore necessary:

- to study carefully how the adoption of renewable energy sources will be specifically carried out,
- to assess accurately the total cost of renewable energies throughout the supply chain,
- to encourage research into their commercialization, of less mature renewable energy technologies. On the other hand, both the EU and Japan should avoid costly support for the deployment of mature renewable energy sources which distort the energy market.

Storage of Energy (such as batteries)

Storage batteries can contribute to ironing out fluctuations in the supply and demand for energy. As a convenient way of storing electricity and thermal heat, they can be used at any time and in any location.

Thanks to the development of smart grids, storage batteries have the potential for use in a wide variety of applications, including cars, houses, and commercial buildings. Japan and EU should continue to cooperate in the development of storage battery technology and the harmonization of standards, in order to achieve low-cost production and to improve energy efficiency of batteries.

Feed-in-tariff system

The objective of a feed-in-tariff programme is to accelerate investment in

renewable energy by providing a predictable revenue stream. In order to minimize the cost burden on business and private households, the capital cost of such schemes should be thoroughly evaluated to ensure that it reflects the amount of cost reduction achieved in accordance with the legal provisions. Feed-in-tariff programmes need also to take into account the cost of the reinforcement of the power grid etc.

Recognizing that the cost of renewable energy generally is still too high to be widely used with economical sense, Japan and the EU should prioritize support for R&D to facilitate innovation that lower the cost of renewable energy drastically.

Actions taken so far

As for renewable energy, as it is an important power source in terms of strengthening energy security as well as creating a low carbon society, the basic policy of the government is to encourage its maximum introduction.

On the other hand, as it has problems such as relatively high electric power cost, the GOJ strongly promoted it through combining technological development and demonstration to lower the cost, rationalization of regulations, centering on the 'Feed-in Tariff System'.

As for storage battery for the supply and demand adjustment of electric power, technological development for the cost reduction and demonstration of large-sized battery have been conducted. Also, as for industrial (stationary) lithium secondary battery, the international standard on performance was issued by the joint proposal of Japan and France at IEC (International Electrotechnical Committee).

Future outlook

In order to realize the introduction rate of renewable energy (22 - 24 % of total power generation in 2030) specified in the energy mix formulated in July 2015, the government will tackle proper management and review of 'Feed-in Tariff system,' technological development and demonstration, rationalization of

regulation and so on.

As for storage battery for the supply and demand adjustment of electric power, the introduction will be continuously promoted by achieving cost reduction through research, development and demonstration. As for industrial (stationary) lithium secondary battery, the international standard on safety will be prepared by the joint proposal of Japan and France at IEC (International Electrotechnical Committee).

7. Utilization of renewable bio-based resources as versatile raw materials (WP-E/#07**/EJ to EJ)

BRT Recommendation

The development and implementation of technologies and processes to convert biomass to fuels and chemicals are important to replace fossil resources with bio-based ones, thereby drastically reducing greenhouse gas emission.

Support for R&D and technology demonstration

In order to accelerate the practical implementation of technologies to convert non-edible plant-based resources, such as agricultural waste and woody biomass, to fuels and chemicals, the EU and Japan should increase public support for collaborative R&D and technology demonstrations by companies and academic institutions in Japan and EU.

Promotion of the use of bio-based fuels and chemicals

To promote the use of products made with renewable bio-based technology, the EU and Japan should provide subsidies and preferential tax systems, for bio-based fuels and chemicals.

Actions taken so far

The GOJ is conducting research and development to produce bioethanol from cellulose materials and a bio-derived jet fuel from microalgae and by the gasification and liquefaction of biomass. In addition, it is tackling to develop technology to produce alternative petrochemical products from inedible woody biomass and to separate and utilize cellulose nanofiber.

To promote the diffusion of biomass products, the GOJ promotes major oil companies to introduce the bio-derived fuel by setting the target for the introduction and taking taxation measures to facilitate the introduction. Moreover, it is preparing an international standard to evaluate the product performance of cellulose nanofiber.

