



Commission Services Progress Report
on the

**EU-Japan Business Round Table
Recommendations 2014**

**"EU-Japan Cooperation
New opportunities for global growth"**

Brussels, March 2015

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Working Party A

Trade Relations, Investment and Regulatory Cooperation

Recommendations from both European and Japanese industries

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

Reply

The Commission agrees on the need to further strengthening the EU-Japan relationship so as to foster growth and jobs both in the EU and in Japan and welcomes the support expressed by the BRT to the FTA/EPA negotiations.

The Commission attaches great importance to this negotiation with a major trading partner and in this regard it is positive to note that the review process which was conducted by the EU following the first year of negotiations was concluded positively in 2014 and that nine rounds of negotiations have already taken place

The objective is now to reach an early conclusion of a highly comprehensive and ambitious agreement, keeping in mind that only an agreement with ambitious commitments not only on trade in goods but also on issues such as non-tariff barriers, public procurement, investment, harmonisation/mutual recognition of regulations and standards, or intellectual property and geographical indications will be acceptable to the EU.

The Commission also fully agrees with the assessment of the BRT on the key role that this agreement should have in promoting regulatory cooperation and standards harmonization.

WP-A / 02/ EJ to EJ Call for effective and quick implementation of WTO ‘Bali Package’ and work on a future WTO work program;

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.

Reply

The EU agrees with the importance of the rapid ratification of the Trade Facilitation Agreement so as to ensure its entry into force as quickly as possible. The EU supports the objective of achieving the necessary number of ratifications (2/3 of WTO Members) by the 10th WTO Ministerial Conference in Nairobi in December 2015.

The EU also agrees on the importance of advancing with the preparation of the post-Bali work-programme. The EU believes that all WTO Members need to work with the objective of preparing a work-programme which sets the WTO on a credible path toward the rapid conclusion of the DDA. In this regard, the EU emphasises the need to look at realistic and doable solutions which would allow WTO Members to advance on all DDA issues, including agriculture, non-agricultural market access and services.

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.

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.

Reply

To facilitate and increase bilateral trade in goods between the EU and Japan by preventing, identifying and eliminating unnecessary regulatory obstacles, is high on the agenda of the Commission. To this end, there exist several tools, the first one being what is currently negotiated within the FTA/EPA framework. Within the FTA/EPA there will be provisions regarding the Technical Barriers to Trade (TBT) agreement and its corresponding rights and obligations, the need for greater transparency and better regulation. The FTA/EPA as such will not create a harmonised regulatory framework between the EU and Japan but rather set the frame, the objectives and the conditions towards that goal. The second tool is the Regulatory Cooperation Joint Document which is an agreement between METI and DG Grow to further develop regulatory cooperation in line with the objectives described in the recommendation from the BRT e.g. exchange of information on legislative work programme, prevention of regulatory divergences through mutual information and dialogue.

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.

Reply

The chemicals legislation of both the EU and Japan do have some similarities but also many differences in how substances are treated. Within the EU-Japan Policy Dialogue Working Group, there have been exchanges of information relating to the progress in managing the legislation and latest developments on emerging issues. Establishing a common list of restricted substances would be quite difficult as both the EU and Japan have to follow the processes and procedures foreseen in their legislations. That being said, exchanging information on each other's activities might provide opportunities to coordinate activities related to given substances better in the future. REACH does impose obligations for upstream companies to provide information to downstream users specifically to ensure that actors in the supply chain are informed of data on substances.

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.

Reply

We share such an approach which is in line with discussion taking place at international level (G20 Energy Sustainability WG and Action plan).

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.

Reply

Mutual Recognition of AEOs including further benefits are discussed by AEO experts from both sides in their regular meetings concerning the implementation of the mutual recognition decision between the EU and Japan. Moreover, EU and Japanese experts are working towards an automated solution for the future data exchanges.

In general, the possibility of expanding the benefits under the MRA is part of the agreement and reflects the common understanding of both parties that, with the practical implementation and the experience gained, additional benefits for the economic operators should be identified. However, it should be taken into account that the current scope of the agreement is restricted to 'security and safety' only. Therefore any considerations on possible simplification of import procedures going beyond the 'security and safety' processes and procedures require parallel thinking of the necessity for a legal base and all other implications related to this.

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.

Reply

IPR customs enforcement remains a top priority for Customs in the EU. In the daily completion of their IPR enforcement-related tasks, Customs use risk analysis technics for targeting suspected shipments and available IT tools. Increased cooperation between Customs and right holders remains a cornerstone for the effective enforcement of registered rights at the EU external border. Customs are committed to cooperation with the other IPR enforcement authorities in the EU and relevant authorities in third countries in order to reduce the volumes of international trade in IPR infringing goods and its impact on global economy.

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.

Reply

In the motor vehicles sector, the EU shares the view of the BTR that the adoption of the relevant Regulations developed under the 1958 UN Agreement, thus benefitting also from the mutual recognition foreseen therein, is the most important avenue for minimizing duplication of requirements and related conformity assessment procedures, and lowering the costs of regulatory compliance of both EU and Japanese manufacturers. This explains why, since some years, the uptake of newly adopted UN Regulations (and their revisions) into the EU is automatic.

The EU has also been fully committed to develop UN Regulations and/or global technical regulations which establish technical requirements for vehicles using innovative and environmentally friendly power-train technologies such as clean diesel, electric vehicles, hybrid vehicles and fuel-cell vehicles. This work is developed in close partnership with Japan.

The EU, in partnership with Japan, is also active in the review process of the 1958 Agreement and in the development of the IWVTA (International Whole Vehicle Type-Approval). The overall objective for the process is two-fold: (1) to maintain a robust and reliable international framework to ensure sufficient level of safety and environmental protection; and (2) to make the framework more attractive for emerging countries. The UN WP29 has agreed on a roadmap to carry out the 1958 Agreement review and the IWVTA establishment by the target year of 2016.

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.

Reply

Social Security is not harmonised in the EU and it is for Member States to organise their own social security schemes and to lay down their own national conditions according to which social security benefits (including pensions) are granted, the contributions to be made, the amount of the benefits and the period for which they are granted. Accordingly, the possible refund of contributions paid into a Member State's social security system is a matter of national law and is not regulated at EU level.

The problem of double contributions can be addressed by concluding bilateral social security agreements with Member States. It is the competence of Member States to conclude social security agreements with third countries. Such agreements can allow workers posted from Japan to work on the territory of a Member State, but be exempted from contributing to the Member State's social security system for an agreed period of time.

