



**Commission Services Progress Report**  
on the

**EU-Japan Business Round Table  
Recommendations 2013**

**“Opening a New Chapter  
in EU-Japan Relations”**

**Brussels, March 2014**

## Table of contents

	<b>Page</b>
<b>Working Party A</b>	<b>3</b>
<b>Working Party B</b>	<b>24</b>
<b>Working Party C</b>	<b>29</b>
<b>Working Party D</b>	<b>39</b>
<b>Working Party E</b>	<b>47</b>

## **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**

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

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

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.

The Commission attaches great importance to this negotiation with a major trading partner and in this regard it is positive to note that four rounds of negotiations have already taken place and that the next one is scheduled on 31 March-4 April 2014 in Tokyo.

It should also be noted that one year after the start of the negotiation the EU will conduct a review process by which it will be assessed how Japan implemented the commitments it took during the scoping exercise. If the progresses reached are considered to be unsatisfactory Member States will have the possibility to call for a suspension of the negotiation.

Finally the Commissions also fully agrees that in order to generate as much benefits as possible, this agreement will have to be deep and comprehensive and cover not only trade in goods but also issues such as non-tariff barriers, public procurement, investment, harmonisation/mutual recognition of regulations and standards, or intellectual property and geographical indications.

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

The EU notes with satisfaction the positive outcome of the 9<sup>th</sup> WTO Ministerial Conference held on 3-6 December 2013 and the completion of negotiations on the Trade Facilitation Agreement. The success of the Ministerial Conference strengthens the multilateral trading system and provides the necessary impetus to advance on the rest of the Doha Development Agenda. With regard to future work in the WTO, the EU underlines that the immediate priority is the implementation of the agreements reached in Bali, including formally adopting the Trade Facilitation Agreement by end July 2014 and agreeing on a work programme on the remaining Doha Development Agenda issues by end 2014.

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

1. *The BRT urges both authorities to adopt international product standards and certification procedures where applicable, and, to promote harmonisation of standards and certification procedures, mutual recognition of product certification and, when possible, and appropriate, mutual acceptance of functionally equivalent regulations governing the application process for importing and selling/using products in sectors such as Construction Materials, Organic Products, Cosmetics, Medical Devices, Veterinary Products, Automobiles and Processed Food.*

The EU reiterates its commitment to achieving greater harmonization between EU and Japan on the basis of international standards and the use of a proportionate, risk-based approach to conformity assessment, including the greatest possible reliance on supplier's self-declaration of conformity in lower risk sectors as a means to show compliance with mandatory requirements. The EU confirms that these are among our objectives in the on-going Free Trade Agreement negotiations for Japan in the regulatory area. This is notably the case for the motor vehicles sector, where the EU shares the view that the adoption of all relevant Regulations developed under the 1958 UN ECE 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.

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

The European Commission supports global discussions aiming to streamline the global patent system, and considers it important to move forward. However, still key substantive patent law matters rests within the competence of EU Member States. The main role of the European Commission is to coordinate position among EU Member States and to facilitate progress.

Progress at WIPO Standing Committee on the Law of Patents (SCP) on international substantive patent law harmonisation continue to be blocked by divergent interests of developed and developing countries, the latter mostly interested to tackle exceptions and limitations to patent rights, technology transfer, patents and health.

In Group B+ (contracting countries of the European Patent Convention and the other members of WIPO Group B: Canada, the US, New Zealand, Australia, Japan, South Korea), progress has remained slow. However, future progress could be facilitated by the adoption in 2011 of the latest patent reform in the US, and the four studies drawn up by the Tegernsee Experts Group of the Group B+ on four key elements of global patent law harmonization: grace period, 18-month publication, treatment of conflicting applications and prior user rights.

Any EU-Japan harmonization agreement cannot be made in isolation. At least US, and preferably other blocs such as China, should be involved in any global deal on patent harmonization. For example, should EU accepts a prefilling patent "grace-period", it should be only done if US publish all its patent applications within 18-months and provides so-called user prior rights during the above "grace period".

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

4. *[Mutual Recognition 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.*

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 will also commence working towards an automated solution for the future data exchanges. The results of those discussions are reported to the EU-Japan Joint Customs Cooperation Committee for consideration.

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.

- 6,7. *[ICT in Customs:] The two Authorities should create a framework between the EU and Japan in the development of practical application of new technologies, such as RFID and biometrics authentication technologies. This will enable and enhance cooperation among companies in the EU and Japan, and will also promote new international standardisation and lead to its dissemination.*

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

The European Union Customs Policy aims to facilitate legitimate trade, whilst applying the level of controls necessary for guaranteeing the safety and security of citizens and protecting public health, environment, financial and economic interests of the EU and its Member States. The EU aims to cooperate with its trading partners to ensure end-to-end security and facilitation of the international supply chain.

DG TAXUD considers security research and development to be an instrument of fundamental importance to enable and support the European Union customs policy to enhance supply chain security and trade facilitation. DG TAXUD will continue its proactive approach towards the use of modern technologies in the area of risk management and detection equipment.

**WP-A / # 04\* / EJ to EJ Supporting timely development of business****2. Liberalisation of the movement of intra-corporate transferees in the framework of an FTA/EPA**

We expect that the issues raised in the BRT progress report will be addressed to a large extent by the proposed Directive on Intra-Corporate Transferees, which is likely to be adopted soon. Although the UK (like Denmark and Ireland) does not participate in this Directive nor in the Directive 2003/109/EC on long-term residents, the Protocol on the position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice foresees that it could opt in at any time.

- The proposed Intra-Corporate transferee Directive will facilitate such transfers to the EU considerably. It also foresees simplified procedures for trusted companies, which could be exempted from having to provide certain documents and/or benefit from accelerated procedures. The ICT permit will entitle the ICT to stay and work, and no additional work permit will be required. No labour market test will be applied.
- The maximum duration of 3 years for an ICT permit reflects the consensus among Member States and we believe it answers most business needs. Member States may also allow consecutive transfers. However, to ensure the transfers remain part of circular migration, Member States may impose a mandatory absence and applications should be made outside their territory.
- The current compromise text, if adopted, would allow family members who are granted family reunification the right to work without delay. Integration measures cannot be applied before the persons concerned are granted family reunification;

**WP-A / # 05\* / EJ to EJ Better Regulation**

*The BRT recommends that Japanese and European policy-makers increase mutual understanding of existing and upcoming regulations on each side and their impact on foreign business to exclude unwittingly taking initiatives that create barriers to trade. Both sides should commit to exchanging annual legislative work programmes at the earliest stage to prevent regulatory divergence and new trade barriers. In addition, the two sides should agree to an early warning system for draft legislation in order to make the dialogue effective. The EU and Japan should also develop a joint strategy to promote better regulation, learning from each other's experience and adopting a common system of good governance. Currently the views of businesses in Japan and the EU are not sufficiently taken into account in the regulatory process.*

The Commission supports the BRT recommendation on deepening mutual understanding of regulatory developments. The Commission is confident that the new context for EU-Japan relations provided by the FTA negotiations will lead to enhanced regulatory cooperation, including mechanisms for cooperation at an early stage in the respective regulatory processes, with a view to identifying potential areas for common regulatory work while also preventing obstacles to trade due to unnecessary regulatory divergences.

As part of its Better/Smart Regulation Policy, the Commission is fully committed to a transparent regulatory process that provides adequate opportunities to stakeholders, including foreign ones, to provide input at all stages of the regulatory lifecycle. The Commission shares the view of the BRT that good governance improves the quality of legislation, contributes to greater

accountability of the system and ensures not only that legislation is not more burdensome than necessary to achieve its legitimate public interest objectives but also that it remains fit for purpose.

Every year towards the end of October the Commission publishes Annual Work Programmes identifying the main policy and regulatory initiatives for the year to come. All proposals with significant economic, social and environmental impact are subject to a detailed impact assessment, whose findings are made public. A web-based public stakeholder consultation is held as part of the impact assessment, seeking interested parties' views on possible policy options. All consultations are accessible via a single access point on the internet ("Your Voice in Europe" – <http://ec.europa.eu/yourvoice>), anybody can participate, regardless of their location, and a minimum 12 week period is allowed for sending comments. To enable stakeholders to prepare well in advance, detailed roadmaps are prepared for each proposal that provide information about the content of the initiative and the timing of the planned public consultation. Stakeholders are also involved in the evaluation of legislation in force with a view to assessing their continued adequacy and identifying potential for simplification and cutting unnecessary compliance costs and administrative burdens.

For further details, reference is made to the most relevant recent policy documents relating to the Commission's Better / Smart Regulation Policy:

- Commission Communication on Regulatory Fitness and Performance (REFIT): Results and Next Steps – COM(2013) 685 final of 2.10.2013
- Commission Staff Working Document – Regulatory Fitness and Performance Programme (REFIT): Initial Results of the Mapping of the Acquis – SWD(2013) 401 final of 1.8.2013
- Commission Communication on EU Regulatory Fitness – COM(2012) 746 final of 12.12.2012
- Commission Staff Working Document – Review of the Commission Consultation Policy – SWD(2012) 422 final of 12.12.2012
- Commission Communication – Commission Work Programme 2014 – COM(2013) 739 final of 22.10.2013
- Commission Communication on Smart Regulation in the European Union – COM(2010) 543 of 8.10.2010
- and, more generally, to the Commission's Smart Regulation website: [http://ec.europa.eu/smart-regulation/index\\_en.htm](http://ec.europa.eu/smart-regulation/index_en.htm)

## Recommendations from Japanese Industry to the EU

### ***WP-A / # 15 / J to E Europe 2020 and the Single Market Act***

*The BRT expresses our continued support for Europe 2020 and in particular, the Single Market Act – the initiative of the European Commission to relaunch the single market. In addition, The BRT looks forward to the adoption of Horizon 2020, the EU's RTD program for 2014-2020 and to increased international cooperation between businesses in the EU and Japan.*

1. *The BRT would like to repeat the importance of the single market for the EU and the Europe 2020 strategy.*

2. *The EU should make utmost efforts to realise all of the commitments that it has made under Single Market Act I and II. The BRT would like to emphasise the importance of the following priorities for the single market.*

- *Intellectual property rights*
- *Consumer empowerment*
- *Services*
- *Networks*
- *The digital single market*
- *Taxation*
- *Business environment*

The Commission adopted on 3 October 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, ten actions have already been completed. As for the Single Market Act II, by the end of 2013, the Commission had presented its legislative proposals for all 12 key actions. Of these, to date, only four have been formally adopted by the European Parliament and Council.

#### ***WP-A / # 16\*\* / 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.*

Negotiations for a Free trade Agreement with Japan are on-going and the objective is to reach a deep and comprehensive agreement with the full liberalisation of trade in goods on both sides and the elimination of non-tariff barriers which hamper bilateral trade.

#### ***WP-A / # 17\*\* / J to E      Customs Classification***

##### ***17.1. IT products***

*The BRT requests that the authorities of the EU should acknowledge the concerns and difficulties that businesses are facing and that, based on the panel reports of the WTO on information technology dispute issued in August 2010, the authorities of the EU should take steps to increase predictability and improve transparency upon importation of the IT products, in particular, in the framework of recently launched negotiations on expanding the current product coverage of the ITA.*

The EU has taken part from the beginning in the negotiations on the expansion of the ITA and has proposed and accepted inclusion of a large number of electrical and electronic products in ITA. The negotiations are stalled because of lack of engagement by another major trading partner. The EU and Japan work closely together in these negotiations. Concluding the expansion of ITA will mean significant further progress on classification problems on IT products.

It should also be noted that the entry into force of the new EU regulation on monitors last year has ended many of the problems flagged on classification by Japanese industry in this product area and has effectively ended the panel dispute on implementation of ITA.

Classification of goods needs to be done on a case-by-case basis taking into account the objective characteristics and properties of each individual product and the existing international (HS Nomenclature, HS Explanatory notes, WCO classification opinions) and European (CN, CN Explanatory Notes, classification regulations, CJEU rulings) legal framework. In the EU, economic operators can obtain, in the form of a Binding Tariff Information (BTI), an advance ruling on the classification of the goods which they want to import. Although the issuing of BTIs falls under the competence of the 28 national customs administrations, every BTI is valid for the holder throughout the EU, regardless of the Member State which issued it. When Member States have divergent views on the classification of a certain product, a decision is taken on an EU level (in the form of a classification regulation) which is directly applicable in the whole EU.

## 17.2. Packaged IGBT device

*The BRT requests the authorities of the EU to implement without delay in all the Member States the ruling made by the HS Committee of WCO at its 50<sup>th</sup> Session in September 2012 on a packaged insulated gate bipolar transistor (IGBT) device to classify it in heading 85.41 (subheading 8541.29).*

The EU is implementing the WCO classification opinion on the packaged IGBT devices since 2013.

## **WP-A/#18\*\*/J to E                      CHEMICAL REGULATIONS**

### **18.1 REACH**

1. *Concerning REACH, the BRT recommends as follows:*

- *The BRT asks the authorities of the EU to soon unify the interpretation of the Article as stipulated in the Guidance document so that actors in the supply chain can avoid the fragmented compliance requirement in EU market.*

In order to ensure harmonised interpretation of the 0.1% w/w threshold in Articles 7 and 33 of REACH, the Commission has launched infringement proceedings against six Member States on the basis of their current practices regarding the application of those provisions. The Commission sent letters of formal notice in June 2012 and in January 2013 and is now considering the replies of the Member States. If the Commission is not satisfied with the replies, the next step would be for the Commission to address reasoned opinions to the Member States. In the meantime the French Conseil d'Etat has submitted a request for a preliminary ruling to the Court of Justice of the European Union under Article 267 TFEU concerning the interpretation of these provisions. Below is a link to the decision of the French Court on that matter:

<http://www.legifrance.gouv.fr/affichJuriAdmin.do?oldAction=rechJuriAdmin&idTexte=CETATEXT000028663284&fastReqlid=1229553336&fastPos=1>

- *In Denmark, despite the objection by the ECHA (European Chemicals Agency), phthalates are banned in its new national law published in its official journal on 30 November 2012. The authorities of the EU should take action against Denmark.*

The Commission services consider that by enacting a national law restricting the placing on the market of articles intended for indoor use and articles that may come into direct contact with the skin or mucous membranes containing certain phthalates, Denmark acted in breach of the REACH Regulation. The Commission services are currently discussing with Denmark (through the EU Pilot mechanism) whether the situation can be resolved. The Commission may launch infringement proceedings against Denmark under Article 260 TFEU.

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

- *Although the number of SVHC increases steadily, the ECHA is not involved in its dissemination. It is left to industry. The authorities of the EU should facilitate the dissemination of such information in supply chains through the publication of guidance.*

It is not clear what is meant by “dissemination” of SVHC information. The process of identifying SVHCs under REACH is transparent and involves a public consultation in which interested parties may participate. Once a substance is identified as a SVHC and included in the candidate list, its inclusion is published on the ECHA website. In accordance with Articles 7 and 33 of REACH, suppliers and producers of articles must provide information about the presence of an SVHC in the article above a concentration of 0.1% weight by weight. The notification and information obligations resulting from the inclusion of a substance in the candidate list are explained in the ECHA Guidance on substances in articles.

- *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.*

Recital (48) of the REACH Regulation states “this Regulation should be without prejudice to the full application of the Community competition rules”. Economic operators acting in the context of REACH should always ensure that their activities comply with EU competition rules irrespective of the form of cooperation they choose. The scope of their activities should be limited to what is necessary under REACH and a certain type of information is to be exchanged with caution. In particular, operators may be induced to exchange information on individual production, import or sales volumes and therefore have to be very careful. For example, if an OR, who has to keep up to date information such as quantities imported, represents several non-EU manufacturers of a substance, those manufacturers may be induced to exchange individual volume information through their OR. ECHA’s Guidance on data sharing provides some tips on how to avoid such exchanges constituting an infringement of EU competition law rules.

The Only Representative Organisation website (link below) provides further information <http://www.onlyrepresentative.org/>

- *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 accordance with Article 119 of REACH, information from registration dossiers is disseminated on ECHA's webpage, subject to the limitations imposed by Article 118 of REACH. Therefore, this information is publicly available and free.

- *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.*

The Commission is aware of the challenges in achieving effective and timely cooperation between registrants and the Competent Authorities of the Member States (MSCA) responsible for conducting substance evaluation. The European Chemicals Agency (ECHA) promotes the exchange of experience and best practices among Member States and stakeholders via periodic workshops on Substance Evaluation. One outcome of this has been the publication by ECHA of a document entitled "Recommendations on best practices for the informal interaction between evaluating MSCAs and registrants during substance evaluation" (see link below), which aims to provide guidance on a common approach to such interaction. The guidance paper contains recommendations for best practice to promote open and efficient interaction between the evaluating MSCAs and registrants. These recommendations are based on experience gained from the first year of evaluation. They will be revised when necessary based on further experience of evaluating MSCAs and registrants in the substance evaluation process.

[http://echa.europa.eu/documents/10162/13628/interaction\\_ms\\_reg\\_sev\\_en.pdf](http://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf)

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.*

There have been repeated reports to the Commission of shortcomings in the functioning of substance information exchange forums (SIEFs). In order to identify the issues at stake (mainly the price of LoA, the high number of potential SME registrants, etc.), the Commission organised, in cooperation with the European Chemicals Agency (ECHA), a workshop which took place in Brussels in December 2013 and involved various stakeholders. The Commission is currently working on the follow-up to the workshop and the most appropriate ways to remedy the issues identified, in time for the 2018 registration deadline. Below is a link to the presentations made at the workshop

<http://www.euconf.eu/reach2013/en/registration/speakers.html>

## **18.2 Appropriate approach to Endocrine disruptor and combined effect**

*The BRT requests that the authorities of the EU should regulate endocrine disruptors not by using the categorisation like CMR (carcinogenic, mutagenic or toxic for reproduction), but by using the risk assessment based on sound science because*

*endocrine disruption is not the endpoint of toxicity but the mode of action to the adverse effects.*

Several pieces of EU legislation contain specific provisions regarding endocrine disruptors. However, scientific criteria for the identification of endocrine disrupting substances that can be used in all of these cases are not yet available.

The Commission is preparing a roadmap which will compare several options for defining criteria to identify endocrine disruptors. The roadmap is expected to be published in the first half of 2014. It will be followed by an impact assessment of the options and their health and socio-economic effects once incorporated in the various EU legislation. The impact assessment involves a public consultation phase lasting 3 months during which input from industry will be possible.

### **18.3 RoHS**

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

The relationship between REACH and other Union legislation regulating chemical substances was addressed in the REACH Review, published in February 2013. The Review, based on a comprehensive study of hundreds of pieces of legislation, found no major instances of conflict, but identified the potential for inconsistency or double regulation. The Commission is addressing the most problematic interfaces between REACH and other Union legislation by drawing up 'Common Understanding' papers.

A Common Understanding paper on the ROHS Directive and REACH has been prepared and was presented to Member States and industry representatives in November 2013. It aims to provide practical guidance for regulators on the best option for managing risks presented by substances that are used in electrical and electronic equipment (EEE). It looks at three scenarios-

- Where REACH measures are already in place when it is proposed to add new substances to the scope of ROHS;
- Where measures are already in place under ROHS when a restriction, or making a substance subject to the authorisation requirement, is proposed under REACH;
- No measures have yet been introduced under REACH or ROHS

The paper is based on the premise that the ROHS Directive is capable of affording proper or adequate control of risks presented by the use of substances in EEE, enabling such use to be exempted from the REACH authorisation requirement and REACH restrictions. Comments on the Common Understanding paper have since been received from industry and some Member States and the Commission is currently examining whether there is a need to modify aspects of the paper in the light of these. Once finalised, the paper will be made publicly available.

### **18.4 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.*

The CLP Regulation incorporates the internationally agreed GHS criteria into European Union law. It applies to all manufacturers, importers and downstream users of substances and mixtures. Therefore, importers, importing substances or mixtures originating from exporters outside the EU, are also subject to the requirements of the CLP Regulation.

The EU implements the GHS in line with the GHS building block approach, leaving a degree of flexibility regarding the GHS components that are implemented. Based on this approach, the biennial revisions of the GHS are incorporated in the CLP Regulation through regulations adopted by the Commission (Adaptations to Technical Progress, ATP). The implementation of the latest revision of the GHS (the fifth revised edition) in the CLP Regulation is currently being discussed and the corresponding ATP is expected to be adopted in 2015.

Whereas the general principle is that every economic operator needs to self-classify chemicals in accordance with the classification criteria developed under the GHS and implemented in the CLP Regulation, some substances are subject to a system of harmonised classification and labelling (in accordance with the GHS criteria). These substances are included in an Annex to the CLP Regulation which is regularly updated following a scientific process involving public consultation and notification of the draft rules under WTO/TBT.

## 18.5. 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.*

The definition of nanomaterials is intended to define which materials are considered to be nanomaterials, independently of their applications and the exposure those applications may cause. Consideration of exposure is part of the risk assessment for nanomaterials. The degree of exposure also plays a role in defining policy options, including regulation, and explains why certain products with high exposure to consumers (e.g. cosmetics, food, biocides) have been selected for policy action while others have not.

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.*

The European Commission is currently working on an impact assessment on transparency measures on nanomaterials. The options assessed include a mandatory EU registry but also non-regulatory alternatives and an option to harmonise structures of national registries on a voluntary basis. It is currently too early to indicate which option will be preferred.

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.*

The European Commission is active in the development of standard measurement methods, methodologies and guidance needed for the measurement of nanomaterials. In 2012 work began on Mandate M461 "Standardisation activities regarding nanotechnologies and nanomaterials" by

CEN (the European Committee for Standardisation). This will feed into the sampling and measurement of workplace, consumer and environment exposure and the development of methods to simulate exposure to nanomaterials. However, due to the technical complexity of the work, achieving a final set of validated measurement methods (ideally as simple as possible and internationally harmonised) will take several years.

In the meantime, the European Commission (Joint Research Centre) has started work to study measurement methods that can be used to implement the nanomaterial definition (a first report on existing measurement methods is available at <http://publications.jrc.ec.europa.eu/repository/handle/111111111/26399>).

For the time being, existing measurement methods need to be applied. The absence of a full set of measurement methods should however not lead to delays in applying policy measures where they seem to be appropriate and necessary.

The European Commission is also actively participating in the OECD Working Party on Manufactured Nanomaterials where adjustments are being made to existing OECD Test Guidelines and guidance is being developed for the testing of adverse effects, exposure measurement and mitigation, and risk assessment. This work is using the results of scientific research done in EU projects under the 7<sup>th</sup> Framework Programme (FP7) of Research and Development and in Member States. The outcome of OECD co-operation is important for the Guidance of European Chemicals Agency (ECHA) which has also published specific guidance on the safety assessment of nanomaterials.

Details of these activities can be found at

OECD-WPMN:

<http://www.oecd.org/env/ehs/nanosafety/publicationsintheseriesonthesafetyofmanufacturednanomaterials.htm>

EU FP7:

[http://www.nanosafetycluster.eu/uploads/files/pdf/2013\\_NSC\\_Compendium.pdf](http://www.nanosafetycluster.eu/uploads/files/pdf/2013_NSC_Compendium.pdf).

ECHA: [http://echa.europa.eu/view-article/-/journal\\_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated](http://echa.europa.eu/view-article/-/journal_content/title/the-iuclid-user-manual-for-nanomaterials-has-been-updated)

## 18.6 HFCs

*The BRT recognises the following issues and requests the authorities of the EU to take them into account during the deliberations of the legislative proposal.*

- *The charging of refrigerants on site, due to pre-charge ban, could result in frequent leaking of HFC gases into the air even if carried out by qualified people because of less than ideal work environment. The charging of refrigerants in factories should be allowed.*

During the legislative process which led to first-reading agreement on a compromise text, the original proposal of an almost full ban of pre-charged equipment has been abandoned. The final wording of Article 12 of the F-Gases Regulation states that as from 1 January 2017 refrigeration, air conditioning and heat pump equipment pre-charged with HFCs shall not be placed on the market unless the HFCs charged into this equipment do not exceed the maximum allowed quantity for the year in question according to the limits introduced by the new Regulation. Therefore, pre-charging will remain allowed following the entry into force of the Regulation, as long as it does not exceed the overall quota.

- *The pace of the reduction of the use of HFCs is too steep. It should be revised by taking account of safety (replacement refrigerants could be inflammable), performance (lower performance would result in less CO2 reduction) and cost (cost for users and cost for the society in general).*

During negotiations, European Parliament and the Council decided to accept the original Commission proposal for a progressive reduction of the allowed use of HFCs. The co-legislator agreed that the proposed reduction path had duly taken all relevant aspects into consideration, is both technically realistic and economically reasonable, and will provide enough time to economic operators to develop and introduce alternatives to the use of HFCs.

- *In order to realise a single market in chemical materials, there should be one rule on banned chemical materials that is applicable throughout the EU. If Member States have the discretion of banning additional chemical materials, it would lead to market fragmentation.*

The new F-Gases Regulation does not allow Member States to ban additional HFCs. It therefore creates a level-playing field for the market in substances covered by the Regulation.

#### **WP-A / # 19\*\* / J to E      Japanese expatriates**

See reply under Recommendation 4

#### **WP-A / # 20 / J to E      Fight against counterfeited, pirated and contraband goods**

*The BRT would like to see the EU to take further necessary steps such as a possible proposal for modification of the Enforcement Directive with a view to step up efforts in all the EU Member States to fight against counterfeited, pirated and contraband goods, both inside and outside the EU.*

*The BRT reiterates its support of a proposal for a Regulation concerning customs enforcement of intellectual property rights of 24 May 2011, COM(2011)285, which reflects some of the BRT's key recommendations such as simplifying the procedure and mitigating the financial burden of the importers of the authentic goods. The EU should further seek ways to mitigate their financial burden.*

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

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

In November 2012 the Commission launched a survey to gather evidence to evaluate the efficiency of existing national IP civil enforcement systems. The survey ran for 4 months and a summary of responses was published on the Commission's website in July 2013. There is still ongoing reflection on the follow-up to be given to the consultation. In the meantime, a consultation on a modernization of copyright rules was carried out between November 2013 and

March 2014. Following this consultation, a White Paper, including questions on enforcement of copyright, will be adopted by the Commission in June 2014.

In May 2011, a representative group of stakeholders (right holders, trade associations and internet platforms) signed a memorandum of understanding (MoU) on the sale of counterfeit goods over the internet. This MoU aims at developing good practices addressing online counterfeiting. Following several meetings aimed at discussing the functioning of the MoU, practical experiences and the expected outcomes of this initiative, the signatories acknowledged the contribution of the MoU to the good progress of their dialogue. The Commission is currently developing new stakeholder dialogues within the advertising industry and with the online payment service providers, as part of its "Follow the Money" approach.

Regulation (EU) No 386/2012 of 19 April 2012 entrusted the Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights. The first plenary session of the Observatory was held in September 2012.

All Member States are enforcing Regulation 1383/2003 and will enforce the future regulation on the customs enforcement of IPR. Cooperation between Customs and right-holders is a pillar of these regulations. The costs incurred by customs to enforce IPR will continue to be borne by right-holders.

EU Customs is stepping up efforts to combat infringements of IPRs at the EU external borders and for this purpose, an EU action plan to combat IPR infringements for the years 2013 to 2017 was adopted by Council (Council resolution 2013/C80/01, OJEU of 19.3.2013). A new legal framework was also put in place and Council regulation 1383/2003 was repealed by Regulation (EU) 608/2013 of the European Parliament and of the Council of 12 June 2013 concerning customs enforcement of intellectual property rights (OJ L 181, 29.06.2013, p. 15). The new Regulation covers more rights, requires right holders to provide customs with high quality information, allows for simplified destruction of goods applicable when holder of the goods and right holder agree, introduces Specific procedure for small consignments as well as a Union database to register applications and infringements (COPIS) and focusses on further international co-operation.

Increased cooperation between Customs and right holders remains a cornerstone for the effective enforcement of registered rights by Customs as is evidenced in the provisions of the new legal framework

#### **WP-A / # 21 / J to E                      Unitary Patent**

*The BRT welcomes the adoption of the two Regulations that implement enhanced cooperation in the area of the creation of unitary patent protection. The BRT urges the Member States to ratify the international agreement that will create the unitary patent court as swiftly as possible.*

The reform of the EU patent system remains a top priority, as indicated in the EU 2020 Strategy and the Single Market Act I.

The envisaged reform of the patent system comprises of two main elements: the creation of unitary patent protection and the setting up of a unified specialised patent court. It is still foreseen concluding both initiatives by end 2012 and accomplishing the target of registering the first unitary patent by mid-2014.

### Unitary patent protection

In April 2011, the Commission proposed two regulations implementing enhanced cooperation in the area of unitary patent protection as authorised by the Council on 10 March 2011. The first regulation sets out the substantive rules on obtaining unitary effect for granted European patents, and the second contains the applicable translation arrangements. The enhanced cooperation on unitary patent protection is based on the existing system of European patents. Under the proposed system, once a European patent is granted by the European Patent Office, the patent holder will have the possibility to request a unitary effect for 25 EU Member States participating in the enhanced cooperation, instead of validating the patent in each of them separately.

At this stage, Spain and Italy have decided not to take part in the enhanced cooperation. However, these Member States could join the enhanced cooperation at a later stage, as well as Croatia, which joined the EU in July 2013.

All companies, irrespective of their establishment can obtain a unitary patent. Therefore, companies operating in the EU, including Japanese companies would have in their innovation toolbox the following options: national patents, traditional multi-territory bundle patents (centrally granted by the European Patent Office and validated in selected member states) and the new unitary patent.

### Unified Patent Court

Member States have been negotiating an international agreement on the Unified Patent Court (UPC). The UPC would have competence for litigation related to the infringement and validity of European patents and future European patents with unitary effect. This Court would take decisions covering the territory of the EU Member States which are party to the agreement. The establishment of the Unified Patent Court will in particular enhance legal certainty by reducing the number of decisions in parallel cases with diverging outcomes.

EU Member States not participating in the enhanced cooperation in the area of unitary patent protection can, however, be part of the agreement on the UPC.

On 29 June 2012, the Heads of State or Government of the participating EU Member States agreed on the seat of the Central Division of the Court of First Instance of the UPC. That seat, along with the office of the President of the Court of First Instance, will be located in Paris. Given the highly specialised nature of patent litigation and the need to maintain high quality standards, it was also agreed the creation of thematic clusters in two sections of the Central Division, one in London (chemistry, including pharmaceuticals, classification C, human necessities, classification A), the other in Munich (mechanical engineering, classification F).

Concerning actions to be brought to the central division, it was agreed that parties will have the choice to bring an infringement action before the central division if the defendant is domiciled outside the EU. Furthermore, if a revocation action is already pending before the central division the patent holder should have the possibility to bring an infringement action to the central division. There will be no possibility for the defendant to request a transfer of an infringement case from a local division to the central division if the defendant is domiciled within the EU.

So far, Austria, Malta and France have ratified the UPC Agreement.

Entry into force of the agreement on the UPC is contingent on the ratification by 13 Member States (including France, Germany and UK). The ratification process would take place throughout 2014.

**WP-A / # 22 / J to E      Taxation****22.1 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.*

The Commission welcomes the comments from BRT and confirms that the Commission remains firm on the elements of the CCCTB as proposed: an optional system with consolidation and with simple and less burdensome implementation rules.

Since December 2012 that a first technical reading of the Directive has been completed in Council, the discussion in the Council working group has focused on the examination of topics linked to the tax base (excluding the aspect of consolidation) where Member States are encountered with considerable difficulty in reaching compromises.

**22.3 EU Transfer Pricing Documentation:**

*To provide sufficient incentive to the compliance with the EU TPD, the EU and the Member States should commit themselves to exemption from penalties (i.e. penalties related to non-compliance with documentation requirements, penalties related to transfer pricing adjustment and interest related to adjustments) if a company submits an EU TPD acting in good faith and in a timely manner.*

In a Resolution of the Council (27 June 2006 reference 2006/C176/01) that established a Code of Conduct on transfer pricing documentation for associated enterprises in the European Union the following references are made:

7. Member States should not impose a documentation-related penalty where taxpayers comply in good faith, in a reasonable manner and within a reasonable time with standardised and consistent documentation as described in the Annex or with a Member State's domestic documentation requirements and apply their documentation properly to determine their arm's length transfer prices.

And in Annex:

20. Taxpayers avoid cooperation-related penalties where they have agreed to adopt the EU TPD approach and provide, upon specific request or during a tax audit, in a reasonable manner and within a reasonable time, additional information and documents going beyond the EU TPD referred to in paragraph 18.

It would appear that if there is evidence of tax evasion the requirement to "comply in good faith" will not have been met.

**22.4 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 realized swiftly and in such a way that a business group could easily and cost effectively centralise VAT administration in the EU.*

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 Commission also intends 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 a project to succeed, the involvement of all the tax authorities will be key.

**WP-A / # 23 / J to E      *On the legislative proposal on non-financial disclosure***

*The BRT supports the initiatives taken by the European Commission to involve stakeholders and facilitate dialogue in order to improve the transparency of companies with regard to non-financial information disclosure.*

*The BRT recommends that a principle-based approach which enables businesses of different sizes, sectors and organisational structures, to choose the reporting framework which best represents their company values should be adopted.*

*The BRT strongly favours an EU-wide approach in light of the global context concerning non-financial information disclosure.*

*The BRT recommends the possibility for companies to report either at group or at consolidated level under the future EU regulatory framework for non-financial disclosure.*

The European Parliament and the Council have reached agreement on the Commission's proposal to amend the existing accounting directive to improve the transparency of certain large companies on social, environmental and diversity matters. This is expected to be formally adopted by the European Parliament in April 2014, and subsequently by the Council. Member States will have two year for transposition into national legislation.

Companies concerned will disclose information on policies, risks and outcomes as regards environmental matters, social and employee-related aspects, respect for human rights, anti-corruption and bribery issues, and diversity on boards of directors. Companies, investors and society at large will benefit from increased transparency. The new rules will only apply to some large companies with more than 500 employees, as the costs for requiring small and medium-sized enterprises (SMEs) to apply them could outweigh the benefits.

Large public-interest entities with more than 500 employees will be required to disclose relevant and useful environmental and social information in their management reports. This includes listed companies as well as some unlisted companies, such as banks, insurance companies, and other companies that are so designated by Member States because of their activities, size or number of employees. The scope includes approx. 6 000 large companies and groups across the EU.

The approach taken ensures that administrative burden is kept to a minimum. Companies will be required to disclose useful information necessary for an understanding of their development, performance, position and impact of their activity, rather than a fully-fledged and detailed report. Furthermore, disclosures may be provided at group level, rather than by each individual affiliate within a group.

The draft Directive has been designed with a non-prescriptive mind-set, and leaves significant flexibility for companies to disclose relevant information in the way that they consider most useful, or in a separate report. Companies may use international, European or national guidelines which they consider appropriate (for instance, the UN Global Compact or ISO 26000).

**WP-A / # 25 / J to E      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 requests that the European Commission should consult stakeholders more widely – preferably through public consultation when draft guidance for the New Legislative Framework is ready.*

The Commission adopted on 13.2.2013 a package of legislative and policy proposals to improve product safety in the EU by, in particular, strengthening market surveillance in the EU Member States, including checks by Customs at the EU external border on products imported from third countries. This will contribute both to strengthening consumer protection and to creating a level playing field for businesses. The package was prepared with full stakeholder involvement and an extensive public consultation had been carried out as part of the impact assessment process.

The package includes two legislative proposals: a draft Regulation on market surveillance of products and a draft Regulation on consumer product safety. It also comprises a Communication on a multi-annual plan for market surveillance of products and a Report on the implementation of Regulation 765/2008.

These proposals are currently under discussion in the European Parliament and in the Council of the EU.

As regards in particular market surveillance, the proposed package of measures aims to provide:

- more effective tools to enforce safety and other product-related requirements and to take action against dangerous and non-compliant products across all sectors through a single, coherent legal framework for market surveillance in the EU for all non-food products (both consumer and non-consumer products);
- alignment of the general obligations on all economic operators in the supply chain with clearer responsibilities for manufacturers, importers and distributors;
- improved product traceability requirements throughout the supply chain;
- strengthened cooperation among market surveillance authorities across the EU to be achieved through the implementation of the 20 actions identified in the proposed multi-annual action plan for market surveillance;

- streamlined procedures for the notification of dangerous products, and synergies between the existing Rapid Alert Information System for non-food products (RAPEX) and the Information and Communication System for Market Surveillance (ICSMS) that links together national market surveillance authorities.

For further details, please see: [http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/market-surveillance/index\\_en.htm](http://ec.europa.eu/enterprise/policies/single-market-goods/internal-market-for-products/market-surveillance/index_en.htm) (DG ENTR) and <http://ec.europa.eu/consumers/safety/psmsp/> (DG SANCO)

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](http://ec.europa.eu/enterprise/policies/single-market-goods/documents/internal-market-for-products/new-legislative-framework/index_en.htm#h2-3)

### **WP-A / # 29 / J to E      EU policy on company law**

*The Council should adopt a proposal for a Council Regulation on the statute for European Private Company without delay. The statute should realize the following points.*

1. *Widely accessible, easy to set up and inexpensive to run*
2. *Allowing a great deal of flexibility to founders and shareholders to organize themselves in the way that is best suited to their activities: and*
3. *As uniform throughout the EU as possible.*

The proposal for a regulation on the Statute for a European Private Company ("the SPE") tabled in June 2008 will be withdrawn from the Council in the coming months.

### **WP-A / # 30 / J to E      Access of third countries goods and services to the EU's Public Procurement Market**

*The BRT believes and recommends the following:*

1. *Non-legislative policy measures should be adopted to achieve the objective of opening public 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 public 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.*

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.

In this context it is important to note that the European Parliament by a large majority on 15 January voted in favour of entering into formal negotiations with the Council, which is currently discussing the proposal.

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.

## **Working Party B**

### **Life Sciences and Biotechnologies, Healthcare and Well-being**



## ***Recommendations from both European and Japanese Industries Healthcare***

### ***WP-B / # 02 \* / EJ to EJ Regulatory harmonization and MRA for pharmaceuticals***

The EU and Japan are currently discussing two aspects of the expansion of the pharma GMP MRA:

1. Firstly, recognition by JP of the new EU Member States' GMP inspection authorities under the MRA; Japan has replied positively, indicating that it will do so as soon as Japan becomes a member of PIC/S (Pharmaceuticals Inspection Cooperation Scheme) which is scheduled for May 2014. The EU has closely collaborated with JP to assure its fast accession to PIC/S is looking forward to Japan's PIC/S accession this spring.
2. In parallel, the Parties are working to expand the scope of the MRA to other products than those in oral solid form (e.g. steriles, biologicals except vaccines and blood products, and active ingredients (API) in a first step; vaccines and blood products in a second step). Preparatory work in this regard between, on the one hand, the Commission and the European Medicines Agency and, on the other, the MHLW and the Pharmaceuticals and Medical Devices Agency (PMDA) on the other is ongoing, and will continue throughout the coming months.

In sum: We are working on achieving industry's recommendation to expand the MRA to the above-mentioned products. Timeline for achieving this is unclear as this is a complex endeavour with lot of technical work.

On vaccines, the EU is aware that MHLW has been conducting regular reviews of the Minimum Requirements for Biological Products (MRBP) including one in autumn 2013. We appreciate MHLW's efforts to revise MRBP to further align them with international practices, and, more generally, the progress that has been achieved in the past few years for the development and registration of vaccines in Japan and reduction of the vaccines gap; however, we consider that further efforts are necessary in order for Japan to solve the issue of the vaccines lag once and for all – in particular a more fundamental revision of the MRBP.

In sum: We will continue to discuss this issue in the FTA negotiations.

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

The objective of the FTA in this area is, indeed, ensuring the maximum convergence of the two sides' QMS to international standards. The EU is pleased that the MHLW is currently preparing a revision of the QMS Ordinance, with a professed intention of enhancing its harmonization with international standard ISO 13485 and streamlining QMS audits. The QMS Ordinance revision is part of MHLW's implementing work for the revision of the Pharmaceuticals Affairs Law, which should be ready in Nov. The EU hopes that, in accordance with scoping and FTA discussions, this revision will indeed address all remaining deviations between the Japanese system and the ISO standard.

In sum: We are addressing this in the FTA negotiations, we will be able to ascertain later this year when the revised QMS ordinance is published, whether the desired progress has been achieved.

**WP-B / # 05\* / EJ to EJ Mutual recognition of medical devices product licenses**

The Commission is not discussing an MRA on medical devices in the FTA and have not considered this possibility, at least not yet. It is difficult to have a position on this recommendation, as both the EU and Japanese legislation are under revision – so two moving targets. Just to note that, for low risk class II medical devices (mentioned in the recommendation) there is no need for Notified Body certification, so an MRA would not make sense.

**WP-B / # 06\* / EJ to EJ Mutual recognition of clinical trial results for medical devices**

The objective of the FTA in this area is to ensure that both Parties ensure maximum possible convergence to ISO 14155 and that foreign clinical trial data is accepted during the review process without additional ad-hoc requests for domestic based data or studies provided that such trials are appropriately designed to address safety and effectiveness concerns and are conducted with the necessary data integrity, while understanding the existing difference of data requirements between Japan and the EU.

However, we have not seen progress on this issue from Japan, and this is not addressed in the current revision of the PAL.

**WP-B / # 07\*\* / EJ to EJ Evaluation of innovation values for pharmaceuticals in prices**

Member States' health insurance schemes are not EU competence and very sensitive issue, so not up for negotiation in the FTA.

**WP-B / # 12\*\* / EJ to J Full-fledged implementation of the new drug pricing system and abolishment of market expansion re-pricing**

Only the first part (new drug pricing system) was discussed in the FTA context – scoping roadmap. It is a substantive pricing scheme and we cannot take any commitments ourselves on pharma pricing. There have been positive developments

The EU is pleased to hear that the pilot pricing system for fostering the development of innovative/unapproved/off label drugs, first introduced in 2010, was recently fine-tuned and extended again – the third time – for two more years (FY2014-2015). In the EU industry's opinion, this new system has demonstrably led to an increase in applications for unapproved drugs and indications and positively influenced the development activities of pharmaceutical companies, thus representing a clear shift of Japan's mentality towards encouraging more innovation in this sector.



## **Working Party C**

### **Innovation, Information & Communication Technologies**



## Recommendations from both European and Japanese Industries

### **WP-C / # 01 \*\* / EJ to EJ Economic growth by ICT utilisation**

*The BRT requests steady implementation of the EC's IT strategy "Digital Agenda" action items.*

The EU continues to recognise that companies in Europe need to use ICT to do better business and to help with the recovery from the crisis. We therefore continue to work on implementation of the Digital Agenda for Europe to ensure fast broadband, secure systems, and digital skills for workers and citizens. The right regulatory frameworks are therefore important, especially to overcome fragmentation in the EU market. The identified priorities include getting cloud services to work properly across the EU; for roaming bills to come down, for greater competition in services, for higher broadband quality and security, and for greater skills for employees.

Recent progress includes having given the telecom sector single market a boost, with proposed rules for a connected continent to make it easier to offer pan-European services and an end to roaming surcharges in Europe. Progress also includes work to make networks more secure, such as work on standard contractual clauses and certification to help develop trust in Cloud Computing. DG Connect has proposed to the Ministry of Internal Affairs and Communications (MIC) to work together in this area. It also includes proposed legislation to build trust online: a Directive on network and information security. A second workshop on ICT security was held with the MIC in this area in December 2013, with the participation of the METI, industry and academia. In addition, the EU aims to address the digital skills gap through promoting education, training, and grassroots activity, by launching a Grand Coalition for digital skills and jobs. The EU also aims to build trust and convenience online with recent EU legislation agreed on e-ID.

The Commission works hard to try to overcome widespread views that ICT issues are only relevant in the ICT sector, and to make it more widely known that the issues relate to widespread issues beyond telecom networks – connected cars, better industrial processes, better retail and logistics, energy and transport networks – and promotes breaking out of sectoral silo mentalities and working across sectors on ICT-related matters. It also tries to learn from the initiatives in other countries, including Japan, including Japan's ICT Growth Strategy published in 2013, which aims to address similar challenges to those identified in the EU.

### **WP-C / # 02 / EJ to EJ Cooperation for maintenance of open, transparent internet**

*The BRT requests both sides' authorities to cooperate in order to maintain an open and transparent Internet environment.*

The EU recognises the global dimension of the Internet and that it has become a key infrastructure. We have a strong commitment to a single, open and secure Internet, based on an inclusive, effective, and transparent multi-stakeholder model of governance. We endeavour to work closely together with other partners to strengthen and improve the model towards the globalisation of core Internet

decisions. Furthermore, we are convinced that human rights apply equally online and offline. The contacts made through the last few EU-Japan ICT Dialogues have paved the way for easy contact to be made throughout each year to exchange views between two like-minded parties in the lead up to key meetings.

### **WP-C / # 03 \*\* / EJ to EJ Cooperation for trade liberalization on ICT services**

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

Four rounds of negotiations of the FTA/EPA already took place, including ICT aspects. ICT aspects are mainly covered under the Trade in services, Investment and e-Commerce chapters.

### **WP-C / # 05 \* / EJ to EJ Building trusted and safe online environment**

*The BRT welcomes that both authorities organised a Japan-EU Internet security forum and requests continued discussion on this matter. Both sides should establish an information sharing/exchange mechanism between the EU and Japan for cyber security (including study on cyber attach information sharing within closed organisations and companies; and study on reporting procedure for cyber-attack disclosure from companies to government). There should be a study on mechanisms for joint training such as simulation exercises involving both forces against cyber-attack; construction of a safety network including government and defence industries; and technology development for prediction and immediate responses against cyber-attack.*

The EU is very clear that freedom online requires safety and security too. Cyberspace should be protected from incidents, malicious activities and misuse; and we aim to work with other governments to ensure a free and safe cyberspace.

A second ICT security workshop was held in the margins of the 20<sup>th</sup> EU-Japan ICT Dialogue in Brussels in December 2013. The EU side proposed three areas for cooperation with Japan which should help to ensure a safe and secure cyberspace, namely: joint awareness raising initiatives; cyber incident management; and sharing good practice on ICT security.

### **WP-C / # 06 / EJ to EJ Building robust critical infrastructure supported by ICT**

*The BRT welcomes the Cyber strategy and Directive, and notes the Cloud operators are required to report incidents to national authorities. The area of reporting requirement should be narrowed and the contents of the report should reflect the risk of each infrastructure. BRT recommends earmarking funding for R&D on ICT solutions for critical infrastructure and give incentives to the private sector.*

The EU acknowledges Information and communications technology as a key backbone of our economic growth, underpinning the complex systems which keep our economies running in key sectors such as finance, health, energy and

transport. We aim to work on the uninterrupted availability of the Internet and the smooth functioning of information systems.

Funding is available now for cyber security under the Commission's Horizon 2020 research programme. The Commission is seeking to develop trustworthy ICT solutions guaranteeing a secure and reliable digital environment in Europe. Horizon 2020 addresses security, trust and privacy in a coherent way from technological, economic, legal and social perspectives, helping to promote innovation and economic growth in the EU, while protecting Europe's society, economy, assets and fundamental rights. In Horizon 2020, cyber-security and online privacy can be found within two research areas: the Societal Challenges of "Inclusive, innovative and secure societies" and the Leadership in enabling and industrial technologies (LEIT) Challenge. In order to have the widest possible participation in such research, an information day on the first three H2020 calls under the societal challenge "Secure societies – Protecting freedom and security of Europe and its citizens" will take place on 1 April 2014 in Brussels.

***WP-C/#07\*/EJ to EJ Balanced approach of personal data protection and innovation in the cloud computing era***

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

Information was exchanged between the European Commission and Japan's MIC during the December 2013 ICT Dialogue in Brussels. The Japan side gave an update on measures for the proper handling of user information on smartphones, while the EU side gave an update on the proposed Data protection legislation. It was agreed that there could be further information exchange on these points in future.

***WP-C/#09/EJ to EJ Fundamental Reform of the Private Copying Levy System (Compensation System for Private Copying)***

*BRT is concerned that EU and Japan should cooperate to reform the private copying levy system.*

EU Member States enjoy a large discretion on how to provide right-holders with fair compensation for acts of private copying. In view of the variety of national practices, the Commission has been working with all relevant stakeholders to consider a more coherent approach. In the Communication of 24 May 2011 on a single market for intellectual property (the "IPR Communication"), the Commission stated that the proper functioning of the internal market requires reconciliation of private copying levies with the free movements of goods and services.

In order to achieve this, the Commission appointed a high level mediator Mr. Antonio Vitorino to open a dialogue with stakeholders, and to explore new licencing opportunities in the digital environment as well as possible approaches with a view to improve the functioning of levy schemes, in particular in cross-border situations. This dialogue lasted throughout 2012 and concluded on 31 January 2013 when Mr Vitorino presented his recommendations to Commissioner Barnier.

The first part of his recommendations focuses on the need to encourage licensing agreements in the context of new, on-line business models. The second part suggests improving the functioning of levy systems in order to reconcile them with the free movement of goods and services. Private copying forms an integral part of the on-going process of review of the EU legislative framework applicable to copyright, through a public consultation, legal and economic studies and an in-depth impact assessment work.

The European Commission announced in December 2013 the launch of a “Public Consultation on the review of the EU copyright rules” as part of its on-going efforts to review and modernise EU copyright law. The Consultation seeks to address the effect of digitalisation on the manner in which content is created, distributed and accessed and ensure that the EU copyright regulatory framework stays “fit for purpose” in the digital age. Stakeholders were invited to provide opinions on the problems they perceive with the current law and suggestions for legislative or other solutions. The Consultation addresses a range of areas, including private copying.

## INNOVATION IN GENERAL

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

*BRT recommends both sides promote solutions to common challenges through deregulation, easing of investment, notably for SMEs, and inviting expertise; as well as joint R&D projects etc.*

As regards ICT-related research cooperation, six joint projects have been selected out of a first coordinated call on Future Network related subjects, and launched mid-2013, in areas such as optical and wireless communications, cybersecurity, cloud computing, experimental test beds, and energy-efficient information networks. The first annual reviews for these projects are planned for May 2014. In addition, a second coordinated call has been published early January 2014 and information events have been held in the EU and Japan. This second call focuses on four ‘Net Futures’ topics, and projects will be selected after the call closes in April 2014.

On healthy ageing, contacts are taking place to clarify how best to follow up on a workshop held in the margins of the December 2013 ICT Dialogue. Concretely, the EU side is proposing to organise an information session concerning relevant parts of the H2020 work programme; and to set up a web portal so that stakeholders on each side can keep in touch with each other to facilitate participation in future calls. Both sides are considering the viability of a coordinated call in this area.

### ***WP-C / # 11 \*\* / EJ to EJ Better administrative setup of STI cooperation***

- 1. The commitments required of participating organisations should be well defined and not subjected to unexpected changes.*
- 2. The time used to prepare calls, publish them, select the candidate organisations, evaluate their proposals and complete negotiations should be much shorter.*

3. *The procedure for preparation and launch of coordinated calls should be well discussed by both parties and standardised.*
4. *EU and Japanese Authorities should work together towards at least partially interoperable systems for the administration of programmes, for example to allow European systems to retrieve relevant data on Japanese participants from Japanese databases and vice versa.*
5. *Japan should apply the EU's National Contact Point system, subject to several improvements. The system should work both ways to allow bilateral flow of information.*

Research cooperation is going well, as noted under point 10

### **WP-C / # 13 / EJ to EJ Business cooperation between EU and Japanese clusters**

*Strengthen business cooperation between EU and Japanese clusters. Specifically:*

1. *The Authorities of the EU and Japan should support the EU-Japan Centre for Industrial Cooperation and the European Cluster Collaboration Platform to further advance their cluster cooperation agenda.*
2. *A more strategic use of clusters should be made to support SME internationalization and global competitiveness, especially in emerging industries where cluster cooperation would have a strong impact.*
3. *The Authorities of the EU and Japan should intensify cooperation between EU and Japanese clusters by giving a stronger focus to concrete actions. In particular, both authorities should support matchmaking activities and tailored individual approaches between EU and Japanese clusters in strategic areas of mutual interest.*

The European Commission organised an EU-Japan Cluster Matchmaking event in November 2012 focusing on Green Materials and Clean Technologies.

Building upon this EC initiative, the EU-Japan Centre for Industrial Cooperation organised a similar matchmaking mission for EU clusters in Japan in October 2013 in the field of biotech and more of such missions in Japan are envisaged in October 2014 on biotech and January 2015 on nano-technologies. In May 2013, the MoU on cluster cooperation was renewed between the EU-Japan Centre and the European Cluster Collaboration Platform. In June 2013, the EU-Japan Centre updated its report mapping clusters in Japan and made it available on the European Cluster Collaboration Platform website to facilitate the search for Japanese partners for EU clusters. An incoming cluster matchmaking mission for Japanese clusters is envisaged to be organised in Europe by the European Strategic Cluster Partnership for Personalized Healthcare at the occasion of the BioEurope event in Frankfurt in November 2014 with the support of the European Cluster Collaboration Platform.

## **INTELLECTUAL PROPERTY RIGHTS**

### **WP-C / # 14 \* / EJ to EJ Harmonisation of IPR regulations**

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

Any EU-Japan harmonization agreement cannot be made in isolation. At least US, and preferably other blocs such as China, should be involved in any global deal on patent harmonization. For example, should EU accept a prefilling patent “grace-period”, it should be only done if US publish all its patent applications within 18-months and provides so-called user prior rights during the above “grace period”.

## INNOVATION IN SPACE

### **WP-C / # 19 \* / EJ to EJ More Effective Cooperation Among Space Authorities**

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

### **WP-C / # 20 \*\* / EJ to EJ Government-Led Industrial Cooperation in Space**

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

### **WP-C / # 21 \* / EJ to EJ Civil Purpose Satellite Technology**

*In the civil satellite technology field, Japanese space Authorities (at Cabinet level) and European space Authorities (EU Commission, European Space Agency, and Europe’s national space agencies) should establish a common mechanism for a formal and permanent dialogue with the purpose of identifying further mutually beneficial subjects of cooperation.*

At the 21<sup>st</sup> EU-Japan Summit (of November 2013), EU and Japan decided to launch a Japan-EU Space Policy Dialogue;

The relevant paragraph of the Summit Joint Statement reads as follows:

*“Summit leaders affirmed the importance of securing free access to and sustainable use of the outer space and stressed the importance of Japan-EU cooperation in that field. They shared the view that an International Code of Conduct for Outer Space Activities was urgently needed and that both sides would cooperate closely in the multilateral consultations. For further strengthening space cooperation, both sides decided to launch a Japan-EU Space Policy Dialogue”;*

On 20 March 2014 a preparatory meeting took place in Brussels to launch the organisation of the first Space Dialogue meeting;

A productive exchange of information took place and both sides agreed that there are number of areas of converging interests that both sides could benefit from;

- It was agreed that the EU will coordinate internally and, based on the exchanges at the meeting, will, prior to the EU-Japan Summit in May, propose to Japan some four/five areas for the dialogue. Cooperation in the areas of Earth observation, navigation, Space Situational Awareness, space diplomacy, maritime domain awareness, space research and exploration were discussed and are being considered;

- Based on the areas proposed by the EU, the EU and Japan will finalize the areas for the dialogue and agree on the next steps, including the finalization of the decision on the place/date of the Inaugural Meeting sometime this fall;

#### Global Navigation Satellite System (GNSS)

- Japan is developing its own regional satellite navigation system called QZSS, which is intended to cover East Asia. It is a civilian system and their first satellite was launched in 2010. The initial plan was to have a three-satellite constellation, but there are now plans to extend this to seven satellites. Full operational status with at least four satellites is expected by 2020;

A technical agreement to ensure radio frequency compatibility between the first QZSS (Quasi-Zenith Satellite System) satellite and Galileo is in place. This agreement was signed under the framework of the International Telecommunication Union (ITU). It ensures radio frequency compatibility between the first QZSS satellite and Galileo and was signed by the Japanese Space Agency JAXA and the European Commission;

The Commission wants to continue cooperation to ensure compatibility between the full QZSS constellation and Galileo. Interoperability between the systems is also being considered and would have advantages for both sides;

Technical level discussions are on-going (next meeting in Tokyo in May 2014) on compatibility/frequency issues;

Possibilities for a cooperation agreement on GNSS could be discussed.

#### Earth observation – Copernicus

Currently there are not many agreements for participation in Copernicus. The Commission has currently no agreement with the government of Japan;

Assuming an entry into force of the Copernicus Regulation during the 2<sup>nd</sup> quarter of 2014, the approval of the next EU-ESA Delegation Agreement and the first EU-EUMETSAT Delegation Agreement should take place during the 3<sup>rd</sup> quarter of 2014;

The delegated Regulation adopted under the current Copernicus Regulation (covering the period 2011-2013) provides for a free, full and open access to Sentinel data under standard conditions;

This delegated Regulation provides for third countries or international organisations contributing to the operations of Copernicus to access data and service information under the same conditions which apply to EU Member States;

The draft Regulation for the next period (2014 – 2020) follows the principle that access to Sentinel data should be free, full and open, in line with the Joint Principles for a Sentinel Data Policy adopted by the ESA Programme Board for Earth Observation.

At the EU-Japan Industrial Policy Dialogue in January 2013 it was agreed to further explore ways to work jointly on data access and satellite data sharing as well as exchange of information to find areas of mutual interest for cooperation. Task that can be pursued through the Space dialogue.

## Recommendations from Japan Industry to the EU

### ***WP-C / # 47 / J to E      Applying reduced VAT rate to e-Books***

*BRT would like to see an end to discrimination between eBooks and paper books*

EU law is very clear on which goods and services are eligible for a reduced VAT rate. The provision of ebooks is an electronically provided service and as such cannot benefit from a reduced rate. The basic principle of European tax policy is fair competition within the internal market. Questions concerning the tax treatment of physical books and ebooks will be examined as part of the wider EU review of reduced VAT rates.

## **Working Party D**

### **Financial Services, Accounting and Tax Issues**



## Recommendations from both European and Japanese industries

### **WP- D / # 01 / EJ to EJ Issues to be mindful of when proceeding with reform**

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

The Commission is committed to adopt policy measures to support global growth, restore confidence in financial markets and enhance job creation. The EU is approaching the end of its largest ever programme of financial services reform. Around thirty targeted measures have been proposed after comprehensive impact assessments and consultations. Each proposal is carefully calibrated to be bearable for the financial sector and to support the real economy. The EU is also determined to move forward expeditiously on measures to support growth including through completing the Single Market.

Most recently, the European Commission adopted on 29 January 2014 a proposal for a regulation on structural measures improving the resilience of EU credit institutions. This proposal provides for a proprietary trading ban and the potential separation of other trading activities when the supervisor considers this appropriate in view of an assessment made against a number of risk metrics. The Commission proposal would mainly affect large EU banks and their operations wherever located. Foreign banks operating in the EU would also be covered if their EU activities are large enough to be captured by the thresholds set in the proposal. However in order to mitigate possible duplication of similar rules in various jurisdictions the Commission proposal provides for a 3<sup>rd</sup> country equivalence regime applicable to subsidiaries of EU banks operating in those jurisdictions and to foreign banks operating in the EU through branches. The proposal is now in the hands of the EU co-legislators (European Parliament and Council) and expected to be adopted in 2015.

It is important to note that in Los Cabos, in June 2012, G20 Leaders agreed to work collectively to strengthen demand and restore confidence with a view to supporting growth and fostering financial stability. They agreed on a coordinated “Los Cabos Growth and Jobs Action Plan” to achieve those goals. The Commission is committed to implement its regulatory reform agenda to enhance growth prospects and build more resilient financial systems. The Commission also calls for timely and effective implementation of G20 commitments by all Parties. Multilateralism and regulatory dialogues are of even greater importance in the current climate. G20 members recognised the need to take country-specific circumstances into account while promoting strong international standards when appropriate. The Commission supports the work of the Financial Stability Board and other international bodies setting up monitoring tools to ensure that reforms agreed by the G20 are implemented in all major jurisdictions. Regulatory dialogues, like the one with Japan FSA, enable a close follow up to ensure global consistency and to avoid regulatory arbitrage.

Regulatory diversity, where it exists, must neither open loopholes which undermine the effectiveness of our regulation, nor lead to market fragmentation. In this context, equivalence is the right approach to achieve global consistency. It ensures that operators are not subject to double requirements or overlaps, while allowing for the co-existence of different national standards.

The European Banking Authority ensures appropriate cooperation and coordination amongst national supervisors at the EU level, limiting undesirable consequences of national ring-fencing regulations. The Commission monitors these recent developments and is ready to enforce the free movements of capital rules as set in the Treaty on the Functioning of the European Union.

In Cannes (November 2011), the G20 endorsed the FSB's core recommendations for effective resolution ("Key Attributes of Effective Resolution Regimes for Financial Institutions") to be implemented by countries. Consequently and in order to ensure international consistency in addressing financial stability issues, on 6 June 2012, the Commission adopted a legislative proposal for bank recovery and resolution. The proposed framework sets out the necessary steps and powers to ensure that bank failures across the EU are managed in a way which avoids financial instability and minimizes costs for taxpayers.

#### **WP- D / #02 / EJ to EJ US Regulations**

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

The Commission has recently rolled out a series of measures designed to enhance transparency and oversight in commodity derivatives markets in the reviews of the Markets in Financial Instruments Directive (MiFID) and the Market Abuse Directive (MAD). These proposals were adopted by the Commission on 20 October 2011 and are currently discussed in the EP and the Council.

They fully correspond with the latest principles of the International Organisations of Securities Commissions (IOSCO) – published in September 2011 – which has been working under a mandate from the G20 to improve the regulation of commodity derivatives. The IOSCO principles have been endorsed by the G20 at their last summit in Cannes in November 2011.

The review aims at improving further the transparency of trades and prices in commodity derivatives by setting conditions for when commodity derivative products (together with other derivatives) should trade exclusively on organised trading venues. It aims at obtaining more systematic and detailed information on the trading activities of different types of market participants in commodity derivatives, more comprehensive oversight by regulators of commodity derivative positions, including the need for imposing position limits when deemed necessary.

Regulators from EU and Japan are working closely together on the implementation of OTC derivatives reforms. Current international work streams aim at identifying any conflicts, gaps or inconsistencies in the implementation of OTC derivatives reforms in a cross-border context and finding solutions to avoid the duplicative application of differing rules. The EU and Japan continue to coordinate closely in the context of this work stream.

**WP- D / # 03 / EJ to EJ    Accounting Issues in EU and Japan**

*The BRT recommends the following:*

- *In addition to net unrealised gain on available-for-sale securities recognised as other comprehensive income (OCI) and dividend, as net income, realised gain should be recognized net income and not OCI.*
- *Actuarial gains and losses on employee benefits should be recycled.*
- *Operating and finance leases should be treated separately.*
- *A disclosure framework is needed to reduce the burden of preparation.*

All EU companies with publically traded securities are obliged to prepare their consolidated financial statements in accordance with International Financial Reporting Standards (IFRS).

In Japan, the use of IFRS is voluntary and subject to certain conditions. In October 2013 Japanese authorities significantly relaxed these conditions which increased the number of eligible companies from 621 to over 4,000. The number of Japanese companies that actually use IFRS or intend to do so, also increased from 20 (May 2013) to 34 (February 2014).

The European Commission welcomes this significant progress and encourages the Financial Services Agency of Japan, a key partner on the IFRS Foundation Monitoring Board, to continue its efforts towards full adoption of IFRS.

**WP-D / #04 / EJ to EJ    Tax Issues in the EU and Japan**

- *[Tax Treaties] The BRT recommends that EU Member States and Japan modernise the tax treaties which were established a long time ago. Tax treaties should ensure to the greatest possible extent that dividend, royalty and interest payments are exempted from withholdings taxes and provide for corresponding adjustments and arbitration.*
- *[Transfer Pricing Taxation] The BRT requests the harmonisation and simplification of documentary requirements in transfer pricing taxation and the conclusion of bilateral and multilateral APAs in transfer pricing taxation.*
- *[Participation Exemption] The BRT maintains its recommendation to introduce participation exemption and exempt dividends and capital gains received from business investment from further corporate taxation.*

The Commission is in favour of a modernisation of the Tax Treaties. However, it is up to Member States to re-negotiate their Double Tax Conventions.

Within its competence, the Commission has recently adopted a Recommendation addressing aggressive tax planning in the area of direct taxation (C(2012) 8806 of December 6, 2012) in which it encourages Member States to include an appropriate anti-abuse clause in their Double Tax Conventions. Such clause could read as follows:

“Where this Convention provides that an item of income shall be taxable only in one of the contracting States or that it may be taxed in one of the contracting States, the other contracting State shall be precluded from taxing such item only if this item is subject to tax in the first contracting State”.

Moreover, in its Communication on Double Taxation in the Single Market (COM (2011) 712), the Commission recognises that the existing instruments are insufficient to address many of the double taxation situations not covered by the EU legislation (such as the Interest and Royalties Directive and the Parent-Subsidiary Directive) 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 are therefore considering possible solutions to the unsolved cases of double taxation within the Single Market. One of the possible policy options could be the recommendation 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.

Comments (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.

Comments (Exemption):

The Commission is aware that taxation of capital gains and dividends is 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 2013-2014 Commission's plan does not envisage specific legislative proposals to tackle the taxation of capital gains and the 10% threshold in the Parent-subsidiary directive. However, the plan contains the announcement of a broader initiative for the treatment of portfolio dividends in the Single Market. No plan is currently available for 2015 due to the forthcoming elections of the European Parliament in May and the consequent changes at the Commission level.

#### **WP- D / #08 / EJ to E      *Banking Union and Financial System Stability***

*The BRT advocates the EU Banking Union and expects its further development in 2013 to solve the current crisis and restore stability in the financial system.*

The EU makes every effort to rapidly implement measures to re-launch growth, investment and employment. The Commission works with a view to safeguarding the integrity and stability of the single market, to improving the functioning of financial markets and to breaking the feedback loop between sovereigns and banks.

The crisis exposed serious inadequacies, such as regulatory gaps; inadequate supervision; poor corporate governance; opaque markets and overly-complex

products. Experiences during the crisis clearly demonstrated that we need common EU rules, growth-friendly fiscal consolidation and further financial governance. The Commission has pursued its reform programme on regulation and supervision of the financial sector, in line with G20 commitments. The EU is approaching the end of its largest ever programme of financial services reform. Around forty targeted measures have been proposed after comprehensive impact assessments and consultations. Most of these measures have already been implemented.

These reforms are based on a two-pillar approach with, first, measures to stabilise the financial sector and re-establish confidence and, second, measures to ensure the financial sector supports healthy growth and investment. Each measure is carefully calibrated to be bearable for the financial sector and to support the real economy.

The June 2012 European Council agreed on significant measures to address Europe's challenges. It agreed to a single banking supervision mechanism in the euro area, increasing budgetary integration and achieving a genuine Economic and Monetary Union. In September 2012 the Commission adopted a proposal for the establishment of a single supervisory mechanism (SSM) conferring key supervisory tasks and powers to the ECB over all 6,000 credit institutions established within the euro area. This proposal was adopted in 2013. The supervisory powers of the ECB will be fully effective and operational on 4 November 2014. An integrated "Banking Union" will also include a common bank resolution mechanism, underpinned by a single rulebook. The Commission also hopes for quick agreement on the pending proposal for a single European resolution mechanism.

#### **WP- D / #09 / EJ to E      Solvency margin regulation on insurance companies**

*The BRT expects that the procedure regarding the equivalence decision is implemented constructively and Japanese supervisory systems will be regarded as equivalent to European systems.*

The European Insurance and Occupational Pensions Authority (EIOPA) published technical advice in October 2011 concluding that Japan's solvency regime for undertakings carrying out reinsurance activities is equivalent to that set out in the Solvency II Directive but with some caveats. EIOPA's 2011 equivalence assessment is based on draft criteria. EIOPA will revisit its advice once the criteria for Solvency II are finalised in order to verify whether any amendments to the criteria or changes to the Japanese solvency regime affect the conclusions reached in its report. Once this review is complete, the European Commission will take a final decision on the equivalence of Japan's solvency regime.

The implementation of Solvency II (Directive 2009/138/EC) has been delayed by the on-going discussions on the Omnibus II Directive (which amends Directive 2009/138/EC to take account of the new supervisory architecture for insurance, in place since 1.1.2011, and the setting-up of EIOPA). This Directive (Omnibus II) has now been agreed by the co-legislators and should be published in April or May 2014. The Commission must still adopt a delegated act (DA – summer of 2014) containing detailed rules on the items of Solvency II, which is a principles based Directive only. This DA may be subject to objections by the co-legislator for a period of up to 6 months. Solvency II will become applicable as of 1.1.2016.

This means that the European Commission's decision on the equivalence of the Japanese solvency regime will not now be taken in 2014, as previously envisaged.

The Commission and EIOPA are committed to continuing an open dialogue with the Japan FSA to ensure that an equivalence decision can be taken as soon as possible.

### **WP- D / #10\*\* / EJ to E Tax on Financial Transaction**

*The BRT expresses serious concern over the recently released EC's draft Council Directive implementing enhanced cooperation in the area of 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 and multiple taxation.*

*If imposed, the FTT will increase trading costs and result in reduced volume of financial transactions and decreased liquidity. In addition, the FTT on secondary market trading in such a wide scope of asset classes will significantly increase the funding costs and impair legitimate hedging activities by parties such as business corporations in the financial markets. The decreased liquidity in secondary markets is likely to cause impacts on primary market eventually.*

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 instances 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. The European Parliament already expressed a positive opinion on the matter; the actual design of the tax, including the minimum tax rates, is still under discussion in the Council.

## **Working Party E**

### **Energy, Environment and Sustainable Development**



**WP-E / # 04 \* / EJ to EJ *Maintaining and enhancing high-level EU-Japan dialogue on energy***

Energy cooperation has for a long time been on the agenda of bilateral cooperation between the EU and Japan. Energy cooperation was discussed during the 21<sup>st</sup> Japan-EU summit in Tokyo on 19 November 2013, where summit leaders expressed the shared view that achieving secure, sustainable, affordable and safe energy supplies remain key challenges facing both Japan and the EU. Summit leaders emphasised the need to advance their cooperation on liberalisation of electricity markets, nuclear regulatory frameworks, and energy research. In addition, they welcomed the progress of cooperation on gas with a view to promoting the development of a transparent and liquid global gas market driven by supply and demand fundamentals. They also expressed their intention to strengthen cooperation on low carbon policies, the ITER Project and the Broader Approach Activities towards the realisation of fusion energy, and increasing clean energy and energy efficiency, while maintaining overall long term ambition in reducing emissions.

High-level dialogue also took place on the occasion of the visit by Commissioner Oettinger's Head of Cabinet to Tokyo in September 2013, when he met senior officials of the Japanese Ministry of Economy, Trade and Industry.

Currently both sides are discussing the organisation of a high level meeting in 2014.

**WP-E / # 05 \* / EJ to EJ *Promoting and supporting a long-term strategy on stable, competitive and sustainable energy supply***

At the high level meetings and through discussions at operational level between the Japanese Ministry of Economy, Trade and Industry and the European Commission, exchanges take place on long-term energy strategies, as the European Commission's proposals for a policy framework for climate and energy in the period from 2020 to 2030 and Japan's new Basic Energy Plan.

Frequent exchanges take place on mid-to-long-term developments in global energy resources markets, in particular regarding policies for more competitive and liquid gas markets.

In September 2013, a joint EU-Japan workshop took place on the power sector transition, discussing the transformational change of the energy sectors in the EU and Japan, driven by liberalisation, greenhouse gas reduction commitments and, for Japan, the Fukushima events of March 2011.

**WP-E / # 07 \*\* / EJ to EJ *Leadership role to establish world safety standards***

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

Ensuring and continuously improving nuclear safety in the Union and globally is a priority of the EU.

The cooperation between the IAEA and the EU institutions has grown significantly over the last years, with the EU being a major contributor to the activities of the IAEA, both in terms of financing and technical expertise.

In September 2013, the International Atomic Energy Agency and the European Commission signed a Memorandum of Understanding on nuclear safety. The memorandum was signed by EU Energy Commissioner Oettinger and IAEA Director General Amano. It creates an enhanced framework for planning various forms of cooperation, such as expert peer reviews and strengthening emergency preparedness and response capabilities. It will allow both organisations to benefit from each other's work, avoid duplication of effort, and contribute to strengthening nuclear safety worldwide.

#### ***WP-E / # 08 \*\* / EJ to EJ Nurturing skilled independent nuclear safety authority***

*Japan and EU member countries should maintain a highly skilled nuclear safety authority in each country and ensure its independence.*

In 2013, the European Commission has proposed to amend the 2009 nuclear safety directive. The proposal:

- introduces new EU-wide safety objectives;
- sets up a European system of peer reviews of nuclear installations;
- establishes a mechanism for developing EU-wide harmonised nuclear safety guidelines;
- strengthens the role and independence of national regulators;
- increases transparency on nuclear safety matters;
- includes new provisions for on-site emergency preparedness and response.

The European nuclear safety regulators group, ENSREG has expressed interest in cooperation activities with counterparts in Japan's newly created Nuclear Regulation Authority.

#### ***WP-E / # 10 \* / EJ to EJ Cooperation on renewable energy development***

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

Within the EU's 7<sup>th</sup> Framework Programme for RTD and in the frame of the scientific-technical cooperation between the EU and Japan, a collaborative research project is funded on concentrator photovoltaic energy. In this project, New Generation CPV, seven European and nine Japanese leading research centres in the field of concentration photovoltaics (CPV), pursue the improvement of present concentrator cell, module and system efficiency.

Building on the experience with the joint call under FP7, consideration is being given on how to take forward cooperation on research and innovation in renewables in the context of the new EU programme for research and innovation Horizon 2020 and the energy policy review in Japan.

The Commission contributed to the seminar and training course on participation in the Horizon 2020 programme, organised by the EU-Japan Centre for Industrial Cooperation and the Japan Business Council in Europe.

Exchanges between smart grid demonstration projects in the EU and Japan took place in the frame of the IEA Implementing Agreement 'International Smart Grid Action Network'. Both Japanese and European demonstration projects contributed to a global casebook on 'Active Demand Management' to be published in Spring 2014.

***WP-E / # 12 \* / EJ to EJ Sharing best practices for safety and regulation with newcomer civil nuclear energy countries***

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

All nuclear power plants in the EU underwent stress tests and peer reviews in 2011 and 2012. Many other countries and territories also conducted comprehensive nuclear risk and safety assessments, based on the EU stress-test model. These include Switzerland and Ukraine (both of which fully participated in the EU stress tests), Armenia, