

**(Tentative Translation)**

**Report from the Government of Japan**

**Concerning the Recommendations**

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

April 2015

Note: The content of this report is based on the situation as of December 31, 2014.

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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 appreciates the effort made by the EU and Japanese authorities in the FTA/EPA negotiations. With a strong conviction that the EU-Japan FTA/EPA will boost trade and investment, promote job creation, and spur growth in both economies, the BRT renews its call for the EU and Japanese authorities to step up their efforts to tackle and resolve the substance of the outstanding issues so that a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA can be concluded as soon as possible. The BRT reaffirms its commitment to make every effort to support the early realization of an EU-Japan FTA/EPA. BRT Members are ready to make their industry expertise available to achieve this objective.

As two of the world's largest and most advanced economies, the EU and Japan should work together and play a leadership role in promoting global regulatory cooperation and standards harmonization which other so-called 'mega' agreements, such as TPP and TTIP, also try to achieve. The aim should be to develop an open, seamless business environment that will help create new growth opportunities not just for the EU and Japanese economies but also for the rest of the world.

#### < 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

### Action taken so far

During Prime Minister Shinzo Abe's visit to Europe from April to June, PM Abe expressed on various occasions that the Government of Japan aims to reach agreement in principle during 2015 on the Japan-EU EPA, and the leaders of Member States of the EU and the leaders of the EU concurred on the importance of the early conclusion of a comprehensive and high-level EPA, and the "Review" process on the EU side was completed in June. Also at the Japan-EU Summit on the occasion of the G20 Brisbane Summit in October, PM Abe and President of the European Commission Jean-Claude Juncker concurred on the acceleration of the negotiations, aiming to reach agreement in principle on the Japan-EU EPA. Furthermore, at the meeting between Minister for Foreign Affairs, Kishida and European Commissioner for Trade, Malmström, they confirmed that the goal of reaching agreement in principle during 2015 is an ambitious but achievable goal, and that both sides will further accelerate the negotiations toward achieving a comprehensive and high-level EPA.

In addition, in the Joint Statement issued at the 22nd Japan-EU Summit Meetings on 7 May 2014, both leaders welcomed the recommendations adopted by the BRT in April that a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA should be concluded as soon as possible.

In these contexts, 5 rounds of negotiations on the Japan-EU EPA took place during 2014. At these meetings, fruitful discussions were conducted in areas such as trade in goods, trade in services, investment, intellectual property rights, non-tariff measures and government procurement.

### Future outlook

The Government of Japan accelerates the negotiations toward the realization of comprehensive and high-level EPA, aiming to reach agreement in principle during 2015.

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**

Following extensive negotiations, the 9th annual WTO Ministerial Conference (MC9) held in Bali Indonesia in December 2013 was able to agree on a compromise called the “Bali Package”, for some of the sectors covered by the Doha Development Agenda (DDA) negotiations.

Such an outcome was made possible through continuous negotiations under a new bottom-up approach, which was applied since 2011, where partially agreeable outcomes were aggregated and integrated rather than seeking a blanket agreement on DDA negotiations. BRT welcomes the advancement in the DDA negotiation.

The agreement on trade facilitation 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 WTO members to quickly implement the trade facilitations agreement.

Moreover, at an informal meeting held in Davos, Switzerland, on January 25, 2014, a number of WTO members expressed their views that:

- it is important to steadily and gradually operationalize 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 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.

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.

#### < Recent Progress >

The “Bali Package” agreed upon the 9th WTO Ministerial Conference is composed of three sectors: (1) trade facilitation; (2) a part of agriculture sector; and (3) development. Especially for trade facilitation, transparency improvement and expediting customs processes will assuredly benefit both developed and developing countries, and provide favorable and significant impacts upon trade promotion. In addition, the agreement on trade facilitation is a set of multilateral rules that will cover all member countries for the first time since the establishment of WTO. It should help to energize and revitalize the inert Doha Round negotiations.

Moreover, the informal meeting held in Davos on January 25, 2014, assessed the “Bali Package” and addressed the future work program on the remaining issues of Doha Round negotiations (DDA).

#### < Background >

The BRT is a strong supporter of the multilateral trading system, whose core functions are trade liberalization, 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.

With the prospects of great uncertainty, the WTO must demonstrate its ability to deliver results for the business community. As the only international organization 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 but needs to be updated in order to respond to a changing global economic landscape.

#### Action taken so far

Following up with the outcome of the 9th WTO Ministerial Conference last December, Japan has actively worked on the implementation of the Bali decisions and procession with the formulation of Post-Bali Work Program. However, due to the objection by a very small number of countries, the Protocol

of Amendment to insert the Agreement on Trade Facilitation (TFA) into the WTO Agreement could not be adopted by the end of July this year and the implementation of the Bali Package became deadlocked, putting the WTO's negotiating function in a critical situation. In this situation, Japan with WTO members including EU made all possible efforts to put all Bali decisions back on track through various channels such as bilateral and multilateral ways in addition to the discussions in the WTO. As a result, the General Council Decisions, three in total, regarding the adoption of the Protocol, the public stockholding for food security purposes and Post-Bali Work were adopted at the Special Session of the WTO General Council on November 27.

#### Future outlook

Based on the General Council Decisions in November, which would put the work of the WTO back on track, Japan will continue to cooperate with WTO members, including the EU, for steady implementation of the Bali decisions. Japan will actively participate in the discussions on the Post-Bali Work Program and toward the conclusion of the negotiations of the Doha Development Agenda (DDA). Japan will continue to focus on fighting against protectionist measures and reaffirm its commitment to maintain and strengthen the multilateral trading system.

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

#### (1) towards a common regulatory environment

##### BRT Recommendation

The BRT recommends that Japanese and European policy-makers should increase their understanding of the existing and upcoming regulations of the other side. They should study the possible impact of new regulatory developments on domestic and foreign business to avoid taking initiatives that unwillingly 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. To expand a common regulatory environment into the areas that are already regulated, furthermore, the Japanese and European policy makers should also 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.

Where the FTA/EPA does not already create a harmonized regulatory framework between the EU and Japan, the regulatory authorities in Japan and the EU should review their domestic technical regulations and conformity assessment procedures at regular intervals to determine the scope for further regulatory harmonization. The outcome of these reviews, including scientific and technical evidence used, shall be exchanged between the regulatory authorities and provided to industry upon request.

##### <Background>

The BRT believes that a common regulatory environment 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 a common regulatory environment to other bilateral and multilateral relations.

### 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 promoting 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.

### <Reference>

The METI and the EC DG Growth agreed to begin discussion on regulatory cooperation at the Japan-EU Industrial Policy Dialogue in Tokyo on April, 2014, and then they held discussions on regulatory cooperation in Automobiles, Chemicals, Conflict Minerals, and Robotics areas in 2014.

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 revitalizing Japanese economy and to realize private-sector-demand-led growth. The council compiled regulatory reform items into reports in June 2013 and June 2014, taking approaches such as “Test for Most Internationally Reasonable Regulation” examining the necessity and rationality of regulations based on international comparison, “Hotline on Regulatory Reform” widely accepting regulatory reform proposals and hearings from organizations and experts including European Business Council in Japan. In order to steadily realize the regulatory reform items, “Implementation Plan for Regulatory Reform” was endorsed by the Cabinet in June 2013 and June 2014.

### Future outlook

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

At the Regulatory Reform Council regulatory reform items are expected to be compiled into report in June 2015.

(2) International standards and harmonization of standards and certification procedures

#### BRT Recommendation

The BRT urges both authorities to adopt international product standards and certification procedures where applicable, and, to promote harmonization of technical requirements and certification procedures, mutual recognition of product approvals and, when possible, and appropriate, in areas where harmonized standards do not exist, mutual approval of the import, sale or use of products that have been approved on the basis of functionally equivalent requirements in sectors such as Construction Materials, Organic Products, Cosmetics, Medical Devices, Veterinary Products, Automobiles and Processed Food.

#### Action taken so far

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

Please refer to WP-A/#6/ for more detail.

#### Future outlook

In accordance with the WTO's TBT Agreement, Japan will make further efforts to

harmonize JIS with international standards.

Please refer to WP-A/#6/ for more detail.

### (3) 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 policy to support supply chain management in developing countries in cooperation with businesses.

#### Action taken so far

In 2014, the regulatory authorities of Japan and the EU shared information on the current situation of each regulation and exchanged views on regulatory cooperation through the Chemicals WG of EU-Japan industrial policy dialogue. Specifically, Japan and the EU exchanged information on the progress of chemicals regulations and discussed transferring information of chemicals in products and risk assessment approach of existing chemicals, in the expert meeting for EU-Japan regulatory cooperation in July and in the 2nd Chemical WG of EU-Japan Industrial policy dialogue in October.

#### Future outlook

Japan and the EU are going to hold next Chemical WG of EU-Japan Industrial policy dialogue in 2015 in order to continue information exchange with regard to chemical management. In addition to the cooperation with the EU, Japan will keep dialogue with ASEAN countries on systemic challenges on supply chain in ASEAN region.

#### (4) Common energy conservation regulation

##### BRT Recommendation

Given the nature of the issue and the importance for business as well as for society in general, Japan and the EU should work together at the multilateral level to promote international harmonisation of energy conservation regulations, relevant labelling rules, and environmental and carbon footprint offset programs.

##### Action taken so far

The Energy Conservation Labelling Program introduced by the Japanese government primarily targets at products used in household (presently, 21 items have been targeted).

Additionally, the Japanese government has introduced the Retailers' Labelling Program targeting at retailers, using a Unified Energy Conservation Label that indicates multiple evaluation levels for each targeted items (presently, 6 items have been targeted).

Regarding the visualization of reduction of CO<sub>2</sub> emission, the Japanese government carried out the pilot project of Carbon Footprint of Products (CFP) from May 2009 to March 2012. Since April 2012, a private sector has taken over the above-mentioned CFP scheme, and has operated it as the CFP Communication Program.

Also, the Japanese government confirmed the CFP Communication Program was compliant with ISO/TS 14067 as of May 2013.

##### Future outlook

The GOJ will be committed to expand the targeted items of the Energy Conservation Labelling Program and the Unified Energy Conservation Label, and to review the multiple evaluation standards. And also, the government plans to distribute PR material regarding the above programs so that they are more widely recognized.

As previously mentioned, the CFP scheme has already been taken over by the private sector.

## (5) Expand the benefits of AEOs

### 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, 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 January 2014 and discussed the possibility for expansion of benefits 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.

## (6) 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 by which individuals are allowed to bring in or import counterfeits for person consumption.

The BRT reiterates its support of Regulation (EU) 608/2013 of the EP and Council of 12 June 2013 on Customs enforcement of Intellectual Property rights which reflects to some extent the BRT's key recommendations such as simplifying the procedure. However, the BRT requests the authorities of the EU that they should seek ways to mitigate the financial burden of the importers of the authentic goods.

The BRT would like to see an enhanced role of the Observatory on Counterfeiting and Piracy in line with the Regulation adopted by the European Parliament and Council on 19 April 2012.

The BRT suggests that with 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 raise the rate of its coverage.

### Action taken so far

Japan held various training programs, etc. to develop human resources of local authorities such as customs agents and the police of the countries where the problem of IPR infringement occurs.

As countermeasures against the websites where counterfeit and pirated goods are traded, Japan provides information regarding such websites to authorities of foreign countries such as China and requests them to close the websites. In

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

Japan also advances countermeasures against IP 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 runs anti-counterfeit annual campaign to raise public awareness of IPR issues.

#### Future outlook

The GOJ will continuously have discussions and share information with related foreign authorities and agencies on the situation of damage due to counterfeit and pirated goods on the internet, etc., and will request them strict crackdown against IPR infringement on the internet.

Furthermore, to combat counterfeit and pirated goods on the internet, Japan will enhance (which already started) cooperation with actors involved in internet trading, such as banks, credit card companies and anti-virus software vendors, and will actively take all necessary and appropriate measures by promoting collaboration among related ministries.

## (7) Adoption of UN-ECE regulations

### BRT Recommendation

In the automobile sector, the Japanese and EU Authorities should accelerate their adoption of UN-ECE 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 >

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-ECE Regulations in one contracting country are exempt from testing in any other signatory country where those regulations have been adopted. Japan has now adopted UN-ECE Regulations in 35 of the 47 areas included in Japanese type approval.

### Action taken so far

The GOJ has been adopting UN/ECE Regulations after the assessment of their validities and the necessary revisions of those regulations, as a part of efforts toward the realization of an International Whole Vehicle Type Approval (IWVTA), which are currently ongoing at the UN/ECE/WP29, while taking into consideration safety and environmental protection in Japan. The GOJ has been actively contributing in cooperation with the European Commission to promoting IWVTA through such efforts as acting as co-vice-chair of an expert meeting on IWVTA in WP29.