In this context, the Commission is aware that a growing number of bilateral social security agreements between Japan and EU Member States have been concluded, or are being negotiated at present. The Commission wishes to encourage closer cooperation between Member States in the conclusion and operation of bilateral agreements with non-EU states. Additionally, it believes that the possibility to make common EU agreements on social security with certain non-EU states such as Japan should be explored.

In addition, the Council of the EU and the European recently adopted Directive 2014/66/EU dealing with the conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer (ICT). The aim of the Directive is to attract non-EU workers with much-needed skills, in particular key personnel of transnational corporations temporarily transferred to the EU. The Directive is an important part of the EU common migration policy. The Directive specifically accommodates the fact that key personnel may be sent to work in an EU country yet, by virtue of the application of bilateral agreements made with the country in question, will not be required to make social security contributions there. A key aspect of this Directive is to allow such temporary non-EU workers short-term mobility between Member States in order to serve the needs of their employer

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.

Reply

The new European Commission has identified “Migration” as a key priority in the Political Guidelines for this mandate. The aim is to improve the management of legal migration at EU level, and in particular of labour migration, in order to better address labour and skills shortages and, in particular, at making the EU more attractive to highly skilled migrants. This should also contribute to building a more positive narrative on migration within the EU. The strategy would entail the creation of a Platform on labour migration, to promote a more coordinated approach at EU level and to allow economic stakeholders (e.g. business, trade unions) to contribute their expertise on labour migration.

The Commission will present its vision in a Communication (European Agenda) on EU migration policy, planned for 2015. This Communication will cover all aspects of EU migration policy: setting out the building blocks of a Europe that attracts, integrates and protects migrants. It will set the framework to take action in a more coherent, coordinated and comprehensive manner. A specific focus on labour migration policy and on revising the EU Blue Card Directive, aimed at attracting talents to the EU, will be included.

To deliver on these political priorities and effectively respond to the complex challenges facing Europe, it is necessary to take action in a more coherent, coordinated and comprehensive manner than in the past, with due regard to both the internal and the external dimension at the same time.

Last year we adopted Directive 2014/66/EU of the EP and of the Council on conditions of entry and residence of third-country nationals via intra-corporate transfers. This legal piece creates an attractive EU scheme harmonising the conditions of entry, stay and intra-EU mobility for third-country workers (managers, specialists and trainee employees) being posted by a group of undertakings based outside the EU to an entity based on the EU territory.

The new rules entered into force on 27 May 2014 and must be transposed into national legislation within 2.5 years (i.e. before December 2016). These new, business-friendly, flexible rules for admitting such transferees to the EU will foster growth and facilitate EU-wide investment.

The Directive covers temporary stays, up to 1 year for trainees and 3 years for specialists and managers.

One of the main added values of the new Directive is true EU mobility for these workers. No new application is required and the transferee can continue his/her work in another MS without interruption. There is certainly no need to return to the country of origin.

A number of safeguards are also put in place to allow such far-reaching right to mobility. The scheme scraps labour market tests or economic needs tests.

However, and as in the case for seasonal workers and other categories of immigrant workers, Member States retain the right to set volumes of admission of third-country national workers according to EU basic law (EU Treaty TFEU Art 79.5).

Moreover, indeed the ICT Directive (like all other legal migration Directives) does not apply to the UK, or to Ireland and Denmark. It is very unlikely that the UK will opt in to the ICT Directive in the foreseeable future.

The EU is fully aware of the importance of Working Party/Mode 4 related issues for Japan in the context of EU-Japan FTA negotiations.

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.*

Reply

The commission welcome the EU-Japan Business Round Table recommendations and we praise its special consideration to SME issues. Through our continuous support to EU-Japan Centre for Industrial Cooperation, the Commission aims at increased market access for European companies on the Japanese market. The Centre in pragmatic manner implements already a number of recommendations included in the progress report.

Mutual cooperation can also be strengthened through joint participation like the Enterprise Europe Network. The European Commission invites Japanese business association, research department and regional offices to join the Network.

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. 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.

Reply

The Commission adopted on 3 October 2014 the Single Market Act II, a Communication that sets out its strategy and twelve new key levers for the further development of the single market. The SMA II maintains the balanced political vision promoted by the SMA I that was widely welcomed by the European Parliament, Member States and stakeholders. Like the SMA I, SMA II aims to focus political attention on a restricted number of key actions fast-tracking their adoption for new growth in the single market. It announces 12 key proposals, in four key areas:

1. Developing fully integrated networks in the single market;
2. Fostering mobility of citizens and businesses cross-border;
3. Supporting the digital economy across Europe;
4. Strengthening social entrepreneurship, cohesion and consumer confidence.

Regarding the Single Market Act I, out of the 12 key actions the following 11 are completed: EU patent; revised standardisation system; infrastructure legislation; simplified accounting directives; alternative / online dispute resolution; venture capital funds legislation; social entrepreneurship funds; professional qualifications Directive; revised public procurement directives; posting of Workers Enforcement Directive; e-signatures / e-identity / trust services legislation. One action still with the Council: revised Energy tax Directive

As for the Single Market Act II, out of the 12 key actions the following 5 are completed: the third energy package action plan (non-legislative action); upgraded EURES portal; electronic invoicing in public procurement; facilitate deployment of high-speed broadband; access to basic bank account / transparency of fees / switching of accounts. The following 6 have been proposed by the Commission, but are still to be adopted by the legislator: general product safety and market surveillance package; modernised EU insolvency rules; fourth railway transport package; Single European Sky II+; access to long-term investment funds; Payment Services Directive / Multilateral Interchange Fees.

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.

Reply

Removing tariffs and Non-Tariff Barriers in these and other sectors are high on the agenda of negotiators for the FTA/EPA between the EU and Japan. A first exchange of market access offers and the successful completion of the one year review have

contributed to progress on these issues but more efforts are needed before we can envisage a final agreement.

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.*

Reply

As regards phthalates, we are working closely with the European Chemicals Agency on these substances and also follow closely what is happening outside of Europe in other regulatory regimes.

The Commission launched in 2013 infringement proceedings against the MS having divergent views on the interpretation of the 0,1% threshold in Articles 7(2) and 33 of REACH. However, in the meantime, there was a request from the French High Administrative Court for a preliminary ruling before the Court of Justice of the EU as regards the correct interpretation of those provisions. A hearing in that case C-106/14 took place on 8 January 2015 and a final decision from the Court is pending. When adopted, the Court judgement will lead to full harmonisation in the interpretation of the threshold.

