

(Tentative Translation)

**Report from the Government of Japan**

**Concerning the Recommendations**

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

April 2014

Note: The content of this report is based on the situation as of December 31, 2013.

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

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

#### **BRT Recommendation**

The BRT welcomes the decision to open negotiations on a deep and comprehensive Free Trade Agreement between the EU and Japan, made by EU and Japanese leaders on March 25, 2013, which has marked the opening of a bright new chapter in EU-Japan bilateral relations.

In the expectation that a deep and comprehensive FTA / EPA between the EU and Japan will boost EU-Japan trade and investment and promote job creation and economic growth in both economies, the BRT urges both Authorities to conclude these negotiations as speedily as possible. To unlock the full growth potential of EU-Japan economic relations, the BRT reiterates its call that the resulting EU-Japan FTA / EPA should be ambitious, balanced, mutually beneficial, comprehensive, and tackle major outstanding issues such as tariffs, non-tariff barriers, public procurement, investment, services, competition, IPR, regulatory cooperation including harmonisation and the mutual recognition of regulations, standards and market authorisations. In addition, reciprocity and parallelism of commitments are necessary to guarantee successful negotiations.

#### **< 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**

Japan-EU economic relations have made significant progress in 2013. At the Japan-EU Summit Telephone Talks in March, 2013, both leaders decided to launch the negotiations for a Japan-EU Economic Partnership Agreement (EPA).

Following the decision, the first, second, third and fourth rounds of negotiations on the Japan-EU EPA took place in April, June, October 2013 and January 2014, respectively. At these meetings, fruitful discussions were conducted on areas such as trade in goods, trade in services, investment, intellectual property rights, non-tariff measures, government procurement and others.

At the 21<sup>ST</sup> Japan-EU Summit held in Tokyo in November 2013, both leaders agreed to pursue a comprehensive and high level EPA and reaffirmed their strong commitment to its early conclusion. In the Joint Press Statement issued at the Summit, they welcomed the recommendations adopted by the BRT in April that stated a deep and comprehensive Japan-EU EPA/FTA should be completed as early as possible.

#### **Future outlook**

The fifth round of negotiations on the Japan-EU EPA is scheduled to take place in the week of March 31, 2014. The Government of Japan(GOJ) will continue to press forward the negotiations further in order to pursue a comprehensive and high level agreement.

2. Call for a breakthrough in WTO Doha Development Agenda negotiation and statement of strong support for fight against protectionism (WP-A/#02/EJ to EJ)

#### BRT Recommendation

With a view to the upcoming Bali Ministerial Conference, the BRT expects that in particular an ambitious agreement on trade facilitation will be concluded. Further progress must be achieved in other key areas, such as non-tariff barriers. This would provide a significant boost to international trade.

The BRT also follows with interest the recently launched negotiations for an international services agreement and expects its design will be anchored within the WTO system. The WTO should also advance on plurilateral sectoral agreements, and work towards clearer WTO guidelines on the coherence between bilateral / regional / multilateral trade agreements and the WTO system. Finally, the WTO should explore other topical issues, such as the relationship between trade and investment, competition, energy and raw materials. The BRT counts that, under the new WTO Director General, expected to take office in September 2013, WTO is to pursue an ambitious trade agenda that will also tackle these issues which have a great impact on the business operations of companies today.

By advancing on a case by case basis the WTO should demonstrate its ability to develop new trade rules and help its members see the advantages of trade liberalisation. This should then serve to allow the restart of more comprehensive market access negotiations. Any weakening of the multilateral trade system must be prevented by all means.

#### < Recent Progress >

No tangible progress has been seen for this recommendation. Negotiations are on-going, including the informal ministerial meeting held in Davos, Switzerland in January 2013, towards the Ninth Ministerial WTO Conference in Bali which will take place in December 2013.

#### < Background >

*The BRT is a strong supporter of the multilateral trading system, whose core functions are trade liberalisation, rule-making and dispute settlement. However, to liberalize multilateral trade the initial high level of ambition of the Doha Round, launched in 2001, has not been maintained, resulting in the current deadlock of negotiations which continue to revolve both around a lack of political will and the inability to bridge the gap of 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 organisation creating rules and setting standards on trade at the multilateral level, the WTO must remain leader in this area and take more action. The existing legal framework provides an excellent basis but needs to be updated in order to respond to a changing global economic landscape.*

#### Action taken so far

At the 9<sup>th</sup> WTO Ministerial Conference (MC9) WTO Members agreed on the “Bali Package”, which consists of the three areas: Trade Facilitation, Agriculture and Development. The Bali Package is an epoch-making outcome in the sense that the Trade Facilitation Agreement, once it is finalized, will be the first multilateral agreement, in which all the WTO Members participate, since the establishment of WTO. Japan has played a leading role in the negotiation cooperating with the EU and other major Members. Japan has also actively worked on plurilateral trade negotiations including the expansion of Information Technology Agreement (ITA) and Trade in Services Agreement (TiSA). Regarding resistance to protectionism, at the G20 Saint Petersburg Summit Meeting and the APEC Economic Leaders’ Meeting in 2013, members/economies issued a strong message to reaffirm their commitments to standstill and rollback, exclusion of new restrictions and removal of existing restrictions.

#### Future outlook

The agreement reached at the MC9 will build a momentum for reinvigoration of the DDA negotiations. Japan will actively undertake works toward the early entry into force of the Trade Facilitation Agreement and continue to make contributions to maintaining and strengthening the multilateral trading system. Japan will also continue to conduct negotiations for ITA expansion and TiSA.

Regarding resistance to protectionism, Japan will continue to support maintenance and reinforcement of trade policy monitoring systems at the WTO and other frameworks.



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

#### (1) Global patent

##### BRT Recommendation

The BRT recognises the importance of global patent harmonisation and streamlining of the patent system as a way to promote innovation, reduce costs and boost legal certainty. With the introduction of a harmonised patent system in the EU, the authorities of the EU and Japan should take the lead in these efforts, and work closely in various international fora, such as “IP5”

##### Action taken so far

The IP5 Offices conducted comparative studies on patent systems and relevant practices and the IP5 Patent Harmonization Experts Panel has been discussing harmonization of patent systems and practices based upon the result of these studies. The Tegernsee Group, which consists of the JPO, USPTO, EPO and IP offices from major European countries, also held user consultations in each of the member countries in order to discuss several important issues on patent system harmonization.

At the same time, the JPO and IP offices of major European countries have been working to expand the Patent Prosecution Highway (PPH) initiatives.

In addition, the JPO, EPO, and major IP offices in Europe have been conducting examiner exchange program to deepen mutual understanding and mutual confidence of patent systems and relevant practices.

##### Future outlook

The JPO will further promote discussions on patent system harmonization through various forums such as the IP5 Heads of Offices Meeting and the Tegernsee Group Meeting, while deepening the cooperative relationship with users.

The JPO will also promote discussions on the PPH program to simplify and standardize application procedures among the member countries, while encouraging developing countries to participate in the program.

In regard to the examiner exchange program, the JPO, EPO, and major IP offices in Europe will enhance cooperative partnerships toward solving practical issues at each office while considering extension of the period for the dispatch of examiners.

## (2) Energy conservation, relevant labelling rules, and environmental and carbon footprint schemes

### BRT Recommendation

Given the nature of the issue and the importance for business as well as for society in general, the two Authorities should make an effort to harmonise the regulations for energy conservation, relevant labelling rules, and environmental and carbon footprint schemes. The two authorities should aim at harmonisation at an international level rather than bilateral level.

### Action taken so far

“Energy-saving Labelling System” introduced by the GOJ, which mainly focuses on household products, covers 21 items.

Furthermore, the GOJ has launched a labelling system for retailers. It stipulates that retailers shall provide information of appliances displayed at their shops with the use of “Uniform Energy-Saving Label,” which displays multistage ratings of the related products. 5 products are currently covered by the system.

The GOJ is collaborating on an energy efficiency scheme with IPEEC, which is the international organization for the scheme.

The pilot project of Carbon Footprint of Products (CFP) had been implemented from 2009 to 2012 by the GOJ. The CFP project has been carried out by the private sector since July 2012 and 627 CFPs have been verified for now.

The GOJ has confirmed that this scheme is governed by the international standard ISO/TS14067 published in May 2013.

### Future outlook

In addition to reviewing the multistage rating standard, the GOJ will continue to expand coverage of “Energy-saving Labelling System” for manufacturers and “The Uniform Energy-Saving Label” for retailers. The GOJ will also distribute PR materials to enhance the recognition of the labelings.

The GOJ will continue to harmonise the Japanese CFP system with the ISO, and to promote the system.

### (3) AEOs (Authorized Economic Operators)

#### BRT Recommendation

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

#### Action taken so far

Mutual recognition of the AEOs between the EU and Japan 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 AEO Expert Dialogue in March 2013 and discussed the possibility for expansion of benefits by AEO mutual recognition to global companies.

#### Future outlook

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

(4) Development of practical application of new technologies (RFID, etc.) ,(5) Dissemination of model ICT use

#### BRT Recommendation

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

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

#### Action taken so far

As one example of model ICT use, METI has been establishing a global information network, where anyone can easily share each cargo status data based on interoperable standards for optimization of global supply chain. In this regard, a recommendation to make a foothold for a world-level common platform was issued in May 2012 at Asia-Pacific Economic Cooperation (APEC).

#### Future outlook

As one example of the model ICT use, METI plans to hold a pilot project of transportation of finished-cars by using RFID, and then hold a seminar to introduce the measures on optimization of global supply chain with RFID based on this result.

## (6) International harmonisation at CODEX

### BRT Recommendation

The European Commission and the GOJ should collaborate on achieving international harmonisation at CODEX in the description and standards for food for specified health use/functional foods.

### Action taken so far

With a view to promoting international harmonization, the GOJ has been actively contributing to discussions on establishment of food standards and the bases of the standards in the Codex including CAC, the Codex Committee on Food Labeling and the Codex Committee on Nutrition and Foods for Special Dietary Uses.

### Future outlook

The GOJ intends to continue international cooperation through the Codex activities.

## (7) Automobiles

### 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 34 of the 50 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 EC 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. Harmonisation & mutual recognition of standards and product certifications; acceptance of international standards where applicable (WP-A/#07/E to J)

(1) Construction Products

**BRT Recommendation**

The Government of Japan should work together with the EU Authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials. 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**

It is already possible for a foreign institute to be registered as a Registered Overseas Certifying Body (JAS) or a Foreign Accredited Certification Body (JIS) 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, we do not believe that we are imposing particularly difficult requirements for registration.

We registered some certifying bodies in the EU as the Registered Overseas Certifying Body (JAS).

**Future outlook**

We intend to continue to ensure the appropriate management of the accreditation system, while explaining our system to relevant institutes whenever the need arises.

## (2) 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 positive lists of active ingredients and excipients/additives for so-called “medicated cosmetics”, which are classified as quasi-drugs under Pharmaceutical Affairs Law. On 21<sup>st</sup> July, 2011, the claim of “minimizing the appearance of fine lines due to dryness” was added to the list as No.56 of cosmetic efficacy.

The Ministry of Health, Labour and Welfare has had periodical meetings with the Pharmaceuticals and Medical Devices Agency (PMDA) and the industry to exchange views on rapid review process of quasi-drugs. As a part of the approach for rapid review process of quasi-drugs, the GOJ published mock-up of medicated cosmetics (Cream) on 31<sup>st</sup> October, 2013.

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

### Future outlook

The GOJ will continue to periodically exchange views with the industry for transparency and acceleration of the review process of “medicated cosmetics”.

When there are concrete requests with appropriate data about the alternative animal testing methods which OECD has not adopted, the GOJ will consider its evaluation on and response to them through activities by JaCVAM.



### (3) 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 GOJ and the EU authorities should work toward establishing a mechanism through which test data and certification of railway equipment provided by European organisations is accepted in Japan, and vice versa.

The BRT furthermore recommends Japan to establish a system whereby standards and requirements are available openly so that European companies will have a better understanding of what is needed in order to offer goods and services that meet or exceed the safety measures in the Japanese market.

The BRT, however, recognises the latest development and positively views the first call for tender that was recently published. 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 GOJ did not address this issue in the progress report from April 2013.

#### < Background >

*The combined Japan Railways companies run on more than two-thirds of the railways, whereas the remaining one-third is controlled by more than 80 private carriers. This means that JR testing and acceptance standards serve as de-facto requirements for railway equipment to be exported to Japan. Unfortunately applied standards and requirements have not been openly published leading to a lack of information on exactly what 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 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 Specifications”, which stipulates definitive, interpretative standards with indication of precise figures, in a manner consistent with the above “Technical Standards”. These standards are published in English at the following websites.

(Technical

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 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) The GOJ has been informed that Japanese railways operators generally seek safe and reliable products and that, in fact, they have proactively procured such qualified and conforming products from the EU.

#### Future outlook

Japan and the EU are currently discussing with respect to further opening of mutual market access opportunities with regards to the railways sector, and it is the expectation of the GOJ that Japan and the EU will continue holding constructive discussions going forward.

Furthermore, the GOJ intends to promote cooperation in the field of standardization activities as well as to foster dialogues between Japanese and the EU railways-related experts and industries with a view to deepening their mutual understandings.

#### (4) Medical Devices/Equipment

##### BRT Recommendation

The GOJ 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 >

While there is still a need for improvements, some progress has been made.

##### < 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 GOJ 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 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 is performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial is conducted in accordance with the standards or considered to have equivalent level of quality.

For the purpose of reducing the industry's burden and promoting the efficiency of inspection, through the solution of a few specific non-tariff issues (called "Paragraph 34 process"), the GOJ agreed to align Japanese QMS standard for medical devices with the international standard(ISO13485), which is applied in the EU, with some exceptions.

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 publicized the Action Program for Acceleration of Medical Device Review in December 2008. The GOJ is making efforts to steadily implement the Action Program in cooperation with concerned industrial sector.

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

The revision of the Pharmaceutical Affairs Law including newly-revised QMS audit system has been approved at the extraordinary Diet session in November and will become effective in 2014.

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

## (5) Veterinary Products

### BRT Recommendation

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

- a) Urges the GOJ to take all measures available to speed up product approvals 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 MAFF presented to the Japan Veterinary Products Association a list of 10 action items for change. These items are welcomed by the industry but still fall far short of the definitions of harmonisation described above. In addition, timelines are not yet available for implementation of these items, nor has MAFF made clear the extent of further collaboration with industry to establish the details of such changes.

### < Background >

*While Japan participates in the VICH, the implementation of international and harmonized 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

Japan has been actively participating in the International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) and approximately 50 guidelines have been created so far. Japan has been deeply committed to the creation process and duly implemented these guidelines in Japan, resulting in reducing unnecessary duplications of animal tests used as application data in the technical dossier. In addition, Japan is actively harmonizing national regulation on veterinary medicinal products (VMP) to the international practice, e.g., seed lot system has been incorporated in its regulation for veterinary vaccine since 2008. Moreover, of 10 action items for change which MAFF presented to the Japan Veterinary Products Association in December 2012, Japan has already put 3 action items into practice. For instance, since October 2013, applicants of VMPs have been able to submit the approval of their products, although there are exceptions, with technical dossiers containing data on clinical trials conducted in accordance with VICH guidelines (Good Clinical Practice (GCP) of the EU, the US and Australia). This is the first practice for Japan to accept the application with only the clinical trials in foreign countries among Japan, the EU and the US.

Japan published a guidance for the preparation of Summary Technical Documents (STD) to provide applicants with useful advice on the preparation. Japanese translation of Technical Documents for general pharmaceutical products is exempted, given the STD is well-organized. Furthermore, since October 2012, Japan has extended this procedure to veterinary biologicals and antimicrobial products.

