



Mr. José Manuel BARROSO
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CABINET DU PRESIDENT									
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April 2014

Subject: EU-Japan Business Round Table

Dear President,

The 16th EU-Japan Business Round Table meeting took place in Tokyo on 8 & 9 April and was co-chaired by Hiromasa Yonekura (Chairman & CEO, Sumitomo Chemical Co., Ltd.) and myself.

During the meeting, the BRT adopted Recommendations to the EU and Japanese Authorities, prepared by its Working Parties on Trade Relations, Investment and Regulatory Cooperation; Life Sciences and Biotechnologies, Healthcare and Well-being; Innovation, Information & Communication Technologies; Financial Services, Accounting & Tax Issues and Energy, Environment & Sustainable Development.

The BRT also identified Recommendations it had submitted last year and for which it considers the Japanese Government and the EU Authorities have made significant progress.

With a view to the forthcoming EU-Japan Summit, please find enclosed copies of the Recommendations. Following the conclusion of this year's BRT meeting, Mr Yonekura and I delivered a set of the same documents to Shinzo Abe, Prime Minister of Japan, on 9 April.

On behalf of all the BRT Members, Mr Yonekura and I request your support for the swift implementation of this year's Recommendations.

Yours sincerely,



Encs. EU-Japan Business Round Table 2014 Recommendations
 List of Recommendations from 2013 which have seen significant progress

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European Commission
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EU-Japan Business Round Table

RECOMMENDATIONS

"EU-Japan Cooperation - New Opportunities for Global Growth"

8 and 9 April 2014

(Tokyo, Japan)

1. Introduction

The EU-Japan Business Round Table (BRT) held its Annual Meeting in Tokyo on 8 and 9 April 2014 with the theme of "EU-Japan Cooperation - New Opportunities for Global Growth." The meeting was chaired by Mr. Hiromasa Yonekura, Chairman and CEO of Sumitomo Chemical Co., Ltd., and Mr. Fabrice Brégier, President and CEO of Airbus SAS.

The BRT had the pleasure and honour of welcoming high-level representatives of the Japanese and EU Authorities: Mr. Toshimitsu Motegi, Minister of Economy, Trade and Industry of Japan, Mr. Yoshihiko Isozaki, Parliamentary Vice Minister of Economy, Trade and Industry of Japan, Mr. Norio Mitsuya, Parliamentary Senior Vice-Minister for Foreign Affairs of Japan, Mr. Takao Makino, Parliamentary Vice-Minister for Foreign Affairs of Japan, Mr. Yasumasa Nagamine, Deputy Minister for Foreign Affairs of Japan, Mr. Masahiro Yoshizaki, Vice-Minister for Policy Coordination (International Affairs), Ministry of Internal Affairs and Communications of Japan, Mr. Daniel Calleja Crespo, Director-General for Enterprise and Industry of the European Commission, and Mr. Antonio Parenti, Deputy Chief Negotiator for the EU-Japan FTA, European Commission.

The meeting consisted of the following:

1. Discussion on, and adoption of, general and sectoral recommendations;
2. Discussions on (i) the negotiations on an EU-Japan Free Trade Agreement (FTA) /Economic Partnership Agreement (EPA), (ii) the New Industrial Revolution in relations to sustainability, and (iii) important business themes for the EU and Japan in the post FTA/EPA era;
3. Discussions with the Japanese and EU Authorities.

The BRT Members agreed to submit their joint recommendations to European Council President Herman Van Rompuy, European Commission President José Manuel Barroso, and Prime Minister Shinzo Abe of Japan.

2. Background

The BRT recognises that the Japanese and European economies are now growing, albeit modestly, and is optimistic that that growth will continue given the right policy framework and continued growth in the emerging economies.

The BRT broadly supports the Japanese Government's strategy of 'Abenomics' and specifically the policy measures aimed at spurring private sector-led growth,

including significant regulatory and institutional reform. The Japanese business community anticipates that 2014 will see the Japanese economy steering out of the prolonged deflation and into complete revitalisation. The BRT broadly welcomes the rebalancing of the European economy and the improvement in its external competitiveness, and notes that the growth rates of the EU economy and of the euro area are predicted to increase, and agrees with the European Commission's view that it is important not to be complacent.

As the BRT has stated in the past, it agrees with the view of the EU and Japanese Authorities that concluding FTAs/EPAs with key strategic economic partners will help revitalise their respective economies, strengthen the still vulnerable global economy, as well as transforming the EU-Japan economic relationship.

Since the last BRT meeting in Paris, the BRT issued a Joint Statement¹ welcoming the launch of the EU-Japan FTA/EPA negotiations and urged that the negotiations should be completed as early as possible and their outcome be compatible with the high level of their ambition. Apart from the statement from the BRT, the EU and Japanese business communities have voiced their support on several occasions to promote the earliest possible conclusion of the negotiation, including the sectoral dialogue held in Brussels this March. The BRT appreciates the recognition that the Summit leaders gave the BRT and its recommendations, and the reaffirmation of the Summit leaders' "determination to continue cooperation with the business communities on both sides, notably through the BRT".

3. Calls and Recommendations

The BRT appreciates and welcomes the efforts that the EU and Japanese Authorities have made in the FTA/EPA negotiations. With a strong conviction that an EU-Japan FTA/EPA could boost trade and investment, promote job creation, and spur growth in both economies and that it will also help create new opportunities for global economic growth, the BRT reiterates its call that the EU and Japanese Authorities should step up their efforts to tackle and resolve the substance of the outstanding issues and that a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA should be concluded as soon as possible. The BRT reaffirms its commitment to make every effort to support the early realisation of an EU-Japan FTA/EPA. BRT Members are ready to make available industry expertise to achieve this objective.

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

At the same time, the BRT urges that the EU and Japan should extend and deepen their cooperation beyond the framework of an FTA/EPA to address a wide variety of

¹ "Strengthening the EU-Japan Economic Partnership – Unleashing the potential of economic relations through the swift conclusion of a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA". It was submitted to the EU and Japanese Authorities on 15/11/2013.

global challenges and should particularly explore opportunities to cooperate in businesses in or with third countries as well as in areas relating to innovation, energy, natural resources, environment and climate change, demographic changes, global financial markets, small and medium enterprises and human resources development.

The BRT also calls on the EU and Japanese Authorities to address the following issues:

(A) Trade, Investment, and Regulatory Cooperation

The BRT calls on the EU and Japan to:

- Step up their efforts to tackle and resolve the substance of the outstanding issues so that a comprehensive, ambitious, high-level and mutually beneficial FTA/EPA can be concluded as soon as possible. The BRT reaffirms its commitment to make every effort to support the early realisation of an EU-Japan FTA/EPA.
- Further make efforts to contribute to WTO's DDA negotiations, so as to vitalise and create momentum to move the negotiations forward.
- Strive to mutually recognise products certified under similar and equivalent product standards and to cooperate on harmonising regulations and systems where possible. They should also aim for enhanced cooperation in promoting new global standards.
- Support the timely development of business. Specifically, the BRT calls for expansion of the number of bilateral social security agreements that have been concluded and for liberalisation of the movement of intra-corporate transferees within the framework of an FTA/EPA.
- Develop measures that will promote and assist each other's SMEs within their own jurisdictions. The BRT also calls for cross-support, such as logistic support, various tax incentives, and other measures, to be included in the EU-Japan FTA/EPA negotiations.

Moreover, the BRT calls for the EU Authorities to speedily resolve the EU-specific issues identified in the Working Party A document by the Japanese Members of the BRT, and for the Japanese Government to resolve the Japan-specific issues identified in the Working Party A document by the EU Members of the BRT.

(B) Life Sciences and Biotechnologies, Healthcare and Well-Being

General Introduction

- The EU and Japan should formulate concrete strategies and action plans in Life Sciences & Biotechnology, thereby focus on measures to support the improvement of efficient healthcare practices, food security / supply and innovations in Biotechnology.

HealthCare (Pharmaceuticals, Medical Devices, Medicinal Gases, etc.)

- 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 and medical devices. In addition, MHLW should consult all

key stakeholders with respect to any new HTA (Health Technology Assessment) issues.

- Japan should further support the implementation of new innovation-rewarding pricing systems for pharmaceutical products, including the abolishment of the rule of re-pricing by market expansion, thereby enhance a competitive pricing system in order to promote innovative products.
- Japan should also promote an innovation-rewarding pricing system for medical devices in order to move towards a product-based, market-oriented reimbursement pricing system.
- The EU and Japan should improve the pharmaceutical and medical device business environments by proceeding with regulatory harmonization and further extension of “Mutual Recognition Agreements” in order to avoid redundant inspections of manufacturing facilities (e.g. injectable pharmaceuticals and APIs) and ensure recognition of quality management audit results for lower risk medical devices.
- Japan should support the reinforcement of strict regulations for GMP on medicinal gases.

Animal Health

- Europe should introduce a 1-1-1 concept (one dossier – one assessment – one decision on marketing authorization) for all animal health products, thereby further harmonize the regulatory requirements for product registrations, shorten review times and recognize the GMP certification for veterinary products.
- Europe and Japan should promote the responsible use of antibiotics in Animal Health.
- Japan should clarify registration requirements and shorten the review process of introducing recombinant vaccines from Europe.
- Japan should promote animal welfare in animal drug administration by accepting more overseas data and alternative approach.

Plant Protection & Biotechnology

- The EU and Japan - with the support of companies - should speed up research in Plant Protection & Biotechnology and inform the public regularly and accurately about the state of GMOs, based on sound scientific knowledge, thereby closely working with private sectors.
- The EU should shorten the review times for new applications / product registrations in both plant protection and biotechnology.

(C) Innovation, Information & Communication Technologies

ICT

- Internet drives growth. Both sides' Authorities should continue maintaining an open and transparent online environment under a balanced multi-stakeholder approach.
- The BRT requests both sides' Authorities to cooperate for ITA expansion and liberalisation of services over the internet.

- The BRT calls on both sides' Authorities to increase cybersecurity cooperation to build a safe and robust online environment.
- Balancing privacy protection and innovation is important when reviewing personal data protections regimes. This includes unhindered cross-border business and data flows.

Innovation in General

- Both sides' Authorities should favour joint R&D programmes geared towards international standardisation.
- The procedure to prepare and launch coordinated calls should be well discussed by both parties and better standardised.
- The BRT recommends further enhancement of tax credits for R&D, in particular for SMEs.

Aeronautics

- The BRT requests that the Authorities deepen their dialogue and significantly upgrade the scale of EU-Japan industrial cooperation in aeronautics.
- The BRT recommends a better bilateral cooperation at an increased level on navigation regulations for helicopters.

Space

- The Authorities should significantly upgrade bilateral industrial cooperation.
- The Authorities should bring about a mutual backup cooperation scheme of all government launches using their respective satellite launcher fleets.

Defence

- Japan's three principles on transfer of defense equipment should be complemented by clear and transparent procedures.

Railways

- The Authorities should continue and deepen their bilateral dialogue focusing, among others, on safety and innovation.

(D) Financial Services, Accounting and Tax Issues

- The BRT requests that regulating bodies fully address the impact of reforms and new regulations on the real economy notably in the implementation phase and take a co-ordinated approach to avoid negative effects on global business activities and efficient allocation of resources.
- The BRT recommends that, as to the BEPS (base erosion and profit shifting) Action Plan, the authorities should carefully consider the risks of excessive disclosure requirements and anti-tax avoidance measures so as not to hamper multinational enterprises' business activities.
- The BRT maintains its serious concern over the EC's proposed financial transaction tax (FTT), particularly with respect to its wider application and extraterritorial impact.

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

(E) Energy, Environment, and Sustainable Development

Basic energy policy

- Energy is the basis of all economic activity. Securing a stable energy supply at a reasonable price, developing the necessary infrastructure as well as reducing energy needs are not only crucial for sustainable business activities but also for the creation of new business opportunities. At the same time, it is important to consider the environmental impact of energy use.

Nuclear Energy

- Safe nuclear power generation can play an important role in the energy mix of the EU and Japan. It could be a valuable asset supporting EU and Japanese competitiveness, supplying base load electricity at low cost and contributing to grid stability, economic growth and jobs creation.
- The EU and Japan should establish energy policies which preserve a role for nuclear power, one of the effective means of reducing greenhouse gas emissions, while paying utmost attention to safety.

Safety measures

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

Renewable energy

- Uncertainties remain about the cost and security of supply of renewable energy. However, it has the potential to complement conventional energy with emitting no greenhouse gas and reducing import dependency. Renewable energy sources are available in many forms, including wind, solar, hydro, geothermal, tidal, biomass, etc. Storage batteries can also contribute to ironing out fluctuations in the supply and demand for energy.
It is necessary to study carefully how the adoption of renewable energy sources will be specifically carried out.

Energy conservation and energy efficiency

- The EU and Japan should consider taking further measures to promote energy conservation, by financing research projects to develop technologies and methodologies for improving energy efficiency and by sharing their best practices.

Importance of measures against global warming

- Mitigating global warming is a global challenge. Emerging countries are already overtaking developed countries as the world's major greenhouse gas emitters. It is consequently imperative that emission reductions are also undertaken by



emerging countries. The EU and Japan should work together to create a comprehensive and effective mechanism for reducing global greenhouse emissions.

(A) - (E) summarise the BRT's detailed regulatory and sectoral Recommendations.

The BRT considers that significant progress has been made on the following recommendations submitted last year. The BRT would like to express its utmost gratitude to the Leaders and Authorities of the EU and Japan for the leadership and efforts they have shown in relation to these issues. The BRT Members expect to see similar positive developments on other issues.

WP-A #17 J to E	Customs Classification
WP-A #18.6 J to E	HFCs
WP-A #21 J to E	Unitary Patent
WP-B #01 EJ to EJ	Enhancement of bio-venture activities
WP-B #04 EJ to EJ	Infrastructure improvement and international harmonization of regulation standards for approval of non-invasive diagnostic medicines and devices
WP-B #10 EJ to J	Balance between prevention and treatment in healthcare
WP-B #11 EJ to J	Nation-wide electronic database for individual health/medical records in Japan
WP-B #13 EJ to J	Regulatory transparency and review time by PMDA
WP-B #14 EJ to J	Reinforcement of measures to ensure proper distribution of privately-imported medicines
WP-C / # 21 EJ to EJ	Civil Purpose Satellite Technology
WP-C # 25 EJ to EJ	Cooperation on Active Space Debris Removal
WP-C/ # 28 EJ to J	Relaxation of the Three Principles on Arms Exports
WP-C # 32 E to EJ	Level Playing Field in Civil Aeronautics Markets
WP-C # 35 E to J	Approval of Satellite Launch Service Providers
WP-C # 36 E to J	Legitimate use of Private Finance Initiative projects
WP-C # 42 E to J	Forum for Japanese and EU defence industries to meet and discuss

Note: The above numbers refer to those in the Recommendations issued in 2013.

BRT は、昨年建議した下記の提言項目につき、重要な進展があったと認識しており、日・EU 両政府のリーダーシップと尽力に最大限の謝意を表したい。BRT としては、今後、他の事項についても同様の進展があることを期待している。

WP-A #17 J to E	関税分類
WP-A #18.6 J to E	ハイドロフルオロカーボン(HFCs)
WP-A #21 J to E	一元的特許
WP-B #01 EJ to EJ	バイオベンチャー活動の強化
WP-B #04 EJ to EJ	非侵襲的な体外診断用医薬品・診断機器の製品認可に関する基準の国際調和とインフラ整備
WP-B #10 EJ to J	健康分野における予防と治療の両立
WP-B #11 EJ to J	健康・医療記録の統合電子データベース化へのグランドデザイン策定
WP-B #13 E to J	医薬品医療機器総合機構(PMDA)による審査基準の透明化と審査期間の短縮
WP-B #14 EJ to J	個人輸入による医薬品流通の適正化対策の強化
WP-C/ #21 EJ to EJ	民間向けの衛星技術
WP-C # 25 EJ to EJ	宇宙デブリの除去に関する協力
WP-C/ #28 EJ to J	日本の武器輸出三原則の緩和化
WP-C # 32 E to EJ	民間航空市場に関する均等な機会
WP-C # 35 E to J	衛星打ち上げサービス事業者の認定
WP-C # 36 E to J	PFI プロジェクトの合法的活用
WP-C # 42 E to J	日本とEU の防衛産業が参加するフォーラム開催による話合い

注) 上記の提言番号は、2013 年の提言書に基づくものである。

**Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan**

Tokyo, 8 & 9 April 2014

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

Working Party Leaders:

Co-Chair

Mr. Danny Risberg
Chairman
European Business Council (EBC)
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List of Abbreviations

Abbreviation	Meaning
AEOs	Authorised Economic Operators
APEC	Asia-Pacific Economic Cooperation
ATP	Adaptation to Technical Progress
BPR	Biocidal Products Regulation
CAA	Consumer Affairs Agency
CBCR	Country by Country reporting
CCCTB	Common Consolidated Corporate Tax Base
CE	Conformité Européenne (European Conformity)
CLP	Classification, labelling and packaging
CMR	Carcinogenic mutagenic or reprotoxic
CoRAP	Community Rolling Action Plan
DDA	Doha Development Agenda
DC	Direct Current
ECHA	European Chemical Agency
ELV	End of Life Vehicle
EN	Européen de Normalisation de Normalisation (European Standards)
EP	European Parliament
EPA	Economic Partnership Agreement
EU	European Union
FDI	Foreign Direct Investment
FTA	Free Trade Agreement
FSA	Financial Services Agency
G8	Group of Eight
G20	Group of Twenty
GATS	General Agreement of Trade in Services
GCP	Good Clinical Practise
GDP	Gross Domestic Product
GHS	The Globally Harmonized System of Classification and Labelling of Chemicals
GoJ	Government of Japan
GPA	The Agreement on Government Procurement
GPS	Gross Product Strategy
HSE	Health Safety and Environment
ICTs	intra-corporate transferees
IEC	International Electrotechnical Commission
IPM	Interface Public Members
ISO	International Organisation for Standardisation
JAS	Japan Agricultural Standard
JELMA	Japan Electric Lamp Manufacturers Association
JET	Japan Electrical Safety & Environment Technology Laboratories
JETRO	Japan External Trade Organisation

JIS	Japan Industrial Standard
JR	Japan Railways
KPIs	Key Performance Indicators
LED	Light-Emitting Diode
LoA	Letter or Access
MAFF	Ministry of Agriculture, Forestry and Fisheries
METI	Ministry of Economy, Trade and Industry
NOL	Net Operation Loss
OECD	Organisation for Economic Co-operation and Development
OR	Only Representative
PMDA	Pharmaceuticals and Medical Devices Agency
PPPR	Plant Protection Products regulation
PSE	Electrical Appliance and Material Safety Law
QMS	Quality Management System
R&D	Research & Development
REACH	Registration, Evaluation, Authorization and Restriction of Chemicals
RoHS	Restriction of Hazardous Substances
RTD	Research and Technology Development
SDR	Special Drawing Rights
SDS	Safety Data Sheet
SIEF	Substance Information Exchange Forum
SMEs	Small and Medium size Enterprises
SVHC	Substance of Very High Concern
TPP	Trans-Pacific Strategic Economic Partnership Agreement
TTIP	Transatlantic Trade and Investment Partnership
UNECE	United Nations European Commission for Europe
VAT	Value Added Tax
VICH	International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products
WCO	World Customs Organisation
WHO	World Health Organization
WTO	World Trade Organization
WP	Working Party

Introduction

Japan is the EU's seventh largest trading partner and the EU ranks as Japan's third largest trading partner. While already significant, this trade relationship has considerable upwards potential and the benefits of the EU-Japan FTA/EPA, currently under negotiation, will stretch beyond the many European and Japanese companies already operating in each other's home markets to all those, attracted to the new opportunities it creates. Working Party A stresses that any agreement must address the specific concerns of European and Japanese businesses reflected in this and previous reports. With so much at stake, we are urging the authorities on both sides to ensure that the necessary progress is made. Many reforms are required to secure a fair and competitive environment for business and have been identified from the extensive first-hand operational experience of Working Party A members in the Japanese and European markets. This report sets out concrete recommendations that address the following key issues:

- Creating a common regulatory environment, mutual recognition of regulations, standards and market authorisations to the extent possible and adoption of international standards
- Elimination of both tariff and non-tariff measures as well as unnecessary bureaucracy
- Ensuring fair competition and equal treatment of all companies, domestic & foreign
- Ensuring fairer and more open competition in services, and procurement markets
- Improving conditions for foreign direct investment. And finally,
- Further enhancing incentives for growth of SMEs and for investment in R&D

Working Party A members reiterate that the EU-Japan FTA/EPA bilateral agreement must be balanced, comprehensive and ambitious in order to dismantle these barriers holding back EU-Japan trade and investment and significantly promote growth both economies.

To highlight priority issues in the text that follows, one asterisk (*) indicates "priority" recommendations and, two asterisks (**) indicate "top priority" Recommendations. (e.g. WP A / # 01** / EJ to EJ)

Recommendations from both European and Japanese industries

WP-A / # 01 / EJ to EJ Strengthening the EU-Japan Economic Relationship**

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

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

< Background >

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

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

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

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

The agreement on trade facilitation can serve as a boost to global trade by reducing costs of trade by 10-15%. Its objectives are to speed up customs procedures, make

trade easier, faster and cheaper, provide clarity, efficiency and transparency, reduce bureaucracy and corruption, and use technological advances. The BRT calls upon WTO members to quickly implement the trade facilitations agreement.

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

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

The BRT strongly supports the progress in these issues, and requests the authorities of the EU and Japan to further make efforts to vitalize and earn momentum in order to move the DDA negotiations forward.

Additionally, the BRT suggests that the authorities of the EU and Japan should, together with other WTO members, explore further topics that are essential for the smooth functioning of global value chains.

< Recent Progress >

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

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

< Background >

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

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 a leader in this area and take more and stronger action. The existing legal

framework provides an excellent basis for such action but needs to be updated in order to respond to a changing global economic landscape.

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

1. Towards a common regulatory environment

The BRT recommends that Japanese and European policy-makers should increase their understanding of the existing and upcoming regulations of the other side. They should study the possible impact of new regulatory developments on domestic and foreign business to avoid taking initiatives that unwillingly create barriers to trade and investment. They should exchange annual legislative work programmes at the earliest stage to prevent regulatory divergence and the creation of new trade barriers. In addition, they should agree to an early warning system for draft legislation to facilitate an effective bilateral dialogue. To expand a common regulatory environment into the areas that are already regulated, furthermore, the Japanese and European policy makers should also develop a joint strategy to promote better regulation by learning from each other's experience and adopting a common system of good governance. Throughout the process, the two authorities should have close dialogue with businesses.

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

<Background>

The BRT believes that a common regulatory environment will be a key to the economic prosperity of the two economies. Once an FTA/EPA is concluded, it will be important not only to ensure that new regulations do not nullify or impair the market access benefits accruing to either party under the agreement or create new barriers to bilateral trade, but also to expand and strengthen the relations between the two economies so that the benefits of their cooperation will further increase and so that they will eventually be able to expand such a common regulatory environment to other bilateral and multilateral relations.

2. International standards and harmonization of standards and certification procedures

The BRT urges both authorities to adopt international product standards and certification procedures where applicable, and, to promote harmonisation of technical requirements and certification procedures, mutual recognition of

product approvals and, when possible, and appropriate, in areas where harmonised standards do not exist, mutual approval of the import, sale or use of products that have been approved on the basis of functionally equivalent requirements in sectors such as Construction Materials, Organic Products, Cosmetics, Medical Devices, Veterinary Products, Automobiles and Processed Food.

3. A common chemicals regulation

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

4. Common energy conservation regulation

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

5. Expand the benefits of AEOs

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.

6. Fight against counterfeited, pirated and contraband goods

The BRT would like to see the EU and Japan to step up efforts to fight against counterfeited, pirated and contraband goods, both inside and outside the EU and Japan. For example, they should better cooperate with each other and with the third country authorities to secure the closure of sites trading in fake goods.

The BRT requests that the authorities of Japan should make all trade with fake goods illegal by closing the loophole by which individuals are allowed to bring in or import counterfeits for person consumption.

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

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

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

7. Adoption of UN-ECE regulations

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 for 7 >

In 1998, Japan became the first country in Asia to accede to the UN-ECE 1958 Agreement on the Mutual Recognition of Type Approval for Vehicles etc, which provides that vehicle components which have received type approval according to UN-ECE Regulations in one contracting country are exempt from testing in any other signatory country where those regulations have been adopted. Japan has now adopted UN-ECE Regulations in 35 of the 47 areas included in Japanese type approval.

< General Background for 1-7 >

Implementation of these recommendations will lead to a significant improvement in the business environments of both the EU and Japan.

WP-A / # 04* / EJ to EJ Supporting timely development of business

1. Social security contributions (avoiding double contributions):

The BRT welcomes the conclusion of social security agreements between Japan and 10 EU Member States. The BRT requests that, Japan and the Member States of the EU should make further efforts to expand the network of Social Security Agreements. In addition, they should introduce an interim measure, by which a host country should either exempt contributions to pension funds unilaterally or refund the contributions in full, not only partially, when expatriates return to their home country.

< Recent progress >

There has been a limited progress in the past year

< Background >

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

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

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

- A framework agreement between the mother company, which sends expatriates, and the host country, stipulates the maximum number of expatriates. Within the agreed limit, the mother company is free to send intra-corporate transferees to that country without further obtaining individual work permits.
- When the mother company concludes such an agreement with several Member States in which its subsidiaries or branches have operations, movement of intra-corporate transferees between those countries does not require a new work permit as long as the total number in each agreement is respected.

< Background >

For the smooth and efficient running of international businesses, it is essential that companies are able to dispatch key personnel, including directors without going through red tape. Such transfers do not have any negative impact on the labour market of the host country. On the contrary, they will expand employment in the host country through the development of the business concerned. In addition, expatriates themselves tend to pay high income taxes to the host country. The requirement to obtain work and residence permits for intra-corporate transferees between the EU Member States and Japan is usually a formality and it is rare that the application of an intra-corporate transferee is questioned and required to submit substantial reasons. However, the recent economic situation in some Member States has caused the authorities to be more reluctant to issue work permits in general, which sometimes affects intra-corporate transferees by delaying the issuance of work permits to them. As the burden on companies as

well as employees and their family members is substantial, it does constitute an obstacle to the swift development of business.

The European Parliament and the Council have reached an agreement on the final text of a Directive on conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer. This agreement will prove very useful for Japanese companies sending their employees to the EU because, for example, it will facilitate an assignment that involves several Member States and allow accompanying family members to have access to the labour market. However, unfortunately,, the new Directive will not be applied in the UK, Ireland and Denmark due to the opt-out of those Member States. Japanese nationals in the UK, where their number is the highest among the EU Member States, will not benefit from this Directive. It is therefore imperative that such liberalisation is realised within the framework of an EPA/FTA so that it will be applicable to all intra-corporate transferees between the Member States of the EU and Japan.