Future outlook

The GOJ is going to carry out the continuous research and development on the technology to produce the jet fuel from cellulosic and microalgae, and on biomass-derived chemicals. In particular, it aims to put biomass-derived chemicals to practical use in cooperation with the chemical and paper manufacturing companies around 2030.

To promote the diffusion of the biomass products, an additional duty exemption will be applied to the biomass-derived fuel, and it will provide support on biomass-derived chemicals, making a connection with policies such as energy-saving measures and global warming countermeasures.

8. Energy conservation and energy efficiency (WP-E/#08/EJ to EJ)

BRT Recommendation

Enhancing energy efficiency and conservation in all fields

The construction of energy efficiency and conservation buildings, as well as the energy efficiency and conservation renovation of domestic houses and office buildings with high level insulation materials and high-performance windows, are very effective in reducing energy consumption.

The development of energy-efficiency and conservation technologies for electrical equipment, such as refrigerators, air conditioners, servers and LED lights, is also ongoing. In the transport sector, EV, PHEV, Clean Diesel and Hydrogen Fuel Cell Vehicles all have considerable potential to make automobiles more energy efficient and conservational. Japan and the EU should work together to develop harmonized standards to facilitate their early market introduction.

In all fields, it is clear that the implementation of energy management systems is an effective means for improving energy efficiency and conservation.

Japan and the EU should consider taking further measures to promote energy efficiency and conservation, by financing research projects to develop technologies and methodologies for improving energy efficiency and conservation and by sharing their best practices. At the same time, the reality is that active measures must be complemented by passive measures, which affect building insulation and temperature stabilization. Japan and the EU should support such moves, in particular by setting as early as possible regulations and mandatory standards for better energy-efficiency and conservation buildings and houses to reduce energy consumption and expenses at a family and country level, to decrease CO₂ emissions and to enhance health.

Action taken so far

The energy efficiency and conservation policy system in Japan can be classified into 'Industrial Sector', 'Consumer (Business and Residential) Sector' and 'Transportation Sector' and, in each sector, both the restriction measures by the Act on the rational use of energy and the supportive measures by budget and,

taxation system have been implemented.

As for the restriction measure, in order to improve the energy efficiency performance of buildings, the GOJ proclaimed an act imposing the obligation of newly constructed non-residential buildings over a certain size to conform to the energy efficiency standards (Building Energy Saving Law) in July 2015.

As for the supportive measure, the GOJ encourages enterprises to invest in energy efficiency and conservation by supporting the introduction of equipment with energy efficiency and conservation effect as well as promotes the diffusion of such equipment through the cost reduction. It also supports the diffusion of energy efficiency and conservation measures through best practices by providing free energy- and electricity efficiency and conservation diagnosis to small-to-medium-sized enterprises and by transmitting examples of energy efficiency and conservation efforts and technologies based on the result of such diagnosis.

Future outlook

The GOJ will reinforce energy efficiency and conservation measures in each sector to realize a thorough energy efficiency and conservation society.

9. Energy research and international cooperation (WP-E/#09*/EJ to EJ)

BRT Recommendation

Energy research for reducing greenhouse gas emissions and developing energy technologies for achieving long-term goals:

The emission of greenhouse gases that trigger climate change and impact the environment is an issue that affects the entire human race, and requires international knowledge and cooperation to solve. Global-scale research is therefore required to develop technologies to reduce GHG emissions in power generation using fossil fuels and ones to utilize non-fossil energy sources, such as renewable and nuclear energies in practical applications with assured safety.

Human resources development

Energy is crucial for every nation and industry. Japan and the EU should consider how to create systems, including personnel exchange, to produce and train energy-related specialists uninterruptedly.

Actions taken so far

As for the research and development in the energy sector, the GOJ is conducting technological development of off-shore wind power generation as a type of renewable energy as well as technological development serving to upgrade the safety measure such as the upgrading of comprehensive risk assessment method of nuclear power plants.

As for the education for energy-related specialists, the GOJ supports the human resources development of the practicing engineers to maintain nuclear power plants as well as those related to nuclear safety in the industry, which is needed to abolishing Tokyo Electric Power Company Fukushima Daiichi Nuclear Power Plant and to ensure safety of the existing nuclear power plants.