#### Future outlook

Regarding VICH activity, approximately 20 guidelines are now under consideration and they will further reduce repetitive studies. Japan tackles the remaining 7 action items of the MAFF presented 10 action items for change in December 2012.

International standards for the approval of veterinary medicinal products have not been established yet and substantial differences in the approval standards remain among Japan, the EU and the United States. In the development of international standards for approval, dialogues among three VICH regions, including the U.S., are essential. In particular, approval concepts on biotechnology based products including regenerative medicine products and/or chemical products for food producing animals are quite different among the regions. The three regions should consider launching further cooperation to establish an international approval criteria based on science to mutually accept such products accordingly.

There is a need for Japan to introduce from the EU in-vitro veterinary diagnostics for infectious diseases to fill the shortage of such products in Japan. On the other hand, it takes us time to review and approve the products from the EU, because the efficacies and qualities of products marketed in the EU are not officially evaluated due to the lack of approval system for veterinary diagnostics in the EU. Japan recommends that the EU industry adopt the Japan's established approval criteria and control system for veterinary diagnostics on a voluntary basis, and then, ask the EU government to implement them in the region, in order not only to accelerate Japan's approval procedure for EU products, but also to improve the quality of the veterinary diagnostic products marketed in the EU.

Japan recognizes that it is important to mutually understand the approval system of each authority to promptly review the dossiers of VMPs already approved in each country. Japan believes that it is a good start for both sides to explore a possibility of launching an exchange program of officials in charge of approval for VMPs between the EU and Japan. Japan requires VMPs approved and distributed in Japan to comply with the Japanese GMP to ensure that products are consistently produced and controlled under the quality standards appropriate to their intended use and as required by the marketing authorization. The requirements of Japanese GMP for the manufactures of VMPs are not more burdensome than those of EU GMP. Consequently, we conclude that the mutual recognition of GMP is not a problem in acquiring Japanese approval for veterinary medical products already approved in the EU.

## (6) Processed Food

### BRT Recommendation

For processed food, the combination of differences between EU and Japanese standards and technical requirements as well as cumbersome border procedures results in high costs for EU exporters. High conformity costs are incurred because Japanese authorities do not accept evaluations made by the EU or international bodies, and the FSC is constantly asking for tests to be carried out in Japan. The market potential for European exporters would be greatly enhanced by:

- a) Substantially increasing the list of permitted additives, 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.

### < Recent progress >

There has been no concrete progress

### < 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

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 for 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.

MHLW has made the utmost efforts to streamline the designation process for food additives, which is a big concern of the EU. Specifically, MHLW has facilitated communication with the Food Safety Commission (FSC), a risk assessment body, made efficient clerical work needed before safety assessments are requested to FSC, and cooperated with FSC so that assessment can be carried out in a more speedy manner.

As for sunflower lecithin, which is one of EU industries' concerns, the assessment by FSC has been completed and MHLW is proceeding with formalities for designation.

Since 2002, the GOJ, on its own initiative, has been proceeding with discussions towards the designation concerning the 45 food additives (excluding flavorings), including substances requested by the EU, whose safety has been confirmed internationally and are widely used.

In September 2012, the GOJ drew up 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 FSC.

Subsequently, seven substances have been designated by December 2013. As for two of the remaining eight, polyvinylpyrrolidone and  $\beta$ -apo-8'-carotenal, the assessments by FSC have been completed and MHLW is proceeding with formalities for designation. The other six substances are under discussion of the Experts Committee of FSC. Four substances of the six are, however, aluminum-containing additives and the GOJ recognizes that the EU also restricts the use of them.

#### Future outlook

The two substances for which MHLW is proceeding with formalities for designation, namely polyvinylpyrrolidone, and  $\beta$ -apo-8'-carotenal, and sunflower lecithin are under review by the Pharmaceutical Affairs and Food Sanitation Council and MHLW will soon take the necessary procedures, including the invitation of public comment, for these substances. As for the remaining six substances, which are under discussion of the Experts Committee of FSC, MHLW will initiate formalities for designation as soon as assessment is completed. MHLW will continue the swift designation process that has been carried out until now.

In 2002 MHLW listed the 45 substances with the intent to designate them. At that time, these substances were already proven safe by JECFA and being widely used as food additives in many countries including the EU member states and the United States. MHLW took the opinions of many countries including 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 US, do.



## (7) 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 >

This is a new issue.

### < 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 Appliance and Material Safety Law has two technical requirements the Japanese original technical requirements (Section1 requirements) and the requirements harmonized with the standards stipulated by IEC (Section2 requirements). Manufactures and Importers in Japan shall comply with either (Section1 requirements) or (Section2 requirements).

LED lamps were designated as items subject to regulation for the Electrical Appliance and Material Safety Law in 2011 and technical requirements were determined. Among the LED lamps which were subject to regulation, Bulb type LED lamp's Technical requirements were developed based on JIS C8156:2011 that was harmonious with IEC / FDIS 62560:2000 and Section1 requirements the incandescent light bulb. As for the LED lighting equipments, technical requirements were developed based on JIS C8156:2011 and the household type hanging fluorescent lamp apparatus's requirements in Section1 requirements, because there was no appropriate IEC standard for them. However, the straight-tube-type LED lamp is not yet designated as Electrical Appliances and Materials in the Electrical Appliance and Material Safety Law.

As for Section2 requirements which are consistent with the IEC standard, J61347-2-13 (H21) lamp controller - Part 2-13: Particular requirements for DC or AC power supply for LED module controller (harmonized with JIS C 8147-2-13:2008, IEC 61347-2-13 (2006)), J60598-2-12 (H23) Part 2-12:Safety requirements for electrical outlet mounting night-light(harmonized with JIS C 8105-2-12:2009, IEC 60598-2-12(2006)), J60598-2-13 (H23) Part 2-13: Safety requirements on the ground embedded luminaires (harmonized with JIS C 8105-2-13:2009, IEC 60598-2-13(2006)) can fulfill the technical requirements in Japan .

There is no international standard (ISO, IEC) for the remote control devises for LED lamps and luminaries. Therefore, it is defined in Section1 requirements of Electrical Appliance and Material Safety Law in Japan.

#### Future outlook

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

## (8) Labelling rules

### BRT Recommendation

The GOJ should issue clarifying orders to provide retailers with flexible alternatives for providing Japanese consumers with globally sourced products while taking full responsibility for the quality and safety of the products. A simple example of an inflexible labelling rule that has substantial labelling cost implications for European companies is that the dimensions of furniture must be expressed in millimetres and not centimetres, although use of the latter is common practice in other countries using the metric system.

### < Recent progress >

The Consumer Affairs Agency will during 2013 look into the Household Labelling Law. However, so far, nothing concrete has been presented. 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 Law currently cover a total of 90 goods in the following categories: Textile Goods, Electrical Appliances, Plastic Manufactured Goods, and Miscellaneous Manufactured Goods. The rules stipulate the minimum information which must be carried on labels to provide useful information to consumers, and also demand compliance with these minimum requirements for each designated goods. In 1997 labeling methods for all goods were revised to provide more flexibility in terms of the fonts used and the methods of presentation of guidelines concerning use. And also, in 2010, we researched consumers and business operators, including overseas Japanese juridical person, about their evaluation of the Household Goods Quality Labeling Law and their requests, and also researched labeling system in other countries. In 2012, we summarized the study results to review the subject products and the content of labeling as necessary with reference to the 2010 survey results. Since then, we have conducted appropriate sequential reviews of required labeling content with reference to the 2012 study results and the diversified and complex circumstances of products.

### Future outlook

In the context of growing importance of consumer protection as well as diversification, complexity and globalization of products, the importance of the labeling stipulated by the Household Goods Quality Labeling Law is also increasing. Therefore, with reference to the 2012 study results we will continue to review the subject products and the content of labeling as necessary. We will also continue to facilitate understanding of the Household Goods Quality Labeling Law among business operators including overseas business operators by publishing information on the web and other media.

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

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

#### BRT Recommendation

The BRT urges the GOJ to tackle the lack of free and open competition in Japan's services markets. In particular, the Government should:

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

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, but rather backward movement.

#### < 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

Since we introduced firewall regulations between banking and securities businesses in 1993, we have reviewed the regulations in keeping with the actual business practices and eased them when we

found that the deregulation would have little negative impact in light of the purpose of the regulations.

In 2013, JFSA released the proposal for the revision of a Cabinet Office Ordinance and the relevant supervisory guideline, in response to the requests for the further relaxation of the firewall regulations.

This proposal for revision includes the following points:

1. Non-public information of another party, an issuer for instance, can be shared with a parent company and subsidiaries without the issuer's written consent if the information is used for the business management and settlement operations, on condition that the appropriate measures are taken to prevent information leakage; and
2. Requirements for acquiring a written consent from an issuer are relaxed in case that the issuer is a foreign corporation.

The JFSA issued this proposal for revision for public comments from November 15, 2013 to December 16, 2013.

#### Future outlook

Taking into account the public comments received, the JFSA will amend the related Cabinet Office Ordinance and others.

## (2) Japan Post

### BRT Recommendation

The BRT urges the GOJ to tackle the lack of free and open competition in Japan's services markets. In particular, the Government should:

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

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:

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- 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, but rather backward movement.

### < 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

(a) 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 the regulations as other life insurance companies, which ensures the consistency with international obligations such as WTO agreements. In addition to the Insurance Business Act, etc., the regulations under the Postal Services Privatization

Act apply to JPI as “add-on regulations” in the course of privatization.

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

The application for renewal of education endowment insurance product filed by JPI on September 3rd, 2012, was approved by 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 30th of that year. On January 24th, 2014, it was confirmed by MIC and FSA that the conditions were fulfilled. At the same time, the application was approved by FSA based on the Insurance Business Act.

The *kyosai* cooperative societies are mutual-aid organisations 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 organisation provides. These services form part of a broad range of mutual-aid services available to the members (joint ventures, loans, welfare services, etc.). Because of their unique nature they need to be regulated separately, and each of them operates within the scope of the laws and under the supervision of the relevant government authorities. It would therefore be inappropriate to apply the Insurance Business Act, which governs private-sector insurance companies, to *kyosai* cooperative societies.

(b) 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 services 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. We 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**

(a)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.

NA.

(b)NA.



## 6. Government procurement (WP-A/#14/E to J)

### BRT Recommendation

#### < General Recommendations >

The GOJ should increase its efforts to facilitate better access to the public 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 ten cities are included<sup>1</sup>.

#### < Background >

*Studies have shown that over 80% of the total government procurement market in Japan is not covered by the GPA.<sup>2</sup> Currently some sectors are exempted from the threshold of 5 million SDR. Government Procurement was included in the so-called paragraph 34 discussions, where Japan promised to set up a data base where all tenders, national and regional would be posted. However, significant improvements are required to bring Japanese public procurement closer to the levels of the EU.*

#### < 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.

#### < Background >

- a. *Although cheaper is not necessarily better, almost all Japanese government tenders still have an evaluation system merely based on price competition.*
  - b. *Procurement by some governmental agencies (such as fire fighting and disaster relief) is still tied to this constraint. In some cases the time between the bid award and the requested delivery is less than six months, which is much too short for helicopter manufacturing, considering also the hurdles of local certification upon import. This condition has been relaxed in the past few years (for police procurement for instance).*
- Procurement of integrated systems of space ground equipment should be encouraged

#### < Recent progress >

There has been little progress.

#### < Background >

*Japan's international procurement of space ground equipment is often broken up in small lots tailored for Japanese companies. Integrated systems have better cost performance and are more reliable.*

*It should, however, be mentioned that a call for tenders was published for the railway sector during 2012, the first ever case of its kind.*

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<sup>1</sup> Comment by the GOJ: 19 Cities were included at the revised GPA conclusion as of March 2012.

<sup>2</sup> Copenhagen Economics, “Assessment of barriers to trade and investment between the EU and Japan”, 2009

#### Action taken so far

##### (Threshold in GPA)

Japan has adopted voluntary thresholds (100,000 SDRs) in GPA, lower than the binding threshold in GPA (130,000 SDRs), for the procurements of goods and services (except construction service and engineering services) of the Annex 1 entities of Japan, thus has been conducting open tendering for procurements of wider goods and services than those bound by GPA .

As a result of the re-negotiation of GPA which was concluded in March 2012, Japan reduced these thresholds in the revised GPA to 100,000 SDRs. And hereafter, Japan will conduct open tendering for the procurements of goods and services above these new thresholds under the revised GPA. These thresholds are the lowest among all the GPA Parties' thresholds.

##### (Operational safety clause)

In the view of the GOJ, the “operational safety clause” of the WTO Government Procurement Agreement applies to the following five categories.

- 1) Supplies forming railway facilities
- 2) Rolling stocks and supplies for rolling stocks
- 3) Supplies and equipments 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

#### Future outlook

##### (Threshold in GPA)

After adopting the revised Agreement in March 2012, the GOJ has been taking necessary procedures to accept the revised GPA. Japan will continue to conduct procurements in accordance with the Agreement.

##### (Operational safety clause)

With a view to further presenting mutual market access opportunities, discussions are currently being held with respect to railways-related issues that are relevant to both Japan and the EU, including such request from the EU in connection with the operational safety clause as indicated in the above BRT recommendations. It is the GOJ's expectation that Japan and the EU will continue holding constructive discussions going forward.

Furthermore, the GOJ intends to provide opportunities for dialogues between railway operators and suppliers of Japan and the EU, with a view to deepening their mutual understandings.

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

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

#### **BRT Recommendation**

The regulatory harmonization and further extension of “Mutual Recognition Agreement” should be proceeded in order to avoid redundant inspections of manufacturing facilities. In addition to oral dosage forms, API, Sterile and Bio products are being requested to apply to the MRA. The new initiative of PIC/S> PIC/S stands for "Pharmaceutical Inspection Convention” and “Pharmaceutical Inspection Co-operation Scheme”, it jointly refers to PIC/S". A PIC/S guideline enforces the harmonization of inspections among PIC/S countries. This is an agenda point for the European industry (30 countries), EFPIA, the Japanese industry, JPMA, and PMDA.

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

Some progress has been seen for this recommendation in that MHLW applied for PIC/S in March 2012. A practical evaluation is planned to start in spring 2013 by PIC/S organization and it is anticipated that Japan’s PIC/S application will be approved within the next three years.

#### **<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 to 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 and expansion of MRA.*

#### **<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*
- *Sharing knowledge and information of inspections by each regulatory authority through PIC/S*

##### **Mutual Recognition Agreement:**

- *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*

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

Regarding safety measures of pharmaceuticals, the GOJ has been proceeding 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, 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 after the expert considering the comments from the industry including the EFPIA.

MHLW, PMDA and Prefectures applied for membership of PIC/S in March 9, 2012.

The GOJ has been discussing MRA with the EU during the negotiations on the Japan-EU Economic Partnership Agreement and other occasions.

#### Future outlook

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

With regard to PIC/S, the GOJ will respond adequately to the review for accession approval and endeavor to ensure further international harmonization of the Japanese GMP regulations with reference to PIC/S GMP guideline and others.

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

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

### BRT Recommendation

Improve mutual recognition of Quality Management System (QMS) audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical 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 obliged to keep the additional Japanese requirements.

### <Recent Progress>

Some progress has been seen for this recommendation.

### <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

For the purpose of reducing the industry's burden and promoting the efficiency of inspection, through the solution of a few specific non-tariff issues (called "Paragraph 34 process"), the GOJ agreed to align Japanese QMS standard for medical devices with the international standard(ISO13485), which is applied in the EU with some exceptions.

### Future outlook

The revision of the Pharmaceutical Affairs Law including the newly-revised QMS audit system was approved at the extraordinary Diet session in November and will become effective in 2014.

The GOJ continues to discuss the global harmonization of (QMS) regulation which is necessary for the mutual recognition of QMS audit with not only between Japan and the EU, but also jointly with the U.S. and other countries 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/#05/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 with taking the difference of classification of medical device 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 Europeenne (CE) marking of class II medical device in the EU but reviewed by NBs in Japan.

#### <Recent Progress>

No progress and no dialogue have been seen for this recommendation.

#### <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 with not only between Japan and the EU, but also jointly with the U.S. and other countries. For this reason, the GOJ will continue to discuss 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/#06/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.

##### <Recent Progress>

Some progress has been seen in the area of mutual recognition of clinical trial results.

##### <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 is performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial is 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. Evaluation of innovation values for pharmaceuticals in prices (WP-B/#07/EJ to EJ)

### BRT Recommendation

The EU government should reinforce its innovation policy to member states and clarify its healthcare policy, resulting in the appropriate evaluation of the value of pharmaceuticals. In addition, MHLW should initiate the HTA (Health Technology Assessment) dialogue among stakeholders.

### <Recent Progress>

No progress has been seen for this recommendation.

### <Background>

*In the EU, innovation policy is stated by the Lisbon declaration and the G10 group report indicating the importance of innovation in pharmaceuticals. However, each state operates its own healthcare system in different ways, resulting in gaps in survival rates and the QOL of citizens. Under the current economic recession, prices of pharmaceutical products are targeted as a major tool for medical cost containment. BRT members call on the EU and Japan to clarify its healthcare policy and to discuss and totally improve healthcare situations in member states by securing appropriate healthcare budgets, preventing interference with patient access to new medicines and considering the proper utilization of healthcare technology assessment.*

### Action taken so far

With regard to HTA, the Central Social Insurance Medical Council (Chuikyo) has been discussing the possibility of introducing the measures for cost effectiveness evaluation of health technology including pharmaceutical products in Japanese Health Care Insurance System.

### Future outlook

The GOJ will continue to consider introducing the policy from the viewpoint of cost efficiency to evaluate the value of health technology in Health Care Insurance System.



## 6. Nation-wide electronic database for individual health/medical records in Japan (WP-B/#11/EJ to J)

### BRT Recommendation

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

MHLW and MIC started this initiative. One of the hurdles is that there are no single social security numbers and centralized data handling in Japan. A strong project promotion is necessary to safeguard people from potential disasters.

### <Recent Progress>

Good progress has been seen regarding the national data base; however, the establishment of the electronic database for individual health/medical records needs to be accelerated. It was planned to be submitted to the 2012’s diet. However, this initiative is on hold now. Furthermore, integration of this system and the Citizens ID numbering system should be considered in future.

### <Background>

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

### Action taken so far

The Cabinet of the GOJ adopted the new IT strategy named “Declaration to be the World’s Most Advanced IT Nation” on June 14, 2013. With respect to the healthcare field, it is stated that the policy for “systems will be created to improve and manage health and prevent disease by gaining the understanding of all members of the public about the effectiveness of using data, leading to autonomous use by the public. Sustainable structures that facilitate the acceptance with peace of mind of effective and efficient healthcare and nursing care and livelihood support services when needed will also be created.”

And a separate roadmap was also formulated defining the division of roles and the things to be achieved.

To carry out this new IT strategy steadily, an advisory body for the healthcare field was created under the IT strategic Headquarters to establish a controlling and promoting system for PDCA (Plan, Do, Check, Act) cycle.

### Future outlook

The above advisory body for the healthcare field will study the specific policies and assessment guidelines that are necessary for carrying out the strategies relating to the field, review the roadmaps,

and assess the status of measures. In so doing we will promote and control the PDCA cycle for carrying out this new IT strategy steadily.

## 7. Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing (WP-B/#12/EJ to J)

### BRT Recommendation

The premium for new drug creation and elimination of unapproved/off-label use drug (the premium for new drug creation) will be continued until March 2014. 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 include topics such as “NHI pricing for long-listed products” and “continuation vs. discontinuation of incentives for innovative drug development” it does not include “abolishment of market expansion re-pricing”. We urge to abolish the re-pricing rule by market expansion, which is contrary to the policy of evaluating pharmaceutical innovation.

### <Recent Progress>

Some progress has been seen for this recommendation, however, the new drug pricing system should be implemented firmly and permanently (not only a 2-year trial). On the other hand, 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 2014. 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. However, in the draft for FY2012 drug pricing system reform, the premium for new drug creation was determined to continue operation as a trial basis. Therefore, 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 FY2014 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 2014 in the drug system reform in 2012.

The Chuikyo will decide the continuation of the premium for new drug creation after April 2014 in the next drug pricing system reform by reviewing the following factors:

- (a) Financial impact of the premium,
- (b) Development and launch of unapproved / off-label use drugs,
- (c) Development of drugs which truly contribute to improvement in quality of medical care in Japan, and
- (d) Utilization of generic drugs.

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 2012.

#### 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.

## 8. Appropriate assessment of innovative values of medical devices in prices (WP-B/#15/EJ to J)

### BRT Recommendation

Promote sub-dividing the current functional classification, enhance the premiums for C1 or C2 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>

Insufficient progress has been seen for this recommendation.

### <Background>

*Different from pharmaceutical brand-oriented pricing systems, about 300,000 medical devices are classified into about 700 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 2012 price revisions, the government's efforts to progress forward the assessment of innovative values can be seen, such as implementation of the device lag reduction premium and expansion of the improvement premium. However, further government's efforts are still required.*

### 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.

### Future outlook

For the medical fee revision in FY2014, 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.

9. Acceleration and dissemination of scientific knowledge on GMOs by both the governments and the private sector (WP-B/#16/EJ to EJ)

#### BRT Recommendation

The Governments and the private sector of Japan and the EU 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>

This is a new 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 two aspects of expectation and concern regarding the of recombinant DNA technologies among people, the GOJ strives to provide people with scientific and objective information so as to gain their understanding.

#### Future outlook

The GOJ continues current approaches.

10. Support research in Plant Protection & specifically Biotechnology (WP-B/#17/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 biotechnology, considerable money is spent on plant molecular biological research but the budget is recently decreasing and no GM products are developed in Japan. 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 agriculture products, 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, genomic selection and so-called NPBTs. The DNA markers to be developed by this project include those related to characteristics such as pest/disease resistances of crops and health-related constituents of horticulture crops. The research institutes 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 government, universities and private companies.

**Future outlook**

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

## 11. Regulatory harmonization for animal health products (WP-B/#18/E to EJ)

### 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.

### <Recent Progress>

Some progress has been seen for this recommendation.

### <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, and therefore, a product which is readily available to veterinarians and animal owners in Europe cannot be used in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products.*

*An additional important aspect is the negative impact on animal welfare: since the regulatory requirements are not harmonized, the companies are required to repeat 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.*

*Japan still requires local clinical trials, which are not only scientifically unnecessary but also problematic from an animal welfare point of view, as the efficacy and safety of the products would have been proven already by trials in the EU and / or the USA. Animal breeds are largely the same worldwide in both livestock and pet animals and so is their feed. Japanese regulations do not stipulate the use of breeds particular to Japan, so there is no conceivable benefit in additional testing.*

### Action taken so far

Refer to the response to WP-A / # 07 / E to J, above.

### Future outlook

Refer to the response to WP-A / # 07 / E to J, above.



## 12. Mutual recognition of GMP and marketing authorization for animal health products (WP-B/#19/E to EJ)

### BRT Recommendation

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 as described in #25. 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 manufacture of veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative work.*

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

### Action taken so far

Refer to the response to WP-A / # 07 / E to J, above.

### Future outlook

Refer to the response to WP-A / # 07 / E to J, above.

### 13. Responsible use of antibiotics in animal health (WP-B/#20/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. However, no activities by MAFF are known or have been seen over the last 12 months in this regard.

#### <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 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.*

#### Action taken so far

The monitoring systems for antimicrobial resistance and use of antimicrobial agent which are encouraged internationally have been conducted in Japan. Risk management measures to ensure responsible and prudent use have been implemented in correspondence to risk assessment based on sound science. MAFF developed procedures on formulating risk management measures concerning veterinary antimicrobial drugs and antimicrobial feed additives in 2012 and 2013, respectively. In accordance with the procedures, risk management measures of eleven antimicrobial agents have been decided based on the results of risk assessment in the last 12 months (Dec. 2012 – Nov. 2013). Therefore the comment that “no activities by MAFF are known or have been seen over the last 12 months” is not correct.

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

#### Future outlook

In order to collect appropriate data, the current monitoring system of antimicrobial resistance will be revised to be more practically effective. Relevant risk management measures for responsible and prudent use will be continuously developed based on the risk assessment. Furthermore a guidance document for veterinarians and farmers on responsible and prudent use is going to be issued in the near future.

14. Requirement of Japanese version of the clinical trial protocol and investigators brochure (WP-B/#22/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.

<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 aren't required to be translated into Japanese and documents in English can 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 used as important information by clinical trial sites (doctors, nurses and other medical professionals) and trial subjects. Considering this situation, the current amount of documents or materials to be submitted in Japanese should be maintained.

15. Shorten or eliminate national tests for hemophilia-derived products and vaccines (WP-B/#23/E to J)

#### BRT Recommendation

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

#### <Recent Progress>

Some progress has been seen for this recommendation.

#### <Background>

*For a long time, there have been no critical quality issues in Albumins or Immunoglobulins. In addition, production is done according to GMP and PMDA periodical audits of production sites. 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 imported haemophilia-derived products and 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 plasma-derived products or 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. We recognize that the EU also has a similar system to this.

Although BRT recommendation says that “concerning the national test results which are published by MOU (memorandum of understanding), manufacturing countries should be accepted by the Japanese authority”, it is not true that the results of lot release has been published by MOU. As a matter of fact, we do not acknowledge what the recommendation says.

#### Future outlook

The GOJ continuously attempts to operate the lot release system properly, concerning plasma-derived products and vaccines.

## 16. Shortening review times for animal health products (WP-B/#24/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.

### <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 to be completed. Hence, delaying the access of animal owners and animals to innovative animal health products.*

### Action taken so far

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

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

### Future outlook

With close cooperation among MAFF, FSC, and MHLW, we will continuously consider the followings in order to improve efficiency:

- Application of provisions, for instance the case in which the FSC assessment is unnecessary
- Measures for implementing concurrently each procedure of the three bodies to the extent possible.

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

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

### **1. Economic growth by ICT utilisation (WP-C/#01/EJ to EJ)**

#### **BRT Recommendation**

The BRT requests the GOJ to synchronize action plans under its Growth and ICT strategies reviewed by the new administration, aiming for economic growth by ICT utilization. Further ICT deployment is required in e-Government, healthcare, education, security, disaster mitigation, agriculture, logistics, etc.

On the EU side, the BRT requests steady implementation of the European Commission's IT strategy "Digital Agenda" action items.

Both the EU and Japanese Authorities should create conditions to facilitate the development of internet, web, mobile and cloud environments that openly share public 'big data' collections (such as geographical information systems) and expose interfaces to them, to allow the growth of independent and free markets of third party products and services using these public environments and their data in the areas listed above..

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

In July 2012 the GOJ made a second revision of its June 2010 Roadmaps. In December 2012 the EU commission released priority actions to be executed for 2013-2014.

#### **< Background >**

*The ICT industry creates many jobs as a major industry in both regions and plays a major role in industrial competitiveness by supporting other industries. The Digital Agenda IT strategy published in May 2010 is positioned as a pillar of the EU growth strategy. The GOJ is considering growth and ICT strategies under a new administration.*

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

To be an IT Utilization Society at the World's Highest Levels, the Cabinet of the GOJ adopted "Declaration to be the World's Most Advanced IT Nation" in June 2013. The declaration is linked to the policies in 'Japan Revitalization Strategy'.

In addition, a specialized investigation body has been created under the IT Strategic Headquarters and subcommittees have been formed under the specialized investigation body for priority fields such as electronic government, healthcare and health, and human resource development to serve as the implementing and managing body for the PDCA cycle of this Strategy.

With regard to public data, a roadmap was adopted to promote private sector's access to public data owned by the government (open data).

In addition, a trial version of data catalogue site was established which guides users and enables cross-sectional data searching through public data released by ministries.

### Future outlook

To ensure realizing “Declaration to be the World’s Most Advanced IT Nation”, progress management will be consulted and conducted in the specialized investigation body and the subcommittees.

With regard to public data, the data catalog site will be launched with full-scale operation. To encourage the use of public data, active measures by various means such as the use of contests will be taken to identify and encourage needs of use, to develop and spread models of use, and to support the improvement of highly-skilled human resources that can use data in order to support the creation of new businesses and new services.

## 2. Cooperation for trade liberalization on ICT services (WP-C/#03/EJ to EJ)

### BRT Recommendation

The BRT requests that both authorities intensively work on the trade liberalization of services over the internet with the purpose of promoting the international flow of information and the abolishment of compulsory requirement of local facilities and subsidiary for provisioning of services. This includes rule making through the WTO's new international agreement on services and bilateral trade agreements.

### < Recent Progress >

The EU and The United states released a set of trade principles for information and communication technology services on 4<sup>th</sup> of Apr. 2011. Japan and the United States published similar ICT service trade principles on 25<sup>th</sup> of Jan, 2012. The EU and Japan share basic principles on ICT services.

### < Background >

*As the ICT service sector evolves rapidly compared to other sectors, global trading rules and regulations do not sufficiently reflect and match the current landscape of this high-growth-potential ICT service sector.*

### Action taken so far

In order to support the overseas expansion of Japanese business in the rapidly growing ICT services sector, it is indispensable for the GOJ to improve the business environment by ensuring regulatory transparency in each country, preserving open networks, and ensuring cross-border free flow of information and so on.

On January 27, 2012, the GOJ developed trade principles for ICT services with the United States. And also, the GOJ is making efforts to encourage other countries to adopt these principles.

In particular, the GOJ actively carries out activities such as proposal of rules for ICT in the negotiations of TiSA (Trade in Services Agreement), which started this year. Also, we engaged in the negotiations of the Japan-EU EPA/FTA for the liberalization of ICT services.

### Future outlook

We will continuously negotiate in TiSA negotiations and others while encouraging other countries to adopt these principles.



### 3. ITA expansion (WP-C/#04/EJ to EJ) conclusion

#### BRT Recommendation

The BRT requests that both sides' Authorities endeavour to reach an early, successful to the current negotiations to expand the ITA. The broadest possible expansion of the product scope of the Agreement to including large portions of Chapters 84, 85 and 90 will ensure that additional categories of electronics goods can be traded duty free and minimize the risk of current and future innovative technological developments giving rise to product classification uncertainties.

- (1) The EU should urgently complete its implementation of the WTO panel in the ITA dispute without further delay to avoid new convergence technology ITA products being reclassified as dutiable.
- (2) The geographical coverage of the ITA should be expanded by encouraging more countries to join the ITA. Membership should be promoted as a means of boosting efficiency and productivity, improving the investment climate, helping bridge the digital divide, and enabling the move to a more energy-efficient and climate-friendly society.
- (3) Compulsory review mechanisms are needed to ensure the ITA is always kept up to date so that it will reflect technological developments.

#### < Recent Progress >

Both sides' Authorities have made sizeable progress on this Recommendation.

#### < Background >

*By extending duty-free status based on the ITA, Japan and Europe will benefit from the development of a major industrial sector that is a driver of productivity, innovation, job creation, improved competitiveness and service quality in virtually all other sectors and in public services.*

*An ITA expansion would boost trade in the whole electronics sector, remove uncertainties relating to product classification and would ensure technological developments in the sector are more likely to be reflected as newly-developed products are more likely to fall in these chapters.*

*The BRT applauds the launch of the WTO/ITA expansion negotiations and welcomes the ongoing work in Geneva. The BRT especially welcomed APEC's reaffirmation, on 8-9 September 2012 in Vladivostok, Russia, of its support for the WTO/ITA expansion of product coverage and membership and applauds the call to action at the meeting by the leaders of the 21 APEC economies urging APEC economies to work in earnest in order to swiftly achieve a good outcome of the negotiation .*

#### Action taken so far

As for the WTO dispute settlement case regarding the ITA, the EU ministerial council adopted a new regulation which stipulates duty free treatment of flat panel displays in September, 2013.

As regards the ITA expansion negotiation, 15 negotiation sessions have taken place in Geneva since the launch of the negotiation in May 2012 (roughly one negotiation session per month). The membership has increased to 55, and the negotiation is now at an advanced stage where a draft final list is being discussed. However, due to China's persistence on its long sensitive list during the negotiation sessions in November 2013, a swift conclusion before MC9 (the 9<sup>th</sup> WTO Ministerial Conference) was not realised.

#### Future outlook

As for the WTO dispute settlement case regarding the ITA, the GOJ keeps a close watch on the appropriate implementation of EU's new regulation.

As regards ITA expansion negotiation, the negotiation is important for the international economy and the GOJ aims at its early conclusion in collaboration with the EU and the industries, asking China a positive stance. And also, the GOJ will work for the expansion of the membership of the ITA.

#### 4. Building trusted and safe online environment (WP-C/#05/EJ to EJ)

##### BRT Recommendation

The BRT welcomes that both authorities organized a Japan-EU Internet security forum and requests continued discussion on this matter.

- (1) Both authorities should establish an information sharing / exchange mechanism between the EU and Japan for cyber security
  - 1) Study on cyber-attack information sharing within closed organizations and companies.
  - 2) Study on reporting procedure for cyber-attack disclosure from companies to government (even if the personal data is included in the disclosure, companies can be exempted from legal responsibility on personal data protection.)
- (2) Study on mechanism for joint training such as simulation exercises involving both forces against cyber attack
- (3) Construction of a safety network including government and defence industries.
- (4) Conduct of technology development for prediction and immediate responses against cyber-attack

##### < Recent Progress >

The European Commission released a EU Cyber security strategy and directive on Network and Information Security in Feb. 2013. The EU and Japan confirmed that international cooperation is important for ensuring internet security at the Japan-EU Internet security forum held in Nov. 2012. In Oct, 2012, at Cyber Europe 2012, a demonstration exercise was organized with participation of major financial institutions, telecom operators, internet service providers and central and local governments. A Convention on Cybercrime became effective in Japan from Nov. 2012.

##### < Background >

*Cyber-attacks against governments and companies are increasing recently. In this highly connected digital world, threats comes from anywhere in the world. Especially organised attack and interference targeting certain entities is a beyond control of one enterprise therefore to address this serious issue, it needs close cooperation with public and private sectors.*

*Enhancing trust on the internet environment among societies and businesses is a fundamental pillar for creation of ICT enabled new services and business models, which will lead economic growth and job creation.*

##### Action taken so far

The Information Security Policy Council (ISPC) in Japan, which is chaired by the Chief Cabinet Secretary, formulated the “Cybersecurity Strategy” as a new basic strategy covering the three years to fiscal 2015 in June. In addition, “International Strategy on Cybersecurity Cooperation” was endorsed at the October meeting of the ISPC.

The EU and Japan held the EU-Japan ICT Security Workshop in Brussels in December 2013, as the second meeting of the EU-Japan Internet Security Forum the first meeting of which was held in Tokyo in November 2012. Both authorities continue the cooperation with discussing each

cybersecurity strategy and sharing good practices etc. regarding cybersecurity.

At the Japan-EU Summit held in November 2013, summit leaders decided to bring together their experts to explore the possibility of launching a regular dialogue in the area of cybersecurity.

#### Future outlook

Japan will make efforts toward constructing a safe cyberspace based on "Cyber Security Strategy" (Information Security Policy Council (ISPC, June 2013), and "International Strategy on Cybersecurity Cooperation—j-initiative for Cybersecurity—" (ISPC, October 2013).

Both Japan and the EU will continue to consider measures for strengthening cooperation in the area of cybersecurity including holding relevant meetings.

5. Balanced approach of personal data protection and innovation in the cloud computing era (WP-C/#07/EJ to EJ)

BRT Recommendation

Both the EU and Japan are in the process of modifying their respective personal data protection regimes. The BRT is concerned that the EU and Japan would pursue their own ways without due consideration to the international aspects of personal data protection and, in particular, the streamlining of the regimes between the EU and Japan.

(1) The BRT suggests that, to realise streamlined personal data protection regimes between the EU and Japan, the two authorities should consult closely with each other through such dialogues as the FTA/EPA negotiation and with businesses in the process of revising their respective regimes so that the two regimes should not become more diverse or too costly for businesses.

Concerning the EU's proposal for a Regulation of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data and on the free movement of such data (General Data Protection Regulation);

(2) The BRT would welcome the envisaged facilitation of BCRs in Article 43 of the proposal as BCRs could become a key tool for those businesses with the possibility of global data transfers such as cloud computing. The BRT suggests that adherence to and compliance with recognised certification schemes in and/or outside the EU and mutual recognition among them should be taken into account in their approval process to further facilitate BCRs. The utility of BCRs could be enhanced further by expanding their applicability across groups of companies with valid BCRs (not just within the same group).

(3) The BRT is concerned about its extraterritorial applicability according to Article 3, point 2 and requests the authorities of the EU to spell out precise conditions for exclusion from its territorial scope.

(4) The BRT suggests that the transfer of the employee data of a subsidiary located in the EU to the parent company in a third country should be explicitly stated as permissible in Article 44 1 (a) the consent of the data subject or (b) for the performance of a contract between the data subject and the controller.

(5) The BRT is concerned that the maximum fines stipulated in Article 79 of the proposal are set too high for enterprises and that it could unduly deter business activities. Fines should be not only proportionate but also equitable. Part of the collected fines should be used for countermeasures to improve and expand cyber security.

(6) The BRT is concerned about the obligation to notify personal data breaches within 24 hours. The notification deadlines should be flexible (ideally the Regulation should provide that the notification must take place without undue delay) so as to reflect the different degrees of complexity in identifying the nature and scope of the breaches in question.

The BRT believes that the recognition of the adequate level of protection in Japan by the EU

would further promote the business activities across the two regions.

- (7) The authorities of Japan should make sure to build on the report of July 2011 of the Special Commission about Personal Information Protection established in the Consumer Commission with a view to realising a harmonised data protection regime between the EU and Japan.
- (8) The two authorities should then launch the adequacy-finding procedure under the EU Directive as soon as feasible.
- (9) In parallel with the above process, the authorities of the EU and Japan should launch a dialogue in order to seek an international framework by enhancing cooperation with third countries and international organisations. It should eventually lead to the closer alignment of data protection regimes around the world that would enable global businesses to transfer, analyse and process personal data by complying with one regime.
- (10) In addition, the authorities of the EU and Japan should improve legal certainty surrounding the use of new technological tools such as cloud computing applications and services. The BRT believes that such improved legal certainty would support and enhance the application of new technological developments while maintaining the degree of data protection currently provided.

#### < Recent Progress >

EU released its communication “Unleashing the Potential of Cloud Computing in Europe” in Sep. 2012. In this communication, legal harmonization with international partners including Japan for promotion of cloud computing is mentioned.

#### < Background >

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

#### Action taken so far

- Cabinet Secretariat set up a study group to further promote the utilization of personal data. The study group formulated the institutional review policy with a view to taking a new legal measure, including the establishment of a third-party organization.
- With regard to the Special Commission on Personal Information Protection’s report in July 2011, “Working Group on Personal Data”, of which objective is to clarify rules issued for the utilization of personal data in consideration of personal information and privacy, has been established. The group has been discussing topics such as a third-party organization mentioned in the report, taking advice from experts from the industry.
- With regard to the recommendation on launching a dialogue in order to seek an international framework by enhancing cooperation with third countries and international organizations in May

2013, the Liaison Meeting of the Concerned Government Ministries has decided to participate in the APEC Cross-Border Privacy Rules (“CBPR”) system which authenticates the compatibility to the principles of APEC PRIVACY FRAMEWORK.

- The Ministry of Internal Affairs and Communications in Japan (MIC) released a report titled “Study Group on use and flow of personal data” in June 2013, and indicated the basic direction for promoting the use and flow of “personal data” (information about an individual) on the network, which takes into account internationally harmonized privacy protection, etc. In addition, MIC also released “Smartphone Privacy Initiative II – Ideal Third-party Verification of Applications –”(SPI II) in September 2013.
- In the 20th Japan-EU ICT Dialogue (December 2013 in Brussels), both sides adopted cloud computing as a subject, and shared information regarding the efforts related to cloud computing. In addition, the GOJ presented the above-mentioned SPI II in this dialogue. Both authorities also exchanged views and shared information on policy trends, such as their actions for user information of Smartphones.
- The Ministry of Economy, Trade and Industry (METI) published in May 2013 'IT Integration Forum Personal Data Working Group report', which proposed several actions to be taken by businesses, based on the recognition that it is most important to formulate relations of trust between consumers and businesses to drive forward the utilization of personal data.
- Based on the report, with a view to formulating trustworthy relations, METI has been studying evaluation criteria to be met by private companies to obtain consents from consumers when businesses provideservices in which they utilize personal data.
- In January 2013, METI held an APEC workshop regarding the General Data Protection Regulation of the European Parliament and of the Council, inviting the officials from the Directorate-General for Justice of the European Commission, for the purpose of APEC Economies promoting the understanding for this regulation.

#### Future outlook

- According to the roadmap shown in the institutional review policy, Cabinet Secretariat will promote the use of personal data by specifying the conditions of utilization, considering for international coordination as well.
- The “Working Group on Personal Data” whose issues to be discussed are included in the Special Commission on Personal Information Protection report in July 2011, will formulate a policy to clarify rules for the utilization of personal data in consideration of personal information and privacy, and review the current system to take new legal measures, including the establishment of a third-party organization by the end of this year, and will start study work based on the policy after the turn of the year.
- Japan and the EU agreed at the Japan-EU ICT Dialogue in December 2013 to continue sharing information to promote cloud computing services.
- In the field of Smartphones, MIC has been making efforts towards proper handling of user information (making and publishing a privacy policy, and Third-party Verification), in cooperation with “Smartphone Privacy and Security Council (SPSC)” which related organizations and industry groups participate.
- METI will continue to study evaluation criteria to be met by private companies to obtain

consents from consumers when businesses provide services which they utilize personal data, with a view to formulating of relation of trust and standardizing of the criteria.

- Japan and the EU continue to discuss about the state of the personal data protection system including the compatibility of the legal system of Japan and the EU.



## 6. Enhanced Cooperation between the EU and Japan on 21<sup>st</sup> Century societal challenges (WP-C/#10/EJ to EJ)

### (1) Innovative solutions and implementation of flagship demo projects

#### BRT Recommendation

The BRT recommends that both sides' Authorities swiftly implement flagship demo projects and innovative solutions to common societal challenges through deregulation, easing of investment, notably for SMEs, and inviting expertise from EU and Japanese industry.

#### Action taken so far

“Japan Revitalization Strategy-JAPAN is BACK -” adopted at the Cabinet meeting in June 2013 stated as follows:

(The English summary of the Strategy is available through [http://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/en\\_saikou\\_jpn\\_hon.pdf](http://www.kantei.go.jp/jp/singi/keizaisaisei/pdf/en_saikou_jpn_hon.pdf))

- In sectors where the power of the private sector had not been sufficiently leveraged until now, or where the private sector could not start business, regulatory and institutional reform will be implemented and government enterprises will be opened up in order for Japan to become a “minimum regulation country.” This will not only promote private participation in regulated sectors and government enterprises, but attract private funds, human resources, technologies, and know-how to these sectors, so that these industries will become a new growth engine of the Japanese economy filled with motivated personnel, new technologies and provide employment opportunities.
- The government will significantly enhance innovation capability by abolishing vertically-segmented administrative system, implementing science technology policies and IT strategies with a global perspective. The government will strive for being a “minimum regulation country” through regulatory reform, through utilization of special zones and drastic improvement of competitiveness as a business hub.
- Certified experts who support SMEs in their daily operations, their concerned companies, support organizations such as professionals, SME-related organizations and regional financial institutions, as well as the government and local governments, work together in order to use, mobilize, and commercialize regional resources as brands, to accelerate the restructuring of SMEs, and to promote initiatives in the frontier areas in Japan and overseas. Additionally, the government will try to formulate “the most comprehensible” policies for SMEs from their point of views and continue to review and improve support system of SMEs such as further reduction and simplification of application forms.
- The government will improve business environment so that all companies and human resources could enjoy the benefits of the global economy and facilitate full-fledged globalization in Japan in order to attract outstanding overseas manpower and technologies to Japan and to create employment and innovation. In addition, the government will promote education and use of a big pool of global human resources and actively accept highly-skilled human resources from overseas to support unified domestic and foreign global economic activities by Japanese companies.

#### Future outlook

The GOJ will continue to take measures toward the implementation of “JAPAN Revitalization Strategy”.

## (2) Enhancement of joint R&D projects between the EU and Japan

### BRT Recommendation

The BRT recommends further enhancement of joint R&D projects between the EU and Japan. Work towards international standardisation should gain particular attention for such projects.

### Action taken so far

After the entry into force of the Agreement between the GOJ and the European Community on Cooperation in Science and Technology in March 2011, the GOJ and the EU held the First Japan-EU Joint Committee on Scientific and Technological Cooperation in Tokyo, June 2011, and the Second Joint Committee in Tokyo, June 2013. In this course, Japan and the European Commission launched joint calls in the fields of “Energy,” “Critical Raw Metals,” “Aeronautics,” and “ICT”, under the EU Seventh Framework Programme for Research and Technology Development (FP7), as well as a pilot joint call in two fields of “Resilience against Disasters” and “Efficient Energy Storage and Distribution” as a part of the CONCERT-Japan Project.

### Future outlook

In the Joint Press Statement at the 21th Japan-EU Summit held in Tokyo, November 2013, both leaders called for further efforts to promote greater collaboration as partners for research and innovation. The GOJ seeks the possibility of wider cooperation, in consideration of international standardization, including cases which could be commercialized in the future, by following up progress of the joint research which has been launched so far. In this context, the GOJ is preparing for new collaborative initiatives, such as joint calls in the field of ICT, under the Horizon2020 which will start at the beginning of 2014.

### (3) Strategic budget allocation to innovation investment

#### BRT Recommendation

The EU, Member-States and Japan should continuously allocate strategic budgets to innovation investment particularly on education in science, technology, engineering and mathematics fields, and on developing competent human resources in STI, as well as to R&D Infrastructures in national laboratories and universities. Strong ties with business should leverage this investment.

#### Action taken so far

As the formulation of the Comprehensive Strategy on Science, Technology and Innovation in June, 2013 shows, the GOJ positions and promotes STI policy as the foundation of the national strategy. The Council for Science and Technology Policy (CSTP), which is under the Cabinet Office, endorsed the “Policies for the Allocation of Resources including the S&T Budget -FY2014-” in July 2013. As the Policies indicated the GOJ will promote measures toward promoting science and technology innovation which would give impact to the economy, while putting emphasis upon “Response to the Priority Issues Facing Japan” and “Response toward creating environment suitable for science, technology and innovation”.

As for the “Response to the Priority Issues Facing Japan”, GOJ has been reinforcing measures in such a manner as to promote cross-ministerial collaboration and overlook it from basic research to implementation and commercialization, thereby promoting the prioritization of science- and technology- related budgets. More specifically, CSTP have been encouraging relevant ministries to formulate proper policy measures on the basis of “Action Plan for Science and Technology Priority Measures” (AP), and promoting establishment of budget allocation system, which will be newly established by Cross-Ministerial Strategic Innovation Promotion Program” (SIP) in which CSTP has own budget.

#### Future outlook

The GOJ will continue to initiatives to optimize budget allocation required for promoting STI policy by utilizing various tools like AP.

#### (4) Tax credits for R&D

##### BRT Recommendation

Tax credits for R&D should be expanded to encourage continued private sector investment in R&D.

##### Action taken so far

The GOJ decided to take the following two measures in the FY2013 Tax Reform:

- (1) Raise the maximum deductible amount of tax credit based on total R&D spending from the current 20% to 30% of a corporation's corporate income tax liability;
- (2) Add certain joint research to the scope of special experiments and research expenditures from April 1<sup>st</sup> in FY2013 Tax Reform:

##### Future outlook

The GOJ plans 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 FY2013 Tax Reform.

## 7. Better administrative setup of STI cooperation (WP-C/#11/EJ to EJ)

### BRT Recommendation

- (1) The commitments required of participating organisations should be well defined and not subjected to unexpected changes.
- (2) The time used to prepare calls, publish them, select the candidate organisations, evaluate their proposals and complete negotiations should be much shorter.
- (3) The procedure for preparation and launch of coordinated calls should be well discussed by both parties and standardised.
- (4) EU and Japanese Authorities should work together towards at least partially interoperable systems for the administration of programmes, for example to allow European systems to retrieve relevant data on Japanese participants from Japanese databases and vice versa.
- (5) Japan should apply the EU's National Contact Point system, subject to several improvements. The system should work both ways to allow bilateral flow of information.

### < Recent progress >

This is a new recommendation. Both sides' Authorities have made efforts towards more bilateral STI cooperation, but concrete results are too few to be of much significance towards future industrial cooperation.

### < Background >

*This Recommendation refers to the administrative effort to be made towards certain reciprocity / use by Japan and the European Commission of the EC's Framework Programme / Horizon 2020 programme for bilateral cooperation in STI, as well as Japanese programmes open to European partners (the latter chiefly affiliates of European entities in Japan). Much more EU-Japan STI cooperation is urgently needed. Since 2011 the EU and Japan have an agreement on S&T cooperation, but practical problems remain. The Japanese administration of international cooperation has little structure and many discretionary aspects. The administrative and legal constraints of EC calls, on the other hand, are inconvenient (and their criteria sometimes irrelevant) for Japanese partners that EU industry would need as key participants in important cooperation projects.*

### Action taken so far

With a view to facilitating the participation of Japanese entities to the programmes under the Horizon 2020 which will start at the beginning of 2014, the GOJ nominated a National Contact Point (NCP) for the EU Framework Programme in Japan.

### Future outlook

The GOJ will appropriate a budget necessary for the activities of the NCP, in order to support the NCP system which enables smoother flow of the information between Japan and the EU. Moreover, Japan and the EU will meet at official level to explore a way forward, in order to unlock the potential of Japan-EU science and technology cooperation and to promote greater collaboration as partners for

research and innovation.

## 8. Harmonisation of IPR regulations (WP-C/#14/EJ to EJ)

### BRT Recommendation

EU and Japanese IPR regulations should be harmonised, such as grace period for patents, etc.

#### < Recent progress >

This is a new recommendation.

#### < Background >

*In 2012, the European Parliament has voted the Unified Patent System. It has three courts of justice for mediation and arbitration (Paris, London and Munich). This is a great step forward to simplify European patent applications. However, many practical details remain to be discussed and harmonised. For instance the grace period is 0 in the EU, 6 months in Japan.*

### Action taken so far

The Tegernsee Group, which consists of the JPO, USPTO, EPO and IP offices from major European countries, held user consultations in each of the member countries in order to discuss important issues on patent system harmonization (grace period (GP), 18-month publication system for all patent applications, conflicting applications and prior user rights).

The IP5 Offices also conducted comparative studies on patent systems and relevant practices and the IP5 Patent Harmonization Experts Panel has been discussing on harmonization of patent systems and practices based on the result of these studies. Meanwhile, in Europe, the federation of All European Academies (ALLEA) held a workshop on the GP.

At the workshop, the JPO made contributions to sharing experiences related to the legal revisions in dealing with the GP issue, and a statement supporting the GP was adopted.

Meanwhile, the GP is not 0 but 6 months in the EU. The main difference between the EU and Japan, in terms of the GP, is the mode of disclosure, i.e. in the EU, the GP can be evoked only when disclosures are made at international exhibition.

### Future outlook

The JPO will further promote discussions on patent system harmonization through a variety of forums such as the Tegernsee Group Meeting and the IP5 Heads of Offices Meeting, while deepening the cooperative relationship with users on patent system harmonization through, for example, generating a summary of the results of the user consultations that were held in each of the member countries of the Tegernsee Group.



## 9. Government-Led Industrial Cooperation in Aeronautics (WP-C/#15/EJ to EJ)

### BRT Recommendation

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

#### < Recent progress >

No concrete progress has been seen on this recommendation over the past twelve months.

#### < Background >

*Europe's aeronautics industry has long been a major supplier to the world market. Japan also has many advanced technologies. Both are now challenged by new entrants. In this context, joint technology and project development are necessary for both sides' companies to maintain technological leadership and competitiveness. It is also a necessity for governments faced with severe budgetary constraints. Europe-Japan industrial cooperation already exists to a certain extent in helicopters and aeroengines but the potential is much greater. More government-led cooperation between Japanese and EU industries would result in many gains for both sides.*

*In the civil airliner area, EU-Japan industrial cooperation has stagnated since the early 2000s, when 21 Japanese suppliers joined the A380 programme. Japan lost many opportunities of working with European industry in aerostructures. The situation is better for Japanese participation in engine programmes and as suppliers of carbon fibre materials. The aerospace industries of other countries have evolved significantly in recent years, both in skills and capacity, and price competitiveness has become a key decision criterion.*

### Action taken so far

Since June 2012, the Ministry of Economy, Trade and Industry (METI) and the European Commission (EC) have made a coordinated call in the field of aeronautics and air transport and adopted anti-icing systems, surface heat exchanger of aero-engines, and high speed aircraft as a theme. Those projects were launched officially in February 2013.

In June 2013, METI and EC agreed to establish a regular basic Working Group co-chaired by the Director of Transport, the Directorate General for Research and Innovation of EC and the Director for Aerospace and Defense Industry Division, METI. Based on this agreement, METI and EC signed Terms of Reference of the European-Japanese Working Group on Civilian Aeronautics Research.

In June 2013, METI and the Directorate General for Civil Aviation (DGAC) of the Ministry of Ecology, Sustainable Development, and Energy of the French Republic also agreed to establish a Civil Aeronautical Industry Cooperation Working Group which will be jointly headed by the Director of the Department of International cooperation, DGAC and the Director for Aerospace and Defense Industry Division, METI. METI and DGAC signed the Memorandum of Cooperation (MoC) in Civil Aeronautical Industry. Based on this MoC, METI and DGAC held the 1<sup>st</sup> Working Group in Tokyo in

December 2013. Concurrently with the Working Group, METI and DGAC also held the workshop aimed at finding some future cooperation between Japanese and French companies.

#### Future outlook

The GOJ will continue to support for the collaboration between the Japanese aircraft industry and those of European countries utilizing the Japan-EU and Japan-French cooperation framework.

Japan and EC are going to have a joint workshop in March 2014 in order to find future cooperation for the next coordinated call projects.

## 10. Environmental Issues in Aeronautics Technology (WP-C/#16/EJ to EJ)

### BRT Recommendation

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

#### < Recent progress >

Minor progress has been made on this recommendation.

#### < Background >

*Europe and Japan support mostly separate research programmes on environmental issues, from noise to emissions. One joint effort is a British-Japanese cooperation on the Trent family of wide-body engines. Japanese involvement is slowly growing as new models are being added. Another effort is part of a small French-Japanese programme on high speed aeronautics technologies. 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 June 2012, the Ministry of Economy, Trade and Industry and the European Commission made a coordinated call in the field of aeronautics and air transport. The topic adopted included environmentally-enhancing surface heat exchange and zero-emission targeted high-speed aircraft. Those projects were launched in February 2013.

Japanese companies have been involved in the latest Airbus A350XWB project. In addition, they have also been involved in Rolls Royce's Trent 1000 and Trent XWB aircraft engine projects, working jointly with Rolls Royce on development.

### Future outlook

With respect to efforts to develop environmentally-friendly aircraft technologies cooperation between Japanese aircraft industry and those of other countries including the EU is vital from the viewpoint of improvement of Japanese companies' technological capability and competitiveness. The GOJ intends to continue assisting in forging ties between Japanese aircraft industry and those of European countries, utilizing Japan-EU collaborative research programs.

## 11. Cooperation in aircraft certification (WP-C/#17/EJ to EJ)

### BRT Recommendation

Cooperation between Japanese and European aircraft certification authorities should be upgraded. Specifically, EU-Japan cooperation should be upgraded at the level of a full bilateral agreement. The use of English for all relevant documents should be permitted.

### < Recent Progress >

Progress is made towards a BASA between Japan and the EU.

### < Background >

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

### Action taken so far

In order to enhance cooperation between Japan and the EU for a high level of civil aviation safety, Ministry of Land, Infrastructure, Transport and Tourism (MLIT) and the European Commission (EC) agreed to launch preliminary discussions toward the conclusion of Bilateral Aviation Safety Agreement (BASA) at the Japan-EU Transport Dialogue held in July of 2011. In accordance with the agreement, the Japan Civil Aviation Bureau (JCAB), the European Aviation Safety Agency (EASA), and the EC held the first preliminary discussion. Although JCAB has kept proposing a subsequent meeting, the European side has not accepted our proposal for their own reason.

Regarding the Type Certificate of aircraft, the international standards of International Civil Aviation Organization (ICAO) require that importing States conduct technical evaluation on the basis of satisfactory evidence, even though the exporting States issue type certificate. Based on the international standards, JCAB validates Type Certificate of all imported aircraft equally, and the validation on Type Certificate of European aircraft, including optional equipments, is conducted in accordance with the Working Arrangement between civil aviation authorities of Japan and the EU.

Pilots need to understand the flight manuals, which include the operational limitation, the emergency

procedures, etc., easily and surely at any situations in order to secure the safe operation of aircraft. The users of flight manuals are not specified because flight manuals belong to aircraft, and flight manuals should be understood properly even by those who are not secured English proficiency. Therefore, JCAB basically requires and approves the Japanese flight manuals. JCAB have heard from some aircraft manufactures that flight manuals are prepared in the language other than English in some States.

JCAB's type certification activities for Japanese manufacturing aircraft, including MRJ, have been carried out by the special organization, which has been separated from the organization for the inspection of imported aircraft, and the organization for the imported aircraft itself has been strengthened. Therefore, the type certification activities of MRJ have no impact on the certification activities of foreign aircraft.

#### Future outlook

JCAB will continue to work with EU for the early conclusion of BASA.

## 12. More Effective Cooperation Among Space Authorities (WP-C/#19/EJ to EJ)

### BRT Recommendation

Major bilateral meetings of Space Authorities should not only involve ESA and JAXA but also the European Commission and Japan's Cabinet Office in order to discuss broader issues.

### < Recent progress >

This is a new recommendation.

### < Background >

*The European Space Agency and JAXA have regular meetings, but they are not frequent enough and yield few concrete results. Space issues are not limited to only technology and science, but also extend to major global policies and politics.*

### Action taken so far

At the 21st Japan-EU Summit held in Tokyo on November 2013, Summit leaders decided to launch a Japan-EU Space Policy Dialogue.

### Future outlook

The first meeting of a Japan-EU Space Policy Dialogue will be held in 2014. Ministry of Foreign Affairs (MOFA), Cabinet Office (CAO), Ministry of Education, Culture, Sports, Science & Technology (MEXT), Ministry of Economy, Trade and Industry (METI), and other space-related ministries and agencies will participate in the meeting.

### 13. Government-Led Industrial Cooperation in Space (WP-C/#20/EJ to EJ)

#### BRT Recommendation

The Authorities of Japan and the EU should significantly upgrade the scale of EU-Japan industrial cooperation in space, stimulated by government funding.

#### < Recent progress >

No progress has been seen on this recommendation.

#### < Background >

*Europe's and Japan's space industries have been major suppliers to the world market: European companies with systems and subsystems, and Japan companies with components and the ground segment. Joint technology and project development are necessary for both sides' companies to maintain technological leadership and competitiveness. It is also necessary for governments faced with severe budgetary constraints. Europe-Japan cooperation already exists in some technology areas but the potential is much greater. More government-led cooperation between Japanese and EU industries would result in many gains for both sides.*

#### Action taken so far

At the 21st Japan-EU Summit held in Tokyo on November 2013, Summit leaders decided to launch a Japan-EU Space Policy Dialogue.

#### Future outlook

The first meeting of a Japan-EU Space Policy Dialogue will be held in 2014. Ministry of Foreign Affairs (MOFA), Cabinet Office (CAO), Ministry of Education, Culture, Sports, Science & Technology (MEXT), Ministry of Economy, Trade and Industry (METI), and other space-related ministries and agencies will participate in the meeting.

#### 14. Civil Purpose Satellite Technology (WP-C/#21/EJ to EJ)

##### BRT Recommendation

In the civil satellite technology field, Japanese space Authorities (at Cabinet level) and European space Authorities (EU Commission, European Space Agency, and Europe's national space agencies) should establish a common mechanism for a formal and permanent dialogue with the purpose of identifying further mutually beneficial subjects of cooperation. Of particular interest to both the EU and Japanese industries are advanced broadband and mobile communications services that would be applicable, among other cases, to the rescue of populations hit by a natural disaster.

##### < Recent progress >

Nearly no progress of interest to industry has been seen on this recommendation, except for minor cooperation in some specific device development.

##### < Background >

*Europe and Japan have many complementarities in satellite technology and similar needs in terms of space telecommunications, broadcasting and observation. Note that discussions and cooperation on advanced technologies are also useful to promote common EU-Japan standards and thus benefit both sides' industries.*

##### Action taken so far

At the 21st Japan-EU Summit held in Tokyo on November 2013, Summit leaders decided to launch a Japan-EU Space Policy Dialogue.

##### Future outlook

The first meeting of a Japan-EU Space Policy Dialogue will be held in 2014. Ministry of Foreign Affairs (MOFA), Cabinet Office (CAO), Ministry of Education, Culture, Sports, Science & Technology (MEXT), Ministry of Economy, Trade and Industry (METI), and other space related ministries and agencies will participate in the meeting.



15. Expanding the scope of “Self-verification of conformity” procedure on telecommunication equipment (WP-C/#31/E to J)

#### BRT Recommendation

The Japanese government should consider expanding the scope of “Self-verification of conformity” procedure, including radio base stations for cellular networks, WLAN equipment, etc.

#### < Recent Progress >

To our knowledge there has been no progress on this Recommendation.

#### < Background >

*The “Self-verification of conformity” process allows a manufacturer to take its own responsibility for verifying whether its telecom products meet the relevant technical requirements, and then to introduce them to the Japanese market. However the scope is limited and excludes radio base stations for cellular networks, WLAN equipment, etc.*

#### Action taken so far

MIC expanded the scope of “self-confirmation of technical regulations conformity” procedure in June 2013 to the Wireless LAN mounted in cell-phone, based on "Policy on Regulatory and Institutional Reform" adopted at the cabinet meeting in July 10 2012 and the report of "Investigative Commission for Promotion of Effective Use of Radio Spectrum" in December 25 2012.

#### Future outlook

Because a risk to the distribution expansion of the non-compliance equipment exists, further expansion is difficult under the current situation. The report of "Investigative Commission for Promotion of Effective Use of Radio Spectrum" said that careful examination is necessary for further expansion of scope of “self-confirmation of technical regulations conformity” procedure as well.

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

### 1. Issues to be mindful of when proceeding with financial market reform (WP-D/#01/EJ to EJ)

#### **BRT Recommendation**

- The BRT recommends avoiding excessive ‘ring-fencing’ in each jurisdiction and duplication of regulations with effective supervision by the home country and international coordination, because any constraint on flow of global banking services may eventually cause negative effects on corporate business activities including increased cost of funding, inefficient cash and asset management and negative effects on other cross-border transactions in various occasions.
- The BRT requests that, while seeking resiliency of the wider financial system, any financial market reform should fully address its impact on effective functioning of relevant financial and capital market activities, particularly for liquidity in the markets.

#### <Recent Progress>

The Basel Committee on Banking Supervision (BCBS) and the International Organization of Securities Commissions (IOSCO) have issued in July 2012 its first consultative paper on margin requirements for non-centrally cleared derivatives on which comments were submitted by end of September. Thereafter, in February 2013, BCBS and IOSCO have issued a second consultative paper as a near-final proposal seeking further public comments by 15 March 2013. The FSB has published in November 2012 an initial set of recommendations to strengthen oversight and regulation of shadow banking and asked for comments to be submitted in January 2013.

#### <Background>

For successful completion of global financial market reforms, the BRT believes that internationally consistent regulations should be built and implemented through multilateral discussions on a global basis to ensure level-playing field among players and markets. Among other things, the impact on the revitalisation of global economic growth and cumulative impacts due to regulatory reforms being implemented concurrently should be taken into account fully.

With regard to liquidity, two of the current global regulators’ proposals, namely i) margin requirements for non-centrally cleared derivatives and ii) regulations over securities lending and repos in the context of shadow banking regulation (e.g. proposal of minimum haircuts in particular), are of particular concerns. If imposed as proposed, these regulations would cause negative impacts on financial markets, credit extensions and eventually economic growth, which is an unintended consequence to be avoided.

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

As to OTC derivative market, introduction of margin requirements for non-centrally cleared derivatives could lead to the financial stability through the reduction of systemic risk and the promotion of clearing by central counterparty. In addition, as to the regulation over repo and securities lending, the government has taken note of ensuring that the regulations should not have an adverse influence upon real economy such as loss of liquidity while the regulation lead to financial stability to restrain the excessive leverage and to reduce systemic risk in the market.

#### Future outlook

Japan will consider steadily implementing the international agreement while bearing in mind considering the influence on the financial stability by margin requirements for non-centrally cleared derivatives, financial and capital market and real economy. Minimum standard for methodologies to calculate haircuts is scheduled to be agreed in April 2015. Japan will actively participate in the discussion and implement the agreement while considering the economic reality in Japan.

## 2. US Regulations (WP-D/#02/EJ to EJ)

### BRT Recommendation

The European and Japanese authorities and industries should continue to unite their efforts to ensure internationally consistent and level-playing field implementation of US regulations while preventing excessive extra-territorial and other prejudicial application thereof.

### <Recent Progress>

The BRT appreciates the Authorities coordination in the implementation of OTC derivatives reforms. Some results were observed. In December 2012, the US Securities and Exchange Commission's Office of International Affairs released a joint statement which reflects statements of European, U.S. & other OTC derivatives regulators. The statement suggests some potential changes from the Commodities Futures Trading Commission's cross-border proposal.

### <Background>

*For the derivatives market and business, it is particularly important that regulators in both sides of the Atlantic fully coordinate and streamline all requirements for the trading, clearing and reporting of swap transactions as well as associated dealer registration or other licensing requirements, envisaged under the proposed EMIR (European Market Infrastructure Regulation), the MiFID Review (Markets in Financial Instruments Directive) and the US Dodd-Frank Act. There are also other areas where extraterritoriality or inconsistent and discriminatory applications could be an issue for non-US parties, such as the anticipated impact of the rule proposed by the Federal Reserve Board on non-US banks.*

### Action taken so far

We believe that it is important to avoid conflicts, inconsistencies and gaps in the regulation of cross-border OTC derivatives activities. With this in mind, we have participated in international discussions. In September 2013, the OTC Derivatives Regulators Group reported for the G20 summit on how the group has resolved these cross border issues. In the report, the ODRG agrees that a flexible, outcomes-based approach should form the basis of final assessments regarding equivalence or substituted compliance, and that there should be appropriate transitional measures and a reasonable transition period for foreign entities, which reflected Japanese authority's insistence. Furthermore, to avoid the results of duplication of regulations, the US Commodity Futures Trading Commission (CFTC) published comparability determinations for six jurisdictions (Australia, Canada, the European Union, Hong Kong, Japan, and Switzerland) for substituted compliance purposes in December 2013, for a broad range of entity-level requirements.

### Future outlook

We will continue to discuss with US authorities the matter where the CFTC has not determined comparability determination at this time. In addition, we will continue to implement the OTC derivatives reforms based on international agreements among G20 and the ODRG, etc. and actively take part in international discussions.

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

### **1. Maintaining and enhancing high-level EU-Japan dialogue on energy (WP-E/#04/EJ to EJ)**

#### **BRT Recommendation**

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

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

Japan and the EU held a new (their 4<sup>th</sup> since it was established in 2007) energy policy dialogue in June 2012, this time at the ministerial level (METI Minister Edano and EU Commissioner for energy Oettinger), where both sides could exchange views on:

- ➡ Energy policies
- ➡ Nuclear energy and nuclear safety
- ➡ Cooperation in energy technology research
- ➡ Energy security
- ➡ Liberalisation of the energy sector
- ➡ Raw materials
- ➡ Etc.

The EU side strongly hopes the new government in Japan will continue holding these dialogues.

#### **< Background >**

*The three first such dialogues were held at senior officials levels (the Agency for Natural Resources & Energy on the Japanese side, and the European Commission Directorate for Energy on the EU side).*

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

Atg the 21st Japan-EU Summit in November 2013, cooperation in the field of energy was discussed between both leaders. Such dialogues at high and working levels have been held continuously.

In the context of the cooperation between Japan's Ministry of Economy, Trade and Industry and the Directorate General for Energy of the European Commission, Japanese and European experts have been engaged in consultations on developments of the gas markets since June 2013.

This cooperation had the aim of sharing respective views and analysis on changes of gas markets in recent years, assessing how markets should ideally function, and discussing how government could support the transition towards more liquid and flexible global gas markets.

On September 10, 2013, on the occasion of the second LNG Producer-Consumer Conference held in Tokyo, the achievements derived from this research cooperation were made public.

#### **Future outlook**

Japan is willing to continue cooperation with the European Commission for further promotion of collaboration in the field of energy.

2. Promoting and supporting a long-term strategy on stable, competitive and sustainable energy supply (WP-E/#05/EJ to EJ)

#### BRT Recommendation

The EU and Japan should work together through sharing of best practices implemented by both EU countries and Japan to secure a stable, sustainable economical and environmental energy supply, so that the EU and Japan can establish respective long term strategies.

#### <Recent Progress>

This is a new recommendation.

#### < Background >

*With respects to energy-intensive and carbon-intensive industries, Japan and the EU face similar challenges in securing a stable yet competitive energy supply. Developing a common understanding of actions undertaken by both sides to address these challenges.*

#### Action taken so far

Japan recognizes that achieving secure, sustainable, affordable and safe energy supplies is essential for Japan's energy policy. Japan and the EU have been sharing best practices and knowledge through Japan-EU Energy Dialogue or international conferences such as IEA.

#### Future outlook

Japan is willing to continue cooperation with the European Commission through bilateral or multilateral frameworks for further promotion of collaboration in the field of energy.

### 3. Expediting collaboration on nuclear fuel cycle policy (WP-E/#06/EJ to EJ)

#### BRT Recommendation

The EU and Japan should collaborate in helping each other implementing and achieving their nuclear fuel cycle policy, including:

- Recycling of spent nuclear fuel in countries adopting a closed-fuel cycle policy
- Furthering R&D efforts on technologies aiming at reducing the volume and activity of radioactive waste, paving the way towards Gen IV nuclear reactors
- Furthering R&D efforts on nuclear waste management technologies such as dry storage, final repository

#### <Recent Progress>

This is a new recommendation.

#### < Background >

*The policies and practices of EU and Japan on radioactive waste and spent fuel management reflect their historical, scientific and technological development, as well as their international commitments in terms of non proliferation and pacific use of nuclear energy:*

- *In EU, currently five states use the reprocessing option and two states are actively pursuing spent fuel direct disposal option. The Commission proposed in 2010 to set up an EU legally binding and enforceable framework to ensure that all Member States will apply the common standards developed in the context of the International Atomic Energy Agency (IAEA) for all stages of spent fuel and radioactive waste management up to final disposal. Gen IV technologies are also part of the European Strategic Energy Technology Plan.*
- *Japan has developed over the past 30 years a closed nuclear fuel cycle policy: the Rokkasho Reprocessing Plant is close to completion, and will allow Japan to reprocess spent fuels and recycle uranium and plutonium. Japan recently confirmed its commitment to the fuel recycling policy which confirms Japan's long-term vision on nuclear energy. As for the management of used fuel, the recovery and recycling of valuable materials remaining in used nuclear fuel will lead to the effective use of resources and reductions in radioactive waste. In addition, R&D efforts will be made on direct disposal and technologies aiming at reducing the activity/volume of radioactive waste such as the prototype Fast Breeder Reactor, Monju, which will be dedicated to this research.*

#### Action taken so far

- Japan and the EU should collaborate to implement their nuclear fuel cycle policy

For cooperation in the area of civil nuclear energy between Japan and EU, the efforts have been made for better understanding on their nuclear fuel cycle policies including the plutonium management on occasions such as the Third Meeting of Japan-France Nuclear Cooperation Committee on 8 October 2013 and the Second Annual UK-Japan nuclear dialogue on 30<sup>th</sup> and 31<sup>st</sup> October 2013.

- Recycling of spent nuclear fuel in countries adopting closed-fuel cycle policies

Japan has consistently adopted the nuclear fuel cycle policies to reprocess spent fuel and reuse reprocessed U and Pu, aiming at the effective use of uranium resources and the reduction of the amount and toxic level of radioactive wastes.

- Furthering R&D efforts on technologies for reducing the volume and toxic level of radioactive waste, paving the way towards Gen IV nuclear reactors

The safety design guideline of Sodium-cooled fast reactor, which has the potential for the reduction of the amount and toxic level of radioactive wastes, is being established under the scheme of the international collaboration, the Generation IV International Forum (GIF).

- Furthering R&D efforts on nuclear waste management technologies such as dry storage, final repository

Japan understands the importance of nuclear fuel management technologies such as dry storage and final repository. For example, the geological disposal of HLW is evaluated as feasible technologically in Japan, based on the R&D over 20 years. Based on the evaluation, the R&D on geological disposal has been conducted in order to improve safety and confidence of the technologies.

#### Future outlook

- Japan and the EU should collaborate each other to realize and implement their nuclear fuel cycle policies

Aiming at realizing and implementing nuclear fuel cycle policies, we will strengthen the cooperative relationship through Japan - EU communicative frameworks such as the Meeting of Japan-France Nuclear Cooperation Committee and the Annual UK-Japan Nuclear Dialogue.

- Promoting recycling of spent nuclear fuel in countries adopting closed-fuel cycle policies

Japan will promote the nuclear fuel cycle policy to reprocess spent fuel and reuse reprocessed U and Pu through the communication with related local municipalities and the international community.

- Furthering R&D efforts on technologies aiming at reducing the volume and activity of radioactive waste, paving the way towards Gen IV nuclear reactors

Japan will make efforts to establish safety design standards and will promote the R&D in collaboration with the countries which are developing fast reactors.

- Furthering R&D on nuclear waste management technologies such as dry storage, final repository

With a view to improving the credibility on geological disposal technologies, R&D on nuclear waste management technologies will be promoted. These technologies include retrievable storage technology, direct disposal technology, alternative technologies.



#### 4. Leadership role to establish world safety standards (WP-E/#07/EJ to EJ)

##### BRT Recommendation

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

##### <Recent Progress>

Nuclear safety is currently being reassessed in Japan, with new standards due in July 2013. Japan has set up an independent safety authority in September 2012 who is in charge of revamping these standards. 3 Foreign experts including French ASN's Andre-Claude Lacoste but also Mike Weigtman (head of the UK nuclear regulation office) and Richard Meserve (former chairman of the US Nuclear Regulatory Commission) will advise the newly established Japanese nuclear authority.

The safety of nuclear power plants and nuclear energy in general were among the topics addressed during the 4<sup>th</sup> energy dialogue between EU and Japan held in June 2012, with joint commitment in enhancing common activities such as:

- Continue discussing on respective nuclear safety stress tests;
- Enhance international legal framework on nuclear safety through closer cooperation and consultation within the framework of the IAEA and the upcoming extraordinary meeting of the Convention on Nuclear Safety;
- Stimulate bilateral discussions between specialists on both sides on the capabilities and technologies in nuclear plant decommissioning projects, decontamination and waste management.

Japan also organized a ministerial conference on nuclear safety which was held in Fukushima Prefecture in December 2012. The conference provided an opportunity to share lessons from the Fukushima accident. Experts and ministers from several countries including Japan and EU countries could present their recommendations on nuclear safety. The conference was co-sponsored by IAEA, who compiled the main proposals that emerged from the 3 Working Sessions: lessons from the Fukushima accident, strengthening of nuclear safety and emergency preparedness & response, and protection of population and environment. These proposals stressed on:

- The necessity of stricter, internationally peer-reviewed safety standards;
- The importance of establishing and maintaining international cooperation frameworks to address issues such as: accident response, people and environment protection, decontamination and decommissioning, etc.

##### < Background >

*As an alternative energy with a stable energy supply, excellent economic potential, and zero CO<sub>2</sub> emissions nuclear energy is being reassessed by nations around the world. The serious accident at the Fukushima-Daiichi nuclear power plant, following the dramatic tsunami that struck Japan on 11 March 2011 also triggered a re-assessment of the safety measures and emergency response systems of nuclear power by all nations using or contemplating the use of nuclear energy.*

*Rising Expectations for Nuclear Energy calls for a Strengthened Safety Framework*

*According to the Nuclear Energy Agency of the OECD (OECD-NEA), nuclear power accounted for 14% of global electricity production in 2009. This figure is expected to rise to 24% by 2050. As of January 2010, the International Atomic Energy Agency (IAEA) estimated that 437 nuclear power reactors were in operation worldwide, while a total of 56 reactors were under construction.*

*In the majority of the countries worldwide, there is still a growing interest in nuclear power generation to prevent dependence on fossil fuels, and a continuous stream of construction projects for nuclear power plants is underway. However, nuclear energy requires the highest safety standards. A lot has been done for several years at the national level, at the EU level, and at the international level (IAEA, Convention on Nuclear Safety, ...). The industry has significantly improved the safety of its current reactor design. Now, the accident at Fukushima, caused by an extreme situation, demonstrates that safety must be continuously improved. As nuclear power will remain an attractive energy source for a large number of countries in the world (contribution to energy security and a low-carbon society), it is even more important to define world safety standards. The EU and Japan must play an active role in promoting and defining such standards.*

*While enhancing safety, it will be necessary to deal with the ageing of existing plants, improve facility utilization rates, and properly manage the nuclear fuel cycle (e.g., the management of used nuclear fuel). It will be essential to understand the mechanism of degradation of machinery and equipment as well as to conduct maintenance of ageing plants to maintain and restore their functions and performance. Therefore, the EU and Japan must promote, through international discussions like those held by the OECD-NEA, the exchange of information related to the technological assessment of ageing plants and to techniques associated with the appropriate maintenance of existing plants.*

**Action taken so far**

Japan believes that it is our 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, and has promoted international discussions in order to strengthen international nuclear safety.

In 2013, Japan transparently shared with the international community further experience and lessons learned from the accident and promoted cooperation to strengthen international nuclear safety by receiving IAEA's missions on decommissioning and remediation, through workshops held at the IAEA RANET Capacity Building Center designated in Fukushima Prefecture, and also through a project by OECD/NEA to assess the reactors' situation at the Fukushima Daiichi Nuclear Power Station (BSAF Project: Benchmark Study of the Accident at the Fukushima Daiichi).

Moreover, Japan co-sponsored the ASEM 2<sup>nd</sup> Seminar on Nuclear Safety and contributed to enhancing international nuclear safety.

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

### Future outlook

Japan will continue to promote international discussions and proactively participate in international efforts such as reviewing IAEA safety standards for the improvement of international nuclear safety by providing the international community with accurate information of the accident at the Fukushima Daiichi Nuclear Power Station in an open manner and sharing lessons learned with the international community.

## 5. Cooperation on renewable energy development (WP-E/#10/EJ to EJ)

### BRT Recommendation

Japan and the EU should cooperate on the development of renewable energies, such as wind and photovoltaic power generation, and on other low-carbon technologies such as carbon capture and sequestration (CSS).

### <Recent Progress>

Some progress has been seen for this recommendation:

- Renewable energies in general were also among the topics addressed during the 4th energy dialogue between EU and Japan held in June 2012, with joint commitment in implementing joint activities in the research area, such as coordinated research calls on PV and energy storage and reciprocal technical visits on CCS, and further information exchange in other areas such as wind, ocean energy and Smart Grids.
- Some Smart Community demonstration projects jointly carried out by Japan (through NEDO) and some EU countries such as Spain and France were also launched in 2011.
- Specific CCS projects at the commercial level and research level are in progress in European countries and Japan.

According to the 2013 Progress Reports from the GOJ Concerning the Recommendations from the EU-Japan Business Round Table, and the 2012 Progress Reports from the European Commission Concerning the Recommendations from the EU-Japan Business Round Table, Japan and EU are cooperating on new and renewable energy research. Among specific activities in this field, a coordinated research call on ultra-high efficiency concentration photovoltaic (CPV) cells, modules and systems photovoltaic (PV) was included in the Seventh Framework Programme in 2011 and projects under this call are currently under implementation.

### < Background >

*The EU aims to get 20% of its energy from renewable sources (including wind, solar, hydro-electric and tidal power as well as geothermal energy and biomass) by 2020 and a 10% share of renewable energy specifically in the transport sector. Japan also established a new energy strategy in September 2012, calling for ambitious 2030 renewable targets. The newly established government (December 2012) confirmed it would push for the adoption of more renewable energy in Japan's energy mix in the long term.*

*Energy from renewable sources suffers from intermittency – the EU and Japan should cooperate to develop Smart Grid technology, Appliances and Energy Storage to utilise renewable energy to its maximum. 40% of total energy demand worldwide is consumed in buildings. Development should therefore focus on intelligent systems (e.g. smart grids) which maximise the use of renewable energy. Market mechanisms should reward the generation, transmission and consumption of renewable energy throughout the supply chain. The EU and Japan should harmonise their approach to the Renewable Energy Chain.*

### Action taken so far

Japan and European countries such as France and Spain have started the Smart Community demonstration projects utilizing renewable energy since FY2011. New Energy and Industrial Technology Development Organization (NEDO) has been implementing these projects with the support of French and Spanish governments.

In addition, Japanese and European institutions have been cooperatively developing technologies of the concentrator photovoltaic cells based on the cooperation framework that was agreed between NEDO and European Commission (FP7) in May, 2011.

The Ministry of Economy, Trade and Industry (METI) started to design and construct necessary facilities (more than 100,000 tonnes of CO<sub>2</sub> will be captured per year) for the demonstration projects of CCS at the Tomakomai site (Hokkaido) in FY2012.

#### Future outlook

The Smart Community demonstration projects with France and Spain will continue until FY 2015.

The collaborative research of concentrator photovoltaic cells will continue until FY 2014.

The Ministry of Economy, Trade and Industry (METI) will continue to design and construct necessary facilities for the demonstration projects of CCS until FY2015.

6. Sharing best practices for safety and regulation with newcomer civil nuclear energy countries (WP-E/#12/EJ to EJ)

**BRT Recommendation**

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

<Recent Progress>

Some progress has been seen for this recommendation. According to the 2013 Report from the GOJ Concerning the Recommendations from the EU-Japan Business Round Table, Japan has actively taken part in the Asian Nuclear Safety Network (ANSN) of the IAEA for supporting to establish nuclear safety infrastructures in emerging nuclear power countries in Asia, and attended its General Conference held in September, 2012 and steering committee meeting held in November, 2012. Japan also organized the Fukushima Ministerial Conference on Nuclear Safety in Koriyama-city of Fukushima Prefecture in December, in co-sponsorship with the IAEA, where Japan shared with the international community further knowledge and lessons learned from the accident, further enhanced transparency, and discussed the progress of the international efforts aimed at strengthening nuclear safety

In 2012, Vietnam and EU launched a nuclear safety cooperation project through the EC-financed Instrument for Nuclear Safety Cooperation with regard to the technical assistance for improving the legal framework for nuclear safety and strengthening the capabilities of the regulatory authority of Vietnam.

< Background >

*As an alternative energy with a stable energy supply, excellent economic potential, and zero CO<sub>2</sub> emissions nuclear energy is being reassessed by nations around the world. The serious accident at the Fukushima-Daiichi nuclear power plant, following the dramatic tsunami that struck Japan on 11 March 2011 also triggered a re-assessment of the safety measures and emergency response systems of nuclear power by all nations using or contemplating the use of nuclear energy.*

*Rising Expectations for Nuclear Energy calls for a Strengthened Safety Framework*

*According to the Nuclear Energy Agency of the OECD (OECD-NEA), nuclear power accounted for 14% of global electricity production in 2009. This figure is expected to rise to 24% by 2050. As of January 2010, the International Atomic Energy Agency (IAEA) estimated that 437 nuclear power reactors were in operation worldwide, while a total of 56 reactors were under construction.*

*In the majority of the countries worldwide, there is still a growing interest in nuclear power generation to prevent dependence on fossil fuels, and a continuous stream of construction projects for nuclear power plants is underway. However, nuclear energy requires the highest safety standards.*

*A lot has been done for several years at the national level, at the EU level, and at the international level (IAEA, Convention on Nuclear Safety, ...). The industry has significantly improved the safety of its current reactor design. Now, the accident at Fukushima, caused by an extreme situation, demonstrates that safety must be continuously improved. As nuclear power will remain an attractive energy source for a large number of countries in the world (contribution to energy security and a low-carbon society), it is even more important to define world safety standards. The EU and Japan must play an active role in promoting and defining such standards.*

*While enhancing safety, it will be necessary to deal with the ageing of existing plants, improve facility utilization rates, and properly manage the nuclear fuel cycle (e.g., the management of used nuclear fuel). It will be essential to understand the mechanism of degradation of machinery and equipment as well as to conduct maintenance of ageing plants to maintain and restore their functions and performance. Therefore, the EU and Japan must promote, through international discussions like those held by the OECD-NEA, the exchange of information related to the technological assessment of ageing plants and to techniques associated with the appropriate maintenance of existing plants. As for the management of used fuel, the recovery and recycling of valuable materials remaining in used nuclear fuel will lead to the effective use of resources and reductions in radioactive waste.*

*According to the EU Authorities Progress Report on the EU-Japan BRT 2011 recommendations, the European Commission held in June 2011 a meeting with representatives of EU neighbouring countries which operate or own nuclear installations or which have plans for the development of nuclear power – Armenia, Republic of Belarus, Republic of Croatia, Russian Federation, Swiss Confederation, Republic of Turkey and Ukraine. An agreement was reached with these countries to undertake voluntary safety assessments taking into account the EU specifications and methodology, including the principle of peer reviews. Two of these countries – Switzerland and Ukraine – participate fully in the EU stress-test process.*

*According to the Japan Authorities Progress Report on the EU-Japan BRT 2012 recommendations, Japan provided training programs for the capacity building of regulators and licensees of China and Vietnam through Japan Nuclear Energy Safety Organization (JNES). Japan also has advanced bilateral cooperation, regional cooperation, and cooperative activities through international organizations to communicate the situation of the accident at TEPCO's Fukushima Daiichi Nuclear Power Station to emerging nuclear power countries, and share the lessons learned from the accident with them.*

#### Action taken so far

Japan has been promoting bilateral and, regional cooperation as well as cooperation with international organizations in order to share the experience and lessons learned from the accident at the TEPCO's Fukushima Daiichi Nuclear Power Station, providing the international community with accurate information of the accident in an open manner.

In 2013, Japan transparently shared with the international community further experience and lessons learned from the accident and promoted cooperation to strengthen international nuclear safety by

receiving IAEA's missions on decommissioning and remediation, through workshops held at the IAEA RANET Capacity Building Center designated in Fukushima Prefecture, and also through a project by OECD/NEA to assess the reactors' situation at the Fukushima Daiichi Nuclear Power Station (BSAF Project: Benchmark Study of the Accident at the Fukushima Daiichi).

Moreover, Japan co-sponsored the ASEM 2nd Seminar on Nuclear Safety and contributed to enhancing international nuclear safety.

#### Future outlook

Japan will continue to promote bilateral and regional cooperation as well as cooperation with international organizations in order to share the experience and lessons learned from the accident at the TEPCO's Fukushima Daiichi Nuclear Power Station, providing the international community with accurate information of the accident in an open manner.



## 7. Fostering international harmonization for EV safety and charging infrastructure (WP-E/#15/EJ to EJ)

### BRT Recommendation

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

#### <Recent Progress>

Some progress has been seen for this recommendation. According to the proceedings of the 158<sup>th</sup> session of UN-ECE WP 29, regulation proposals addressing battery electric vehicle safety remain listed as “adopted proposals” and is discussed by the Informal group on Electric Vehicle Safety, but their entry into force remain unclear at the present stage. The terms of reference (TOR) of the Informal Group on EVS including the protection against electrical shock were agreed during this 158<sup>th</sup> session, according to the 2013 Report from the GOJ Concerning the Recommendations from the EU-Japan Business Round Table

Standardization of charging infrastructure has also been discussed in international discussion table such as IEC, according to the 2013 Report from the GOJ Concerning the Recommendations from the EU-Japan Business Round Table.

#### < Background >

*Rechargeable batteries are used in the electric and plug-in hybrid vehicles being developed and promoted by several Japanese and European car manufacturers. Both the European and Japanese industry are actively seeking to improve the performance and costs of next-generation vehicle batteries to enable the more widespread use of EVs and PHVs.*

*The commercialization of next-generation electrically charged vehicles, including fuel-cell vehicles, will contribute to the conservation of energy, as well as a reduction in CO<sub>2</sub> emissions:*

- *EVs offer a means to decarbonise transport, while providing a flexible distributed energy storage asset. They can be connected to the electricity grid and charged at different times to suit grid conditions and therefore maximise the use of electricity generated from renewable sources.*
- *The primary energy consumed for heating, cooling and hot water provision is comparable to that consumed in transport. A similar approach should be taken in this sector by using technologies such as smart thermal storage and heat pumps to manage the consumption of grid electricity to ensure the penetration of renewable generation is maximised.*
- *Japan and the EU should seek to find common ground in the electrification of heating as well as transport.*

*To facilitate their market acceptance, the EU and Japan should cooperate on developing internationally harmonized requirements for the type approval and safety of electrically charged vehicles and common standards for accessing the battery-charging infrastructure. The objective should be to ensure that electric vehicles can be charged everywhere, at all times.*

*As an example, in the UK 36% of all primary energy is used for space and water heating in buildings. Significantly cutting emissions means taking the carbon out of heating by managing demand through energy and resource efficiency, and replacing fossil fuels with low carbon alternatives. Japan and the EU should promote[encourage] the industry to innovate and develop heating solutions that deliver sufficient comfort levels that utilise the least amount of primary energy and take into account the future energy generation and supply and its inherent intermittency.*

#### Action taken so far

Regarding requirements for the safety and type approval of electrically charged vehicles, the Informal Group on Electric Vehicle Safety (EVS) was established in the World Forum for Harmonization of Vehicle Regulations (UN/ECE/WP29). The Group has been discussing to establishing the Global Technical Standards on EVS under the initiative of U.S., EU and Japan. WP29, at its 158th session held in November 2012, agreed the terms of reference (TOR) of the Informal Group on EVS including the protection against electrical shock. At its 161th session held in November 2013, the Informal Group reported on the progress of the group's study work.

Standardization of charging infrastructure has been discussed in the framework of formulating international standards table such as the IEC.

#### Future outlook

Based on the TOR of Informal Group on EVS agreed at the 158 session of WP29, U.S., the EC and Japan will advance consideration toward an establishment of a global technical regulation on EVS by the end of 2014 in cooperation with each other.

When discussing standardization of charging infrastructure, we should develop them so that we could ensure drivers' benefits and convenience and that infrastructure development would not be exclusive to the existing vehicles and chargers.

## 8. Cooperating on pre-commercial development of batteries

### BRT Recommendation

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

### <Recent Progress>

No progress has been seen for this recommendation. Both Japan and EU are conducting R&D projects at national levels.

### < Background >

*Both the EU and Japan are developing next-generation rechargeable batteries. The rechargeable battery is a potential key component in the development of smart grids worldwide, such as the “Smart City Project” in Japan, as well as a groundbreaking advanced application technology contributing to the promotion of renewable energy.*

*Rechargeable batteries can be placed at power stations for large-scale photovoltaic or wind-power generation in order to store low-cost off-peak electricity and deliver it during peak demand times, ensuring the delivery of a stable supply even when wind or sun power generation falls due to their inherent variability. As smart grid components, batteries can also be installed in commercial districts and large-scale apartment housing complexes to store electricity and cut peak demand electricity.*

### Action taken so far

The GOJ has been conducting R&D for more durable and safer battery with lower cost and more energy density as a national project.

In particular, the GOJ is developing advanced materials, modules and systems for the purpose of enhancing the performance of lithium-ion batteries, and engages in a study to establish a method to evaluate their lifetime and to assess their safety. Moreover, the GOJ has embarked a study on innovative batteries that surpass the performance of lithium-ion batteries (post- lithium-ion battery).

As for the results of these projects, relevant information has been constantly shared with researchers in the EU through various symposiums such as the discussion parties on battery that are periodically held in Japan.

### Future outlook

The GOJ will continue R&D to enhance the performance of batteries and to improve their safety.

9. Establishing in the near future a new, fair, and effective international framework addressing Global-Warming Issues (WP-E/#19/EJ to EJ)

#### BRT Recommendation

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

#### <Recent Progress>

Some progress has been seen for this recommendation, as the main actions already undertaken jointly by both countries were furthered in 2012. Japan and the EU are actively contributing to negotiations toward the adoption of a new legal document which will establish a fair and effective international framework in which all major economies participate. These negotiations mainly take place under the UNFCCC. The negotiation tracks of the Durban Platform, established during COP17, currently represent the best opportunity for establishing such a framework. In this respect, negotiations around the “Ad Hoc Working Group on the Durban Platform for Enhanced Action”, were furthered during COP18 (November 2012), and, according to the 2013 Report from the GOJ Concerning the Recommendations from the EU-Japan Business Round Table, decisions were made on the arrangements for negotiations in the related working group from next years onward.