WP-A / # 05* / EJ to EJ Support for SMEs

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

This would include:

1. Providing each other's SMEs the same general support and privileges as provided to one's own SMEs.
2. Establishing permanent local assistance in language, paperwork, hiring local personnel, legal and regulatory matters, as well as advice on financing and banking, etc.
3. Providing tax breaks and incentives, tax deduction for total research expenses, income tax breaks for foreign experts, tax exemption for doctoral students, tax relief for R&D, tax deduction for joint and entrusted researches based on industry-academic-government cooperation, as well as tax and other facilities and incentives for investors.
4. Helping graduates with international backgrounds find local jobs with the other side's SMEs.
5. Creating a joint investment fund for both Japanese and European SMEs.
6. Exchanging best practices and tested solutions in industrial policy for SMEs.
7. Expanding the SME-related programmes already run by the EU-Japan Centre for Industrial Cooperation.

< Recent progress >

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

< Background >

SMEs are new sources of growth and jobs in both Europe and Japan. Their success in bilateral trade is a major factor in their development and also helps to revitalise both Japanese and EU industries by disseminating new products and technologies. However, market access problems and various impediments noted in

other BRT recommendations are even harder to tackle or manage for SMEs. While the Japanese government, the European Commission and most EU Member States have internationalisation programmes for their own SMEs, existing help programmes for foreign companies are mostly geared towards large foreign direct investments in established industries and are inadequate for SMEs. Aiming to provide local help to all potentially interested foreign SMEs is not realistic, but increasing and sustaining help to SMEs that have established a local base is realistic in the context of a bilateral agreement. The BRT is aware of the major work being done for both Japanese and European SMEs by the European Commission and the Government of Japan through the programmes run by EU-Japan Centre for Industrial Cooperation.

Recommendations from European industry to Japan

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

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

Automobiles

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

< Recent progress >

This is a new recommendation

Construction Products

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.

Cosmetics

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.

Railways

Though standards are not so different and data generated at European research facilities are relevant for Japan, duplicate testing in Japan is required for the Japanese market. This has repeatedly been communicated by one JR company. Duplicate testing raises the costs of imports, making them less competitive than domestic products. The Government of Japan and the EU authorities should work toward establishing a mechanism through which test data and certification of railway equipment provided by European 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. These requirements and standards should preferably be used by all operators in Japan, which currently is not the case as each individual operator can choose its own standards and requirements. As a first step, test results and approvals by one operator should be accepted by other operators.

The BRT, however, recognises the latest development and positively views the first call for tender by a Japanese operator. The BRT recommends Japan to make better

use of the tendering system as this leads to more competition and better transparency, while not negatively affecting safety.

< Recent progress >

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

< Background >

Japanese safety standards and regulations are not publically available. There is, therefore, no possibility for foreign manufacturers to know exactly what requirements must be fulfilled. Furthermore each operator can in principle have their own testing requirements as there is no legislation on exactly what safety requirements need to be fulfilled.

Medical Devices/Equipment

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

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

< Recent progress >

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

< Background >

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

new treatments in the human healthcare market in Japan and to bring Japanese rules in line with global standards.

Veterinary Products

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

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

< Recent progress >

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

< Background >

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

Processed Food

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

- a) Substantially increasing the list of permitted additives, in addition to speeding up and fundamentally revising the approval process

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

< Recent progress >

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

< Background >

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

LED lamps and luminaries

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

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

The BRT requests Japan to harmonise with international standards and technical requirements in order for Japan to avoid being left behind in the global market. The market for LED lamps and luminaries is rapidly expanding and these products are expected to play an important role in saving energy on a global basis.

< Recent progress >

No concrete progress has been made.

< Background >

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

Labelling rules

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

< Recent progress >

This issue was brought up in the Regulatory Reform Council where both representatives for European companies as well as domestic companies argued for a revision of the Household Labelling Law. The CAA has so far not presented anything concrete. This issue was not touched upon in the GoJ progress report of April 2013.

< Background >

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

WP-A / # 07 / E to J Automobiles**

The Government of Japan should put kei cars and other motor vehicles on the same fiscal and regulatory footing.

< Recent progress >

The changes in the taxation of kei-cars proposed for FY2014 are a welcome first step but they do not go far enough. In the FTA negotiations, the GOJ should commit to further fiscal and regulatory changes so that European compact cars can compete on equal terms with kei-cars in the Japanese market.

< Background >

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

WP-A / # 08 / E to J Ensuring free and open competition in services**

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

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

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

< Recent progress >

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

< Background >

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

WP-A / # 09 / E to J Freight and logistics**

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

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

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

< Recent progress >

There has been no progress.

< Background >

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

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

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

< Recent progress >

This is a new recommendation.

< Background >

Currently Japan has nine separate customs area and no real central customs authority. This leads to discrepancies between the treatments of imported goods depending on the port of entry. This also makes it difficult for European logistics

companies, which lack multiple regional offices in Japan to expand their regional coverage as licensing is per region, ie. the license given by Tokyo Customs is not valid in Yokohama.

WP-A / # 10* / E to J Promoting foreign direct investment

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

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

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

< Recent progress >

While Japan has established incentive programmes for FDI, they are often limited in scope and application procedures are very inflexible. There are also some indications that Japan is contemplating shorting the period.

< Background >

Despite its position as the world's second largest economy, Japan's level of inward FDI as a proportion of GDP remains one of the lowest among all OECD countries. Even with the reorganisation of JETRO and the efforts starting with former Prime Minister Koizumi to increase FDI to Japan, only very small improvements have been seen. According to WTO FDI in 2011 was only 3.9 % of GDP.

WP-A / # 11 / E to J Procurement**

< General Recommendations >

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

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

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

< Specific Recommendations >

- In the bidding process in public tenders for helicopters>
 - a. More balanced competition should be ensured by comprehensive evaluation systems that also take aircraft performance into account.
 - b. Single year budget procurement constraints should be relaxed.
- Procurement of integrated systems of space ground equipment should be encouraged.
- The share of open tendering as a means for procurement by the Japanese utilities should be increased substantially.

< Recent progress >

There has been little progress.

< Background >

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

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

Recommendations from Japanese industry to the EU

WP-A / # 12** / J to E Europe 2020 and the Single Market Act

The BRT expresses our continued support for Europe 2020 and in particular, the Single Market Act - the initiative of the European Commission to relaunch the single market. In addition, The BRT looks forward to deeper cooperation between Japanese and European industries and research institutes under Horizon 2020, the EU's RTD program for 2014-2020. The BRT also supports the European Commission's call for immediate action for a European Industrial Renaissance.

- 1) The BRT would like to repeat the importance of the single market for the EU and the Europe 2020 strategy.
- 2) The EU should make utmost efforts to realise all of the commitments that it has made under Single Market Act I and II. The BRT would like to emphasise the importance of the following priorities for the single market.
 - Intellectual property rights
 - Consumer empowerment
 - Services
 - Networks
 - The digital single market
 - Taxation
 - Business environment
- 3) The BRT requests that the EU should add the realisation of the true single market of chemical materials as a priority.

< Recent Progress >

Europe 2020 is evolving and progress has been made on Single Market Acts I and II. The realisation of the true single market of chemical materials is progressing albeit slowly.

< Background >

For global businesses to flourish, the regulatory environment should be, as much as possible, consistent throughout the world. In this context, a level playing field in the single market is of key importance.

The BRT believes that a policy with social objectives such as environmental policy and social policy cannot be formed independently from economic and industrial policies. It is important to achieve synergy between these different policies. For example, in order to realise more energy efficient economy, innovative and competitive products and processes provided by industries will be essential not only in the manufacturing sector but also in the transport and household sectors. It goes without saying that sustainable social infrastructures for the aging society such as social security systems depend on the business activities that create growth and jobs.

Furthermore, the international coordination of regulatory policies and close cooperation amongst governmental and other institutions involved in policy-making process is important to realise a level playing field globally.

The European Commission calls on the Council and the Parliament on 22 January 2014 to adopt proposals on energy, transport, space and digital communications networks, as well as to implement and enforce legislation to complete the internal market. Furthermore, it states that industrial modernisation must be pursued by investing in innovation, resource efficiency, new technologies, skills and access to finance, accelerated by the use of dedicated EU funds. It promotes a more business-friendly Europe through actions to simplify the legislative framework and improve the efficiency of public administration at EU, national and regional levels. Other key issues include easier access to third country markets through harmonisation of international standards, open procurement, patent protection and economic diplomacy.

WP-A / # 13 / J to E Revision of high customs tariffs on audio-visual products and passenger cars**

The authorities of the EU should abolish or drastically reduce high customs tariffs, for example, 14% for audio-visual products and 10% for passenger cars. In the absence of a progress in global trade negotiations, such reduction should be realised through bilateral negotiations, notably, through an EPA/FTA between the EU and Japan.

< Recent Progress >

It can be said that a progress has been seen for this recommendation because the EU-Japan bilateral negotiations on an EPA/FTA have been launched.

< Background >

The EU is protecting some sectors of its industries by maintaining high customs tariffs even though these industries are at the forefront of international competition and need stimuli for competition rather than protection. Such protection will not help enhance international competitiveness of those sectors. Furthermore, it is only their users and consumers in the EU who unfortunately have to pay the resulting higher prices.

WP-A / # 14 / J to E Chemical Regulations**

14.1 REACH

1. Concerning REACH, the BRT recommends as follows:

- ✓ The BRT asks the authorities of the EU to proceed swiftly against the Member States which do not follow the interpretation of Article as stipulated in the Guidance document so that actors in the supply chain can avoid the fragmented compliance requirement in the EU market.
- ✓ The BRT requests the authorities of the EU to introduce one consistent policy in the EU concerning phthalates for indoor use. The BRT would also like to

make remarks that it will even be better if the policy is harmonised between the EU and Japan.

< Recent Progress >

Some progress has been seen for the recommendation on the interpretation of the Article. Progress on phthalates is limited and unsatisfactory.

< Background >

REACH, though it is a Regulation, has not realised a single market in the EU because its interpretation is diverse. The authorities of the EU should realise a single market through the clarification of interpretation that is accepted throughout the EU.

The interpretation of "Article" applied to 0.1% threshold for SVHC (Substance of Very High Concern) is still disharmonized among EU member states. The Guidance on Requirements for Substances in Articles in REACH regulation states that the 0.1% threshold should apply to an article as a whole produced or imported. Five Member States and Norway, however, insist that the threshold should apply to the parts of complex articles based on the "Once an article – always an article" concept.

In Denmark, despite the objection by the ECHA (European Chemicals Agency), phthalates for indoor use are banned in its national law published in its official journal on 30 November 2012. Its implementation has been postponed for two years. In addition, although Denmark had proposed its EU-wide ban by submitting dossiers in accordance with Annex XV of REACH, the proposal was rejected by committees of the ECHA in June and December 2012. This kind of disaccord could negate the benefits of the Single Market.

2. The Authorities of the EU should prepare a practical guidance to facilitate the implementation of REACH. In particular:

- ✓ The number of SVHC increases steadily. The ECHA publishes its list on its website. However, especially for SMEs in supply chains, such information is difficult to digest. The authorities of the EU should take an initiative to facilitate the setting up of a database into which upstream suppliers could input data and with which downstream manufactures could consult.
- ✓ The BRT requests that the authorities of the EU should issue a clarification on the obligation of ORs under the Article 8 of REACH and its implication under the EU competition law.
- ✓ The disseminated dossier information that is purchased from Lead Registrant in ECHA home page for HSE (health safety and environment) purposes (such as GPS - Global Product Strategy - and SDS - Safety Data Sheet) should be made accessible for free and made available worldwide.
- ✓ In the evaluation of a substance allocated to a Member State in the framework of CoRAP - Community Rolling Action Plan, a private business is often requested to provide information on the substance which it holds. However, it is sometimes requested at a short notice and/or a not-well-organised manner, which is not effective. The authorities of the EU should publish the best practice for the Member States so that private businesses can help them more efficiently and effectively.

< Recent Progress >

No progress has been seen for the recommendation on SVHC.

< Background >

REACH includes requirements that are practically very difficult to implement for businesses.

Concerning the obligation of ORs, the Article 8 of REACH states that the OR 'shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet'. However, in practice, there is a risk of infringing the EU competition law if OR collects customer-of-customers-information, such as customer names and imported volumes, especially from indirect supply routes, because under the EU competition law such supply chain information (i.e. market information) may be considered critical and sensitive. In addition, it remains unclear whether or not the competent authorities of each Member State will accept the use of a third-party trustee in the collection of such information in order to avoid possible infringement of the EU competition law. The reason is that Article 8 only relates to OR and there is no other indication in REACH that such OR obligation could be outsourced to a third party. The authorities in Germany appear to interpret that the use of a third-party trustee is not allowed. Furthermore, the use of the service of a trustee requires a significant additional cost. As the EU manufactures do not have to collect information on the quantity of imports, this only affects ORs – i.e. non-EU manufactures, which creates unfair market conditions.

3. The BRT recommends that the authorities of the EU should summarise and publish issues and concerns coming out of the latest registration – such as difficulty to identify Lead Registrants and no transparency of the cost for LoA (Letter of Access), and their solutions in time for the following joint submission. The authorities of the EU should, instead of relying upon agreement among the participants of SIEF, actively monitor and, if necessary, initiate corrective measures in order to realise transparency of the cost for LoA and the equity in cost sharing.

< Recent Progress >

Some limited progress has been made due to the introduction of data sharing dispute mechanism but more active involvement of the authorities of the EU is desirable.