### Future outlook

The GOJ will continue to adopt un-adopted regulations among the UN/ECE Regulations for passenger cars, after the assessment of their validities and the

necessary revisions of those regulations at the UN/ECE/WP29, as a part of efforts toward the realization of IWVTA, while taking into consideration safety and environmental protection in Japan.

#### 4. Supporting timely development of business (WP-A / # 04\* / EJ to EJ): 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 agreement between Japan and Italy has been signed. Furthermore, negotiations are underway between Japan, and Luxembourg and Sweden, and are at the preparatory stage between Japan, and the Slovak Republic, Austria and Finland.

##### Action taken so far

(a) The GOJ has been making efforts to conclude social security agreements with EU member states. The GOJ has already concluded social security agreements with Germany, the UK, Belgium, France, the Netherlands, the Czech Republic, Spain and Ireland, and the agreement with Hungary entered into force in January 2014. In addition, the GOJ signed the agreement with Luxembourg in October 2014. Furthermore, the GOJ is forwarding government-level negotiations with Sweden, and exchanges of information and opinions with the authorities of Slovakia, 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 upon withdrawal” according to the coverage periods in case that foreign nationals return to their countries after their short stay in Japan.

#### Future outlook

The GOJ intends to continuously proceed with negotiations as well as exchanges of information and opinions with a view to concluding social security agreements with 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. 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 new 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 revitalize both Japanese and EU industries by disseminating new products and technologies. However, market access problems and various impediments noted in other BRT recommendations are even harder to tackle or manage for SMEs. While the Japanese government, the European Commission and most EU Member States have

internationalization 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. Aiming to provide local help to all potentially interested foreign SMEs is not realistic, but increasing and sustaining help to SMEs that have established a local base is realistic in the context of a bilateral agreement. The BRT is aware of the major work being done for both Japanese and European SMEs by the European Commission and the Government of Japan through the programmes run by EU-Japan Centre for Industrial Cooperation.

#### Action taken so far

With a view to supporting foreign SMEs which are considering investment in Japan as well as Japanese SMEs which seek to expand their business to the EU, the GOJ has been providing various forms of assistance such as improvement in the provision of necessary business information, support for business-matching and consultation with experts through related organizations such as the Japanese Embassies, Consulate-Generals EU-Japan Centre for Industrial Cooperation, the Japan External Trade Organization(JETRO), the Organization for Small & Medium Enterprises and Regional Innovation, JAPAN (SMRJ). 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 continue to support SMEs through related institutions. In addition, the GOJ will continue cooperating 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)

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

(1) Automobiles

#### BRT Recommendation

The Government of Japan should adopt the relevant UN Regulations in all areas where Japan requires certification for passenger cars but does not currently accept a UN approval as demonstrating compliance with Japan's national requirements, so that a vehicle certificated in the EU can be sold in Japan without modification or further testing.

< Recent progress >

This is a new recommendation

#### Action taken so far

Please refer to the response to WP-A / # 03 / EJ to EJ, 7. above.

#### Future outlook

Please refer to the response to WP-A / # 03 / EJ to EJ, 7. above.

## (2) Construction Products

### BRT Recommendation

The Government of Japan should work together with the EU Authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials. This is unfortunately still rather common in the flooring sector as well as for roofing sheets. Mere reference to ISO standards within JAS/JIS, has not proved to be adequately helpful in facilitating the process.

The Government of Japan should, furthermore, better support local and regional authorities to ensure that transparent and consequent interpretations are made in regards to technical regulations and guidelines.

#### < Recent progress >

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

#### < 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.

### Action taken so far

Japan has been developing JAS/JIS complying with WTO/TBT Agreement.

Under JAS/JIS marking systems, 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.

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 difficult requirements for registration.

Some certifying bodies of the EU are registered as the Registered Overseas Certifying Body (JAS).

## Future outlook

The GOJ continues to ensure the appropriate management of the accreditation system, while explaining its system to relevant institutes whenever the need arises.

### (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 >

There has been limited progress.

#### < 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.

#### Action taken so far

The GOJ has developed and published the positive list on active ingredients and excipients/additives used in so-called “medicated cosmetics,” which are classified as quasi-drugs under the Pharmaceutical Affairs Law in Japan. On the July 30th, 2014, the Ministry of Health, Labor and Welfare (MHLW) published the collection of standards on the additives used in quasi-drugs, which include medicated cosmetics, by the Pharmaceuticals and Medical Devices Agency (PMDA).

The MHLW together with the PMDA, regularly has meetings with the industry to exchange views and opinions on rapid review process of quasi-drugs. As a part of the approach to the rapid review process of quasi-drugs, the MHLW published the points in review process and the important matters on written-application-for-approval creation about medicated cosmetics (Shampoos and Rinses) on May 2nd, 2014. Moreover, the MHLW published Q&A about marketing application for approval of quasi-drugs and cosmetics standard on

June 13th, 2014.

Regarding the alternative testing methods, the GOJ has already accepted not only OECD alternative methods for animal tests but also alternative 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 MHLW will continue to exchange views with the industry for the purpose of ensuring transparency in the approval process and rapid review on “medicated cosmetics.”

And also, when other alternative methods for animal tests that the OECD has not adopted are requested with appropriate data, the MHLW will consider them through activities on their validation by 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 JR company. Duplicate testing raises the costs of imports, making them less competitive than domestic products. The Government of Japan and the EU authorities should work toward establishing a mechanism through which test data and certification of railway equipment provided by European organizations 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. These 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, recognizes 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 >

There has been some progress. The Government of Japan did not address this issue in the progress report from April 2013.

##### < 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.

## Action taken so far

- 1) Railway safety standards have been developed in each country, reflecting its own specific situations relating to transportation and 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, each railways operator has its own responsibility to verify the safety of its railways products by conducting demonstrations and testing, 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.
- 2) The GOJ establishes a legally-binding ministerial ordinance on “Technical Regulatory Standards”, which stipulates essential compliance requirements for railways operators in ensuring the safety of railways transportation. The GOJ 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.  
(Technical Regulatory Standards  
[http://www.mlit.go.jp/english/2006/h\\_railway\\_bureau/Laws\\_concerning/03.pdf](http://www.mlit.go.jp/english/2006/h_railway_bureau/Laws_concerning/03.pdf))  
(Approved Model Specification  
[http://www.mlit.go.jp/english/2006/h\\_railway\\_bureau/Laws\\_concerning/14.pdf](http://www.mlit.go.jp/english/2006/h_railway_bureau/Laws_concerning/14.pdf))
- 3) Japan, with the central role played by the Japanese Railway International Standards Center (J-RISC), 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, with respect to such relating to testing methods, based on its active cooperation extended to development of international standards.
- 4) Japanese railways operators seek safe and reliable products and that, in fact, 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 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 opening of mutual market access opportunities 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) Medical Devices/Equipment

### BRT Recommendation

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

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

#### < Recent progress >

Progress has been made with the passing of the new Pharmaceutical Affairs Law in the area of QMS, and we expect to see further alignment with ISO13485. There is, however, still a need for improvement regarding GCP.

#### < Background >

The EU's export of medical devices to Japan is limited by the costly and cumbersome approval process. Development costs for EU medical device producers are increased by requests for additional clinical trials from the Japanese authorities. Excessive Japanese standards and regulatory requirements result not only in a significant device lag, but also together with the insufficient reimbursement system, a device gap. The BRT calls on the government of Japan to intensify the work to simplify and harmonise the regulatory processes in the field of medical devices with that of the EU. Japan needs to reduce the time and costs associated with introducing innovative new treatments in the human healthcare market in Japan

and to bring Japanese rules in line with global standards.

#### Action taken so far

Discussions have been held since 1992 on harmonizing regulations in the medical device sector by the Global Harmonization Task Force (GHTF), which is composed of the regulatory authorities of Japan, the EU, the United States, Australia, and Canada as well as the industrial sector. In the revised Pharmaceutical Affairs Law that came into force in 2005, internationally harmonized regulations were introduced in terms of essential principles and classification of devices. In addition, with regard to the establishment of Approval Standards, Certification Standards and standards for Quality Management Systems, the Government of Japan (GOJ) basically accepts the international standards of the ISO and the IEC.

Foreign clinical trial data has been accepted as a part of application dossier when: i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality. For your reference, the guidance for the Japanese medical device GCP clearly states that ISO 14155:2011 is equivalent to the Japanese GCP.

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

#### Future outlook

Regarding acceleration of medical device review, the GOJ is making efforts in

cooperation with concerned industrial sector from April 2014, according to the “Collaboration Plan to Accelerate Review of Medical Device.”

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

## (6) Veterinary Products

### BRT Recommendation

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

- a) Urges the Government of Japan to take all measures available to speed up product approvals and fully harmonise domestic regulations with international practices.
- b) Requests Japan to work towards mutual recognition of European and Japanese marketing authorisations for veterinary products. This should start with mutual recognition of GMP certification for veterinary medicines. Harmonisation of regulations on animal vaccines, and ensuring product conformance under a unified GMP regime, should also be addressed.
- c) Asks Japan to better facilitate the use of English in applications without the need for a summary in Japanese.

### < Recent progress >

Limited progress has been made. On December 3, 2012 the MAFF presented to the Japan Veterinary Products Association a list of 10 action items for change. These items are welcomed by the industry however still fall far short of the definitions of harmonisation described above. Changes in four of the above mentioned ten action items have been implemented, however timelines are not yet available for implementation of the remaining six.

### < Background >

While Japan participates in the VICH, the implementation of international and harmonised standards is often slow and Japan-unique elements are added. MAFF has to a certain extent facilitated the use of English, but have at the same time added a requirement to add a summary in Japanese, as mentioned above.

### Action taken so far

The MAFF has been working positively to accelerate approvals of veterinary

medicinal products (VMPs) through frequent exchanges of views with Japan Veterinary Products Association (JVPA) and Marketing Authorization Holders of VMPs. (Please see Attachment #1. MAFF has held relevant meetings 9 times in 2013 and 2014.)

The GOJ is strongly concerned with the BRT Recommendation that touched upon the 10 action items for change presented to the JVPA by MAFF in December 2012, stating that “timelines are not yet available for implementation of the remaining six,” since this statement is not correct. In fact, the MAFF has already implemented 7 items. Of the remaining 3 items, MAFF will implement 1 item by the end of March 2015, and is actively working on the remainder. (Please see Attachment #2, showing timelines for 20 action items related to expedition of approval of VMPs including above mentioned 10 items.)

Moreover, the MAFF prepared the documents related to the progress of the action plan in English to provide for branches of foreign manufacturers in Japan and encourage them to communicate with their head offices.

The MAFF is very concerned about the fact that EU business does not utilize such information which the MAFF has been proactively providing.

The 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. The 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, the MAFF decided to accept an application with clinical trial data conducted only in foreign countries in accordance with VICH guidelines (Good Clinical Practice (GCP) of countries participating VICH (ie, the EU, the US and Australia)) with the exception of biologicals and antimicrobials containing active ingredients such as fluoroquinolones and 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins which are considered to be very important in terms of human healthcare. As far as the MAFF understands, among VICH countries (i.e. Japan, the US, the EU and Australia), only Japan accepts such application, 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 “Background” of the Recommendation.

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

Japan has been accepting technical data in English which are the significant part of application documents of VMPs. However, summary technical documents (STDs) in Japanese are essential to accelerate approval procedures of VMPs. Since there is no recommendation of language for application in VICH, it is fairly reasonable for each country to require documents in their local languages. Besides, in order to prepare STDs efficiently, the MAFF published guidance for the preparation of STDs to applicants.

VMPs approved and distributed in Japan must 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 the EU, and the GOJ is 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, the BRT’s comment “This should start with mutual recognition of GMP certification for veterinary medicines.” is not appropriate.

#### Future outlook

Regarding VICH activity, approximately 20 guidelines are now under development. Japan will implement VICH guidelines in accordance with VICH rules on harmonization. Japan is actively tackling the remaining 3 items of the 10 action items for change presented by the MAFF in December 2012.

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. Japan requests EU businesses to make a concrete proposal on this issue if the EU has reasonable and feasible methods to standardize evaluations of technical dossiers.