#### < Background >

*Since 2010 the international community has recognized the scientific evidence that global warming needs to be held below 2°C above the pre-industrial temperature in order to prevent climate change from reaching dangerous proportions. However, international action taken to date is still not sufficient to prevent this ceiling from being exceeded. Scientific evidence indicates that a temperature rise of more than 2°C could have irreversible and potentially catastrophic environmental consequences with high costs in human and economic terms*

*Both Japan and the EU countries are actively promoting the reduction of GHG emissions, and hold regular bilateral dialogues to further exchange views on these issues. EU and Japan have ambitious targets in terms of GHG emissions reductions, but the situation differs between the two countries:*

- *According to the European Commission's annual progress reports, The EU is leading by example through its domestic action to tackle climate change. Despite economic growth of almost 40% since 1990, the EU-15 is well on track to achieve and exceed its 8% emissions cut under Kyoto. Taking all 27 EU Member States together, GHG emissions in 2010 were 15.5% lower than in 1990 while GDP was 41% higher. For 2020, the EU has committed to cutting its emissions to 20% below 1990 levels. This commitment is one of the headline targets of the Europe 2020 growth strategy and is being implemented through a package of binding legislation.*
- *In 2009, Japan expressed an ambitious 25% emission reduction target by 2020, provided major CO2 emitting nations participate in same framework with clear definitions of international fairness or selection of base year., However the new Japanese Government decided in January 2013 to conduct zero-based review of of the 25% emission reduction target by COP19 in November. as the Japanese utilities recorded a huge rise in the use of fossil fuels since the Fukushima nuclear accident and the consecutive shutdown of the Japanese fleet of nuclear*

*reactors. Also new Japanese government announced to conduct a zero-based review of the energy and environment strategy of the former government and to forge a responsible energy policy taking account of the needs for stable energy supplies as well as the reduction of energy cost.*

*The need to reduce GHG emissions to counter climate change remains unchanged. It is essential to establish a new, fair, and effective international framework with the participation of all major emitters. Designing such an international framework and setting targets at the national level must be done with due consideration for their short and mid-term economic impact, and take into account the opportunities and constraints of the global economy.*

#### Action taken so far

Japan has been actively contributing to negotiations at the Ad Hoc Working Group on the Durban Platform for Enhanced Action (ADP) which was established at the seventeenth session of the Conference of the Parties to the UNFCCC (COP17) in 2011, with a view to establishing a fair and effective international framework applicable to all Parties. The COP19 held in Warsaw in November 2013 decided to invite all Parties to initiate domestic preparations for their intended nationally determined contributions and to communicate them well in advance of the COP21 (by the first quarter of 2015 by those Parties ready to do so), and the ADP was requested to identify, by the COP20, the information that Parties will provide when putting forward their contributions. The GOJ has thus achieved its goal in COP19 of organizing preparatory work toward an agreement at COP 21 on a new legal framework applicable to all Parties. In addition, Japan announced Actions for Cool Earth (ACE) with a view to contributing to global emission reduction through Japan's advanced technologies.

#### Future outlook

With regard to a new legal framework beyond 2020, aiming for an agreement at COP21, Japan will continue to actively contribute to negotiations in accordance with the decision in Warsaw, and utilize possible venues and opportunities including various international conferences and bilateral meetings, while implementing the Actions for Cool Earth (ACE).

## 10. Setting CO<sub>2</sub> emission targets in a fair and transparent way (WP-E/#20/EJ to EJ)

### BRT Recommendation

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

#### <Recent Progress>

Some progress has been seen for this recommendation:

- Global warming and greenhouse gases emissions reduction were addressed in the new energy policy announced by Japan in September 2012, which targeted a 20% reduction of GHG emissions in 2030 compared to 1990 level (the previous target was -25% by 2020). However the setting of CO<sub>2</sub> emissions targets and the overall implementation of this policy is now being reconsidered by new Japanese government. New strategies of climate change and future framework of CO<sub>2</sub> emission reduction will be presented at COP19 in November.
- EU has put in place binding legislation to cut emissions to 20% below 1990 levels by 2020, as part of the Europe 2020 Growth Strategy, and confirmed this commitment at the Doha Climate Change Conference in 2012.

#### < Background >

*According to the European Commission, the EU has offered to increase its emissions reduction to 30% by 2020 if other major emitting countries in the developed and developing worlds commit to undertake their fair share of a global emissions reduction effort. For 2050, EU leaders have endorsed the objective of reducing Europe's greenhouse gas emissions by 80-95% compared to 1990 levels as part of efforts by developed countries as a group to reduce their emissions by a similar degree. According to the European Commission Services Progress Report on EU-Japan BRT 2012 Recommendations, the 'climate and energy package' was agreed by the European Parliament and Council in December 2008, after extensive, inclusive and transparent consultations with all stakeholders, and taking into account domestic circumstances. It then became law in June 2009. The European Commission published a roadmap in 2011 that charts a cost-effective pathway for making the necessary transition to a competitive, low carbon European economy by mid-century. Future climate legislation at the EU level will continue to be based e.g. on open consultation and full transparency, and answering the findings of science.*

*In Japan, the Fukushima-Daiichi nuclear accident and the consequent switch to fossil fuels to compensate power loss from idled nuclear reactors. In the short-term, Japan's CO<sub>2</sub> emissions are therefore projected to climb. It is expected the new Japanese government (December 2012) will define new targets in the upcoming months/years.*

#### Action taken so far

At COP19 in November 2013, Minister of Environment Mr. Ishihara put forward a target of 3.8% emission reduction in 2020 compared to the 2005 level. This new target is the current one which does not take into account the emission reduction effects resulting from nuclear power, given that the energy policy and energy mix, including the utilization of nuclear power, are still under consideration.

After the conference, on November 29, the GOJ registered the reduction target of 3.8% on condition that it has the nature described above, replacing the 25% reduction target which had been submitted to the UNFCCC in accordance with the Copenhagen Accord. Moreover, on December 27, the GOJ submitted the Biennial Report mentioning climate change measures and policies.

#### Future outlook

A determined target will be set, based on a further review of the energy policy and energy mix.

11. Continuously improving incentives and regulations to promote the adoption of energy-efficient technologies and processes (WP-E/#23/EJ to EJ)

#### BRT Recommendation

The EU and Japan should continue to refine their regulations and incentives to promote the efficient use of energy (energy efficiency as well as energy savings). Setting as soon as possible mandatory principles for standards for building and house insulation plays a major role in reducing energy consumption and dependency and in achieving a significant reduction in CO<sub>2</sub> emissions. Japan and the EU should also share best practices to implement energy efficiency regulations, innovation processes, trainings, experimental programmes of construction and renovation regarding products and services.

#### <Recent Progress>

On the EU side, the Directive 2012/27/EU on energy efficiency was approved on the 25 October 2012. It establishes a common framework of measures for the promotion of energy efficiency within the Union in order to ensure the achievement of the Union's 2020 20 % headline target on energy efficiency and to pave the way for further energy efficiency improvements beyond that date. Other measures include rules designed to remove barriers in the energy market and to overcome market failures that impede efficiency in the supply and use of energy, as well as the establishment of indicative national energy efficiency targets for 2020.

#### < Background >

*In the current context of economic crisis and increase of primary energy prices, energy efficiency and energy savings measures are the solution. An efficient use of energy is necessary for better fighting global warming, for reducing energy demand and consumption, energy dependency and for eliminating energy waste. There is an important potential for reducing consumption in energy-intensive sectors such as manufacturing and transport, and even more significantly in the building sector.*

*According to the International Energy Agency, residential, commercial and public buildings account for 30 to 40% of the world's energy consumption (and in each country too) and for 25 to 35% of the current world's CO<sub>2</sub> emissions. Huge energy efficiency improvements can be expected in this sector if authorities take appropriate measures, such as adopting high level and binding standards ,implementing building renovation programmes, coherent financing strategy for promoting energy efficiency, setting binding targets, ensuring compliance of energy efficiency related legislation, promoting training programmes and information regarding energy efficiency initiatives.*

#### Action taken so far

Japanese energy efficiency and conservation policies consist of both regulation measures through “Energy Conservation Law” and supportive measures through budget and tax incentive, which are applied to industry, transportation, and residential and commercial building sectors.



In 2013, Japan set a renewed energy saving standards on residences and buildings, including heat insulating performance and evaluation on facilities. In December 2012, Japan set a low carbon standard for residences and buildings to induce higher criteria of green residences and buildings compared to energy efficiency standards.

In June 2013, Japan decided the roadmap to 2020 to oblige all new residences and buildings to conform to the energy conservation standards in a step-by-step manner.

Japan has taken measures called "Top runner program" to improve energy efficiency of household appliances and automobiles, and in May 2013, amended the law to add building materials as the scope of the Top runner program. Japan often exchanges information with other countries in international conferences such as the IEA, the IEF and IRENA.

#### Future outlook

Japan will oblige all newly built residences and buildings to conform to the energy conservation standards in a step-by-step manner by 2020 sufficiently taking into account the necessity, degree and balance of regulations.

Japan will add certain equipments to the Top runner program and review energy efficiency standards.as well as proactively will share the information of its energy efficiency and conservation policies in international conferences.

## 12. Promoting action to minimize commodity price volatility (WP-E/#25/EJ to EJ)

### BRT Recommendation

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

#### <Recent Progress>

Japan and the EU are furthering discussions on these issues at several international conferences such as G20 (Mexico 2012), the Asian Ministerial Energy Roundtable Meeting, International Energy Forum, etc., and organizations such as IOSCO.

- According to the 2013 Report from the GOJ Concerning the Recommendations from the EU-Japan Business Round Table, in the 13<sup>th</sup> IEF Ministerial Meeting held in June 2012, the GOJ pointed out that it is necessary for producing countries to behave responsibly toward the stabilization of the energy supply for the market stability, commented that GOJ will contribute actively to the continuous effort to strengthen the market stability and the producer-consumer dialogue.
- Several legislative proposals and initiatives were proposed by EU in 2011:
  - The European Market Infrastructure Regulation (EMIR, regulation for over the counter derivative trading) regulation was adopted in June 2012;
  - Proposals reviewing Directives on Market Abuse (MAD) and Directives on Markets in Financial Instruments (MiFID) were adopted in 2011; these new measures increase transparency and reporting in trading of commodity derivatives

Both Japanese and EU initiatives are in line with G20 principles and are backed (i.e. surveyed and approved) by principles defined by IOSCO such as: “Principles for the Regulation and Supervision of Commodity Derivatives Markets” or “Principles for the Oil Pricing Reporting Agencies”.

#### < Background >

*The rising cost, price volatility, and unstable supply of raw materials are a concern for Europe and Japan business. The policies of resource-rich countries can alleviate or exacerbate such a concern. Stable access to rare metals is critical to expanding the production of rechargeable batteries, as well as to several other industries. There are diversified sources of supply of positive-electrode materials such as lithium, manganese, cobalt, and nickel used for rechargeable batteries. However, some other rare earths are currently only available from China. The EU and Japan should reinforce their efforts to diversify their sources of supply and to secure a stable yet competitive supply of rare metals.*

*The rapidly growing demand for energy and natural resources mainly comes from developing countries, notably China and India. International competition to secure energy and natural resources is intensifying. Moreover, raw-material and energy-access diplomacy has been on the rise and has the potential to distort markets. The inflow of financial funds has contributed to the price volatility of major mineral resources. The mining regulations and trade policies of the resource-rich countries can heavily influence the availability and price of some raw materials. All these developments put pressure on the competitiveness and stable and profitable development of Japanese and European*

*industry. Rapidly rising raw material prices could adversely affect corporate profits and the world economic recovery. Commodity-price volatility in the agricultural sector is also a threat to global growth and food security.*

#### Action taken so far

At international conferences such as the International Energy Agency (IEA) Ministerial Meeting, the Asian Ministerial Energy Roundtable and the LNG Producer-Consumer Conference, price volatility of fossil fuels and transparent markets have been discussed. At the 5th Asian Ministerial Energy Roundtable held in September 2013, the GOJ asked oil-producing countries to supply oil in accordance with the demand for the stability of the international oil market. In order to improve the market transparency, GOJ have been contributing actively to strengthening the market stability and producer-consumer dialogue through additional contribution for the further development of JODI by IEF and its expansion to the field of natural gas.

Additionally, the GOJ, as a member of the International Organization of Securities Commissions (IOSCO), worked for a report of “the Principles for Financial Benchmarks” which was published in July 2013 for enhancing the integrity and reliability of benchmarks and the oversight on benchmark administrators, and took part in the survey on the implementation of “the Principles for Oil Price Reporting Agencies” published in October 2012.

#### Future outlook

Japan continues to tackle stabilizing fossil fuel price through various international conferences.

Additionally, within 2014, the GOJ will work in IOSCO to make a report on the implementation of “the Principles for Oil Price Reporting Agencies”, and to assess the impact of “the Principles for the Oil Price Reporting Agencies” on physical markets, and the impact on deliveries at storage facilities and prices in commodity derivatives market.

### 13. Supporting R&D for recycling and material substitution (WP-E/#26/EJ to EJ)

#### BRT Recommendation

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

#### <Recent Progress>

“Recycling of Rare Earths Metals” was one of the themes of the 2nd Trilateral EU-Japan-U.S. on Critical Materials held in March 2012. Discussions and seminars were held on R&D policies on the development of substitutes for rare earths and the reduction of the use of rare earths, trends in resource development, recycling, business strategies on supply chain management. The EU and Japan decided to collaborate in the substitution of rare materials by launching a joint call for proposals in July 2012 (FP7-NMP-2013-EU-Japan).

#### < Background >

*Critical materials such as rare earths and rare metals are essential for producing several key components of high-technology devices produced by the industries of both Japan and the EU. Ensuring ways to secure supplies of strategically important rare earths and other critical materials is vital to both industries.*

#### Action taken so far

Following the large-scale reduction of the export quotas of Chinese rare earth in 2010, the GOJ has been promoting cooperation with consuming countries such as the EU, in order to secure raw materials including rare metals.

The Third Trilateral EU-Japan-U.S. Conference on Critical Materials for a Clean Energy Future was held in Brussels on May 29-30, 2013, following the Second Trilateral Conference held in Tokyo in March 2012. At this conference, the EU, Japan and the U.S. shared the recognition of the importance of working on the development of alternative materials and technologies for reducing usage and promoting recycling under the cooperation among consuming countries.

#### Future outlook

The 4th Trilateral EU-Japan-U.S. Conference will be held in U.S. in 2014. “Recycling of rare metals” will be proposed as one of the themes of the conference.

#### 14. Supporting long-term strategy on resources use and technology development (WP-E/#27/EJ to EJ)

##### BRT Recommendation

The EU and Japan should work together in:

- Sharing knowledge, best practices implemented by both EU countries and Japan to secure raw material supply (including rare earths);
- Establishing global rules on access to raw materials (including rare earths), tackling issues such as: export restrictions, export taxes, quotas, double pricing, etc.

##### <Recent Progress>

This is a new recommendation

##### < Background >

*Japan and the EU face similar challenges in accessing and securing raw material supplies; they also have similar positions as resource-poor countries with lots of resource-intensive industries. Developing a common understanding of actions undertaken by both sides to address these challenges will help Japan and the EU countries establishing a common, long-term strategy regarding the sustainable / stable supply and use of key resources. This will eventually benefit the industries in both Japan and the EU.*

##### Action taken so far

Japan attended “the US-Japan-EU Trilateral Workshop on Critical Raw Materials “organized by the DG Enterprise and Industry of the European Commission in Brussels December 2013, and exchanged information with each other on raw material policies and critical materials.

##### Future outlook

Japan will continue to exchange information on raw material with the EU as appropriate although there is no specific substantial plan or occasion in mind at the moment.