< Background >

New challenges are already foreseen in the SIEF operation as the result of 2013 registration deadline, and a further 2018 deadline, namely, less data available, inexperienced Lead Registrants, mostly SMEs in the supply chain, and heavy financial burden. The BRT is concerned that the SIEF activities will stagnate due to such concerns.

The ECHA's testing proposals and evaluation of registered dossiers, and the Member States' evaluation of substances would result in renegotiation of cost sharing in a SIEF. LoA revenue from latter registrants would have to be distributed amount former registrants. To realise transparent and equitable cost sharing, the authorities of the EU would have to monitor and intervene more actively.

14.2 Appropriate approach to Endocrine disruptor

The BRT requests that the authorities of the EU should regulate endocrine disruptors not by using the categorisation like CMR (carcinogenic, mutagenic or reprotoxic), but by using the risk assessment based on sound science because endocrine disruption is not the endpoint of toxicity. The hazard assessment should be conducted by identifying adverse effect based on the endocrine mode of action defined by the WHO, and characterising with taking into account of potency, lead toxicity, severity and irreversibility.

< Recent Progress >

Some progress has been made as the result of ongoing discussion.

< Background >

Currently, the authorities of the EU are reviewing the current legislations such as REACH, PPPR (Plant Protection Products regulation) and BPR (Biocidal Products Regulation), and they are contemplating a policy measure.

14.3 RoHS

The BRT requests that SVHC, authorisation or restriction under REACH and exemption under ELV/RoHS should not lead to duplicated regulation.

The number of restricted hazardous substance is going to increase. The authorities of the EU should continue to involve the industry in the process of identifying additional substance.

< Recent Progress >

Some progress has been made. The European Commission has given priority to the issue.

< Background >

First of all, the BRT appreciates the action of the European Commission which is already involving the industry. REACH and RoHS are independent with each other. However, they regulate chemical substances. Both of them impose restrictions and exemptions thereof. Although currently the BRT is not aware of any discrepancy as to the restricted or exempted chemical substances between the two regulations, the BRT is nonetheless concerned about the risk of duplication due to the complexity of the two regulations.

14.4 CLP Regulation

- ✓ The BRT requests that, to alleviate burden on exporters, the authorities of the EU should accept GHS classification and labelling at the custom clearances.
- ✓ The BRT requests, in addition, that the authorities of the EU should take GHS into consideration from ATP (Adaptation to Technical Progress) stage.

< Recent Progress >

Some progress albeit very limited and unsatisfactory for businesses has been seen for the recommendation.

< Background >

CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures) affects not only the EU manufactures and importers but also exporters outside the EU. While CLP is comparable to UN GHS, CLP does not take some of GHS classification but introduces the EU's own classification. As a consequence, the exporters to EU are forced to be compliant with both GHS and CLP.

14.5. Nanomaterial

1. Definition

The BRT requests that the authorities of the EU should implement the prospective policy tools on nanomaterials by taking into consideration the degree of exposure of nanomaterials released from a product.

2. Reporting scheme

The BRT requests that the authorities of the EU should take an initiative and establish a harmonized reporting system at the EU level.

3. Standardization of measurement method

The BRT requests that the authorities of the EU should standardise a practical measurement method of nanomaterials. Such a measurement method should be simple and internationally harmonised.

< Recent Progress >

Some progress has been made:

As to the definition, the European Commission has carried out public consultation.

As to the reporting scheme, the European Commission is currently in consultation with the Member States. However, some Member States, such as France and Belgium, are going their own ways. A unified reporting scheme is critical for industry.

As to measurement method, although the Joint Research Centre issued a report in 2012 titled 'Requirements on measurements for the implementation of the European Commission definition of the term „nanomaterial', there remain the issues of practicality and cost. .

< Background >

The European Commission Recommendation on the definition of nanomaterial (2011/696/EU) was published on 18 October, 2011.

Several EU Member States plan to enact their own nanomaterial reporting schemes at a national level. It would oblige their manufacturers and importers make multiple reporting in different formats, which would not only be inefficient but also create confusion in their supply chains.

Different measurement methods are used in the measurement of nanomaterials to meet regulatory requirements such as notification. As a result, there is a risk that the results of measurement by different actors are not comparable.

WP-A / # 15 / J to E Taxation**

15.1 Common Consolidated Corporate Tax Base

The BRT welcomes the proposal for CCCTB (Common Consolidated Corporate Tax Base) proposed on 16 March 2011. The BRT hopes for its swift adoption. CCCTB should realise the following points to improve the competitiveness of the EU economy.

- 1) Non-taxation of unrealised gains on goodwill within a group of companies that form CCCTB
- 2) Non-application of arms-length principle within a group of companies that form CCCTB.
- 3) Off-setting of profits and losses within a group of companies that form CCCTB.

< Recent Progress >

No progress has been seen for this recommendation.

< Background >

Many Japanese companies are implementing integration and rationalisation of their European business organisations in order to remain competitive in the Single Market. Examples are the centralisation of such functions as sales support and accounting.

The relation between intra-group transactions and taxation is an important element in decision making in a business. It is highly desirable that companies with international business should be allowed to compute the income of the entire group according to one set of rules and establish consolidated accounts for tax purposes in the EU.

15.2 Merger Directive

The scope of the Merger Directive (90/434/EEC) should be expanded to include the transfer of real estates and other intangible assets in reorganisation. Furthermore, the shareholding requirements should be abolished.

< Recent Progress >

No progress has been seen for this recommendation.

< Background >

In the communication COM (2001)582, the European Commission referred to its intention to extend the scope of the Merger Directive to tax on the transfer of real estates. The amendments to the Directive (2005/19/EC), however, do not include provisions related to this issue.

By extending the scope of the Directive to the transfer of real estates and other intangible assets in reorganisation, companies could reduce the cost of reorganisation and increase competitiveness.

The Merger Directive (90/434/EEC) provides for the deferral of corporate tax in the qualified cross-border restructuring of business. In certain EU Member States, companies are required to hold shares that they have received in exchange of contributed assets for a number of years even if those holding companies cease to function as an operating company. There appears to be no ground in the Directive to support such measures.

In addition to the cost of maintaining these empty companies, it increases the risk of double taxation. Dividends paid by the subsidiaries do not qualify for Japanese foreign dividend exclusion for the portion distributed through the empty holding company if the shareholding of Japanese parent in it is below 25%.

15.3 The fundamental reforms of VAT regime under consideration

The BRT welcomes the strategy of the European Commission to fundamentally revise the VAT system and to establish a simpler, more efficient and robust VAT system tailored to the single market as described in Com (2011) 851.

The BRT hopes that the new regime will be realised swiftly and in such a way that a business group could easily and cost effectively centralise VAT administration in the EU.

< Recent Progress >

Some progress albeit limited has been seen for this recommendation.

< Background >

Many Japanese companies are implementing integration and rationalisation of their European business organisation in order to remain competitive in the Single Market. Accounting functions including VAT administration are often targeted for centralisation with the aim of reducing overall costs and increasing efficiency.

Although the VAT system in the EU is a common system, in reality, differences among Member States are significant mainly due to derogations. Presently, therefore, the centralisation of VAT administration carries a high financial risk.

For example, if centralised accounting staff with limited country specific knowledge makes a mistake in a repetitive transaction, the accumulated amount that should be rectified could become high over a relatively short period. In addition, a penalty may be imposed. To avoid such a high risk, businesses have to either leave accounting staff in local operations or employ a number of accounting staff with country specific knowledge in a central location. In either case, cost-effective centralisation of accounting functions is unlikely to be realised.

16.1 Conflict minerals

<Recommendations>

The BRT acknowledges that the proposal for a Regulation has taken up certain feedback from businesses such as promoting internationally recognised frameworks, taking a voluntary approach of self-certification and publication of a list of responsible smelters and refiners. The BRT recognises that, although self-certification by responsible importers is voluntary, administrative burden will be substantial for responsible importers that choose to self-certify. The BRT suggests that administrative burden should be reduced as much as possible in order to facilitate the take up of self-certification.

Concerning Incentives laid down in the Joint Communication, the BRT requests a clarification on the definition of equivalence to the OECD Due Diligence Guidance in terms of Procurement and on the benefits and duties of a company that signs the Letter of Intent as to industry commitments. The BRT also requests good internal coordination in implementing Procurement Incentives.

<Recent progress>

This is a new recommendation.

<Background>

The European Commission submitted on 5 March 2014 a Proposal for a Regulation of the European Parliament and of the Council setting up a Union system for supply chain due diligence self-certification of responsible importers of tin, tantalum and tungsten, their ores, and gold originating in conflict affected and high-risk areas (COM(2014)111). The proposed Regulation is accompanied by a joint Communication by the European Commission and the High Representative to the European Parliament and the Council: Responsible sourcing of minerals originating in conflict-affected and high-risk areas - Towards an integrated EU approach (JOIN(2014) 8).

16.2 Country by country reporting (CBCR)

<Recommendations>

The BRT recommends that the authorities of the EU should carefully consider the risks of excessive disclosure requirements that could unduly hamper multinational enterprises' business activities.

<Recent progress>

This is a new recommendation.

<Background>

The final text of a Directive amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large companies and groups requires the European Commission to report on CBCR by 21 July 2018: the report shall consider, taking into account developments in the OECD and the results of related European initiatives, the possibility of introducing an obligation requiring large undertakings to produce on an annual basis, a country-by-country report for each

Member State and third country in which they operate, containing information on, as a minimum, profits made, taxes paid on profits and public subsidies received.

The European Council made reference on 22 May and 20 December 2013 to extending CBCR to large companies and groups.

The EU law already requires financial institutions to disclose annually, specifying, by Member State and by third country in which they have an establishment, profit or loss before tax, tax on profit or loss, and public subsidies received from 2015. The EU law also requires large undertakings and all public-interest entities active in the extractive industry or the logging of primary forests to prepare and make public a report on payments made to governments from 2016.

Within the context of the G8 and the G20, the OECD has been asked to draw up a standardised reporting template for multi-national undertakings to report to tax authorities where they make their profits and pay taxes around the world.

16.3 Non-financial disclosure

<Recommendations>

The BRT appreciates that the final text agreed by the European Parliament and the Council addresses a number of concerns raised by businesses including the BRT such as making non-financial KPIs non-binding, allowing reporting at a consolidated level and limiting the scope of entities that the new rules become applicable. The BRT looks forward to consultation by the European Commission during their preparation of non-binding guidelines on methodology for reporting non-financial information, including non-financial key performance indicators.

<Recent progress>

There has been a good progress.

<Background>

The European Commission submitted a proposal for a Directive (COM(2013) 207) in April 2013. The European Parliament and the Council reached an agreement in February 2014 on the final text of a Directive amending Directive 2013/34/EU as regards disclosure of non-financial and diversity information by certain large companies and groups. According to the final text:

- *Large undertakings which are public-interest entities exceeding on their balance sheet dates the criterion of average number of employees during the financial year of 500 shall include in the management report a non-financial statement containing information to the extent necessary for an understanding of the undertaking's development, performance, position and impact of its activity, relating to, as a minimum, environmental, social and employee matters, respect for human rights, anti-corruption and bribery matters.*
- *The Commission shall prepare non-binding guidelines on methodology for reporting non-financial information, including non-financial key performance indicators, general and sectorial, with a view to facilitate relevant, useful and comparable disclosure of non-financial information by EU undertakings. In doing so, the Commission shall consult relevant stakeholders. The Commission shall*

publish the guidelines no later than 24 months after the entry into force of this Directive.

WP-A / # 17* / J to E Product Safety/Market Surveillance

17.1 Product safety and market surveillance package proposal

The BRT requests the authorities of the EU to proceed prudently in the deliberation of the Product Safety and Market Surveillance Package, in particular, Article 7 of the proposal for a Regulation on consumer product safety by which the indication of the country of origin would become mandatory. The BRT believes that the mandatory indication of the country of origin would not necessarily improve safety for consumers but that it would place substantial administrative burden on manufacturers and/or importers. The BRT therefore believes the mandatory indication of the country of origin should not be included in the Package.

<Recent progress>

This is a new recommendation.

<Background>

The European Commission proposed on 13 February 2013 the Product Safety and Market Surveillance Package – A proposal for a Regulation on market surveillance of products (COM(2013)75) and a Proposal for a Regulation on consumer product safety (COM(2013)78). The package is now at a final stage of deliberations in the Council. The Article 7 of a Proposal for a Regulation on consumer product safety requires manufacturers and importers to ensure that products bear an indication of the country of origin of the product.

17.2 Market Surveillance under the New Legislative Framework

The BRT supports the general direction the European Commission and the Member States are taking for harmonising market surveillance. This is an important step for fair movement of products. The BRT requests the European Commission and the Member States to disclose all the relevant information regarding the progress of this process and the implementation of the market surveillance in each Member State. The BRT also requests the European Commission and the Member States to give industry an opportunity for contributing to developing the framework of harmonised market surveillance.

The BRT would like to thank the Directorate General of the European Commission concerned for the involvement of the industry and requests that it should continue to consult stakeholders widely – preferably through public consultation when draft guidance for the New Legislative Framework is ready.

< Recent Progress >

Some progress has been seen for this recommendation.

< Background >

In 2008, the Regulation 765/2008/EC, setting out the requirements for accreditation and market surveillance relating to the marketing of the products, and the Decision 768/2008/EC, a common framework for the marketing of products, were adopted. The Regulation has been applied as from 1 January 2010.

The Regulation and Decision address and complement missing elements, namely, accreditation and market surveillance, in the existing sectoral legislations. The existing legislations are being amended based on the Decision when they are reviewed. The objectives of the so-called New Legislative Framework are to introduce harmonised and transparent market surveillance and accreditation for all economic operators. The Decision provides definitions, the obligations of economic operators, traceability provisions and safeguard measures. National authorities were to develop their market surveillance programmes and communicate them to the Commission by 1 January 2010.