Future outlook

As for the research and development in the energy sector, the government will

continue to develop the technology of offshore wind power generation, and the technology contributing to upgrade the safety measure including the upgrading of comprehensive risk assessment method of nuclear power plants.

As for the education for energy-related specialists, the GOJ will continue the support to human resources development of the practicing engineers to maintain nuclear power plants as well as those related to nuclear safety in the industry.

10. Importance of measures against global warming and to reduce greenhouse gases emissions (WP-E / # 10** / EJ to EJ)

BRT Recommendation

Mitigating global warming is a global challenge. Emerging countries are already overtaking developed countries as the world's major greenhouse gas emitters. It is consequently imperative that emission reductions are also undertaken by emerging countries. Japan and the EU should work together to create a comprehensive, fair and effective mechanism for reducing global greenhouse emissions.

Situation in Japan following the Great East Japan Earthquake and issues to be resolved

The scenario initially envisioned by Japan of reducing greenhouse gas emissions by increasing nuclear power generation has been derailed by the Great East Japan Earthquake and subsequent accident at the Fukushima-Daiichi nuclear power plant, following which all of Japan's nuclear power plants remain idled and the country continues to rely heavily on fossil fuels. Japan is now working on the details of its COP21 commitment.

A government plan to move the country in the direction of restarting some of the idled nuclear reactors, known as the Basic Energy Plan, was determined in April 2014; however, the unresolved nature of the unstable energy supply continues to suppress corporate investment. For these reasons, and also to help mitigate global warming, the GOJ should urgently present a comprehensive vision of the country's future energy mix.

Measures to be taken by the EU:

In January 2014, the EU Commission published a white paper policy framework for climate and energy for the period from 2020–2030, proposing a cut in carbon emissions by 40 % below the 1990 level in 2030. Such a single ambitious CO2 emissions reduction target by 2030 is, together with the structural reform of the European Trading System, a key signal to return to robust prices for CO2. Furthermore, it would give a strong signal of the EU's commitment to fighting against climate change before the upcoming international negotiations (COP21 in 2015). It is therefore important EU maintain such ambitious objectives without

Carbon Leakage and the means to realize a cost-effective low-carbon society in the long-term. A global dialogue on these issues should also be maintained.

Actions taken so far

Japan has actively been contributing to negotiations at the Ad Hoc Working Group on the Durban Platform for Enhanced Action (ADP) which was established in the seventeenth session of the Conference of the Parties to the UNFCCC (COP17), with a view to establishing a fair and effective international framework applicable to all Parties. At the COP21 held in Paris in December 2015, the COP adopted “the Paris Agreement” applicable to all Parties including emerging countries, which the GOJ has long called for.

Following the Strategic Energy Plan, which the Cabinet approved in April 2014, the Long-term Energy Supply and Demand Outlook (energy mix) was decided in July 2015. In formulating the energy mix, the basic principle is to simultaneously achieve specific policy goals: on the major premise of ensuring safety, 1) to improve self-sufficiency rate to the level higher than before the Great East Japan Earthquake (approx.25%), 2) to lower the electric power costs than at present, and 3) to set the energy mix that contributes to a greenhouse gas reduction target compatible to EU and the U.S..

Future outlook

Japan will continue to actively contribute to negotiations toward the effective implementation of the Paris Agreement.

11. International contributions (WP-E/#11/EJ to EJ)

BRT Recommendation

Contributions by Japan and EU to global warming countermeasures

It is important for developed and developing countries to cooperate on measures to mitigate climate change by creating mechanisms to achieve lower carbon growth. Advanced technologies, products, and expertise from Japan and EU can contribute to mitigating global warming worldwide.

Bilateral offset mechanisms are effective solutions for emerging countries, whose energy demand is increasing rapidly, to reduce greenhouse gas emissions. Japan and the EU should work together at both government and industry levels to design systems to support emerging countries in their efforts to combat global warming.