- *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.*

Reply

Denmark has repealed the ban in the course of 2014.

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.*

Reply

Under Art. 33.1 of REACH, there is the responsibility of any supplier of an article containing a SVHC above 0.1% to inform the recipient of the article. Communication in the supply chain is a task of industry. We understand that the Japanese industry, in cooperation with METI, is working on an IT-Tool that will facilitate the tracking of substances through supply chains, which eventually could be made available internationally. The EU industry has expressed its interest to get involved in this activity. For the registered SVHCs, the ECHA dissemination website should already contain information on the hazard and uses. More information is available in the Annex XV dossier for SVHC identification (accessible via a link from the Candidate List page).

REACH provides that the registration dossier of the OR should comprise all uses of the importers covered by the registration (in that case they are downstream users). The OR shall keep an up-to-date list of EU customers (importers) but only within the same supply chain of the 'non-EU manufacturer' and the tonnage covered for each of these customers, as well as information on the supply of the latest update of the SDS. Although the only representative is legally responsible for the registration, it can be anticipated that in many cases, it will be the 'non-EU manufacturer' that will provide him with all necessary data for his registration dossier.

It is true that the only representative can represent one or several 'non-EU manufacturers'. However, if he acts on behalf of several 'non-EU manufacturers', he must submit a separate registration for each of these manufacturers. The tonnage of the substance to be registered in each registration is the total of the tonnages of the substance covered by the contractual agreements with the only representative and the specific non-EU manufacturer represented by him. The information requirement for the registration dossier shall be determined according to this tonnage. By making separate submissions, the confidential business information of the 'non-EU manufacturer' can be preserved and equal treatment with EU manufacturers can be ensured (EU manufacturers must submit separate registration dossiers for each legal entity). It is noted that only representatives are required to submit separate registrations not only for each 'non-EU manufacturer' they represent but also for quantities of the same substance which they manufacture themselves or import from other 'non-EU manufacturers'. Those rules ensure compliance with the EU competition law.

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.

Reply

The Commission is very aware of SIEFs issues, as was stated in the REACH Review of 2013. Since then it has been working on a number of initiatives to ease the burdens for SMEs, including further reducing their fees. In addition, an implementing act addressing the operation of Substance Information Exchange Forums (SIEFs) specifically with regard to transparency of costs related to data-sharing under REACH should be adopted this year.

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.

Reply

The REACH Regulation required the Commission to carry out a review as regards the authorisation regime for EDs, i.e. whether the so-called adequate control route for authorisation should be excluded for EDs. The review report addresses in particular the threshold/no-threshold issue for EDs, concluding that thresholds for EDs might exist, but that it is for industry (registrants/applicants for authorisation) to demonstrate the existence of the threshold and determine it. This is congruent with other provisions of REACH, which is placing the burden of proof of safe use of a substance to industry.

The Commission has made substantial progress in its work to define criteria for the identification of endocrine disruptors (EDs). A roadmap describing four different options of how to define criteria for EDs has been published on 17 June 2014. The options are based on the WHO/IPCS definition. One option is based on a categorical approach. Another option takes potency into account. The roadmap includes further options for changes to the regulatory decision making (requiring changes of the Regulations) under the BPR and PPPR. Which of the options will finally be chosen will be decided, in line with the Commission's procedures, after an impact assessment will have been finalized.

A public consultation collecting input for the impact assessment was conducted between 26 September 2014 and 16 January 2015. A first analysis of the results has been published by DG SANTE (see link below), with a detailed analysis to be followed soon.

http://ec.europa.eu/dgs/health_food-safety/dgs_consultations/food/consultation_20150116_endocrine-disruptors_en.htm.

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.

Reply

Response: "The European Commission recognises the potential for overlap between the REACH Regulation and Directive 2011/65/EU (RoHS) and has prepared and published on its website (link below) a "Common Understanding paper explaining how the services of the Commission intend to manage the interface between the two instruments. The paper is based on the premise that, as far as possible, RoHS should be given priority to regulate issues pertaining to the use of substances in electrical and electronic equipment."

http://ec.europa.eu/growth/sectors/chemicals/reach/special-cases/index_en.htm

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.*

Reply

Importers of chemicals in the European Union are required to comply with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the 'CLP Regulation'). The CLP Regulation is largely aligned to the classification and labelling rules under GHS. The European Union is committed to implementing GHS through the CLP Regulation in accordance with the Building Block approach, as defined in GHS Section 1.1.3.1.5:

"Countries are free to determine which of the building blocks will be applied in different parts of their systems. However, where a system covers something that is in the GHS, and implements the GHS, that coverage should be consistent".

Accordingly, CLP Annex I on classification follows closely the structure and content of the GHS (including the numbering) and applies most GHS hazard classes and their related labelling elements. The CLP Regulation carries forward some additional elements from its predecessor legislation (such as a limited number of additional hazard statements).

The European Commission regularly adopts Commission Regulations amending the CLP Regulation for the purpose of its adaptation to technical progress (ATP) in order to implement revisions of GHS. Most recently, Commission Regulation (EU) No 487/2013 aligned the CLP Regulation to the fourth revision of GHS; an alignment to the fifth revision of GHS is under preparation.

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.

Reply

Point 1: The Commission Recommendation on the Definition of a Nanomaterial (EU No 696/2011) applies to natural, incidental and manufactured materials that comply with size determinants of the nanomaterial under the scope of specific EU legislation. Accordingly, the definition itself is not based on the degree of exposure. However, the degree of exposure is taken into account in relevant legislation, such as the REACH registration obligations for substances, mixtures and foreseeable releases from articles. It is also considered in the context of European standardisation activities concerning nanotechnologies and nanomaterials, e.g. through standards or technical specifications for filters for nanoparticles.

Point 2: Similarly to other chemicals, substances with nanoforms are subject to registration requirements under the REACH Regulation (Regulation (EC) No 1907/2006) and to notification requirements under the CLP (Classification, Labelling and Packaging) Regulation (Regulation (EC) No 1272/2008). The Commission is currently working on an impact assessment on possible amendments of the Annexes to the REACH Regulation to ensure clarity on how nanomaterials are addressed and safety demonstrated in registration dossiers.

In addition, the Commission is preparing an impact assessment on potential transparency measures for nanomaterials on the market. Policy options under assessment include a Nanomaterials Observatory to collect and present relevant information on nanomaterials from existing sources and new market studies, a single EU Nanomaterials Registry mandating the notification of nanomaterials and products containing nanomaterials, a recommendation on best practices for national registries, or no additional action compared to the current legal framework.