The European Commission is in the process of preparing the guidance for the New Legislative Framework and intends to publish it in 2014.

17.3 Consumer protection

The new Directive, 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights, still maintains the discretion of the Member States to set a guarantee period longer than 2 years set in the Directive 1999/44/EC, which the BRT believes could constitute an obstacle in the single market. The BRT would like to ask the European Commission to review the advantage and disadvantage of this discretion to set a guarantee period longer than 2 years in the future review.

< Recent Progress >

No progress has been made for this recommendation

< Background >

The BRT believes that, to maximise the benefit of the single market, any legislation that affects cross-border transactions should be harmonised to the extent that businesses and consumers do not have to be concerned about difference in implementation among the Member States.

WP-A / # 18* / J to E Access of third countries goods and services to the EU's Procurement Market

The BRT believes and recommends the following:

1. Non-legislative policy measures should be adopted to achieve the objective of opening procurement markets internationally;
2. Any measures should incorporate an effective mechanism to prevent the EU from arbitrarily excluding third-country goods and services from its procurement market and to ensure legal stability and predictability for businesses; and
3. Any measures should contain clear and transparent criteria for the scope and conditions of their application based on an appropriate and balanced analysis.

4. The authorities of the EU and its Member States should increase their efforts to facilitate better access to the respective public procurement markets.
5. The authorities of the EU and its Member States should make more information available in English. The BRT requests the use of English when submitting tender proposals to be allowed or at least partially allowed, especially for the technical specifications and communication.

< Recent Progress >

No progress has been made for this recommendation.

< Background >

The reform of the legislative framework of procurement is one of the twelve priority actions set out in the Single Market Act adopted in April 2011. As part of this reform programme, the European Commission announced on 31 March 2012 a proposal for a Regulation on the access of third-country goods and services to the EU public procurement market. (COM (2012) 124).

The BRT has a serious concern about the measures in the proposed Regulation that would enable the EU to close its market unilaterally. The BRT is concerned because, by exercising the proposed unilateral measures, the EU could send a signal to its trading partners that the EU is closing its procurement market discreetly, which could trigger a chain reaction of protectionist measures all over the world. Should it happen, the EU's intention and objective of opening procurement markets internationally would not be achieved.

WP-A / # 19* / J to E The deployment of alternative fuels infrastructure

The BRT supports the plan to expedite the deployment of alternative fuels infrastructure as described in a proposal for a Directive on the deployment of alternative fuels infrastructure, and understands that the detail of the contents has been in discussion in Trialogue session to be finalized in middle of April.

The BRT requests the authorities of the EU, however,

- 1) To delete the disproportionate emphasis on specific technology.
- 2) To confirm that the Directive will not exclude the fast charging technologies other than Type "Combo2" from becoming an authorized recharging system in the EU, and will not remove them from the European market.

< Recent Progress >

Under the Trialogue session.

< Background >

The European Commission adopted a proposal for a Directive of the European Parliament and of the Council on the deployment of alternative fuels infrastructure (COM(2013)18) on 24 January 2013. When adopted by the European Parliament

and the Council, it would require the implementation of common technical specifications for the interfaces between recharging points and vehicles. In Annex III 1.2 of the proposal, it stipulates that Direct Current (DC) fast recharging points for electric vehicles shall be equipped, for interoperability purposes, with connectors of Type "Combo 2" as described in the relevant EN standard, to be adopted by 2014.

As stated in the preamble (26) of the proposal, technical specifications for interoperability of recharging and refuelling points should be specified in European standard. However, such a standard is yet to be finalized for DC fast recharging points. Therefore, it is premature to refer to any specific technologies as a part of European standards.

Furthermore, the future Directive should make dual chargers with the existing DC fast charging technologies an option because a technical specification to become available in the market in near future may be specified as is the case in the current proposal. The fact is that there are more than 50,000 electric vehicles equipped with a fast charging technology on the road in Europe today. Dual chargers that can serve the existing electric vehicles as well as future ones will be important not only for the convenience of the drivers of the existing vehicles but also for the market to develop.

**Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan**

Tokyo, 8 & 9 April 2014

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

Working Party Leaders:

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Member of the Board of
Management
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List of Abbreviations

Abbreviation Meaning

ABS	Access and Benefit Sharing
ARCB	Association of Registered Certification Bodies under PAL
CBD	Convention on Biological Diversity
CE	Conformite Europeenne
EFPIA	European Federation of Pharmaceutical Industries and Associations
EFSA	European Food Safety Authority
EU	European Union
FSC	Food Safety Commission
GLP	Good Laboratory Practice
GMP	Good Manufacturing Practice
HTA	Health Technology Assessment
IFAH	International Federation of Animal Health
iPS	induced Pluripotent Stem
J-PAL	Japanese Pharmaceutical Affairs Law
JPMA	The Japan Pharmaceutical Manufacturers Association
LS & BT	Life sciences and Biotechnologies
MAFF	Ministry of Agriculture, Forestry and Fisheries
MDD	Medical Device Directive
METI	Ministry of Economy, Trade and Industry
MHLW	Ministry of Health Labor and Welfare
MIC	Ministry of Internal Affairs and Communications
MNC	Multinational Corporation
MOF	Ministry of Finance
MRA	Mutual Recognition Agreement
NB	Notified Body
NHI	National Health Insurance
PIC/S	Pharmaceutical Inspection Convention and Pharmaceutical Co-operation Scheme
PMDA	Pharmaceutical and Medical Device Agency
QMS	Quality Management System
VPD	Vaccine Preventable Diseases
WP	Working Party

Introductory Statement

Both, Japan and the EU are facing numerous challenges due to e.g. an aging population, shifting demands in just about all domestic markets and rising costs in many aspects of the welfare system with a need to accelerate and focus on high-end innovations. This particularly in the areas of

- Healthcare
- Plant Protection, and
- Biotechnology.

The enclosed recommendations of WP-B have the clear aim to improve the innovation capabilities of both the EU and Japan through concrete action plans in life sciences and biotechnology, which focus on measures to enhance efficient healthcare practices, food technology / supply and biotechnology.

Recommendations from both European and Japanese industries

Healthcare

WP-B / # 01* / EJ to EJ Regulatory harmonization and MRA for pharmaceuticals

The regulatory harmonization and further extension of “Mutual Recognition Agreement” should be proceeded in order to avoid redundant inspections of manufacturing facilities. In addition to oral dosage forms, API, Sterile and Bio products are being requested to apply to the MRA. Full support is requested to expand the MRA of GMP to liquids, and sterile forms, API and bio products to avoid redundant inspections and testing

<Recent Progress>

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

<Background>

As currently only oral solid dosage forms are included within the MRA between Japan and the EU, there are still a lot of redundant inspections of manufacturing facilities. This is not only a costly process, but it also slows down the launching of new drugs in Japan creating a significant disadvantage for Japanese patients. In order to eliminate this problem and integrate EU-Japan economics more efficiently, harmonization of standards / guidelines and expansion of MRA should be conducted under mutual agreements. Below-mentioned are highly prioritized items for harmonization. Also, the MRA issue is one of items of the EPA negotiation between EU and Japan.

<Other prioritized items for harmonization and MRA>

Harmonization:

- Safety measures from surveillance to vigilance should be harmonized with international standards*
- Clinical development guideline and biological preparation standards for Vaccine*
- Minimum Requirements for Biological Products*

WP-B / # 02* / EJ to EJ Mutual recognition of quality management audit results for medical devices between EU and Japan

Improve mutual recognition of Quality Management System (QMS) audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical Affairs Law, as a first step.

All industry-related manufacturers request PMDA and MHLW to further harmonize and streamline the QMS audit results. MHLW has notified that RCBs can accept non-Japanese QMS audit results. However, ISO13485 continues to be only one part of the Japanese QMS ministerial ordinance. Hence, part of the Japanese requirements. To resolve this issue, it is recommendable that QMS be evaluated on the basis of ISO13485.

In addition to above, the recognition system of "Application for Accreditation of Foreign Manufacturers" should be considered. Even if QMS is evaluated on ISO13485, all industry-related manufacturers have to be registered and are obliged keeping the additional Japanese requirements.

<Recent Progress>

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

<Background>

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

WP-B / # 03* / EJ to EJ Mutual recognition of medical devices product licenses

Introduce a mutual recognition of medical device product licenses between the EU and Japan. PMDA and MHLW should introduce a mutual recognition of medical device product licenses with low risk of class II devices by taking the difference of classification of medical devices between Japan and the EU into account. By harmonizing QMS and classification it should be possible to introduce new products within the same time frame and in one process. It is desirable that this issue will be solved quickly. Level difference between NBs should also be considered. *It should be recognized that the regulatory approval scheme of class II medical devices in Japan is far from that in the EU, i.e. no need to be reviewed by NBs for Conformance Européenne (CE) marking of class II medical device in the EU but reviewed by NBs in Japan.*

<Recent Progress>

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

<Background>

Mutual recognition of licenses for medical devices in Japan and the EU would make it possible to introduce new products in both the Japanese and European markets within the same time frame and with one process.

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

The evaluation scheme between the Medical Devices Directive of the EU and the Japanese Pharmaceutical Affairs Law are quite similar, with

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

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

WP-B / # 04* / EJ to EJ Mutual recognition of clinical trial results for medical devices

Introduce a mutual recognition of clinical trial results for medical device development. Foreign clinical trial data have been accepted as a part of application dossier when; i) standards for conducting medical device clinical trials are set by the regulations of the country or region where the trial was performed, ii) the standards are equivalent or surpass the Japanese medical device GCP, and iii) the clinical trial was conducted in accordance with the standards or considered to have equivalent level of quality. The GOJ encourages active use of consultation service on individual medical device applications in advance provided by the Pharmaceuticals and Medical Devices Agency (PMDA) to address use of foreign clinical trial data for application of the device.

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

In this regard, the ordinance was released in December 2012 by MHLW and some improvements are expected. Further improvements are required in order to accelerate mutual recognition of clinical trial results for medical devices.

<Recent Progress>

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

<Background>

Differences in the definition of Good Clinical Practice between Japan and the EU currently prevents the use of non-Japanese clinical trial results in the application for new medical devices in Japan. Mutual recognition of clinical trial results would make it possible to make new products available to patients in Japan and the EU within the

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

Healthcare

WP-B / # 05 / EJ to E Evaluation of innovation values for pharmaceuticals in prices**

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.

<Recent Progress>

No progress has been seen for this recommendation. The Directorate-General for Economic and Financial Affairs of the European Commission, ECFIN, issued a report on drug cost containment methods of member states and recommended a "EU reference price". As such, we would suggest to follow a reimbursement / pricing system which clearly recognize innovation and innovative new products.

<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 condition, 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.

Plant Protection & Biotechnology

WP-B / # 06* / EJ to E Shortening review times of plant protection & biotechnology products

Shorten review times for new applications/ registrations.

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

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

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

Animal Health

WP-B / # 07* / EJ to E Introduction of “1-1-1 concept” for all animal health products

Introduce 1-1-1 concept for all products (one dossier – one assessment – one decision on marketing authorization applicable to all EU countries). A concept should be worked out between the respective governments / authorities.

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

One of the key objectives of the European Union is to create a single market for goods. This goal has yet to be achieved for the animal health industry, with the exception of centrally authorized products. In line with the concepts already existing in the EU (i.e. quality, safety and efficacy described in one single EU dossier as the basis for granting marketing authorizations for veterinary medicinal products, one single assessment of the dossier employing the best expertise, resulting in one decision for marketing authorization) the animal health industry in Europe is seeking a systemic change based on the one, one, one concept (“1-1-1 Concept”) for all products. This appears to be the most simple and straightforward way to address all of the major shortcomings of the current system and to finally achieve the goal of a single market for safe and efficacious veterinary medicines.

Healthcare

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

The premium for new drug creation and elimination of unapproved/off-label use drug will be continued until March 2016. It is welcomed as it supports incentives for innovative drug development; however, it is only the continuation of a trial scheme. The Japanese government should finalize the implementation of the new, internationally competitive drug pricing system in Japan based on the industry proposal since in addition to innovation rewards it is also protecting public health. Furthermore, it adds an element of predictability and stability so that the industry can adequately plan, forecast product requirements and effectively manage inventory as well as the distribution of products

across Japan.

The abolishment of the market expansion re-pricing was not accepted by the Central Social Insurance Medical Council (Chuikyo) even though industries insisted to eliminate the system. While the agenda for the 2014 NHI pricing discussion between Chuikyo and the industry included topics such as "NHI pricing for long-listed products" and "continuation vs. discontinuation of incentives for innovative drug development" it did not include "abolishment of market expansion re-pricing". Therefore, we urge to discuss this topic to abolish the re-pricing rule by market expansion in the next pricing system reform in 2016, which is contrary to the policy of evaluating pharmaceutical innovation.

<Recent Progress>

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

<Background>

The NHI price reform proposed by the industry has been positively reviewed by Chuikyo in December 2009 and the government decided to start a pilot implementation in April 2010. This represented a significant improvement, as it provides price stability for innovative drugs and was seen as a positive signal that the Japanese government is willing to reward innovation in the medical field. The premium for new drugs will be continued until 2016. As a compensation for this new scheme, the government will attach a system that fosters the registration of "unapproved/off-label use drugs". Companies have received requests on developments of many unapproved/off-label use drugs and forwarded those constructively. Furthermore, companies received additional requests on developments of another hundreds of unapproved/off label use drugs for several times.