To implement adaptation strategies as well, the governments of Japan and EU should continue to expand more cooperative dynamics such as sharing project opportunities, implementation outline, required technology, financial assistance, etc. to the public, so that industries can participate in the adaptation projects without difficulty. Japan and EU share common interests in securing the establishment of high standard rules and open markets not only in both countries but in third countries.

Visualization of emissions reduction results

“Visualizing” CO₂ emissions reduction results is an effective way to verify the impact of low-carbon technologies and energy-saving products. LCA (Life-cycle assessment) is one of the appropriate techniques to assess the environmental impact associated with all stages of a product’s life from cradle to grave.

Visualization of added value for products and technologies with effect to reduce CO₂ emissions based on LCA analysis should be promoted through public-private collaboration.

Protecting intellectual property rights and developing human resources

An appropriate regulatory framework to ensure the protection of intellectual property rights (IPR) is needed to promote the transfer of commercially developed technologies. Japan and EU should help emerging countries to create such a framework by providing advice on the adoption of supervisory

systems, training, support for licensing, and encouraging technical collaboration.

Actions taken so far

(Contributions by Japan and EU to global warming countermeasures)

Japan has established and been implementing the Joint Crediting Mechanism (JCM) in order both to appropriately evaluate contributions from Japan to GHG emission reductions or 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. The GOJ has established JCMs with 16 partner countries (Mongolia, Bangladesh, Ethiopia, Kenya, Maldives, Vietnam, Lao PDR, Indonesia, Costa Rica, Palau, Cambodia, Mexico, Saudi Arabia, Chile, Myanmar, and Thailand) and held the Joint Committee 30 times in total. The Ministry of Economy, Trade and Industry (METI) and the Ministry of the Environment (MOE) have so far conducted 387 feasibility studies, and implemented 10 demonstration projects and 59 JCM Financing Programs. 10 out of these projects and programs have been registered as JCM projects.

(Visualization of emissions reduction results)

Regarding visualization of CO₂ emissions reduction results, the GOJ carried out the pilot project of Carbon Footprint of Products (CFP) from FY 2009 to 2011. Since April 2012, the private sector has taken over the above-mentioned CFP scheme, and has been operating it as the CFP Communication Program.

The GOJ has been implementing the "DONGURI (Acorn) Project", to put marks on goods and services that offset CO₂ emissions based on the calculation by CFP since November 2012, and "DONGURI Point Project" which promotes those goods and services in the market since November 2013.

(Protecting intellectual property rights and developing human resources)

The GOJ has been actively conducting assistance activities in the field of intellectual property for emerging and developing countries, through bilateral cooperation and regional collaboration based on the specific circumstances in each country as well as cooperation with the World Intellectual Property Organization (WIPO).

In 2015, as in previous years, the JPO conducted seminars and training

programs on examination practices, building its information technology (IT) infrastructure, and on the effective use of intellectual property, as well as IP experts dispatch. Also, the year 2015 being a target year for the ASEAN countries to accede to the Madrid Protocol and the Hague Agreement, based on the ASEAN IPR Action Plan, the JPO conducted its training programs specifically focused on operational practices that would be needed for their accession to the international treaties. Also, the JPO shared its knowledge in order to support the speed-up of patent examinations. In addition, the JPO also implemented the patent examiner exchange programs with India and the Latin American countries, and conducted training programs for patent examinations for them. Also, for the seminar on the Madrid Protocol that was held in Mexico, the JPO sent Japan's IP experts and provided various supports, including a payment of the partial cost for inviting IP experts from foreign countries to this seminar.

Future outlook

(Contributions by Japan and EU to global warming countermeasures)

The GOJ will continue to further support the formation of projects under the JCM, as well as to expand the JCM partner countries, with the aim of making concrete contribution to global GHG emissions reductions or removals. In addition, in the reference information of INDC submitted by the GOJ to UNFCCC in July 2015, it is stated under the title of "JCM and other international contributions", that "apart from contributions achieved through private-sector based projects, 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."

(Visualization of emissions reduction results)

As mentioned above, the private sector has already taken over the CFP scheme. The private sector is scheduled to take over the DONGURI Point Project scheme from April 2016.