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

October 3: Opinion Exchange with JVPA Members

December 24: The JVPA's 24<sup>th</sup> 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 3<sup>rd</sup> Board Member Meeting of JVPA in the Fiscal Year  
of 2013

May 12: The 1<sup>st</sup> 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 25<sup>th</sup> Regular Council Meeting on Veterinary  
Medicine Regulatory Issues

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 3<sup>rd</sup> and 4<sup>th</sup> 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)

## 2. Ongoing Actions

- i. Change of approach to set withdrawal periods of vaccines containing adjuvants for food-producing animals (Preparing to implement it in December, 2014)
- ii. Change of management of animals for clinical trials, and introduction of simultaneous review process by MAFF, MHLW and FSC (List No. 9)
- iii. Change of requirements of data needed for application (general pharmacological testing, toxicity testing and ADME testing of drugs for pet animals) (List No. 10)
- iv. Reclassification of medical devices for veterinary use (Preparing to start the public comments in December, 2014)
- v. Reduction of paper documents for the consultation steps by the Council
- vi. Review of the regulatory framework for veterinary drugs for minor animal species (List No. 4)
- vii. Review of requirement of data sets for application of combined vaccine

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

### < Recent progress >

There has been no concrete progress, although the issue is under discussion in the EU-Japan FTA/EPA negotiations.

### < 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.

### Action taken so far

a, b) The Food Sanitation Law prohibits the use of food additives in Japan except when they are designated under the law 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 defined above, is

initiated based on an application filed by business operators or others. 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 by the time 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.

Sunflower lecithin, which was one of EU industries' interests, was designated in June 2014.

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.

Subsequently, nine substances have been designated by December 2014. As for one of the remaining six (Canthaxanthin), the assessments by the FSC have been completed and the MHLW is proceeding with formalities for designation. The other five substances are under review by the Experts Committee of the FSC. As for one of the five substances (Triethyl citrate), the FSC has compiled a draft assessment report based on the discussion of the relevant expert committee and is now conducting public consultation on the draft. Four substances of the five are, however, aluminum-containing additives and the GOJ recognizes 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

The substance for which the MHLW is proceeding with formalities for designation, namely Canthaxanthin is under review by the Pharmaceutical Affairs and Food Sanitation Council, and the MHLW will soon take the necessary procedures. For the remaining five substances, which are under review by the FSC's Experts Committee, the MHLW will initiate formalities for designation as soon as assessment 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 opinions of the EU and the US into consideration in the listing work. The GOJ believes that the designation of the 45 substances will almost cover the food additives whose need is 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 beyond these 45, based on applications from businesses, as other major countries, including the EU and the U.S., do.

## (8) LED lamps and luminaries

### 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 lamps prepared by the Japanese ministry (i.e. METI) and Japanese lighting industrial association (i.e. JELMA) is not compatible with standards used by manufacturers of other countries
- In terms of fluorescent lamps (tube LED), the Japanese lighting industrial association (JELMA) appoints Japanese test facilities as the only laboratories permitted to test
- The Japanese government continues to support their own standard of remote control for LED lamp and luminaries

The BRT requests Japan to harmonise with international standards and 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 >

No concrete progress has been made.

#### < 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.

### Action taken so far

The Electrical Appliances and Materials Safety Act has two technical

requirements; technical requirements original to Japan (Requirements in Appendix Tables 1 to 11) and requirements harmonized with the international standards (Requirements in Appendix Table 12). Manufactures and importers in Japan shall comply with either “Requirements in Appendix Tables 1 to 11” or “Requirements in Appendix Table 12”.

In 2011, LED lamps were designated as items subject to the Electrical Appliances and Materials Safety Act and their technical requirements were established. Among the LED lamps which are subject to this regulation, Bulb type LED lamps’ technical requirements were established based on JIS C8156:2011 which is consistent with IEC / FDIS 62560:2000, and technical requirements for the incandescent light bulb in “Requirements in Appendix Table 8”. As for technical requirements for the LED lighting equipment, because there was no relevant IEC standard, they were created originally based on JIS C8156:2011 and requirements for hanging fluorescent lamp apparatus for household use in “Requirements in Appendix Table 8”, because there is no appropriate IEC standard. However, the straight tube type LED lamp is not yet covered by the Electrical Appliances and Materials in the Electrical Appliances and Materials Safety Act.

As for “Requirements in Appendix Table 12” which is consistent with the IEC standard, it can be considered to meet the technical requirements in Japan by corresponding to J61347-2-13 (H26) Lamp controlgear-Part 2-13: Particular requirements for d.c. or a.c. supplied electronic controlgear for LED modules (harmonized with JIS C 8147-2-13:2014, IEC 61347-2-13 (2006)), J60598-1 (H26) Luminaires-Part 1: General requirements for safety (hamonized with JIS C 8105-1:2010, Amd.1(2013), IEC 60598-1 (2008)), J60598-2-3 (H26) Luminaires-Part 2-3: Particular requirements for safety-Luminaires for road and street lighting (harmonized with JIS C 8105-2-3:2011, IEC 60598-2-3 (2002), Amd.1(2011)), J60598-2-11 (H26) Luminaires-Part 2-11: Particular requirements-Aquarium luminaires (harmonized with JIS C 8105-2-11:2013, IEC 60598-2-11 (2005)), J60598-2-12 (H23) Luminaires-Part 2-12: Particular requirements-Mains socket-outlet mounted nightlights (harmonized with JIS C 8105-2-12:2009, IEC 60598-2-12(2006)), J60598-2-13 (H23) Luminaires-Part 2-13: Particular requirements-Ground recessed luminaires (harmonized with JIS C 8105-2-13:2009, IEC 60598-2-13(2006)), J60598-2-24 (H26) Luminaires-Part

2-24: Particular requirements-Luminaires with limited surface temperatures (harmonized with JIS C 8105-2-24:2013, IEC 60598-2-24(2013)).

Although there is no international standard (ISO, IEC) for remote controls used for LED lamps and luminaires, it is covered by “Requirements in Appendix Table 8” of Interpretation of the Ministerial Ordinance Specifying Technical Standards for Electrical Appliances and Materials.

#### Future outlook

The GOJ will consider technical requirements the straight tube type LED lamp while taking into consideration of the establishing process of international standards such as "IEC62776 Double-capped LED lamps for general lighting services - Safety specifications."

## (9) Labelling rules

### BRT Recommendation

The Government of Japan should issue clarifying orders to provide retailers with flexible alternatives for providing Japanese consumers with globally sourced products while taking full responsibility for the quality and safety of the products. A simple example of an inflexible labelling rule that has substantial labelling cost implications for European companies is that the dimensions of furniture must be expressed in millimetres and not centimetres, although use of the latter is common practice in other countries using the metric system. There are also examples where the information required on the labels are 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 has so far not presented anything concrete. This issue was not touched upon in the GoJ progress report of April 2013.

#### < Background >

The Household Product Quality Law and accompanying voluntary labelling guidelines, “hyojikitei”, prescribe in extreme detail how household products should be labelled when sold in Japan.

### Action taken so far

The labelling rules prescribed in the Household Goods Quality Labeling Act currently cover a total of 90 goods in the following categories: Textile Goods, Electrical Appliances, Plastic Manufactured Goods, and Miscellaneous Manufactured Goods. The rules stipulate the minimum information which must be included in labels to provide useful information to consumers and the conditions for compliance for each designated goods. In 2010, the GOJ conducted a survey on evaluation of the Household Goods Quality Labeling Act

and labeling system in other countries to consumer and business operator including Japanese entities operating overseas. In 2012, while taking into consideration the survey's outcome, the GOJ compiled a result of studies on which items should require labels and what information to be included in the labels, so that these could be reviewed as necessary.. Furthermore, in 2014, the Cabinet Decision was made to review the labelling requirements etc. in order to response to social changes, to make labels with minimal information necessary while keeping it comprehensible for consumers and to harmonize with international standards. The GOJ is now reviewing the labelling requirements.

#### Future outlook

With the growing importance of consumer protection as well as diversification, complexity and globalization of products, the importance of labels under the Household Goods Quality Labelling Act is also increasing. Therefore, while taking into consideration the study results from 2012 and the Cabinet Decision in 2014, the GOJ will continue to review the content of labelling where appropriate. The GOJ will also continue to promote understanding of the Household Goods Quality Labelling Act among business operators including those operating overseas by utilizing the Internet and other media.

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

### BRT Recommendation

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

On the matter on postal reform, the BRT is disappointed with the decisions taken so far by the Japanese Government. Japan has a duty to abide by its WTO obligations, including the national treatment provision of the GATS. This means establishing equivalent conditions of competition between the Japan Post entities and EU and other private delivery companies, banks, and insurance companies. Specifically:

a. Kampo insurance business should be subject to the same capital, solvency margin, tax and policyholder protection funding requirements as private sector insurers. Limits are needed on expansion of Japan Post's services, including the introduction of new products as well as caps on postal life insurance, until competitive safeguards have been established to prevent cross-subsidies from its existing dominant position. The BRT is particularly concerned by the recent approval of the new or modified products offered by Japan Post Insurance. It is also imperative that Japan Post remains under the jurisdiction of the FSA. The above requests are well within the realm of the GPA. Similarly, the insurance business of cooperative societies (kyosai) should be subject to the same requirements as private sector insurers.

b. Japan Post and private postal delivery operators should be subject to the same customs procedures and formalities. A level playing field for both Japan Post and private postal operators should be ensured in the requirements for dedicated airway bills, obligatory customs, quarantine and security clearance and the funding of these services, as well as in the issuance of parking tickets for delivery vehicle parking infringements.

#### <Recent progress>

There has been no progress. However the State Minister for Financial Services orally stated that Japan Post Insurance should not introduce any new modified products.

<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.

Action taken so far

*(Japan Post Insurance)*

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

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

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

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

2014. In addition, the application for consignment sales of Aflac's cancer insurance products filed by JPI on April 16<sup>th</sup> was approved on June 27<sup>th</sup>, based on the Postal Services Privatization Act and the Insurance Business Act, and JPI has begun to sell the products since July 22<sup>th</sup>.

In the press conference on April 12<sup>th</sup>, 2013, an interviewer asked Minister for Financial Services about an approval of cancer insurance and/or stand-alone medical insurance products of JPI. Minister showed his recognition that equivalent conditions of competition between JPI and other insurance suppliers had to be established and JPI had to have a properly functioning business management system in place, based on the framework of the Postal Services Privatization Act and the Insurance Business Act, which would take at least several years to achieve.

*(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 it is believed that European companies also enjoy benefits under such circumstances.

The international postal service of Japan Post Co., Ltd. is responsible for the exchanging of postal items among the postal operators which are designated by each member country of the Universal Postal Union based on the Universal Postal Convention. On the other hand, the international delivery services of private operators are provided by each operator with its own global-wide network. There is naturally a difference in characteristics between these two services, and therefore, the rules for Japan Post and those for private delivery operators are

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 (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. The GOJ understand that other countries including the U.S. are also applying the official assessment system to, at least, 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)*

NA.

##### *(Japan Post and private delivery operators)*

NA.

## 8. Freight and logistics (WP-A / # 09\*\* / 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. 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, the GOJ considers possible measures to improve for particular issues of private sectors by exchanging opinions and information each other. Since 2014 April, the GOJ improved the procedure so that the contents of export permission can also be changed through NACCS after the registration of shipment.

Japan has Centers for uniform interpretation and application of its laws and regulations to ensure no differential treatment among regions.

As for “broadening the choice of customs office for declaration”, the GOJ is now considering and discussing to allow AEOs to lodge import/export declarations to a customs office other than a customs office where the goods are located as a special case, and to withdraw restriction on area of service of customs brokers, while maintaining general rule that import/export declarations need to be lodged to a customs office where the goods are located.

### Future outlook

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

The GOJ continues to ensure uniform interpretation and application of its 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.

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

### BRT Recommendation

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

The BRT furthermore would like to point out the disadvantageous rules for Net Operation Loss (NOL). Currently Japan only allows carry forward for nine years while the norm in Europe is unlimited. The situation is also more favourable in this respect in Japan's neighbouring countries, countries that Japan is competing with for FDI. There are unfortunately also talks within the ruling party of shortening the nine-year period.

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 WTO FDI in 2011 was only 3.9 % of GDP.

#### Action taken so far

The first round of Council for Promotion of Foreign Direct Investment in Japan, which was held in April 2014, determined that it would promote activities to identify and attract investment projects by monitoring progress and that it would also 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, the Council for Regulatory Reform, and the Council on National Strategic Special Zones, 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.

In order to strengthen the system to facilitate doubling inward FDI stocks, “the Japan Revitalization Strategy Revised in 2014 -Japan’s challenge for the future-”, with the Council for Promotion of Foreign Direct Investment in Japan as the headquarters, approved by the Cabinet in June 2014, states that cross-ministerial efforts will be made to conduct activities focused on identifying and attracting investment projects, and carrying out the necessary institutional reforms to improve the investment environment in Japan, taking foreign enterprises’ needs into consideration.

#### Future outlook

The GOJ, with the Council for Promotion of Foreign Direct Investment in Japan as the headquarters, continues to conduct activities focused on identifying and attracting investment projects, and 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, taking foreign companies’ need into consideration.

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

### BRT Recommendation

#### < General Recommendations >

The Government of Japan should increase its efforts to facilitate better access to the procurement market in Japan. This could be achieved by lowering the threshold for public tenders and better defining 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.

#### < Recent progress >

There has been little progress.

#### < Background >

Studies have shown that over 80% of the total procurement market in Japan is not covered by the GPA.<sup>1</sup> 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.

#### Action 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. 7 designated cities were newly added to the covered Sub-Central Government Entities. Also, 7 services were newly added to the covered services of all covered entities, and 9 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 increase transparency of the scope of the operational safety clause by identifying its scope, 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

Japan-EU Railway Industrial Dialogues were held in Brussels in March and in Tokyo in December 2014, 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 stipulating non-discriminate, fair and transparent procurement procedures in addition to the GPA rules which are applied only to Central Government Entities and Other Entities, 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. Regulatory harmonization and MRA for pharmaceuticals (WP-B / # 01\* / EJ to EJ)

### **BRT Recommendation**

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

#### **<Recent Progress>**

Some progress has been seen for this recommendation in that MHLW applied for PIC/S in March 2012. PIC/S was applied in April 2012 and the practical inspection by the global team has been completed. PMDA is expecting the approval in Q1/2014. As the guideline enforces the harmonization of the inspections among PIC/S countries, this issue might be settled in Q1/2014.

#### **<Background>**

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 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

#### Action taken so far

Regarding safety measures of pharmaceuticals, the GOJ has been proceeding with harmonization with international standards which were developed by the International Conference on Harmonization of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) as guidelines “Post-approval Safety Data Management: Definitions and Standards for Expedited Reporting”, “Periodic Benefit-Risk Evaluation Report (PBRER)”, “Implementation Guide for Electronic Transmission of Individual Case Safety Reports (ICSRs)”.

Guidelines for clinical development of vaccines were published on May 27, 2010, 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 expert had considered the comments from the industry including the EFPIA.

The MHLW, PMDA and the authorities of all Prefectures joined PIC/S in July 1, 2014.

The GOJ has been discussing MRA with the EU, making use of various platforms.

#### Future outlook

The GOJ will continue to discuss the revision of the MRBP, hearing comments from the industry including the EFPIA, as necessary.

After joining PIC/S, the GOJ also continues to harmonize the Japanese GMP regulation more globally with reference to PIC/S GMP guideline and others.

While the GOJ assigns the highest priority to the enlargement of MRA countries within the EU, the GOJ is also planning to discuss the expansion of specific areas of pharmaceutical products in consideration of the schedule for MRA discussion.

## 2. Mutual recognition of quality management audit results for medical devices between EU and Japan (WP-B / # 02\* / 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 Affairs Law, as a first step.

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. Hence, part of the Japanese requirements. To resolve this issue, it is recommendable that QMS be evaluated on the basis of ISO13485.

In addition to above, 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 keeping the additional Japanese requirements.

### <Recent Progress>

Good progress has been seen for this recommendation. Improving QMS is included in the J-PAL revision and the industry should work with the government to prepare ordinance, which aligns with our recommendation. We recommend using ISO13485 audit report for QMS audit as an international standard as soon as possible.

### <Background>

Based on Medical Devices Directive (MDD) of the EU and the Japanese Pharmaceutical Affairs Law (J-PAL), QMS audit results are required for each application for a license to introduce new medical devices in 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. Recently, Japan has started to accept QMS audit results at a specific manufacturing site for products with the same generic name under certain conditions. However, a number of RCBs still require submitting QMS audit results for each application. Further alignment is necessary.

#### Action taken so far

The revision of the Pharmaceutical Affairs Law including QMS audit system came into effect on November 25, 2014. The GOJ agreed to align Japanese QMS standard for medical devices with the international standard (ISO13485), which is adopted in the EU.

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#### Future outlook

The GOJ continues to discuss not only with the EU but also jointly with the U.S. and other countries on the global harmonization of (QMS) regulation which is necessary for the mutual recognition of QMS audit through the activities in the IMDRF (International Medical Device Regulators Forum) and others, which represent a multinational initiative.

### 3. Mutual recognition of medical devices product licenses (WP-B / # 03\* / 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.*

#### <Recent Progress>

No progress / no dialogue has been seen for this recommendation. It is desirable that Japan accepts the use of audit report ISO13485 (ISO14155 for clinical trials) issued by the countries (USA, EU, Canada, Australia) with equal standards. To do so, JIS standard should be eliminated from the QMS basic check list and thus rationalize the licensing process.

#### <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 the Japanese Pharmaceutical Affairs Law 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 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 the activities in the IMDRF (International Medical Device Regulators Forum) and others, which represent a multinational initiative.

#### 4. Mutual recognition of clinical trial results for medical devices (WP-B / # 04\* / 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; i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality.

The 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 are expected. Further improvements are required in order to accelerate mutual recognition of clinical trial results for medical devices.

##### <Recent Progress>

Some progress has been seen in the area of mutual recognition of clinical trial results but there is still a difference in Japan's perception of mutual recognition.

##### <Background>

Differences in the definition of Good Clinical Practice 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

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

#### Future outlook

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

5. Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing (WP-B / # 08\*\* / EJ to J)

#### 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 Japanese government should finalize the implementation of the new, internationally competitive drug pricing system in Japan based on the industry proposal since in addition to innovation rewards it is also protecting public health. Furthermore, it adds an element of predictability and stability so that the industry can adequately plan, forecast product requirements and effectively manage inventory as well as the distribution of products across Japan.

The abolishment of the market expansion re-pricing was not accepted by the Central Social Insurance Medical Council (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 re-pricing rule by market expansion in the next pricing system reform in 2016, which is contrary to the policy of evaluating pharmaceutical innovation.

#### <Recent Progress>

No progress has been seen for this recommendation. The new drug pricing system should be implemented firmly and permanently (not only a 2-year trial). Furthermore, the re-pricing system rule by market expansion can adversely affect innovation in Japan and therefore, should be abolished.

#### <Background>

The NHI price reform proposed by the industry has been positively reviewed by Chuikyo in December 2009 and the government decided to start a pilot implementation in April 2010. This represented a significant improvement, as it provides price stability for innovative drugs and was seen as a positive signal

that the Japanese government is willing to reward innovation in the medical field. The premium for new drugs will be continued until 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 FY2014 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 Japanese government should implement the new premium system for innovative new drugs at the FY2016 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.

#### Action taken so far

The premium for new drug creation and elimination of unapproved / off-label use drug (the premium for new drug creation) will be continued for another two years, i.e., until March 2016 in the drug system reform in 2014.

The Chuikyo will decide whether the premium for new drug creation will be continued after April 2016 in the next drug pricing system reform by reviewing developmental status of drugs which truly contribute to improvement in quality of medical care and the impact on financial conditions, as well as by considering the adequacy of the current system such as drug coverage for the premium.

The market expansion re-pricing is a scheme to reduce new drug prices based on the ratio of their sales expansion when their premise on pricing changes, for example when their real sales far exceed their original estimations. This scheme works as an appropriate apportion mechanism of pharmaceutical expenditures under public health insurance system with limited resources considering critical situation of the NHI, and the Chuikyo itself recognizes this scheme as essential in the drug system reform in 2014.

## Future outlook

The drug pricing system will be reviewed and discussed continuously for the next drug pricing system reform in the Chuikyo, giving enough consideration to the industry opinions.

6. Appropriate assessment of innovative values of medical devices in prices (WP-B / # 09\*\* / EJ to J)

#### BRT Recommendation

Promote sub-dividing 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.

#### <Recent Progress>

Some progress and regress has been seen for this recommendation.

#### <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 product-based 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.

#### Action taken so far

In the revision of medical fee in FY2014, the GOJ took measures to evaluate the value of innovation for medical devices more appropriately through various

measures such as reviewing requirements for the premiums and introducing an exceptional functional classification 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, such as applying the premiums and promoting establishment of new functional classifications or sub-dividing the current functional classifications of medical devices.

7. Acceleration and dissemination of scientific knowledge on GMOs by both the governments and the private sector (WP-B / # 10\* / EJ to EJ)

#### BRT Recommendation

Governments and the private sector should speed up research in Plant Protection & Biotechnology and inform populations 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.

#### <Recent Progress>

No progress has been seen for this recommendation.

#### <Background>

A stable supply of food is an urgent requirement. While world population keeps growing, the limits of enhancing conventional culture on existing farmlands are being reached. 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 people regularly and accurately about the state of play of that research

#### Action taken so far

Since there are both aspects of expectations and concerns regarding recombinant DNA technologies among the people, the GOJ strives to provide its people with scientific and objective information so as to gain their understandings.

#### Future outlook

The GOJ continues its current actions.

8. Support research in Plant Protection & specifically Biotechnology (WP-B / # 11\* / EJ to J)

#### BRT Recommendation

Support research in Plant Protection & Biotechnology.

#### <Recent Progress>

No progress has been seen for this recommendation.

#### <Background>

Overall in Japan the cooperation between governmental institutes and MNC is limited. Applied science is widely done for instance by PPS (Plant Protection Stations) in all prefectures, however, this is not basic research. Also agricultural universities in Japan do some research on an independent basis.

MAFF is spending around 400 Mio. 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 the ownership is with the government or some independent institutes. The project is motivated by the policy to increase food sufficiency rate. 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 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 but the project has been finalized, a smaller post genome project is still running. 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 co-operations among governmental institutes, universities, Japanese domestic companies and MNC.

#### Action taken so far

In June 2013, aiming to enhance the competitiveness of domestic agricultural

products, the Ministry of Agriculture, Forestry and Fisheries of Japan (MAFF) started a five year R&D project in order to develop some plant breeding related technologies such as DNA marker-assisted breeding and genomic selection. The DNA markers to be developed by this project include those related to characteristics such as pest/disease resistances and health-related constituents of crops and horticultural crops. In addition, in July 2014, to meet the demands of horticultural crops' users, the MAFF started new projects to develop DNA markers targeting to characteristics such as long shelf life and anti-browning. The research institutes that undertake the researches and developments have already been identified through a public offering process held in FY 2012. The contractors include independent administrative authorities as research institute, research institutes of local governments, universities and private companies.

#### Future outlook

The MAFF is going to continuously promote the research project in line with the implementation program of the project formulated in June 2013.

## 9. Regulatory harmonization for animal health products (WP-B / # 12\* / 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 and often different conclusions from regulators in other countries.

We propose to harmonize and streamline regulatory requirements for product registration of animal health products. MAFF should start harmonization with related countries as this is the path to the 1-1-1 concept recommended previously.

On Oct. 3rd 2013, J-MAFF already shared the idea at the explanatory meeting of revised JPAL for the first time that J-MAFF, FSC and MHLW started discussion how to shorten review times for livestock products (i.e. Introduction of parallel deliberation amongst the authorities) but they didn't show any timeline on the matter.

Clinical trials should be conducted at least at two sites and one of the trials should be conducted in Japan.

#### <Recent Progress>

Some progress has been seen for this recommendation. In the notification, J-MAFF made clear that marketing authorization will be granted with clinical trial data conducted at least in two sites in foreign countries to confirm the reliability, on the condition that the clinical trials were conducted according to overseas GCP. However, following clinical trials is not beneficial for new notifications. Clinical trials of biologicals and clinical trials of new quinolones, in case the first-choice drug was ineffective.

#### <Background>

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 Japan under the Pharmaceutical Affairs Law before an approval is granted. Restrictions on withdrawal period for innovative oil-adjuvant vaccines are especially stringent in Japan. Increased harmonization

of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products which are readily available in Europe.

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.

#### Action taken so far

First, the GOJ requests the BRT to clarify the meaning of its comment “Clinical trials should be conducted at least at two sites and one of the trials should be conducted in Japan”.

Considering that accepting the result of foreign clinical trials is very effective to accelerate approvals of VMPs, in October 2013, the MAFF decided to accept an application with clinical trial data conducted only in foreign countries in accordance with VICH guidelines (Good Clinical Practice (GCP) of countries participating VICH (ie, the EU, the US and Australia)) with the exception of biologicals and antimicrobials containing active ingredients such as fluoroquinolones and 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins which are considered to be very important in terms of human healthcare. However, the above-mentioned comment by the BRT could be interpreted as dismissing such efforts.

Moreover, the GOJ would like to clarify whether an application with clinical trial data conducted only in foreign countries is accepted in the EU.

Meanwhile, due to the differences in the biological characteristics of pathogenic microorganisms and antimicrobial resistance situation between Japan and other countries, the MAFF requests clinical trial data conducted at least in one site in Japan to estimate the efficacy of biologicals and antimicrobials containing active ingredients such as fluoroquinolones and 3<sup>rd</sup> and 4<sup>th</sup> generation cephalosporins in Japan.

## Future outlook

At this point, the GOJ has difficulty in making response to BRT's recommendation since it is not able to judge the appropriateness of the above-mentioned remarks.

Concerning the MAFF's basic stance on the acceleration of approvals of VMPs, please refer to "Action taken so far" in WP-A/#06/E to J.

10. Mutual recognition of GMP and marketing authorization for animal health products (WP-B / # 13\* / E 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 should work out harmonized regulations leading to the 1-1-1 concept.

The resources freed in MAFF could probably be diverted to speeding up the processing of dossiers in general, where MAFF has a severe lack of resources adding to the delay in drug availability. However, no indication is found that MAFF is planning to make changes.

<Recent Progress>

Some progress has been seen for this recommendation. However, further strong efforts are required to reach mutual recognition of GMP.

<Background>

While laboratory testing is largely acceptable if conducted under GLP and according to VICH standards, Japan still requires local clinical trials as there is no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacturing of veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative work. This research is obsolete as a new research was undertaken in 2012, which showed much improvement.

An EU – Japan Economic Integration Agreement should aim for mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.

#### Action taken so far

Concerning the MAFF's basic stance on the mutual recognition of VMPs, please refer to "Action taken so far" in WP-A/#06/E to J.

#### Future outlook

Concerning the MAFF's basic stance on the mutual recognition of VMPs, please refer to "Action taken so far" in WP-A/#06/E to J.

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

### BRT Recommendation

MAFF should promote responsible use of antibiotics in animal health. Furthermore, 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.

#### <Recent Progress>

Some progress has been seen for this recommendation.

#### <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.

In 2013, J-MAFF and Marketing Authorization Holders have shown activities. It can be an option for J-MAFF to implement the consent from Marketing Authorization Holders in order to facilitate prudent use of FQs (Floroquinolone). Although Marketing Authorization Holders were able to define the addition of a precautionary statement in the section of “dosage and administration”, such as, veterinaries should assess the efficacy of the drug within 3 days after the treatment started and the drug should be changed in case of in-efficacy based on the veterinarian’s judgment. J-MAFF released the general notification but no concrete plan was informed.

### Action taken so far

The GOJ would appreciate further clarifications of the BRT recommendation

above in order to see whether its proposal meets the objectives of the BRT, that is, facilitating trade and investment.

Concerning AMR issues, in accordance with the existing international standards such as the Codex Guidelines and the Codex Code of Practice, the 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.

The GOJ recommends that the EU also implement risk management measures based on the result of risk assessment.

Besides, in November 2014, the MAFF requested marketing authorization holders of Fluoroquinolones to specify precautions such as “Veterinarians should change a medication based on their judgment about the efficacy of the drug within a certain period after the initial administration” on their products within a year.

In addition, the MAFF decided risk management measures on four antimicrobial agents based on the results of risk assessment in the last 12 months (Dec. 2013 – Nov. 2014) in accordance with the guidelines of procedures on formulating risk management measures concerning antimicrobials.

Moreover, Japan has been actively participating in international standard setting activities in WHO, OIE and Codex.

#### Future outlook

The MAFF will review the current monitoring system on antimicrobial resistance in order to improve effectiveness of collecting appropriate data.

The MAFF will continuously implement appropriate risk management measures based on the risk assessment.

12. Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan (WP-B / # 15\* / 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.

#### <Recent Progress>

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 introduction in Japan in Q1/2014.

#### <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 Practices). 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, the GOJ discussed the establishment of industry standards with the industry and then made public “The Standard on Manufacturing Practice for Medical Gases (here in after “the standard”)” on February 13, 2012.

#### Future outlook

The GOJ provides medical gas manufacturers with information on the standard

through prefectures and propagates manufacturing and quality control systems in accordance with the standard.

13. Requirement of Japanese version of the clinical trial protocol and investigators brochure (WP-B / # 16\* / 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.

#### <Recent Progress>

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. Some documents in English are allowed to be used for the application.

#### 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 in terms of 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 sites (doctors, nurses and other medical professionals) including subjects. Considering this situation, the level/type of documents or materials to be submitted in Japanese should maintain the current level.

#### 14. Shorten or eliminate national tests for vaccines (WP-B / # 17\* / 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.

##### <Recent Progress>

Some progress has been seen for this recommendation.

##### <Background>

Vaccine production is done according to GMP and PMDA periodical audits of production sites. However, the higher quality assurance of vaccines is strongly demanded by society. Concerning the national test results which are published by MOU (memorandum of understanding), 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

Although it is not necessarily clear what BRT recommendation means, it is difficult to reduce or eliminate the independent lot release by Japanese National Regulatory Authority, which requires some tests prescribed in Pharmaceutical Affairs Law.

Because vaccines vary considerably in quality, the manufacturer and the government need to double-check the quality of products, when the products are released. The lot release by Japanese National Regulatory Authority is equivalent to the governmental check of the products. The GOJ recognize that the EU also has a similar system.

BRT recommendation states that “concerning the national test results which are published by MOU (memorandum of understanding), manufacturing countries should be accepted by the Japanese authority”, but there is no such fact without foundation that the MOU makes the results of lot release published. As a matter of fact, the GOJ does not recognize what the recommendation states.

### Future outlook

The GOJ continuously attempts to operate the lot release system properly, concerning vaccines.

## 15. Shortening review times for animal health products (WP-B / # 18\* / E to J)

### BRT Recommendation

Shorten review times for new product applications. 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 ADI and 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 importation of recombinant vaccines from Europe should also be implemented.

### <Recent Progress>

No change or improvement was seen for this recommendation.

### <Background>

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

### Action taken so far

The MAFF, the MHLW and the FSC have been cooperating to improve efficiency of review and assessment process for approval of new products. For instance, certain inactivated vaccines which meet specific conditions have been exempted

from the FSC assessment. In addition, the FSC assessment procedures for certain veterinary attenuated live vaccines and combined vaccines have been decided to be simplified.

Therefore there seems to be a misunderstanding in the BRT's comment "No change or improvement was seen for this recommendation".

In addition, the GOJ 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".

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.

#### Future outlook

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

- Application of provisions exempting the FSC assessment; and
- Development of a way to perform each procedure of the three bodies as simultaneously as possible

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

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

1. Cooperation for maintenance of an open, transparent internet (WP-C / # 01\* / EJ to EJ)

### **BRT Recommendation**

The BRT supports the past coordinated efforts on Internet Governance by both 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. 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 Feb. 2014, The European Commission released its communication "Internet Policy and Governance" on the EU's role in shaping the future of Internet Governance.

#### **< Background >**

Internet has become an indispensable social infrastructure to sustain flourishing citizens' life, innovation, and economic growth. The BRT acknowledges that several innovative services using internet have emerged under the multi-stakeholders governance mechanism. At WCIT 2012, revisions of ITRs were discussed by ITU member states. Different positions on governance among countries became obvious. In 2014, important meetings on internet governance are expected such as the 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.

### **Action taken so far**

The GOJ attended NETmundial (the Global Multistakeholder Meeting on the Future of Internet Governance) in Brazil in April 2014 and the ITU Plenipotentiary Conference in the Republic of Korea in October 2014. At both conferences, the GOJ affirmed with other countries and organizations that the Internet has become an indispensable social infrastructure to sustain citizens' enriched life, innovation and economic growth.

## 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 securing free flow of information on the Internet and the Multi-stakeholder approach.

## 2. Cooperation for trade liberalization on ICT services (WP-C / # 02\*\* / EJ to EJ)

### BRT Recommendation

The BRT has serious concerns that some countries are implementing forced localization policies. Both sides' Authorities are requested to take coordinated action against forced localization measures such as compulsory requirements of local facilities and subsidiaries for services provisioning, forced local technology transfers etc., when those measures are not necessary, are unfair, or obviously interfere with the rightful and un-hindered provisioning of services to the users.

The BRT also requests that both sides' Authorities intensively work on an ambitious and comprehensive trade liberalization policy of services over the internet with the purpose of facilitating cross-border business and data flows. This will help actors on all layers (infrastructure providers, operators and service providers) to thrive in synergy for the overall benefit of the final users.

### < Yearly Status Report >

At the 21st EU-Japan summit held in Nov. 2013 in Tokyo. The EU and Japan emphasised the importance of enhancing cooperation in the current negotiations of Trade in Services Agreement.

### <Background>

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

### Action taken so far

In the fast growing Information Communications Technology (ICT) service sector, an environment, such as transparency of regulations in each country, maintenance of an open network and ensuring a free flow of information between countries is essential for Japanese enterprises to operate overseas.

To this end, in negotiations such as the TiSA (Trade in Services Agreement), the GOJ is contributing to creating high-level rules for ICT.

#### Future outlook

The GOJ will continue to be involved in negotiations such as in TiSA, in order to encourage third party countries to introduce appropriate rules.

### 3. Continued efforts for swift conclusion ITA (WP-C / # 03\*\* / 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. The BRT 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 >

Although several meetings were held in 2013 and serious efforts were made to finalize ITA expansion, negotiators were unable to reach a conclusion before the WTO Ministers meeting in Bali in Dec. 2013 due to certain objections.

#### < 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.

The BRT especially welcomes APEC's reaffirmation, on 7-8th October 2013 in Bali, Indonesia, of its swift conclusion of the WTO/ITA expansion. The BRT hopes that China, as the APEC 2014 host, will show a strong leadership and bring the WTO ITA expansion to a successful conclusion before the next meeting of APEC Ministers Responsible for Trade on 17-18th May 2014, Qingdao, China.

#### Action taken so far

After the launch of the ITA expansion negotiations in May 2012, the negotiations

reached a draft final list. However, due to China's persistence on its long sensitive list during negotiations in November 2013, a swift conclusion was not realized.

Since then, Japan closely cooperated with the EU and the US at the Informal WTO Ministerial Gathering in Davos and WTO Informal Ministerial Meeting at the OECD Ministerial Council Meeting to urge China to respond positively. At the Meeting of APEC Ministers Responsible for Trade (May 2014), there was certain progress on discussion of sensitive products between the US and China, though the agreement was not reached.

During the APEC Economic Leader's Meeting (November 2014), the US and China reached an agreement on expanding the scope of products. Following this breakthrough, the negotiations were resumed in December, however, were not concluded by the end of the year.

#### Future outlook

The ITA expansion negotiations are of high importance to the global economy, and Japan will closely cooperate with the EU and its industries to achieve a swift conclusion of the negotiations.

#### 4. Building a trusted, safe and robust online environment (WP-C / # 04\*\* / EJ to EJ)

##### BRT Recommendation

Trust, Safety and Robustness are key pillars expected for cyberspace and physical infrastructure supported by ICT.

The BRT appreciates that both 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, preventing unwanted damaging leaks, 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 cyberattacks should be established by both Authorities.

Cooperation between critical infrastructure operators and ICT service providers is indispensable 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. In this context, the BRT supports the vote of the IMCO committee of the European Parliament to exclude enablers of internet services including cloud operators from the scope of the NIS Directive and clearly mentioned that HW/SW vendors are not covered in the scope of the NIS Directive.

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 >

The European Commission released its Cybersecurity Strategy "An Open, Safe

and Secure Cyberspace" and Directive on Network and Information Security (NIS) in Feb. 2013.

In Mar. 2014, the European Parliament voted to give mandate to negotiate with the Council.

In Oct. 2013 the GOJ released its International Strategy on Cybersecurity Cooperation "j-initiative for Cybersecurity".

At the EU-Japan Summit held in Nov. 2013, summit leaders stressed the growing challenges to maintain a safe, open and secure cyberspace in promoting economic and social development.

On 3 Dec. 2013, the 2nd "EU-Japan ICT Security Workshop" was organized in Brussels within the framework of the 20th EU-Japan High Level ICT Dialogue. Both Authorities and industries shared cybersecurity policies and best practices.

In Jan. 2014 the EU's cybersecurity agency ENISA published a new report to give advice regarding the next steps towards coordinated testing of capability of Industrial Control Systems (ICS) for European industries.

#### < Background >

Risks surrounding Cyberspace are increasing. The revelation of mass surveillance and complicated cyber attacks caused a loss of trust on online environment.

Addressing these serious issues requires a close cooperation of the public and private sectors. The operations of critical infrastructures such as energy, transportation, water, etc., are highly dependent on ICT.

#### Action taken so far

At the 22nd Japan-EU Summit in May 2014, Japan and the EU decided to launch the Japan-EU Cyber Dialogue, and in October, the first meeting was held in Tokyo. Japan and the EU exchanged information such as the measures taken in the field of cybersecurity and discussed various issues including possible

future cooperation.

In Japan, “the Basic Act on Cybersecurity”, which contains provisions such as the enhancement of Japan’s cybersecurity and the responsibilities of relevant parties in the public and private sectors including critical infrastructure operators, was enacted in November 2014.

In the field of critical information infrastructure, the GOJ established the “Basic Policy of Critical Information Infrastructure Protection (3rd edition)” in May 2014 in line with the “Cybersecurity Strategy” that had been established in June 2013, and has made efforts to strengthen cybersecurity measures, including control system security, through public and private partnership.

On October 29th 2014, the Control System Security Center (CSSC) of Japan and the European Network for Cyber Security (ENCS) signed the Letter of Intent.

#### Future outlook

In accordance with the “Basic Act on Cybersecurity”, the “Cybersecurity Strategy”, the “Basic Policy of Critical Information Infrastructure Protection (3rd edition)” and others, Japan will strive to promote measures to build safe cyberspace including the field of critical information infrastructure.

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.

## 5. Balancing privacy protection and innovation (WP-C / # 05 \*\* / 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 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 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 the decision adopted on 20 December 2013 by the IT Strategic Headquarters headed by the Prime Minister of Japan to review the personal data protection regime and propose a draft law to the Diet by January 2015.

The BRT suggests that a ‘safe harbour’ agreement between the EU and Japan or the adequacy-finding procedure under the EU system should be explored after the completion of reforms of the two regimes. The question of independent authorities will affect this potential mechanism.

The BRT thinks that ideally, the new law should 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.

Concerning the draft EU General Data Protection Regulation, the BRT maintains 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, the transfer of employee data to an internationally integrated personnel system abroad, and the maximum fines to be proportionate and equitable.

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 may be adopted by the end of 2014.

Japan's IT Strategic Headquarters headed by Prime Minister Abe adopted a decision on 20 December 2013 to review Japan's personal data protection regime.

< Background >

The European Parliament voted in its plenary session on 12 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.

Negotiations on the proposal between the EP and the Council are unlikely to start before the EP's election in May 2014 because Member States in the Council have not yet agreed on a position.

The government of Japan decided to revise the Personal Data Protection Law, which is a good indication for the enterprises to utilize 'big data'. According to the decision of the IT Strategic Headquarters, the review will consider, among other things, establishing independent authorities. ..

### Action taken so far

To take new legal action for both promoting utilization and protection of personal data, Japan's IT Strategic Headquarters headed by Prime Minister adopted a decision on June 2014 and published "Policy Outline of the Institutional Revision for Utilization of Personal Data", and made open for public comments. Taking into account the comments received, the GOJ published the Outline of the bill on December 2014. The main points are as follows;

- Introduction of a framework that enables personal data to be utilized without consent of the persons, under certain regulations.
- Ensuring the enforcement of an effective system by developing an independent data protection authority.

In addition to this action, with the spread of smartphones and the increasing use of location data, the GOJ's working on efforts, including pilot projects, to deal with personal data taking into consideration specific usage scenes.

### Future outlook

The GOJ is to submit the relevant bills to the ordinary session of the Diet in 2015. After the enactment of the bill, the GOJ will enforce the act one by one and arrange the circumstances in which both utilization and protection of personal data will be promoted while revealing how to deal with it in specific situations.

6. Work towards international standardisation at joint R&D programmes (WP-C / # 07\* / EJ to EJ)

**BRT Recommendation**

Both authorities should specifically favour joint R&D programmes that are geared towards international standardisation.

< Yearly Status Report >

In Jun. 2013, the Abe Administration adopted a “Comprehensive Strategy on Science, Technology and innovation” and a “Declaration on the creation of the World’s Most Advanced IT Nations” as important pillars for its growth strategy. On the EU side, a new Framework Programme for Research and Innovation from 2014 to 2020, “HORIZON 2020”, was adopted in 2013 with focus on innovation

< 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) launched joint calls with the EU since FY2012 under the programme of “Strategic Information and Communications R&D Promotion Programme (International Cooperation),” which aims at international standardisation and application, and has implemented three Japan-EU joint projects in the field of information and

communication technology since FY2013. Moreover, the MIC launched the first joint projects under the Horizon2020 in the areas of Big Data and optical communications from October, 2014.

#### Future outlook

The GOJ continues to seek the possibility of wider cooperation in consideration of international standardization, following up progress of the joint research which has 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. 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.

### < Yearly Status Report >

Several EU-Japan Coordinated calls on STI were made under FP7. With the success of joint calls under FP7, joint calls under HORIZON 2020 are expected.

To further enhance EU-Japan cooperation in research and innovation, a new project called JEUISTE was launched in Sep. 2013 under FP7. Ten organizations are participating in this project with the aims of contributing to the EU-Japan STI policy dialogues, deploying bilateral information services, actively creating innovation partnerships, and offering training opportunities, among others.

In Nov.2013, the EU-Japan Centre for Industrial Cooperation was nominated as the first National Contact Point in Japan for FP7 and Horizon 2020.

The Japanese Government, on the other hand, took initiatives and is launching innovation oriented long-term programmes such as the Cross-ministerial Strategic Innovation Promotion Program (SIP) and the Impulsing Paradigm Change through disruptive Technologies (ImPACT).

The BRT hopes that those initiatives will lead to further EU-Japan strategic cooperation.

< Background >

Science and Innovation are an international endeavour. Ideas cannot be prevented from crossing borders. 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

Action taken so far

The GOJ appropriated a budget measure necessary for the activities of the National Contact Point (NCP) to the EU-Japan Centre for Industrial Cooperation that was appointed as a NCP for the first time in Japan on November 2013.

Moreover, the GOJ and the EU held the Japan-EU officials' meeting on Science and Technology Cooperation on April 2014, and exchanged views for exploring more effective and efficient mechanisms to enhance future research cooperation in the context of the new EU programme Horizon 2020 and the new Japanese 'Comprehensive STI Strategy'. The outcome of the officials' meeting was reported to the 22th Japan-EU Summit on May 2014, where both leaders of Japan and the EU stated that a dialogue would be pursued in order to identify a concrete way forward based on those fruitful discussions.

Future outlook

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

## 8. Tax credits for R&D (WP-C / # 09 \* / EJ to EJ)

### BRT Recommendation

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

### < Yearly Status Report >

The Government of Japan (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.

### Action taken so far

The GOJ resolved to extend for three years the applicable period for special treatment of R&D tax credit(selective system “increased type” or “high-level type”) and expand “increased type” in FY2014 Tax Reform.

### Future outlook

The GOJ resolved to increase the rates for tax credit for “special experiments and research expenditures” such as expenditures for joint research and contract research (from 12% to 20-30%) as well as to set the upper limit on the amount of its tax credit (5% of the corporation tax) separated from “general experiments

and research expenditures” in order to promote open innovation, while keeping the total amount of the upper limit on the amount of tax credit for experiments and research expenditures on the same level (30% of the corporation tax) in FY2015 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 21 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.

#### Action taken so far

In March 2014, the METI and the EU held a joint-workshop in order to consider future cooperation projects based on the Terms of Reference of the European-Japanese Working Group on Civilian Aeronautics Research. The METI and the EU agreed four topics, which are future passenger-friendly cabin architecture and systems, lighter integrated heat exchanger systems, efficient composite structure manufacturing and monitoring, and smarter flight control technologies for enhanced safety, as the next coordinated call projects.

In December 2014, the METI and the DGAC held the 2<sup>nd</sup> Working Group in Paris based on the Memorandum of Cooperation (MoC) in Civil Aeronautical Industry, signed in June 2013. In conjunction with the Working Group, the METI and the DGAC also held a workshop aimed at finding some future cooperation between Japanese and French companies.

#### Future outlook

With respect to efforts to develop environmentally-enhancing aircraft technologies, the cooperation between the Japanese aircraft industry and those of other countries including the EU is vital from the viewpoint of improving Japanese companies' technological capability and competitiveness. The GOJ will continue to support the collaboration between the Japanese aircraft industry and those of European countries utilizing the Japan-EU and Japan-French cooperation framework.

The next coordinated call projects based on the Terms of Reference of the European-Japanese Working Group on Civilian Aeronautics Research will be approved after June in 2015.

## 10. 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.

### Action taken so far

The GOJ is internally discussing the formulation of “the law on space activities”, referring to the US and European third party liability systems for damage 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 discussions.

## **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 fully address the impact of reforms and new regulations on the real economy notably in the implementation phase and take a co-ordinated approach to avoid negative effects on global business activities and efficient allocation of resources.

#### **<Recent Progress>**

In July 2013, the European Commission and the US Commodity Futures Trading Commission (CFTC) announced a Path Forward regarding their joint understandings on a package of measures for how to approach cross-border derivatives. As stated there, there will be considerable co-ordination challenges to avoid cross-border conflicts, inconsistencies and duplication.

The final report on margin requirement for non-centrally cleared derivatives was issued by the Basel Committee on Banking Supervision (BCBS) and the International Organization of Securities Commissions (IOSCO) in September 2013, which includes a threshold of €50 million for initial margin to minimise impact on corporate business activities.

#### **<Background>**

Financial reform and introduction of additional regulations are underway to achieve a more resilient financial system but they should be designed to be appropriate and effective so as to enable financial markets and financial industry support sustainably economic activities and the revitalisation of global economy. The European and Japanese authorities as well as market participants including banks and business corporations should continue to unite efforts to ensure effective influence on US financial regulations which have international reach, particularly cross-border OTC derivatives market reforms, to avoid decrease in liquidity and increase in hedging cost.

#### Action taken so far

In OTC derivative market in Japan, the promotion of clearing through central counterparty would contribute to the financial stability through the reduction of systemic risk. In addition, in order to avoid cross-border conflicts, inconsistencies and duplication, the GOJ has been discussing actively on the equivalence assessments with the EU.

#### Future outlook

Japan will continue to discuss on the recognition of CCPs with the EU. Japan will also consider steadily implementing the international agreement while bearing in mind considering the influence on the financial and capital market and real economy. Regarding the Margin requirements for non-centrally cleared derivatives, Japan has been preparing for the implementation.

## 2. Recommendation on BEPS Action Plan (WP-D / # 02\*\* / EJ to EJ)

### BRT Recommendation

The BRT recommends that, as to the 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.

#### <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 risk leading 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.

### Action taken so far

The purpose of 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.

In September 2014, the first set of the reports about the BEPS Action Plan was published. During the process of finalization of those reports, the GOJ collaborated with business sectors through opportunities to comment on discussion drafts and exchange views at public consultations.

For the GOJ's overall position on tax-system reform of Japan, please refer to the attachment (p.120) of this report.

## Future outlook

The second and third outputs of the Action Plan will be finalized in September/December 2015, respectively.

The OECD's Committee on Fiscal Affairs continues to consult with interested parties through public comments and public consultations. Taking into account the outcome of those efforts, the GOJ would like to gather opinions from a broad range of stakeholders and continue to contribute to development of new global standards for the international taxation.

For the GOJ's overall position on tax-system reform of Japan, please refer to the attachment (p.120) of this report.

### 3. Recommendation on Tax Issues (WP-D / # 03\* / EJ to EJ)

#### BRT Recommendation

The BRT requests that the EU Member States and Japan should modernise the tax treaties between them and ensure that, to the greatest extent possible, dividend, royalty and interest payments are exempted from withholdings taxes and that they provide for corresponding adjustments and arbitration in case of transfer pricing taxation.

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).

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

#### <Recent progress>

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

#### <Background>

In order to enhance direct investment between the EU and Japan, the removal of double taxation and the reduction of compliance costs associated with the transfer pricing taxation including the conclusion of APAs are essential.

Participation exemption, by which dividends and capital gains received from business investment are exempted from further corporate taxation to reward for taking risks associated with foreign investment, will further encourage direct investment.

#### Action taken so far

In view of promoting investment and economic activities between Japan and the EU, the GOJ has been actively expanding and enhancing the tax treaty network

with the EU member states. Protocols amending the tax conventions with the UK and Sweden entered into force in December and October 2014 respectively. These protocols provide for the exemption of withholding taxes in the source country on dividend payments between related parties, interest and royalty payments, as well as the arbitration process in the mutual agreement procedure. Transfer pricing documentation requirements are defined by laws and the National Tax Agency operates its administration in consideration of taxpayers' burdens.

APAs with EU member countries 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 (p.120) of this report.

#### Future outlook

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.

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 countries, the GOJ will continue to implement 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 (p.120) of this report.

(Attachment)

Tax-system-related proposals

In 16th EU-Japan Business Round Table, the followings were proposed with respect to Japanese tax system:

Working Party D:

- (1) Recommendation on BEPS Action Plan
- (2) Recommendation on 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, 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 appropriately reflected in the tax reform process.

#### 4. Recommendation on Japanese Fiscal Soundness (WP-D / # 05\*\* / EJ to J)

##### BRT Recommendation

The BRT requests that Japanese Government shall 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 key for both economic growth and the realisation of fiscal soundness.

##### < Recent Progress >

No agreement has been found.

##### < Background >

The EC announced proposals in September 2011 to impose a Financial Transaction Tax on financial instruments between financial institutions when at least one party to the transaction is located in the EU but it has concluded since that a common FTT system could not be attained within a reasonable amount of time by the EU as a whole. On 14 February 2013, the EC has adopted a proposal for a Council Directive implementing enhanced cooperation between 11 Member States in the area of financial transaction tax.

##### Action taken so far

The GOJ steadily proceeds with fiscal consolidation that is compatible with economic revitalization based on "Medium-term Fiscal Plan" (approved by the Cabinet on 8th August 2013). In this plan, the government set out objectives to halve the primary deficit of the national and local governments to GDP ratio by FY2015 from the ratio in FY2010 and to achieve a primary surplus by FY2020, and thereafter to steadily reduce the public debt to GDP ratio.

Although consumption tax was increased to 8% on April 2014, taking into

account the economic conditions and other factors in a comprehensive manner, the consumption tax increase to 10% will be postponed until April 2017; however the government made best efforts for fiscal consolidation such as thoroughly prioritizing and streamlining expenditures. Through these measures, the FY2015 budget will achieve the target of halving the primary deficit to GDP ratio.

#### Future outlook

The GOJ will surely implement the consumption tax increase to 10% in April 2017. In addition, the GOJ firmly maintains the FY2020 target of achieving primary surplus. To achieve this, the government will prepare a concrete fiscal consolidation plan by the summer of 2015.

Through these efforts, the government aims to achieve both economic revitalization and fiscal consolidation.

## 5. Recommendation on Japanese Tax system (WP-D / # 06\* / 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 of fixed asset tax on depreciable assets is necessary measures for providing a globally competitive business environment.

#### <Background>

While Japanese society is aging rapidly, there is expectation that in addition to revitalisation of Japanese corporates 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.

### Action taken so far

Regarding corporate tax reform, the GOJ has embarked on the reform aimed at reducing the effective corporate tax rate (current: 34.62%) to the twenties in several years while permanent revenues will be secured through such measures as broadening the tax base and so forth.

In FY2015 Tax Reform, while a revenue source will be secured through such measures as broadening the tax base and so forth, the GOJ decided to reduce the tax rate by 2.51% (compared with the current rate) in FY2015 and by 3.29% (compared with the current rate) in FY2016, including front-loaded tax reduction in order to strongly support the realization of a virtuous economic cycle.

Fixed asset tax on depreciable assets has been charged, since its start in 1950, on those who possess fixed assets at a low tax rate, depending on the asset value, based on the benefit principle focusing on the benefit relation between the possession of fixed assets and administrative services by municipalities, as lands and buildings are. The tax has been established as a stable, primary and

independent revenue source for municipalities, and has been their important revenue source.

#### Future outlook

In FY2016 Tax Reform, the GOJ will secure a revenue source through broadening the tax base, etc. and aim to reduce the tax rate further (in addition to the 3.29-point reduction) in FY2016. Reforms will be continued under revisions in subsequent years in order to aim to lower the effective corporate tax rate down to the twenties.

Fixed asset tax on depreciable assets is adopted in some countries as well, and should be comprehensively discussed from various points of views, taking into account of opinions from many municipalities of keeping the current taxation system, those from Local Public Finance Council of being inappropriate to abolish or reduce fixed asset tax on depreciable assets, and the effect of revitalizing local economies by new investment.

## 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**

The Arab Spring revolution that was triggered by the Jasmine revolution in Tunisia in December of 2010 and spread throughout the Middle East and North Africa, including Jordan, Egypt, and Bahrain, has created political and social instability 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-27 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.

#### • **Increased energy demand from emerging countries affects the energy policy 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 to stabilize both energy prices and supply; however, the development of resources by state-owned enterprises from the emerging countries will lead to severe competition to secure stable supplies at affordable prices.

Japan and the EU should cooperate to stabilize natural resources prices and

establish an energy mix policy that reflects the actual energy policy 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 will cause an increase in the acidity of the oceans, raise sea levels, and severely affect many aspects of human life such as agriculture, forestry and fishing, ecosystems, water resources, and human health. Government, industry, and academia in Japan and EU should deepen their dialogue on measures to mitigate global warming. In Japan, in order to reduce greenhouse emissions, restarting the nuclear power plants needs to be thoroughly considered.

Action taken so far

Regarding the cooperation with the EU on energy security, Japan has offered the following proposals in response to the Energy Security Stress Test under the auspices of the European Commission: 1) relaxation of destination clause, 2) better collaboration among consumer nations, and 3) sharing experience on energy efficiency measures.

In April 2014, the Cabinet of Japan approved the New Strategic Energy Plan setting forth Japan's medium to long-term energy policy. The objective of the plan is to achieve an energy supply and demand structure which is both realistic and balanced.

Giving the safety precedence over all other concerns, the GOJ will resume the operations of the nuclear power plants if the Nuclear Regulation Authority certifies that a plant is in compliance with the new regulatory standards.

Future outlook

Regarding the cooperation with the EU on energy security, Japan will work together with the EU through international conferences including the LNG Producer-Consumer Conference to enhance cooperation between consumer

nations, such as stabilizing the LNG markets and improving transparency.

Japan's energy mix will be established as soon as possible under the country's Strategic Energy Plan with full consideration to the resumption of operation of the nuclear power plants, the promotion of renewable sources of energy, and the decisions at the Conference of the Parties to the United Nations Framework Convention on Climate Change (COP) and the other international dialogues concerning global warming.

The legally required processes for the resumption of operation of the nuclear power plants are permission for amendment of the reactor installment license, authorization for the construction plan, and official inspection before the operations and so on. Once these processes are concluded, an operator is legally permitted to resume the operations of the nuclear power plant.

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

### BRT Recommendation

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

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

Energy is the basis of all economic activity. Securing a stable energy supply at a reasonable price, developing the necessary infrastructure as well as reducing energy needs are not only crucial 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. Japan and EU should establish energy policies which preserve a role for nuclear power, one of the effective means of reducing greenhouse gas emissions, while paying utmost attention to safety.

- **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 of 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.

### Action taken so far

The Cabinet of Japan approved the New Strategic Energy Plan, which sets forth

Japan's medium to long-term energy policy, in April this year. The GOJ has launched a number of initiatives, covering the production, distribution and consumption of energy, including the development of technology for commercialization of indigenous resources such as methane hydrate, and the support for the introduction of advanced energy conservation facilities that will serve to build a comprehensive energy conservation society.

The Nuclear Regulation Authority (NRA) put new regulatory requirements into effect on July 2013, and it is reviewing the conformity of the applications of amendment on Installation Permit of Nuclear Power Reactor submitted by the electric power providers, with the new regulatory requirements. On September 2014, NRA granted permission to the Sendai units 1 and 2 of Kyushu Electric Power Company.

Japan has been contributing actively to international and regional fora such as IEA, IRENA and IAEA through chairing those meetings. Moreover, Japan has expanded and deepened the framework of international cooperation through inviting the Executive Director of IEA to international conferences in Japan and various governmental committees.

#### Future outlook

As for research and development in the energy sector, the GOJ will continue to promote various initiatives aiming at the stabilization of energy supply and demand structure and the improvement of energy efficiency.

NRA will continue to review the conformity of submitted applications to the new regulatory requirements.

Japan will continue to actively contribute to international and regional fora, including IEA, IEF, IRENA, IAEA, G8, G20, and APEC conferences.

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

#### **BRT Recommendation**

- **Short, Medium and long-term energy policies**

Large-scale natural disasters, such as the Great Eastern 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 sources 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 that allows for 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 an 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 capable of executing their chosen energy mix policies and consider measures to replace outdated equipment and facilities to improve safety.

#### Action taken so far

In April 2014, the Cabinet of Japan approved a New Strategic Energy Plan setting forth Japan's medium to long-term energy policy. The plan summarizes policy agendas to be tackled and the direction of a long-term, comprehensive, and systematic energy policy, with a perspective on the medium to long-term (approximately in the coming 20 years) energy supply and demand structure. The basic premise of this plan on energy policy is Energy Security, Economic Efficiency, the Environment, and Safety, namely "3E + S", and the plan calls for a realistic and balanced approach towards achieving a suitable energy supply and demand structure. And also, the plan points to a policy direction for the creation of a "multilayered, diversified and flexible energy supply and demand structure".

#### Future outlook

Under the New Strategic Energy Plan, Japan will continue to work on securing resources, achieving a comprehensive energy conservation society, accelerating the introduction of renewable energy, and reformulating the nuclear energy policy.

#### 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 an advantage in terms of cost and stable supply. Research into making the use of fossil fuels more efficient and reducing CO<sub>2</sub> emissions is ongoing. Japan and EU should support this research and the use of more energy-efficient and cleaner fossil fuels by developing countries.

##### Action taken so far

The GOJ is currently promoting the development and demonstration of technologies to gasify coal and to improve power generation efficiency by raising the gas combustion temperature of LNG thermal power generation and the steam temperature of coal thermal power generation. The GOJ has also commenced a large-scale demonstration project of the carbon dioxide capture and storage(CCS) technology. Furthermore, the GOJ has been contributing to global CO<sub>2</sub> reduction through the dissemination of high efficiency and low carbon technologies to the developing countries by the following measures;

- to encourage developing countries to introduce high efficiency low emission power generation technologies through top-sales activities by Ministers including Prime Minister;
- to hold energy policy dialogue with developing countries;
- to support the private sector to identify and formulate energy infrastructure projects in developing countries.

##### Future outlook

Japan will continue to develop the technologies to drastically reduce greenhouse gas emission per unit of electricity generated (such as IGCC) through the major improvement of power generation efficiency. Furthermore, Japan will strive to reduce the burden on the global environment through diffusing Japan's world leading high efficiency power generation technologies to abroad.

## 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, economic growth and jobs creation.

- **Rising global expectations for nuclear energy and the necessity for an enhanced safety framework**

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 cost of generating power in Japan in fiscal 2013 greatly increased due to the use of thermal power plants to compensate for the lack of nuclear power generation. This 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 those nuclear power plants that are verified as being safe by the safety authority.

- **Replacing ageing nuclear reactors with safer models**

The latest nuclear reactors are designed to 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.

- **Nuclear fuel recycling**

Japan and the EU should work together to devise a safe and efficient method of recycling nuclear fuel.

- **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.

#### Action taken so far

Under the Strategic Energy Plan approved by the Cabinet of Japan in April 2014, the GOJ positioned nuclear energy as an important base-load power source because of its advantage in terms of energy security, economic efficiency and low carbon emission.

Giving the safety precedence over all other concerns, the GOJ will resume the operations of the nuclear power plants if the Nuclear Regulation Authority (NRA) certifies that a plant is in compliance with the new regulatory standards.

Confirming the conformity with the new regulatory standards, NRA accepted to amend the nuclear power reactor installation permission of Units 1 and 2 of Sendai nuclear power station (NPS) on September 10, 2014. Furthermore, the governor of Kagoshima Prefecture and the mayor of Satsumasendai City indicated their understanding for the restart of operations of Sendai NPS.

The basic policy of Japan is to promote the nuclear fuel cycle from the viewpoint of the effective utilization of resources and the reduction of volume and harmfulness of high-level radioactive waste.

Therefore, Japan has taken initiatives to deepen understanding on the nuclear fuel cycle policy in cooperation between Japan and the EU in the civilian nuclear

energy sector, such as the 4th Japan-France Nuclear Energy Cooperation Committee meeting in September, 2014, and the 3rd Japan-U.K. Dialogue on Nuclear Power in October, 2014.

The advisory committee for Natural Resources and Energy has debated the issues surrounding the nuclear power policy, such as voluntary efforts and continuous improvement for nuclear safety and appropriate business environment under more competitive market, since June 2014 and conducted intermediate sum up in the end of 2014.

#### Future outlook

The Advisory committee for Natural Resources and Energy will continue to review the issues surrounding nuclear power policy in detail.

The legally required processes for the resumption of operation of the nuclear power plants are permission for amendment of the reactor installment license, authorization for the construction plan, and official inspection before the operations and so on. Once these processes are concluded, an operator is legally permitted to resume the operations of the nuclear power plant.

In order to pursue and implement the nuclear fuel recycling policy, Japan will strengthen the relationship between Japan and the EU and its member states by exchanging views through the framework such as the Japan-France Nuclear Energy Cooperation Committee and the Japan-U.K. Dialogue on Nuclear Power.

## 6. Safety measures (WP-E/#06\*/EJ to EJ )

### BRT Recommendation

- **Measures to assure safety**

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.

- **Consultation**

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

### Action taken so far

The Nuclear Regulation Authority (NRA) has bilateral cooperation frameworks with regulatory organizations of major EU Member States. Under these frameworks, NRA has cooperated on nuclear regulation by means of information exchange meetings. In addition, NRA has been cooperating with the EU through sharing information, as necessary.

Japan believes that it is its responsibility to share with the international community the experience and lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station in March 2011. With this in mind, Japan has provided the international community with accurate information of the accident in an open manner.

### Future outlook

NRA will continue its effort such as information exchange mainly under the bilateral cooperation frameworks.

Japan will continue to share with the international community the lessons learned from the accident at the Fukushima Daiichi Nuclear Power Station, and to provide accurate information of the accident in an open manner.

## 7. Renewable energy (WP-E/#07\*\*/EJ to EJ)

### BRT Recommendation

- **Advantages of renewable energy**

Uncertainties remain about the cost and security of supply of renewable energy. But it has the potential to complement conventional energy since it does not emit greenhouse gas, can reduce import dependency, and be securely utilized through a balanced network. To answer these uncertainties, it is therefore important to correctly assess the total cost of renewable energies along their value chain, and to encourage research into the practical stage of renewable energy sources.

- **Practical project approaches with respect to renewable energy sources**

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 base 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. It is therefore necessary to study carefully how the adoption of renewable energy sources will be specifically carried out.

- **Storage 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.

### Action taken so far

Under the new Strategic Energy Plan approved by the Cabinet of Japan in April

2014, the GOJ has accelerated the introduction of renewable energy as much as possible for three years since 2013 followed by continuous active promotion.” The GOJ has been appropriately managing the feed-in-tariff system as a key factor for achieving this objective, and has been addressing various measures including technological development for the resolution of following challenges: 1) the problem of high costs, 2) the problem of output instability, 3) location restrictions, and 4) the problem of transmission network capacity of the electric power companies.

#### Future outlook

While overcoming the electric grid issue and minimizing the financial burden on the general public, the GOJ will continue to address for achieving the introduction of renewable energy as much as possible.

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

### BRT Recommendation

- Enhancing energy conservation in all fields

The construction of energy efficient buildings, as well as the energy efficient 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-saving technologies for electrical equipment, such as refrigerators, air conditioners, servers and LED lights, is also ongoing. In the transport sector, Hydrogen Fuel Cell Vehicles have considerable potential to make automobiles more energy efficient. 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.

Japan and the EU should consider taking further measures to promote energy conservation, by financing research projects to develop technologies and methodologies for improving energy efficiency 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, and the governments of both countries must be encouraged to support such moves. In particular, setting mandatory regulations for building standards and house insulation plays a major role in reducing energy consumption.

### Action taken so far

Japan's energy conservation policy regime is broken down into the Industrial Sector, the Consumer (Commercial and Residential) Sector, and the Transportation Sector. The GOJ has implemented policies in each sector on two fronts, namely regulatory measures under Act on the Rational Use of Energy and support measures utilizing available budget and tax programs.

On regulatory measures, the GOJ revised the Act on the Rational Use of Energy

in May 2013, and added measures for the equalization of electricity demand and reinforced energy conservation measures in the consumer sector.

On support measures, the GOJ has supported the introduction of energy conservation facilities to promote energy conservation investments by private companies and those facilities through lowering their cost. The GOJ is also supporting the promotion of energy conservation initiatives by offering energy and electricity conservation diagnoses for free to small and medium enterprises and providing information of best practices regarding energy conservation initiatives and technologies based on such diagnoses.

#### Future outlook

The GOJ will enhance the energy conservation initiatives in each sector to realize a comprehensive energy-saving society.

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

### BRT Recommendation

- **Energy researches 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 renewable energy sources and assure the safety of nuclear power, as well as explore new energy fields such as methane hydrates.

- **Human resources development**

Energy is crucial for every nations and industries. Japan and the EU should consider how to create systems to train and develop human resources to become energy-related specialists.

### Action taken so far

On research and development in the energy sector, the GOJ has conducted the following measures; the technological development of off-shore wind power generation which is one of the renewable energy; the development of technologies foundations which contribute to further advancement of safety measures such as the advancement of comprehensive risk assessment method of nuclear power plants; and the development of technology for commercialization of methane hydrate.

With regards to fostering specialists in the field of energy, the GOJ is supporting the training of onsite nuclear facility maintenance technicians and professionals on nuclear safety in the industrial sector for dismantling the Fukushima Daiichi Nuclear Power Plants of Tokyo Electric Power Company and the safety of Japan's existing nuclear power stations.

## Future outlook

On research and development in the energy sector, the GOJ will continue to conduct the technological development of off-shore wind power generation, the development of technologies and foundations which contribute to further advancement of safety measures such as the advancement of comprehensive risk assessment method of nuclear power plants, and the development of technology for commercialization of methane hydrate.

With regards fostering specialists in the field of energy, the GOJ will continue to support the training of onsite nuclear facility maintenance technicians and professionals on nuclear safety in the industrial sector.

## 10. Importance of measures against global warming (WP-E/#010/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 and effective mechanism for reducing global greenhouse emissions.

### Action 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 COP20 held in Lima in December 2014, the Parties adopted a COP Decision, the "Lima Call for Climate Action", that sets out the information to be provided by all Parties communicating their intended nationally determined contributions in accordance with the invitation to do so well in advance of the twenty-first session of the Conference of the Parties (by the first quarter of 2015 by those Parties ready to do so). The Decision also contains "elements for a draft negotiating text" in its annex and decides that the ADP will intensify its work with a view to making available a negotiating text for a protocol, another legal instrument or an agreed outcome with legal force under the Convention applicable to all Parties before May 2015. The GOJ's goal of making sure that the COP20 would complete preparatory work for an agreement at COP 21 on a new legal framework applicable to all Parties has thus been achieved.

### Future outlook

With regard to a new post-2020 legal framework, aiming for an agreement at

COP21, Japan will continue to actively contribute to negotiations in accordance with the decision in Lima, and utilize opportunities including various international conferences and bilateral meetings.

11. Measures to be taken by Japan and EU to reduce greenhouse gas emissions  
(WP-E/#11\*/EJ to EJ)

**BRT Recommendation**

• **Situation in Japan following the Great Eastern 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 Eastern 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 determining the specific details of its COP19 agreement, which is to establish voluntary post 2020 reductions that are to be measured, reported and mutually verified by other countries.

A government plan to move the country in the direction of restarting some of the idled nuclear reactors, known as the Basic Energy Plan, has been drafted; 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 government of Japan 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 CO<sub>2</sub> 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 CO<sub>2</sub>. 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 and the means to achieve a cost-effective decarbonisation in the long-term. A global dialog on these issues should also be maintained.

#### Action taken so far

The New Strategic Energy Plan was adopted by the Cabinet of Japan in April 2014 setting forth the nation's medium to long-term energy policy. The circumstances around energy both at home as well as abroad have been greatly altered following the Great East Japan Earthquake and the Fukushima Daiichi Nuclear Plant accident. Thus, the GOJ was forced to review the past energy policy, radically. The 4<sup>th</sup> Strategic Energy Plan was compiled in order to respond to the new circumstances and to lead the way to the new energy policy. The plan does not provide a long-term energy supply and demand forecast, but sums up a key principle of the energy policy with a perspective on the energy supply and demand structure over the medium to long-term (i.e., coming around 20 years), and indicates the path of the country's energy policy within this time period.

#### Future outlook

Japan aims at setting its energy mix as soon as possible, based on the country's Strategic Energy Plan, taking into consideration the following issues; the resumption of operation of the country's nuclear power plants, the promotion of renewable energy, and the progress of international discussions concerning global warming such as the Conference of Parties (COP) to the United Nations Framework Convention on Climate Change.

## 12. International contributions (WP-E/#12\*/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 an effective solution 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 level to design systems to support emerging countries in their efforts to combat t global warming.

#### **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 in by providing advice on the adoption of supervisory systems, training, support for licensing, and encouraging technical collaboration.

#### **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. Specific methods to visualize reduction results should be developed through public-private collaboration.

### Action taken so far

#### **Contributions by Japan and EU to global warming countermeasures**

The GOJ signed the bilateral documents for the JCM with 12 countries (Mongolia, Bangladesh, Ethiopia, Kenya, Maldives, Viet Nam, Lao PDR, Indonesia, Costa Rica, Palau, Cambodia and Mexico) as of December 2014. The METI and the Ministry of the Environment (MOE) have so far conducted 308 feasibility studies of JCM projects, and 6 demonstration projects and 14 model projects have been implemented. Furthermore,

the JCM special financing scheme was established in collaboration with JBIC and NEXI, and JCM financial support program was established in collaboration with JICA, ADB, etc.

### **Protecting intellectual property rights and developing human resources**

The GOJ, with the understanding that the adequate protection of IPRs is indispensable for promoting the transfer of technologies, actively provides technical assistance in the field of IPRs for emerging and developing countries through a combination of bilateral and regional cooperation as well as cooperative activities through World Intellectual Property Office (WIPO).

In 2014, Japan conducted technical cooperation activities including seminars, trainings, and dispatch of experts in areas such as examination practices, informatization, and utilization of IPRs. Moreover, Japan supported the self-help efforts of ASEAN member states (AMSs) through holding seminars and sending experts concerning the Hague agreement and the Madrid Protocol as AMSs plan to accede to these treaties by 2015.

Furthermore, the Japan Patent Office and each AMS's intellectual property office or the like, after mutual consultation, concluded memorandums of cooperation and/or implementation plans with a view to intensifying bilateral cooperation.

### **Visualization of emissions reduction results**

Regarding the visualization of reduction of CO2 emission, the GOJ carried out the pilot project of Carbon Footprint of Products (CFP) from May 2009 to March 2012. Since April 2012, the private sector has taken over the above-mentioned CFP scheme, and has operated it as the CFP Communication Program.

### **Future outlook**

#### **Contributions by Japan and EU to global warming countermeasures**

The GOJ will continue consultations with interested countries with an aim to increase the number of partner countries to the JCM up to 16 by the end of 2016 in line with "Proactive Diplomatic Strategy for Countering Global Warming" which is titled "Actions for Cool Earth: ACE".

### **Protecting intellectual property rights and developing human resources**

The GOJ will continue to promote bilateral and regional cooperation as well as cooperative activities through World Intellectual Property Office (WIPO).

**Visualization of emissions reduction results**

As previously mentioned, the private sector has already taken over the CFP scheme.

### 13. Environmental technology collaboration (WP-E/#13\*/ 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 industry, 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

It is important for Japan and the EU to cooperate for developing innovative technologies toward reducing GHG and to realize mutual access to the joint projects.

The GOJ launched a global conference, the Innovation for Cool Earth Forum (ICEF) as a global platform for discussions and collaboration among researchers, business persons, and policymakers from around the world to promote innovation of energy and environmental technologies for combating climate change and their dissemination. The GOJ wishes that ICEF will be utilized to discuss international collaboration in R&D.

In particular, aiming for the 21st session of the Conference of the Parties to the UNFCCC in 2015, it is necessary to develop and disseminate technologies of global warming mitigation measures to reduce world's GHG. Furthermore, Japan exerts to measure and observe GHG, and operates the Greenhouse gases Observing SATellite (GOSAT).

## Future outlook

Japan needs to reinforce its efforts for combatting global warming. It is necessary for Japan to promote drastic energy conservation and introduce as much renewable energy as possible, through developing and demonstrating technologies toward reducing GHG, and to realize a self-distributed processing type of low carbon society. And also, Japan is developing a new satellite as a successor to the present GOSAT, planning to launch in FY2017. In addition, the policies and technologies are also important to adapt to the impacts of climate change which is likely to get severer.

Japan would like to promote further Public-Private partnership and hear specific proposals from the private sector.

Japan will hold ICEF every October in Tokyo and develop it as a platform of knowledge where leaders in industry-government-academia in the world discuss to promote innovation which solves global warming.