However, in the FY2014 drug pricing system reform, Chuikyo concluded to postpone full-fledged implementation of the premium for new drug creation to FY2016 revision, even though the industry strongly requested. The conclusion brings the industry deep concerns about sustainability for evaluation of innovations. The Japanese government should implement the new premium system for innovative new drugs at the FY2016 drug pricing system revision to evaluate the companies' efforts for elimination of the so-called drug lag in Japan and research and development of innovative new drugs.

WP-B / # 09 / EJ to J Appropriate assessment of innovative values of medical devices in prices**

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

<Recent Progress>

Some progress and regress has been seen for this recommendation.

<Background>

Different from pharmaceutical brand-oriented pricing systems, about 300,000 medical devices are classified into about 800 functional classes in Japan and one reimbursement price is set for one functional class, based on structure, intended use, effectiveness and so on.

Currently, various old and new products, having various realized prices, have the same reimbursement price within one functional class, which means that the price drop of old products influences the reimbursement price of new ones on the revision of the reimbursement price. This is the reason why the introduction of a product-based reimbursement pricing system is desired.

In Japan's 2014 price revisions, the government's efforts to progress forward the assessment of innovative values can be seen, such as making exception of functional class rule for the excellent and innovative class-C products to keep the independent functional class within the twice price revisions. On the other hand, they strengthened the influence of foreign reference pricing.

We hope the Japanese government will make further efforts to promote medical device development.

Plant Protection & Biotechnology

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

Governments and the private sector should speed up research in Plant Protection & Biotechnology and inform populations regularly and accurately about the state of play on GMOs, based on sound scientific knowledge.

To that effect Japanese and European biotechnology and bio-industry associations should work closely with other sectorial organisations and their respective Authorities.

<Recent Progress>

No progress has been seen for this recommendation.

<Background>

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

WP-B / # 11* / EJ to J Support research in Plant Protection & specifically Biotechnology

Support research in Plant Protection & Biotechnology.

<Recent Progress>

No progress has been seen for this recommendation.

<Background>

Overall in Japan the cooperation between governmental institutes and MNC is limited. Applied science is widely done for instance by PPS (Plant Protection Stations) in all prefectures, however, this is not basic research. Also agricultural universities in Japan do some research on an independent basis. MAFF is spending around 400 Mio. Yen for residue trials on substances used for rice to confirm the level of the residue in rice for feed and the transfer into livestock (cow and chicken) but the ownership is with the government or some independent institutes. The project is motivated by the policy to increase food sufficiency rate. In the future, MAFF should spend more money on basic research / fundamental technologies in order to facilitate research activities in general. In biotechnology, considerable money is spent on plant molecular biological research but the budget is recently decreasing and no GM products are developed in Japan. It should be taken into consideration to develop GM rice in order to increase yield and decrease production costs. In the past, the rice genome project was supported by the government but the project has been finalized, a smaller post genome project is still running. The outcome of the project is only contribution to develop a marker assisting the breeding of rice. From such research where a considerable amount of Japanese tax payers' money is invested, yielding practical applications is desirable through co-operations among governmental institutes, universities, Japanese domestic companies and MNC.

Recommendations from European industry

Animal Health

WP-B / # 12* / E to J Regulatory harmonization for animal health products

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

We propose to harmonize and streamline regulatory requirements for product registration of animal health products. MAFF should start harmonization with related countries as this is the path to the 1-1-1 concept recommended previously. On Oct. 3rd 2013, J-MAFF already shared the idea at the explanatory meeting of revised JPAL for the first time that J-MAFF, FSC and MHLW started discussion how to shorten review times for livestock products (i.e. Introduction of parallel deliberation amongst the authorities) but they didn't show any timeline on the matter.

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

<Recent Progress>

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

<Background>

While such global new veterinary medicinal products go already through rigorous review processes in Europe and the USA prior to registration, it requires substantial additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Restrictions on withdrawal period for innovative oil-adjuvant vaccines are especially stringent in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products which are readily available in Europe.

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

Recognition of animal welfare aspect is not yet optimal in the administration of animal health products in Japan. Japan should minimize the use of animals by accepting more overseas data and alternative approach.

WP-B / # 13* / E to EJ Mutual recognition of GMP and marketing authorization for animal health products

With regard to the Mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products, MAFF should work out harmonized regulations leading to the 1-1-1 concept.

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

<Recent Progress>

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

<Background>

While laboratory testing is largely acceptable if conducted under GLP and according to VICH standards, Japan still requires local clinical trials as there is no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacturing veterinary medicinal products imported into Japan have to be accredited by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative work. This research is obsolete as a new research was undertaken in 2012, which showed much improvement. An EU – Japan Economic Integration Agreement should aim for mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.

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

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

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

In common with the rest of the world, Europeans and Japanese are concerned by the development of resistance to antibiotic medicines used in human health and the potential threat that the use of antibiotics in animal health will accelerate this process. The use of antibiotics as growth promoters has been prohibited in the EU since 2006.

As a responsible industry, the animal health industry seeks to work with veterinarians, farmers and the feed industry to dispel the myths about the use of antibiotics in animals and promote their responsible use.

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

Healthcare

WP-B / # 15* / E to J Application of GMP on medicinal gases (manufacture of medicinal gases) in Japan

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

<Recent Progress>

Some progress has been seen for this recommendation. In February 2012, MHLW noticed to medical gas suppliers to obey voluntary standard by the industry. This standard is almost compatible to GMP standard. PMDA / MHLW will reinforce the GMP for medicinal gases through the PIC/S introduction in Japan in Q1/2014.

<Background>

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

WP-B / # 16* / E to J Requirement of Japanese version of the clinical trial protocol and investigators brochure

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

MAFF, MHLW and FSC should start harmonized ways to shorten review times.

<Recent Progress>

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

<Background>

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

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

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

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

Vaccine production is done according to GMP and PMDA periodical audits of production sites. However, the higher quality assurance of vaccines is strongly demanded by society. Concerning the national test results which are published by MOU (memorandum of understanding), manufacturing countries should be accepted by the Japanese authority and the national tests for vaccines in Japan should be eliminated or reduced to an absolute minimum.

Animal Health

WP-B / # 18* / E to J Shortening review times for animal health products

Shorten review times for new product applications. MAFF, MHLW and FSC should start harmonization to shorten review times. The process is complicated in addition to a

review period that already for pet animal products (not requiring ADI and MRL) is among the longest in the world. A lot of questions are asked in the process that might be academically interesting but are not necessarily safety or efficacy related. Clarifying registration requirements and shortening review times for importation of recombinant vaccines from Europe should also be implemented.

<Recent Progress>

No change or improvement was seen for this recommendation.

<Background>

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

WP-B / # 19* / E to J Japanese customs clearance's (cc) rule for investigational drugs and related materials does not allow efficient investigational drug supply

MAFF should harmonize with VICH guidelines.

<Recent Progress>

Some progress has been seen for this recommendation.

<Background>

To import investigational drugs either 1) the Original Clinical Trial Notification sealed by both sponsor and PMDA or 2) YAKKAN is necessary. Recent clinical trials require frequent investigational drug delivery from overseas investigational drug warehouse to study sites. Since both 1) and 2) should be archived by the sponsor and CC agents do not keep those, frequent and timely CC is not possible. If a certified copy of 1) or 2) (certified by sponsor and kept by CC agent) is accepted by the custom, investigational drug delivery will become efficient.

Recommendations from Japanese industry

Healthcare

WP-B / # 20* / J to E Shorten the approval time to register new micro-organism and introduce new technology for producing seasonings and amino acids

Shortening the approval time needed for registration of new materials and introduction of new technologies which aim for product expansion, cost reduction, environmental concerns or diversification of the fermentation material. Clarification of the approval process is also requested.

<Recent Progress>

Some progress has been seen for this recommendation. Shortening the risk assessment time by EFSA and clarification of the evaluation process are accelerated.

<Background>

The long term process for approving a set of safety evaluation such as the bacteria manufacturing process, test products and co-products, delays the enhancement of production and consequently, competitiveness in the EU market. The slow approval process makes companies hesitate to invest in the EU market. On the other hand, it also weakens the export competitiveness of EU companies. For information: US companies are introducing new technologies aggressively. In a typical case, one application takes 30 month-long review time to complete approval processes by regulatory authority in EU, EFSA.

**Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan**

Tokyo, 8 & 9 April 2014

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

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List of Abbreviations

Abbreviation Meaning

APEC	Asia-Pacific Economic Cooperation
BRT	Business Round Table
EEN	Enterprise Europe Network
ETP	European Technology Platform
EU	European Union
FP	Framework Programme
GOJ	Government of Japan
ICT	Information and Communication Technology
ICS	Industrial Control Systems
IMCO	Internal Market and Consumer Protection Committee
ITA	Information Technology Agreement
ITR	International Telecommunication Regulations
ITU	International Telecommunication Union
JEUPISTE	Japan-EU Partnership in Innovation, Science and Technology
MEXT	Ministry of Education, Culture, Sports, Science and Technology
MoD	Ministry of Defence
NATO	North Atlantic Treaty Organization
NIS	Network Information Security
PFI	Private Finance Initiative
STI	Science, Technology and Innovation
SME	Small and Medium Enterprises
R&D	Research and Development
WCIT	World Conference on International Telecommunications
WTO	World Trade Organization

Introduction

ICT and Innovation

Global trade rules on ICT hardware and services need modernization to reflect latest technology developments and business models. The EU and Japan have a huge potential to influence international negotiations by taking harmonized action based on common principles on internet governance, cybersecurity, resilient ICT infrastructure, privacy protection, data utilization and cross-border data flows. Concrete action is required regarding the forced localization policies observed in some countries.

The EU and Japan face similar societal challenges such as aging populations and climate change. To address these difficult issues, governments can harness the innovation capacity of the private sector with a better R&D business environment. Facilitating bilateral R&D collaboration with participation of academia, public and private sectors will contribute to the creation of innovative products and services that can be deployed in both regions and also to the rest of the world.

Aeronautics

Europe's aeronautics industry is a major supplier to the world market. Japan also has many advanced technologies. Both are challenged by new entrants. In this context, joint technology and project development are necessary for both sides to maintain technological leadership and competitiveness. EU-Japan industrial cooperation exists in helicopters and aeroengines, but the potential is much greater. More government-led cooperation and continued support from both sides' authorities are needed to help the EU and Japanese aircraft industries bring to fruition the development of their relationship while meeting the EU's environment, social and safety requirements.

Space

Both the European and the Japanese space industries are major suppliers of space products. The global space market, however, is small with limited growth prospects. In a context of steadily diminishing budgets, cooperation and mutually open markets are the only way for both the EU and Japan to achieve their goals in space and for the EU and Japanese industries to keep their ranks in the global marketplace.

Defence industries

Cooperation between the Japanese and European defence industries is budding. Japan's new three principles on transfer of defence equipment, approved by the Cabinet on 1st April 2014, are a major step forward but should be complemented as soon as possible by clear and transparent procedures relating to arms export and joint development. The Act on Specially Designated Secrets enacted in December 2013 should not hinder industrial cooperation between Japanese and EU industries.

Railways

Railways are among the high-technology sectors where both the EU and Japanese industries are world leaders and can together continue setting world standards in the face of new competition from emerging economies. This can have deep implications for expanded cooperation in third-country markets. Safety is a particularly promising cooperation area that we hope can be promoted by both sides' Authorities.

Recommendations from both European and Japanese industries

ICT

WP-C / # 01* / EJ to EJ Cooperation for maintenance of an open, transparent internet

The BRT supports the past coordinated efforts on Internet Governance by both Authorities and expresses its utmost gratitude to the Leaders and Authorities of the EU and Japan for the leadership and efforts they have shown in relation to this issue. We request both sides' Authorities to continue cooperating in order to maintain an open and transparent online environment involving multi-stakeholders.

< Yearly Status Report >

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

< Background >

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

WP-C / # 02 / EJ to EJ Cooperation for trade liberalization on ICT services**

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

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

< Yearly Status Report >

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

< Background >

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

WP-C / # 03 / EJ to EJ Continued efforts for swift conclusion of ITA expansion**

The BRT requests that both sides' Authorities set a near-term deadline for WTO talks and try to bring the current negotiations to expand the ITA to a successful conclusion. The BRT requests that, in the expanded ITA, compulsory and periodical review mechanisms be built in order to ensure that the ITA will always be kept up-to-date and reflect technological developments.

< Yearly Status Report >

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

< Background >

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

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

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

WP-C / # 04 / EJ to EJ Building a trusted, safe and robust online environment**

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

The BRT appreciates that both Authorities are already working on joint initiatives on cybersecurity issues, and also encourages further cooperation between the EU and Japan on safe and robust infrastructure based on ICT.

Security of data, preventing unwanted damaging leaks, is a key growing issue, as more and more data go into clouds and are processed from it. A common frame of best practices related to protection from and adequate response to cyberattacks should be established by both Authorities.

Cooperation between critical infrastructure operators and ICT service providers is indispensable to address cyber threats. The BRT considers that security notification reporting should be applied only to critical infrastructure operators and that such a requirement should not be applied to enablers of internet services. In this context, the BRT supports the vote of the IMCO committee of the European Parliament to exclude enablers of internet services including cloud operators from the scope of the NIS Directive and clearly mentioned that HW/SW vendors are not covered in the scope of the NIS Directive.

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

< Yearly Status Report >

The European Commission released its Cybersecurity Strategy "An Open, Safe and Secure Cyberspace" and Directive on Network and Information Security (NIS) in Feb. 2013.