Point 3: The Commission is currently working on measurement and monitoring methods for nanomaterials and their validation to ensure the proper implementation of the nanomaterial definition. Furthermore, the Commission collaborates internationally in the context of the OECD on the harmonisation and standardisation of test methods in support of hazard assessment of nanomaterials. In addition, the Commission promotes the work on nanomaterial characterisation through a mandate to the European Standards Organisations.

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.*

Reply

The Commission welcomes the comments from BRT and wishes to note that a reference to the CCCTB features in Annex I on New Initiatives of the Commission Work Programme 2015. Point 14 envisages an Action Plan on efforts to combat tax evasion and tax fraud, including a Communication on a renewed approach for corporate taxation in the Single Market in the light of global developments. A re-launch of the work

towards a CCCTB is placed within the general context of stabilising corporate tax bases in the EU for a fair tax environment.

In the meantime, the technical work continues under the Latvian Presidency with a focus on the International Aspects of the system.

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.

Reply

The Commission welcomes the comments from BRT and wishes to note that a reference to the CCCTB features in Annex I on New Initiatives of the Commission Work Programme 2015. Point 14 envisages an Action Plan on efforts to combat tax evasion and tax fraud, including a Communication on a renewed approach for corporate taxation in the Single Market in the light of global developments. A re-launch of the work towards a CCCTB is placed within the general context of stabilising corporate tax bases in the EU for a fair tax environment.

In the meantime, the technical work continues under the Latvian Presidency with a focus on the International Aspects of the system.

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.

Reply

The fundamental reform of the VAT system is a longer term process which consists of several steps. The Commission presented in 2013 in the framework of the VAT reform a legislative proposal for a standardised VAT return. This proposal should facilitate compliance for businesses having reporting obligations for VAT in several Member States. The proposal is discussed in the Council. The Commission also intends to modernise and simplify the VAT rules on intra-EU B2B supplies, to expand the One Stop Shop as a priority for B2C sales of goods and services and to set up a web portal to provide business with accurate and reliable information on the details of the VAT regimes in place in the Member States. However, for such projects to succeed, the involvement of all the tax authorities will be key.

WP-A / 16 / J to E Company Law / Corporate social responsibility

16.1 Conflict minerals

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.

Reply

-The Commission welcomes the support of the BRT regarding the Draft Regulation setting up a Union system for supply chain due diligence self-certification of responsible importers of tin, tantalum, tungsten and gold.

-The approach retained by the Commission – focus on upstream importers – is considered to be reasonable and effective with the aim to avoid excessive administrative burden on businesses.

-As regards the accompanying measures laid down in the Joint Communication, the Commission is duly following up on the announced measures and will provide clarification and update on developments when appropriate. Specifically, on public procurement incentives, products purchased through the Commission's public procurement containing tin, tantalum, tungsten and/or gold will need to respect the OECD Due Diligence Guidance or equivalent due diligence schemes in order to satisfy contractual obligations.

16.2 Country by country reporting (CBCR)

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.

Reply

The Commission notes the BRT's call for a careful analysis of implications for multinational enterprises' business activities of any extension of the reporting duties to include a country-by-country report. The Commission will conduct a comprehensive analysis of the pros and cons of such an extension, when the work starts on the review report due by 2018.

16.3 Non-financial disclosure

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.

Reply

No comment.

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.

Reply

The indication of the country of origin is expected to usefully supplement the basic traceability requirements and therefore to facilitate the task of market surveillance authorities in tracing the product back to the real place of manufacture. Following a request of many Member States, the Commission agreed to launch a study to further assess the effects of origin marking. The results of the study should be available before summer 2015.

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.

Reply

Updated guidance on the new legislative framework and the implementation of EU product rules (the so-called ‘Blue Guide’) is available at http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm#h2-3

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.

Reply

In its Work Programme 2015 (COM(2014) 910 final, Action 62) the European Commission has committed to start an assessment of the regulatory fitness of key EU consumer directives, including Directive 1999/44/EC on certain aspects of the sale of

consumer goods and associated guarantees. This assessment will include the rules on guarantees and remedies for defective goods."

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.*

Reply

In its impact assessment on the proposal for a regulation on the access of third-country goods and services to the Union's internal market in public procurement and procedures supporting negotiations on access of Union goods and services to the public procurement markets of third countries, the European Commission has carefully analysed all policy options, including a non-legislative approach. This option was, however, considered as non-appropriate as it would fail to address the lack of leverage on third countries to open up their public procurement market.

The Commission proposal in fact incorporates effective mechanisms to prevent any form of arbitrary measures. Possible restrictions would be limited, reasoned and based on the existence of restrictive policies in the third country concerned. Where the EU has concluded an international agreement on public procurement, exclusion would only be possible where the goods and services concerned are subject to a market access reservation specified in the agreement in question.

The proposal contains additional procedural guarantees which will ensure that no restrictive measure will be taken arbitrarily. For example it establishes a mechanism for consultation with third countries in cases where the Commission concludes that the country concerned maintains a restrictive procurement practice.

The proposal contains clear and transparent criteria for the scope and conditions of the application of measures. Deviations from the principle of openness of the public procurement market will only occur in very limited cases, where exclusions are duly justified because of major problems in the relation with a specific trading partner. Any restrictive measure under the instrument would only be allowed in limited and well-defined cases, concerning a particular country which severely discriminates against European companies. In addition, the decentralised instrument of Article 6 can only be used for contracts above € 5 million and under the control of the Commission.

The proposal will be amended in line with the priorities of the new Commission in order to simplify the procedures, shortening timelines of investigations and reducing the number of actors in implementation.

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 Triologue 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.*

Reply

The Directive 2014/94 on the deployment of alternative fuels infrastructure was adopted by the Council and European Parliament on 22 October 2014.

- It requires Member States to develop national policy frameworks for the market development of alternative fuels and their infrastructure – by November 2016;
- Foresees the use of common technical specifications for recharging and refueling stations; Common connectors were decided (Type2/Combo2) but Member States are allowed to have other type of connectors additionally to the common ones.
- Paves the way for setting up appropriate consumer information on alternative fuels, including a clear and sound price comparison methodology.