(Protecting intellectual property rights and developing human resources)

The JPO will continue to be committed to further promoting its cooperative

activities, including the bilateral cooperation, regional cooperation, and cooperative efforts through the WIPO. In order to (i) assist the efforts to accede to the Madrid Protocol, (ii) provide assistance for the operational practices thereof, (iii) share the JPO's examination methods, and (iv) support human resources development, the JPO will continue welcoming trainees from emerging countries, mainly from the ASEAN countries, India, and the Latin American countries, and conducting training programs for them. In addition, the JPO will send its IP experts and examiners who will work as advisers in each country, to share their experiences and knowledge.

12. Environmental technology collaboration between EU and Japan
(WP-E/#12*/EJ to EJ)

BRT Recommendation

Promoting innovative R&D projects to reduce greenhouse gas emissions in Japan and EU

Japan and EU should promote joint R&D between industries, academia, and governments to develop innovative technologies that can be used to reduce greenhouse gas emissions.

R&D projects

Developing advanced and innovative technologies from the initial research phase, applying them to products, and promoting their use requires considerable time and money. Japan and the EU should therefore provide mutual access to the results of R&D projects implemented with government support.

Action taken so far

As BRT suggested, Japan and the EU should cooperate on and promote the development of innovative technologies for reducing GHG emissions. When they formulate their joint projects, they should ensure the mutual access.

Since 2014, the GOJ has hosted a global conference, the Innovation for Cool Earth Forum (ICEF), which aims at providing a global platform to discuss and cooperate for the promotion of innovation among researchers, business persons, and policymakers from around the world.

In particular, noting that the Paris Agreement applicable to all Parties was adopted in the 21st session of the Conference of the Parties to the UNFCCC in 2015, it is necessary to develop and utilize global warming mitigation technologies to reduce global GHG emissions not only in Japan and the EU but also in developing countries. Furthermore, Japan also puts emphasis on measuring and monitoring GHG concentration and is operating the Greenhouse gases Observing SATellite (GOSAT).

Future outlook

The GOJ has to make more effort to tackle global warming. It is necessary to promote thorough energy efficiency and conservation and the maximum introduction of renewable energy through the development and verification of technologies for reducing GHG emissions, so that we can build a distributed and independent low carbon society.

In addition, the government is developing a new satellite as a successor to the present GOSAT and planning to launch it in FY 2017. Also, the policies and technologies are important to adapt to the impacts of climate change which are likely to become more severe. It would promote the public-private partnership and consider concrete project proposals from the industry.

Japan will hold ICEF every October in Tokyo, and this global intellectual platform will engage in intensive discussions among researchers, business persons, and policymakers from around the world in order to address climate change through innovation.

13. Promote foreign investments and foster long term cooperation (WP-E/#13*/EJ to EJ)

BRT Recommendation

A long term sustainable energy policy requires adequate level of investments and strong international cooperation in order to reach those ambitious challenges. During this last decade, Europe has worked at creating a European Integrated Energy Market aiming at long term sustainability at an affordable price. In spite of the worldwide energy mix shift, those evolutions have created new investments opportunities attracting international investors including large Japanese companies. Japan is currently facing the same challenges with the current Energy Market Reform.

Japan and EU should promote foreign direct investments thanks to a transparent, open and long term predictable investment legal and regulated framework to sustain the energy market reform through increased transmission capacities.

Actions taken so far

As for the frequency converter (FC), though the current installed capacity of 1.2 million kW is planned to be enhanced to 2.1 million kW by 2020, it is confirmed at the national council in April 2015 that, taking the supply-demand maintenance in case of large-scale disaster and the expansion of power market transaction into account and in order to reinforce the power interchangeability between the east and the west power companies, the enhancement of the FC to 3.0 million kW is necessary. Subsequently, Organization for Cross-regional Coordination of Transmission Operators started examining the FC enhancement plan, and the basic requirements were determined in September 2015.

Future outlook

At the earliest possible time in the late 2020s, the FC will be enhanced to 3.0 million kW.