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

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

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

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

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

< Background >

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

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

WP-C / # 05 ** / EJ to EJ Balancing privacy protection and innovation

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

The BRT welcomes the decision adopted on 20 December 2013 by the IT Strategic Headquarters headed by the Prime Minister of Japan to review the personal data protection regime and propose a draft law to the Diet by January 2015.

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

The BRT thinks that ideally, the new law should consolidate the currently fragmented authorities over personal data protection to one independent data protection authority and ensure transparency and foreseeability for both domestic and foreign-based companies.

Concerning the draft EU General Data Protection Regulation, the BRT maintains that the authorities of the EU should balance privacy protection and innovation, and recommends an active use of recognised certification schemes in international data transfers, a clearer definition of extraterritorial applicability, a flexible notification period in case of a breach, the transfer of employee data to an internationally integrated personnel system abroad, and the maximum fines to be proportionate and equitable

Furthermore, both sides' Authorities should launch a dialogue to seek an international framework by enhancing cooperation with third countries and international

organisations. It should eventually lead to the closer alignment of data protection regimes around the world that would enable global businesses to transfer personal data by complying with one regime.

< Yearly Status Report >

There has been good progress on this recommendation.

The draft EU Regulation is in the process of deliberations and may be adopted by the end of 2014.

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

< Background >

The European Parliament voted in its plenary session on 12 March 2014 and adopted the amendments proposed by the committee on Civil Liberties, Justice and Home Affairs (LIBE), the committee responsible for the proposal. The amendments by the EP keep harsh conditions on business entities such as potential fines up to 5% of an enterprise's annual worldwide turnover or 100 million Euros (whichever is greater) for data breach or complicated requirements on consent and erasure, although it introduces a definition of pseudonymous data and the certification program that would be favourable for business enterprises considering the use of personal data.

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

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

WP-C / # 06 / EJ to EJ Fundamental Reform of the Private Copying Levy System (Compensation System for Private Copying)

The EU and Japan should cooperate to reform fundamentally the private copying levy system taking into account the evolution of technology and distribution channels for lawful digital contents.

< Background >

Current compensation is based on private copying levies and sometimes dates back to the analogue era. Private copying levies regulations do not address piracy. New emerging and expanding business models may be hindered by current levy system. Furthermore the rules vary greatly across Europe.

Innovation in General

WP-C / # 07 * / EJ to EJ Work towards international standardisation at joint R&D programmes

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

< Yearly Status Report >

In Jun. 2013, the Abe Administration adopted a “Comprehensive Strategy on Science, Technology and innovation” and a “Declaration on the creation of the World’s Most Advanced IT Nations” as important pillars for its growth strategy.

On the EU side, a new Framework Programme for Research and Innovation from 2014 to 2020, “HORIZON 2020”, was adopted in 2013 with focus on innovation

< Background >

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

WP-C / # 08 * / EJ to EJ Sharing vision and roadmaps for a better coordination of R&D projects/programmes

To make the programmes even more effective to manage and accessible from the industry, the procedure for preparation and launch of coordinated calls should be well discussed by both parties and standardised. Both sides’ Authorities should increase matchmaking activities between EU and Japanese industry to find out common themes. For sharing the vision and working on the common roadmaps, the industry-led activities of European Technology Platforms (ETPs) can be a model.

To increase participation in the respective R&D projects of each region, the BRT recommends authorities to promote the services offered by the newly established National Contact Point in Japan for Horizon 2020 and other relevant instruments (including EEN) to widely circulate R&D call notifications and support the formation of partnerships.

< Yearly Status Report >

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

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

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

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

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

< Background >

Science and Innovation are an international endeavour. Ideas cannot be prevented from crossing borders. Countries can make more effective use of human resources and financial funds if their R&D programmes are coordinated and if mutual access to R&D programmes is easier for participants from both regions

WP-C / # 09 * / EJ to EJ Tax credits for R&D

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

< Yearly Status Report >

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

< Background >

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

Innovation in Aeronautics, Space, Defence and Railways

Aeronautics

WP-C/ # 10/ EJ to EJ Government-Led Industrial Cooperation in Aeronautics**

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

< Yearly Status Report >

Some progress has been made on this recommendation.

< Background >

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

EU-Japan industrial cooperation in civil airliners has stagnated since the early 2000s, when 21 Japanese suppliers joined the A380 programme. The situation is better for Japanese participation in engine programmes and as suppliers of carbon fibre materials. The aerospace industries of other countries have improved significantly in recent years and price competitiveness has become a key decision criterion.

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

WP-C / # 11/ EJ to EJ Cooperation on navigation regulations for helicopters

Establish an increased level and better cooperation between Europe and Japan on the development of low altitude IFR routes and satellite based navigation regulations for helicopters.

< Yearly Status Report >

Progress is seen on this recommendation. Europe's SESAR air traffic management systems programme and Japan's CARATS committee on future air traffic systems established a framework for technical cooperation.

< Background >

The US, Europe and Japan are working on developing their own regulations and

infrastructure without an adequate level of exchange of information and standardisation. European and Japanese territories have more similarities than each has with the US, so that Europe and Japan should work more closely and with a shared approach. Many European helicopters are already equipped with the hardware to interface with ground based / satellite based infrastructure already established to allow low altitude IFR routes, Point-in-Space navigation and GPS precision approaches, but that may prove useless if there is no cross recognition of standards and regulations (software) between the countries.

Space

WP-C / # 12 / EJ to EJ Civil Purpose Space Technology

Japanese space Authorities (at Cabinet level) and European space Authorities (European Commission, European Space Agency, and Europe's national space agencies) should establish a 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 (1) the development of satellites for advanced broadband, mobile communications services, advanced remote sensing and disaster mitigation, (2) the related development of Japan's and Europe's next national launchers, and (3) cooperation in global positioning systems.

< Yearly Status Report >

At the 21st EU-Japan Summit in November 2013, the EU and Japan decided to launch a Japan-EU Space Policy Dialogue. A preparatory meeting took place in Brussels on 20 March 2014. Regarding global navigation satellite systems, technical level discussions are on-going on compatibility and frequency issues. At the EU-Japan Industrial Policy Dialogue in January 2013 it was agreed to explore ways to work jointly on data access and satellite data sharing as well as exchange of information to find areas of mutual interest for cooperation.

< 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.

Europe and Japan will for the first time develop new heavy satellite launchers almost simultaneously. Cooperation in their development could have many technological, budgetary and industrial advantages. If a close bilateral cooperation is not studied at an early stage it will soon be too late for both sides to gain significant advantages.

Europe's Galileo and Japan's Quasi-Zenith Satellite System will soon become reality. Augmentation and various commercial services are among many mutually beneficial applications requiring extensive mutual information between EU and Japanese Authorities and their encouragement and facilitation of industrial cooperation.

WP-C / # 13 / EJ to EJ Mutual Backup of Government Satellite Launches

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

< Yearly Status Report >

No progress has been seen on this recommendation.

< Background >

Europe's launcher Ariane 5 and Japan's H-IIA are in an arrangement to back up each other's commercial satellite launches. This reduces the risk of long launch delays due to launcher technical problems. Years of discussions between the MEXT and the European Space Agency towards a similar back-up arrangement for government launch missions have not produced results.

Defence

WP-C/ # 14 / EJ to J Implementation of the three principles on transfer of defence equipment

Both sides' industries are pleased that Japan intends to contribute more actively to international security.

Japan's new three principles on transfer of defence equipment approved by the Cabinet on 1st April 2014 should be swiftly complemented by clear and transparent procedures relating to arms export and joint development. The Act on the Specially Designated Secrets enacted in December 2013 should not hinder the building industrial cooperation between Japanese and European industries.

< Yearly Status Report >

This is a new Recommendation. Last year's Recommendation "WP-C/ # 28 / EJ to J Relaxation of the Three Principles on Arms Exports" was essentially satisfied by the new principles.

< Background >

The GOJ relaxed its Three Principles on Arms Exports in December 2011. This enabled exports of arms etc.

The new principles adopted on 1st of Apr. 2014 prohibit Japan from transferring defence equipment to countries involved in conflict and to those that violate U.N. resolutions. However, Japanese firms will be able to transfer defence equipment when the deals pass government screenings. The previous rule banned arms exports to all countries, apart from a few exceptions.

The Act on the Specially Designated Secrets makes it possible for the GOJ to declare 23 types of information related to defence, diplomacy, counter-terrorism and intelligence as state secrets for five years, with possible extensions of 30 years or

more. The types of information, however, are so vaguely defined that a widespread fear of violating the law is causing many problems in exchanging even the most innocuous information among companies and administrations alike.

WP-C/ # 15 / EJ to EJ Defence Purpose Satellite Technology and Services

The BRT recommends that the Authorities of Japan and EU Member States establish a regular dialogue to share experience on defence purpose satellites. This should also include a dialogue on the delivery of secure communications services.

< Yearly Status Report >

Little progress has been seen on this Recommendation.

< Background >

In the defence satellite area, EU and Japanese satellite manufacturers have accumulated know-how and experience. Some EU Member States have also developed expertise and know-how in the structuring of PFI for secure satellite communications.

Railways

WP-C / # 16 / EJ to EJ Railway safety certification requirements

The both authorities should establish an open description of compliance requirements as well as current certification processes. The certification procedures relevant for the national railway companies should be made fully transparent to both parties. They should mutually inform of their evolutions. The European Railway Agency and the Japanese Ministry of Land, Infrastructure, Transport and Tourism could establish a dedicated working group in order to better capture the certification processes in both sides' networks.

< Yearly Status Report >

Some progress has been achieved in addressing this topic:

The players in the railway sector of the both sides have made efforts to understand the difference between the two systems for the past year in parallel with negotiations on FTA/EPA. Although it still needs to be improved, their mutual understanding has improved.

A major JR company recently opened its procurement of safety signalling systems to European companies.

A MOU on Railway Industrial Dialogue is in the process of finalisation between the European Railway Agency and the Japanese Ministry of Land, Infrastructure, Transport and Tourism."

< Background >

- (1) *The Japanese railway operators and the EU railways undertaking companies both have a very long and successful experience in the railway safety domain.*
- (2) *The legal requirements, management systems and business practices of railways in the EU and Japan are significantly different. Notably, the responsibility for the safety and reliability of equipment and systems falls on different players: while, in the EU, manufacturers are responsible for obtaining safety certification, in Japan, railways operators are responsible for obtaining safety certification.*
- (3) *Safety certifications drive many railways equipment and systems procurement requirements.*
- (4) *In order to address safety related issues, opening a dialogue between both sides' industry players could be an appropriate way. It would foster the cross-fertilisation of safety performance of the global railways industry.*
- (5) *Efforts to understand the difference between the two systems have been made. As the result, many of the initial misunderstandings have been resolved though some of them are yet to be cleared.*
- (6) *On 27 March 2014, the first dialogue of the railways sector that involve nearly all the players in the EU and Japan in the sector was organised in Brussels under the sponsorship of the European Commission and the Japanese government.*
- (7) *The BRT supports this initiative. Such an industrial-sector dialogue to enhance mutual understanding is useful and should be held regularly.*
- (8) *During the last few years, a significant effort has been undertaken in the EU in order to get better visibility on the certification in EU Member States. These relate to specific requirements for safe operation of relevant railway networks. The European Railway Agency mission is indeed taking care of the certification coordination among EU Member States' National Safety Authorities. In its so-called "Fourth Railway Package" proposal, the European Commission is paving the way for a common authorisation procedure to be granted by the European Railway Agency.*
- (9) *The BRT hopes that win-win solutions will be found through such a dialogue that will help the development of both the EU and Japanese railways industries in and outside the two regions.*

Recommendations from the European industry

INNOVATION IN AERONAUTICS, SPACE AND DEFENCE

Aeronautics

WP-C / # 17 / E to EJ Weight Restrictions on Haneda Airport D Runway

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

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

< Background >

With the purpose of expanding airport capacity in response to the increase in air travel demand as well as to reduce congestion, a fourth runway (D runway) and an international terminal were opened in Haneda in October 2010. So far focusing on flights to and from Asian countries, its use for long-haul international routes will increase in the future. The number of flights will grow together with the demand but will be limited in the end by the capacity in terms of slots. This will prevent Japan from realising its objective to grow the number of visitors from 10 million per annum today to 20 million by 2020, when the Tokyo Olympics will take place. The average size of aircraft departing Haneda (230 seats) is now lower than it was in 1980 (240 seats) when 747s were used domestically. To see traffic grow at Tokyo's airports and more specifically Haneda, work needs to be done to ensure larger aircraft can be used at Haneda. In this regard, the use of new and larger aircraft will be an important part of the airlines' strategies. Under such circumstances, aircraft weight restrictions on the D runway could impede the conversion of Haneda Airport to larger and newer aircraft. In order to avoid disturbing the flow of the Tama River, the D runway was overhauled using a pier-like structure instead of a conventional landfill. Due to this, weight restrictions have been placed upon the aircraft in use, and with the entire lineup of Airbus' newest A380 and A350 series exceeding the weight limit, these aircraft could no longer be used as they currently are (cf. chart below).

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

Space

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

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

< Yearly Status Report >

We have no new information.

< Background >

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

Defence

WP-C / # 19 / E to EJ Internationally recognized procurement processes for defence equipment and services

The following should be applied to all defence procurement processes:

- (1) Japan should improve transparency towards foreign suppliers by making the Statement of Requirements for procurement processes more widely available.
- (2) Japan's MoD should adopt NATO standards for the initial research and development phase to strengthen competition and reduce development risk.
- (3) Japan's MoD should also implement multiyear contract scheme for weapon acquisition in order to obtain the best conditions in terms of prices and local content from foreign manufacturers.
- (4) Greater emphasis should be placed to date on Life Cycle Costs by Japan in its defence procurement. Budgeting based on life cycle costs allows

governments to better plan their defence expenditure. It also creates fairer competition between bidders for contracts as it demands fuller disclosure of cost information.