The required coverage and the timings by which this coverage must be put in place are as follows:

Fuel	Coverage	Timings
Electricity in urban/suburban and other densely populated areas	Appropriate number of publically accessible points	by end 2020
CNG in urban/suburban and other densely populated areas	Appropriate number of points	by end 2020
CNG along the TEN-T core network	Appropriate number of points	by end 2025
Electricity at shore-side	Ports of the TEN-T core network and other ports	by end 2025
Hydrogen in the Member States who choose to develop it	Appropriate number of points	by end 2025
LNG at maritime ports	Ports of the TEN-T core network	by end 2025
LNG at inland ports	Ports of the TEN-T core network	by end 2030
LNG for heavy-duty vehicles	Appropriate number of points along the TEN-T core network	by end 2025

Working Party B

Life Sciences and Biotechnologies, Healthcare and Well-being

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

Reply

The Commission supports the expansion of the MRA both in terms of competent authorities from Member States and scope of products. In this perspective, the Commission welcomed the accession of MHLW and PMDA to PIC/S on 1 July 2014. This accession is considered as a milestone for further collaboration on GMP inspections between authorities from EU and Japan. The Commission expects that the exchange of diplomatic notes that will formalise the recognition by Japan of the inspectorates of all Member States with the exception of Croatia will take place during the first semester of 2015. Technical exchanges are also ongoing in view of progressively expanding the scope of products covered by the MRA to APIs, sterile products and prioritised biological products.

This matter as well as the other items recommended for harmonisation are being discussed in the framework of the FTA negotiations.

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.

Reply:

Since the start of the negotiations for Japan-EU EPA/FTA in March 2013, Japan and the EU have been exchanging information and views on progress and developments in the items relating to Medical Devices and which were identified in the “Roadmaps on EU illustrative List of Non-Tariff Measures”. One of the key items was (and still is) the quality management systems (QMS) audit results for medical devices, i.e. compliance with ISO 13485.

The European Commission acknowledges the progress done by the Pharmaceuticals and Medical Devices Agency (PMDA) on QMS as it seems to go on the right direction. Despite this, the European Commission shows concerns about the duplications that still exist regarding inspections in each site for the same product grouping. The European Commission also points out that predictability of the review processes can be improved by cooperation between reviewers and management. The European Commission also claims for more transparency in this regard. Japan contests this and says that neither transparency nor predictability concerns in relation to QMS have been heard by the Ministry of Health, Labour and Welfare (MHLW) and PMDA.

Another issue is the set of additional Japanese QMS requirements that go beyond ISO 13485. While stating that additional national requirements are a common phenomenon (the EU also has additional requirements into place), the European Commission points out the need to have a clear picture of them. According to Japan the QMS ordinance issued to implement the new law provides clear information in this respect.

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 Europeenne (CE) marking of class II medical device in the EU but reviewed by NBs in Japan.

Reply:

This recommendation touches upon other work items, in particular WP-B / # 02* and WP-B / # 04*. This is the reason why there has been no dedicated dialogue on this BRT's recommendation.

It is true that there are differences between the involvement of Notified Bodies between the EU and Japan's MHLW and PMDA and classification of Medical Devices. It must be acknowledged that in the EU, medical devices of Class IIa and IIb manufacture imply the involvement of Notified Bodies. For certain aspects (sterile and/or measuring devices), even low risk Class I devices can be subject to involvement of Notified Bodies. To give the impression that the European CE mark of Medical Devices authorized by Notified Bodies is less severe than Japan compliance is not correct. However the EU agrees that more harmonization between classification and QMS audits would be an asset in terms of trade for both economies.

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.

Reply

As regards Good Clinical Practices (GCP) compliance with ISO 14155, MHLW has stated that it already acknowledges ISO 14155 at the same level of JP's standards and that it will provide new information about it in the framework of the International Medical Device Regulators Forum (IMDRF), chaired by Japan in 2015. The European Commission advocates the BRT concerns that PMDA does often consider that foreign clinical trial data are not sufficient. In this respect, MHLW has sent to the European Commission services statistics on how many products are approved on basis of foreign clinical data. The trend is that there is an improvement of the recognition of foreign clinical data, that should be sustained in the future and monitored accordingly.

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.

Reply

According to Article 168(7) of the Treaty on the Functioning of the European Union (TFEU) Member States are responsible for the definition of health policies as well as for the organisation and delivery of health services and medical care. This includes measures regulating the prices of medicinal products and their inclusion in national health insurance systems. Decisions taken at national level may or may not take into consideration aspects related to innovation.

However the Commission has advocated a comprehensive approach, i.e. to take into account the sustainability of healthcare systems, access to medicines, innovation and the competitiveness of the industry (for more details see Staff Working Document on the Pharmaceutical Industry of June 2014 <http://ec.europa.eu/DocsRoom/documents/7649>)

In addition, the Commission facilitates an open and constructive dialogue to discuss all subjects related to prices and reimbursement of medicinal products at different levels, notably through multi-stakeholders' workshops bringing together authorities responsible for pricing/reimbursement of medicinal products from Member States with industry, patients', health professionals', trade unions' and insurers' representatives and the Network of Competent Authorities Responsible for Pricing and Reimbursement.

Plant Protection & Biotechnology

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

Shorten review times for new applications/ registrations.

Reply

The European Commission is likewise concerned about a timely market access for innovative and safe products. The European Commission believes that substantial progress was made over the last years especially concerning the objective to reduce the time to market for active substances for plant protection products which are new for the EU market.

The legislation in place since 2011 foresees legally binding deadlines for the different steps in the approval process and provides for a target delay of 25 months for the review of a new application, in case the dossier fulfils the data requirements and quality standards required in the legislation and by the European Food Safety Authority.

The EU is proud about its excellent safety standards concerning human and animal health and the environment, which also apply to plant protection products. These safety standards are based on the application of scientific risk assessment methods in combination with the precautionary principle.

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

Reply

On 10 September 2014, the Commission adopted a proposal for a revision, in the form of a Regulation, of the current regulatory framework for veterinary medicinal products. The Commission proposal provides for the extension of the possibility for any application for a marketing authorisation to be submitted through the centralised procedure, thus going in the direction of the recommendation.

Working Party C

Innovation, Information & Communication Technologies

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.

Reply

The EU and Japan have a similar position on internet governance and continue to cooperate on this matter. The coming DG CONNECT-MIC Dialogue on ICT will be held on 24 March 2015 in Tokyo and will address, as one of its items, internet governance. In particular we will discuss possible agreement to elaborate a common position on internet governance to reach-out like-minded countries at upcoming events.

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 unhindered 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.

Reply

The Commission shares the concerns of the Business Round Table on forced localisation measures that have recently been announced or adopted in a number of third countries and that seem to have been inspired by protectionist rather than legitimate policy objectives.

The Commission is raising its concerns in bilateral dialogues with the countries in question with a view to ensuring that any such measures do not constitute an unjustified discrimination and are not more trade restrictive than necessary.

The Commission also takes good note of the Business Round Table's request for an ambitious trade policy on the provision of services through electronic means that would facilitate cross-border data flows. The Commission fully acknowledges the importance of data flows in today's economy. However the Commission has made it very clear at several instances that personal data protection rules are not part of trade negotiations and that trade agreements shall fully respect EU data protection legislation as it exists today and in the future.

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.

Reply

The Commission especially welcomes the progress made at the APEC-summit on 10-12 November 2014 on the ITA-expansion. However, whereas the bilateral agreement made between the US and China is a step in the right direction, plurilateral agreement has to be found in Geneva on the product list with all the countries concerned. The Commission encourages all parties to take the remaining hurdle and finalise ITA-expansion before the Ministerial meeting in Nairobi later this year.

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 cyber attacks 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.

Reply

EU and Japan will continue the bilateral dialogues on IT security seeking information sharing on relevant policies and initiatives, alignment of positions and support on international cybersecurity issues and exploration of areas for cooperation as for instance on cyber incident management. Japan relevant authority was invited to the ENISA International Conference on Cyber Crisis Cooperation in 2013.

The European Commission acknowledges the opinion of the BRT as regards to the scope of the NIS Directive, and the European Commission share also with BRT their will in building a resilience ICT infrastructures.

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.

Reply

We agree on the recommendation and that international standardisation offers the possibility to promote and disseminate technologies. In Horizon 2020 Work Programme 2014-2015, the coordinated calls with Japan specifically address standardisation activities. The coordinated call with Japan in "Net Futures" (H2020-EUJ-2014; LEIT ICT) seeks at developing common positions, standards and interoperable systems for critical networks and computing platforms. Future standardisation requirements will be considered in relation to the topic "technologies combining big data, internet of things in the cloud". An expected impact is concrete implementations of interoperable solutions that integrate big data, IoT and mobile that are candidates for standardisation. Also, the topic "optimal communications" has as an expected impact the joint contributions to international standardisation. In the topic "access networks for densely located users" an expected impact is the joint identification of standardisation requirements and contribution to standardisation bodies and fora. In addition, the evaluation criterion related to "Impact" in the coordinated call emphasizes the following: "Standards are an important element in the field of international cooperation. Beyond access to additional research capability, international cooperation in the context of industrial research should have global consensus and standards as a main target. Contribution to the elaboration of new standards or adoption of standards through implementation of research results." Also, in the coordinated call in aeronautics (H2020-MG-2015), common standards (including for environmental aspects) are encouraged.

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.

Reply

In FP7, there were 5 coordinated calls with Japan (in energy, Manufacturing/New materials, aviation, ICT, and Manufacturing/Critical raw materials). In Work Programme 2014-2015 of Horizon 2020, there are two additional coordinated calls with Japan (in ICT and aeronautics). In Work Programme 2016-2017, at the moment, preparations are made for a coordinated call with Japan in the field of ICT. The preparations and launch of the above-mentioned coordinated calls are in general always well discussed and coordinated between the EU and the Japanese counterpart. An important instrument we have in our policy dialogue with Japan is the Joint Science and Technology Coordination Committee (JSTCC) meetings under the framework of the EU-Japan S&T agreement,

which are organised in average every 18 months. At these meetings, priorities for future cooperation between the EU and Japan are discussed. In our multiannual roadmap on Japan, we identify key priority areas in our R&I cooperation and other areas with potential for strengthened collaboration. Besides promoting Japanese participation in Horizon 2020, we also stimulate cooperation with Japan through contributing to multilateral initiatives such as the Belmont Forum, International Human Epigenome Consortium (IHEC), the International Human Microbiome Consortium (IHMC), the International Cancer Genome Consortium (ICGC), the Human Frontier Science Programme (HFSP), the Group on Earth Observations (GEO) etc.

The Horizon 2020 NCP for Japan and the FP7 BILAT project JEUISTE provide important activities and services in relation to the dissemination of opportunities offered by Horizon 2020 for Japanese researchers and research organisations, in order to strengthen cooperation between the EU and Japan in research and innovation, and to support the EU-Japan policy dialogue and coordination activities. We agree on the recommendation that these services are promoted in order to increase the participation in the respective R&D projects of each region.

Innovation in Aeronautics, Space, Defence and Railways

Aeronautics

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.

Reply

The Ministry of Land, Infrastructure, Transport and Tourism of Japan (MLIT) and Directorate General MOVE signed an arrangement in July 2011 establishing a framework for cooperation with Japan on future air traffic systems' initiatives (SESAR & CARATS) with the objective to enhance cooperation at working-level for the implementation of interoperable and seamless ATM systems worldwide. While policy issues and the identification of areas for technical cooperation are dealt with by DG MOVE and MLIT, technical cooperation is planned to be carried between the SESAR Joint Undertaking and the Civil Aviation Bureau of Japan (JCAB).

This arrangement could indeed provide the tool for developing cooperation in the suggested domain. In fact, the SESAR JU is working on low altitude IFR routes for rotorcraft using satellite based navigation. However, not much has been happening under the agreement. The Japanese counterpart has been silent both with DG MOVE and SESAR JU. We have been trying to organise yearly meetings for the Arrangement's Steering Board, but we haven't been able to get any reaction from our Japanese contact persons since 2012.

To address the recommendation, it is "recommended" that our Japanese colleagues reactivate the arrangement.

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.

Reply

On 7 October 2014, the first meeting of the EU-Japan Dialogue on Space Cooperation took place in Tokyo, where parties identified opportunities for further cooperation in space.

The main messages that emerged from the dialogue suggest that there is good potential for cooperation on space applications in the satellite navigation (Galileo) domain and in space research (particularly non-critical technologies).

On Earth observation (Copernicus), Japan's primary focus on the security aspects of Earth observation should be complemented in the future with the EU's emphasis on the economic potential of Earth observation data to promote growth and jobs and the need to exchange such data freely between the EU and Japan.

A side event to the Space dialogue – a public-private conference (Space Forum) – took place with the objective to bring together policy-makers and the Japanese and European industry and research community. It provided an opportunity for both the public and private sectors to engage in discussions on key issues, including satellite navigation, Earth observation and space research and industrial cooperation. The event was deemed successful by both sides, and it is expected to be repeated at the next Space dialogue.

EU and Japan have an advanced space science and technology sector and a strong space industry.

Europe's priorities in Space lay in developing space related services for the civil society like Earth observation (Copernicus), Satellite navigation (Galileo) and Space science and technology for the exploration of the solar system and the Universe.

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.

Reply

Under the framework of the EU-Japan FTA negotiations, the EU and Japan are currently exploring concrete modalities to improve their regulatory cooperation on railways technical standards. This implies notably an increased transparency of certification process as well as alleviation for certification requirements imposed to suppliers of the

other Party, based on national treatment and simplified acceptance of testing reports. A discussion on technical standards is taking place also in the EU-Japan Industrial Dialogue on Railways where both public authorities and private sector representatives are present.

Working Party D

Financial Services, Accounting and Tax Issues

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.

Reply

With respect to OTC derivatives regulation, the Commission is committed to continuing its participation in international standard setting groups, as well as in the OTC Derivatives Regulators group which seeks to address cross-border regulatory issues. Through these forums, the Commission will continue to support further harmonisation of international principles at a granular level. In particular, the Commission believes that a revision of the CPMI-IOSCO Principles for Market Infrastructures could be revisited to add a further level of detail. The Commission agrees that continued strong bilateral and multilateral cooperation among the core market regulators of the EU, Japan and the US will be necessary to further promote convergence across our jurisdictions and more broadly.

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.

Reply

The Commission strongly supports the OECD Action Plan on BEPS endorsed by G20 Leaders in September 2013, to address the main challenges of international tax avoidance. It is essential that OECD work can be finalised by the end of this year.

The BEPS Action Plan aims to ensure that profits are taxed where economic activities generating the profits are performed and where value is created, while at the same time give business greater certainty by reducing disputes over the application of international tax rules, and standardising requirements. The BEPS project is therefore a matter of balance between further transparency on the one hand and certainty and predictability for business on the other hand.

As the solutions proposed to address BEPS challenges will require implementation in the EU, the Commission services have also taken an active role to ensure that such solutions are compatible with the EU legal framework.

The Commission Services follow closely the OECD's work on transfer pricing documentation country-by-country reporting and welcome that the EU standard of transfer pricing documentation, i.e. the structure of master file and local file and its content is put on a broader basis. As regards country-by-country reporting, the Commission Services are aware of the various aspects which need to be considered in the context of disclosing information of multinational enterprise groups (MNEs), i.e.

effective tax collection, transparency and legitimate business interest and are working towards a balanced approach.

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.*

Reply

Tax Treaties

The Commission services are in favour of a modernisation of the Tax Treaties. However, it is up to Member States to re-negotiate their Double Tax Conventions. According to our information the protocols amending tax treaties signed by Japan with Sweden and United Kingdom have recently entered into force. Moreover, Belgium, Estonia, Latvia and Lithuania have announced the intention to negotiate (or renegotiate) tax treaties with Japan this year.

The Commission services recognise that the existing instruments are insufficient to address many of the double taxation situations not covered by the EU directives or by the Arbitration Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustments of profits of associated enterprises. The Commission services have recommended amongst possible policy options to re-negotiate the Double Tax Conventions between Member States in order to include in the Mutual Agreement Procedure (MAP) the arbitration mechanism as foreseen in the new version of article 25 of the OECD Model as indicated in its Communication on Double Taxation (COM(2011)712). The Commission services are also involved in the works of OECD/G20. In that sense the developments of Action 14 (Make dispute resolution mechanisms more effective) and Action 15 (Develop a multilateral instrument) could significantly contribute to reduce double taxation.

Transfer pricing

Transfer pricing documentation is addressed at WP – A: 19 (3) above.

Promoting and facilitating bilateral and multilateral APAs is an area of work addressed by the EU Joint Transfer Pricing Forum. That work resulted in a Communication that included guidelines for Advanced Pricing Agreements within the EU. The Communication was subsequently welcomed by Council who noted the commitment of Member States to follow the guidelines and implement them in their national administrative practices as far as legally possible. The following Communication extracts are pertinent:

17. These guidelines focus on bi and multilateral APAs because they are considered as the most efficient tool to prevent double taxation. However the Guidelines also include a section on Unilateral APAs; and

63. Although there may be circumstances where the taxpayer has good reasons to believe that a unilateral APA is more appropriate than a bilateral, bilateral APAs are preferred over unilateral APAs. Where a unilateral APA may reduce the risk of double taxation to some degree, care must be taken that unilateral APAs are consistent with the arm's length principle in the same way as bilateral or multilateral APAs.

These efforts seem to pay out. The JTPF Statistics on APAs reveal that the number of bi and multilateral APAs in force between EU Member States and non EU countries increased from 168 (2012) to 178 (2013). The number of requests for a bi- or multilateral APA increased from 119 (2012) to 139 (2013).

Participation exemption

The Commission services are aware that taxation of capital gains and dividends may be problematic for business as it may result in a double taxation or trigger administrative burdens to recover the taxes paid. The Parent-subsidiary directive is aimed at eliminating these risks for the corporate dividend distribution in the EU, but it requires at least a 10% shareholding. For portfolio dividends, as well as for capital gains, there are currently no provisions at EU level. The recent amendments introduced in Parent-Subsidiary directive have not changed the threshold.

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.

Reply

The Commission understands the arguments raised by the BRT, but considers that the proposal will still deliver in terms of: harmonising financial transaction taxes within the enhanced cooperation zone, making the financial sector pay a fair and substantial contribution (to covering the costs related to the crisis) and improving the efficiency of financial markets. The proposal is fully in line with the principles of international tax law and the Commission invites the BRT to consult the recently updated web page dedicated to the taxation of the financial sector where we have uploaded a document addressing the alleged extra-territoriality of the tax. Issues of double taxation would actually be solved inside the enhanced cooperation zone (not only for the benefit of the economic operators inside the zone, but also for those outside) as a result of the proposal; one harmonised tax regime would be in place instead of 11 (potentially) different ones. For instance where both participating Member States and other countries (including third countries) impose financial transaction taxes, bilateral tax treaties can deal with the double taxation.