- (5) Unlimited liability should be removed from the terms and conditions of public tenders, as this puts foreign bidders at a considerable disadvantage in relation to local contenders.
- (6) If a foreign company is selected, then the Japan MOD should separately select the local industrial partner based on a licenced production and modification package made available by the selected foreign company.
- (7) The MoD should also send a clear message to suppliers that if they do not contract on the basis of their selection there will serious consequences or cancellation of the selection.
- (8) The BRT would also encourage MoD to create an appeal process.

< Yearly Status Report >

The Japanese MoD has made a move to improve the transparency of its decision making process by declaring a point system to determine the winner and providing a debrief as to how the decision was made. However the point system is not that clear and debriefs need to be more detailed.

< Background >

Certain reforms have already taken place in defence procurement processes. Further reforms would strengthen transparency and competition.

**Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan**

Tokyo, 8 & 9 April 2014

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

Working Party Leaders:

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List of Abbreviations

Abbreviation	Meaning
FSB	Financial Stability Board
CFTC	US Commodity Future Trading Commission
BCBS	Basel Committee on Banking Supervision
IOSCO	International Organization of Securities Commission
BEPS	Base erosion and profit shifting
APA	Advance Pricing Agreement
FTT	Financial Transaction Tax

Introduction

Japan and the EU are still facing the challenges of recovery and the need to restore sustainable growth. The leaders of the G20 have agreed to implement regulatory reforms to promote integrity, stability and transparency in the financial sector and such global efforts for the reform implementation are being monitored closely by the Financial Stability Board (FSB) to ensure international consistency. The proposed regulations and prudential measures are expected to prevent the recurrence of systemic crisis, increase accountability and ultimately contribute to economic recovery through support given to real economic activities by a healthy financial sector.

It is essential that governments and global supervisory bodies take a coordinated approach to the introduction and implementation of regulations or measures, to identify their full and cumulative implications on markets which have different circumstances and practices, and to ensure consistency and efficiency. This is also applicable beyond financial regulations, to tax measures for example, as the common objective is to preserve efficient resource allocation for companies operating globally as well as level playing fields for all participants. Japan and the EU should unite their efforts to steer through this challenging time and achieve recovery most effectively.

The above is reflected in our selection of Recommendations for this Working Party D document.

Recommendations from both European and Japanese industries

WP-D / # 01** / EJ to EJ Recommendation regarding Financial Reform and Regulation

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

<Recent Progress>

In July 2013, the European Commission and the US Commodity Futures Trading Commission (CFTC) announced a Path Forward regarding their joint understandings on a package of measures for how to approach cross-border derivatives. As stated there, there will be considerable co-ordination challenges to avoid cross-border conflicts, inconsistencies and duplication. The final report on margin requirement for non-centrally cleared derivatives was issued by the Basel Committee on Banking Supervision (BCBS) and the International Organization of Securities Commissions (IOSCO) in September 2013, which includes a threshold of €50 million for initial margin to minimise impact on corporate business activities.

<Background>

Financial reform and introduction of additional regulations are underway to achieve a more resilient financial system but they should be designed to be appropriate and effective so as to enable financial markets and financial industry support sustainably economic activities and the revitalisation of global economy.

The European and Japanese authorities as well as market participants including banks and business corporations should continue to unite efforts to ensure effective influence on US financial regulations which have international reach, particularly cross-border OTC derivatives market reforms, to avoid decrease in liquidity and increase in hedging cost.

WP-D / # 02 / EJ to EJ Recommendation on BEPS Action Plan**

The BRT recommends that, as to the BEPS (base erosion and profit shifting) Action Plan, the authorities should carefully consider the risks of excessive disclosure requirements and anti-tax avoidance measures so as not to hamper multinational enterprises' business activities.

<Background>

The BEPS Action Plan was proposed by the OECD and endorsed by G20 Finance Ministers and Central Bank Governors in July 2013. The BRT supports the idea of modernising international taxation rules that would include non-OECD countries to cope with the globalisation and digitalisation of economy. However, the BRT is concerned that the requirement of BEPS Action Plan for multinational enterprises to disclose information on their global allocation of income, economic activity and country-by-country taxes paid to all relevant governments would risk leading to an increase of administrative burden on enterprises and of a risk of double taxation. The BRT recommends that the introduction of excessive disclosure and anti-tax avoidance rules should be avoided so that legitimate business activities would not be hampered.

WP-D / # 03* / EJ to EJ Recommendation on Tax Issues

- The BRT requests that the EU Member States and Japan should modernise the tax treaties between them and ensure that, to the greatest extent possible, dividend, royalty and interest payments are exempted from withholdings taxes and that they provide for corresponding adjustments and arbitration in case of transfer pricing taxation.
- The BRT requests the harmonisation and simplification of documentary requirements in transfer pricing taxation and the facilitation of the conclusion of bilateral and multilateral APAs (Advance Pricing Arrangements).
- The BRT recommends the introduction of participation exemption that will exempt dividends and capital gains received from business investment from further corporate taxation.

<Recent progress>

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

<Background>

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

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

WP-D / # 04 / EJ to E Recommendation on Financial Transaction Tax**

The BRT maintains its serious concern over the EC's proposed financial transaction tax (FTT), particularly with respect to its wider application and extraterritorial impact. For instance, as the proposed Directive introduces both a residency and issuance test for such unilateral taxation, it risks causing costly double or multiple taxation. If imposed, the FTT will result in reduced volume of financial transactions and decreased liquidity, significantly increase funding costs and impair legitimate hedging activities by parties such as business corporations. The decreased liquidity in secondary markets is also likely to cause impacts on primary markets eventually.

< Recent Progress >

No agreement has been found.

< Background >

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

WP-D / # 05 / EJ to J Recommendation on Japanese Fiscal Soundness**

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

<Background>

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

WP-D / # 06* / EJ to J Recommendation on Japanese Tax system

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

<Background>

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

**Recommendations
of the
EU-Japan Business Round Table
to the Leaders of the European Union and Japan**

Tokyo, 8 & 9 April 2014

Working Party E
Energy, Environment, and Sustainable Development

Working Party Leaders:

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President
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Introduction

Harnessing a low-cost, abundant, safe and sustainable energy supply is key to both Japan and the EU to meet the energy demands of their companies, industries and people while addressing several other challenges, such as transforming energy systems, reducing energy needs and greenhouse gas emissions, and protecting the environment, while at the same time ensuring each region's preparedness for natural disasters and crisis management.

One asterisk (*) identifies "priority" Recommendations, two asterisks (**) identify "top priority" Recommendations. (e.g. WP A / # 01** / EJ to EJ)

Recommendations from both European and Japanese industries

WP-E/#01*/EJ to EJ Changes and harmonization in energy and environment

- **Significant geopolitical risks in energy-supply areas**

The Arab Spring revolution that was triggered by the Jasmine revolution in Tunisia in December of 2010 and spread throughout the Middle East and North Africa, including Jordan, Egypt, and Bahrain, has created political and social instability in the Middle East, a region that supplies a large portion of the world's energy.

The road to stability in oil-producing countries such as Iraq, Libya, Algeria, and Iran remains unclear.

For Japan, a country that imports more than 80% of its oil from the Middle East, securing the energy required to support the country's economic activities is an issue of vital importance. This applies also to EU, whose average oil import dependency is 83%.

Recent events in Ukraine and Russia also raise concerns over security of gas supplies as the EU-27 imports more than 60% of its energy needs in gas, a quarter of which from Russia.

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

- **Increased energy demand from emerging countries affects the energy policy of other countries' and price stability**

As the world's population continues to increase, the main consumption of energy is shifting from developed to emerging countries. In the long term, exports of shale gas from the United States may help stabilizing both energy prices and supply; however, the development of resources by state-owned enterprises from the emerging countries will lead to severe competition to secure stable supplies at affordable prices.

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

- **Increase in greenhouse gas emissions and its impact on the environment**

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

WP-E/#02**/EJ to EJ Basic energy policy

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

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

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

- **International coordination**

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

Japan and EU should create a comprehensive and collaborative framework to handle the inter-relationship between energy and environment issues.

Japan and EU should also deepen their cooperation through their participation in the IEA and IAEA, as well as through information exchanges at other relevant international meetings in which they participate.

WP-E/#03*/EJ to EJ Energy policy timeline and energy mix policies

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

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

- **Promoting supply stability through a multi-layered energy policy**
All sources of energy sources have their strengths and vulnerabilities; no energy source can meet all demands for stability and affordability. Therefore, it is necessary to build a multi-layered energy supply system supported by an adequate power transmission infrastructure that can function both in normal times and during crises.
- **Creating an energy mix that allows for regional variations and cost**
In Japan and the EU, there are some regions blessed with abundant energy resources, and some that are not.

While some regions have already established an inter-dependent power exchange system, with other countries, some countries have no close neighbours and have therefore had to build an independent supply system.

Deliberations by Japan and EU concerning the stable and safe supply of energy, economic efficiency, and environmental issues should take into account these regional variations.

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

WP-E/#04*/EJ to EJ Fossil fuels

- **Advantages and disadvantages of coal, oil, natural gas, and LP gas**
Fossil fuels emit greenhouse gases, but have an advantage in terms of cost and stable supply. Research into making the use of fossil fuels more efficient and reducing CO2 emissions is ongoing. Japan and EU should support this research and the use of more energy-efficient and cleaner fossil fuels by developing countries.

WP-E/#05/EJ to EJ Nuclear power**

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

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

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

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

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

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

The cost of generating power in Japan in fiscal 2013 greatly increased due to the use of thermal power plants to compensate for the lack of nuclear power generation. This has caused a rise in electricity prices, affecting the competitiveness of the activities of both the EU and the Japanese industries in Japan, as well as increased GHG emissions. In terms of both economical reasons and reducing greenhouse gas emissions, it is necessary to restart those nuclear power plants that are verified as being safe by the safety authority.

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

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

- **Nuclear fuel recycling**

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

- **Financial support**

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

WP-E/#06/EJ to EJ Safety measures**

- **Measures to assure safety**

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

- **Consultation**

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

WP-E/#07/EJ to EJ Renewable energy**

- **Advantages of renewable energy**

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

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

Renewable energy sources are available in many forms, including wind, solar, hydro, geothermal, tidal, biomass, etc. However, with the exception of hydro, which is already a power supply base to a certain degree, renewable energy remains unclear in terms of economic potential, efficiency, and stable supply due to variations in availability to different regions. It is therefore necessary to study carefully how the adoption of renewable energy sources will be specifically carried out.

- **Storage batteries**

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

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

WP-E/#08/EJ to EJ Energy conservation and energy efficiency**

- **Enhancing energy conservation in all fields**

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

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

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

Japan and the EU should consider taking further measures to promote energy conservation, by financing research projects to develop technologies and methodologies for improving energy efficiency and by sharing their best practices. At the same time, the reality is that active measures must be complemented by passive measures, which affect building insulation and temperature stabilization, and the governments of both countries must be encouraged to support such moves. In particular, setting mandatory regulations for building standards and house insulation plays a major role in reducing energy consumption.

WP-E/#09*/ EJ to EJ Energy researches and international cooperation

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

The emission of greenhouse gases that trigger climate change and impact the environment is an issue that affects the entire human race, and requires international knowledge and cooperation to solve. Global-scale research is therefore required to develop renewable energy sources and assure the safety of nuclear power, as well as explore new energy fields such as methane hydrates.

- **Human resources development**

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

WP-E/#10/ EJ to EJ Importance of measures against global warming**

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

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

- **Situation in Japan following the Great Eastern Japan earthquake and issues to be resolved**

The scenario initially envisioned by Japan of reducing greenhouse gas emissions by increasing nuclear power generation has been derailed by the Great Eastern Japan earthquake and subsequent accident at the Fukushima Daiichi nuclear power plant, following which all of Japan's nuclear power plants remain idled and the country continues to rely heavily on fossil fuels.

Japan is now working on determining the specific details of its COP19 agreement, which is to establish voluntary post 2020 reductions that are to be measured, reported and mutually verified by other countries.

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

• **Measures to be taken by the EU:**

In January 2014, the EU Commission published a white paper policy framework for climate and energy for the period from 2020–2030, proposing a cut in carbon emissions by 40 % below the 1990 level in 2030. Such a single ambitious CO2 emissions reduction target by 2030 is, together with the structural reform of the European Trading System, a key signal to return to robust prices for CO2. Furthermore, it would give a strong signal of the EU's commitment to fighting against climate change before the upcoming international negotiations (COP21 in 2015). It is therefore important EU maintain such ambitious objectives and the means to achieve a cost-effective decarbonisation in the long-term. A global dialog on these issues should also be maintained.

WP-E/#12*/ EJ to EJ International contributions

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

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

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

• **Visualization of emissions reduction results**

“Visualizing” CO2 emissions reduction results is an effective way to verify the impact of low-carbon technologies and energy-saving products. Specific methods to visualize reduction results should be developed through public-private collaboration.

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

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

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

WP-E/#13*/ EJ to EJ Environmental technology collaboration

- **Promoting innovative R&D projects to reduce greenhouse gas emissions in Japan and EU**
Japan and EU should promote joint R&D between industry, academia, and governments to develop innovative technologies that can be used to reduce greenhouse gas emissions.
- **R&D projects**
Developing advanced and innovative technologies from the initial research phase, applying them to products, and promoting their use requires considerable time and money. Japan and the EU should therefore provide mutual access to the results of R&D projects implemented with government support.