In its impact assessments the Commission has acknowledged a limited negative impact on the cost of capital (and on the liquidity of certain markets), but estimated that the positive outcomes (reduction of administrative costs and of double taxation, tax revenues, enhanced market efficiency such as investment behaviours oriented more towards the long-term etc.) would surpass the negative impacts. The tax needs to be broad-based in terms of financial instruments, actors and markets in order to ensure tax

neutrality and to minimise potential relocation and substitution. Moreover, further technical background information, among others a trend analysis on the influence of the new French FTT on trading volumes, price levels and/or volatility in the taxed market segment has been added to the Commission's dedicated webpages

(http://ec.europa.eu/taxation_customs/taxation/other_taxes/financial_sector/ftt_background_en.htm)

The European Parliament already expressed a positive opinion on the matter. The actual design of the tax, including its scope and principles relating to "where to tax", the minimum tax rates, is still under discussion in the Council. The Member States authorised to establish enhanced cooperation among themselves in the area of FTT will have to unanimously decide on the final outcome.

Working Party E

Energy, Environment and Sustainable Development

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*

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*

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*

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.

Reply

It should be noted that through adopting the 2030 energy and climate policy framework, the EU has decided on ambitious targets for reducing greenhouse gas emissions, increasing the use of renewable energy and increasing energy efficiency. This strategy is fully in line with the aim of securing the supply of energy to the EU's businesses and citizens.

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

While the EU recognises the role that nuclear can play in decarbonising electricity generation, it is important to recall that the EU and the Commission do not decide on the composition of the energy mix of the Member States; this is generally a national competence. Therefore, irrespective of their merits as such, many of the recommendations that are related to promoting the use of nuclear energy and installing new nuclear power stations cannot be endorsed by the European institutions and should rather be addressed to EU Member States. In this sense, the official EU line on nuclear energy is that, firstly, each EU Member State decides alone whether to include nuclear power in its energy mix or not. Secondly, when it comes to promotional activities, the EU promotes the highest safety standards for all types of civilian nuclear activity, including power generation, research, and medical use.

Reply

In line with the general comment above, the EU level institutions cannot establish energy policies that preserve a role for nuclear power, as the choice of whether to use nuclear energy or not is a question for the Member States.

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.*

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.

Reply

The EU cannot promote the investment in nuclear energy power plants for the reasons explained above. Within the EURATOM Treaty certain aspects of nuclear research can be supported as well as policies and measures to assure the safe and secure use of nuclear energy in those Member States that have chosen the nuclear option

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.

Reply

The wording on renewable energy is generally rather negative (focusing on the disadvantages rather than the benefits). The EU does not view renewable energy as a source that merely “complements conventional energy”. As is clear from the objectives of the 2030 policy framework and the 2050 decarbonisation scenarios, renewable energy is rather to be seen as an important part of our future energy systems.

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.

Reply

The EU continues to show leadership and determination to tackle climate change globally. It aims to be a key driving force behind the negotiations towards a new global climate agreement to be concluded in Paris in December 2015. The European Commission adopted a Communication setting out its vision for a robust Protocol applicable to all to be adopted in Paris.

As a critical step in the negotiations, countries are to come forward with their intended nationally determined contributions (INDCs) to the new Agreement, containing their draft emissions reductions pledges for the period post 2020, well in advance of the Paris conference and by March 2015 for the Parties ready to do so. The EU submitted its INDC on 6 March 2015. The EU considers that timely and ambitious submissions from major emitters such as the EU or Japan are essential for building the global trust required to encourage wide participation in the new Agreement.

The EU has also adopted a climate diplomacy action plan, jointly developed by the European External Action Service and the Commission, aimed at scaling up EU outreach and building alliances with ambitious international partners in the run up to the Paris conference.

The EU is keen to pursue close bilateral cooperation with Japan on these matters, as demonstrated by the May 2014 EU-Japan Summit statement (paragraph 11). The EU is also proposing to strengthen the legal basis for such cooperation through the EU-Japan Framework Agreement.

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

Reply

The EU has now committed, through the agreement by the European Council on the 2030 Climate and Energy Policy Framework in October 2014, to an at least 40% domestic reduction in greenhouse gas emissions compared to 1990 levels by 2030. The European Commission will start coming forward with policy proposals to implement this commitment by mid-2015.

The EU is keen to maintain a global dialogue on decarbonisation policies. An essential vehicle for such a dialogue at present are intended nationally determined contributions (INDCs) to the new climate Agreement. The EU's INDC is formulated in a transparent way and the EU welcomes opportunities for exchange on INDCs. The Commission will organise an international conference to improve mutual understanding of the range of INDCs and the adequacy of their collective ambition, and facilitate an open exchange of views prior to the Paris conference. This conference will aim to bring together partner countries, key experts from academia, think-tanks and international organisations and will take place by November 2015.

Within the EU, different Member States made positive experiences with the market introduction of renewable energies, such as wind power or photovoltaics. They contributed to greenhouse gas reduction targets and created several positive side effects, such as local employment.

WP-E/ 12 / EJ to EJ *International contributions***• *Contributions by Japan and EU to global warming countermeasures***

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.

Reply

A liquid international carbon market can promote cost-effective mitigation and stimulate ambition.

The EU supports an agreement in Paris that is durable and facilitates the international use of markets in order to encourage greater ambition. We remain committed to market based mechanisms as an important instrument of domestic policy, and look forward to linking of domestic carbon markets. It will be important to ensure that use of markets is recognised towards commitments while not undermining those commitments. The only way to accomplish this is through an appropriately designed rules base including accounting rules which ensure the integrity of the future regime.

In order to achieve our climate objective, crediting mechanisms need to deliver a contribution to global mitigation – we need to move away from pure offsetting approaches, and expect all Parties, sectors and activities to make a contribution.

- ***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.

Reply

No specific comments from the Commission side

- ***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.

Reply

The EU sees an effective regime to protect intellectual property rights as a pre-requisite for innovation. An appropriate and efficient use of IPR is in the interest of all countries, but IPR is not a subject of UNFCCC negotiations. The EU sees no need to engage in IPR-related discussions under UNFCCC as it is already being discussed in the appropriate fora. Access to information about available technologies, including through the provision of knowledge tools should be promoted.

The EU sees the UNFCCC's Climate Technology Centre and Network as the institution to provide advice on innovation and technology transfer activities, including related capacity building, to developing countries. Within this structure, further collaboration on climate technologies between the EU Japan is possible.

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.

Reply

With Horizon 2020, the EU has introduced one of the world's largest and most open research and innovation programmes. Japan is already a partner country and cooperation take place in different areas, such as aeronautics. The research activities are normally carried out by public and private actors, who are also responsible for the dissemination of the results of their work. Stronger cooperation between the EU and Japan, in particular in areas such as renewable energy technologies, can bring win-win effects.

Annex***Recommendations for which no reply is provided***

- **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.
- **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.
- **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.
- **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.
- **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.
- **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.
- **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.

- 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.

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

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

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

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

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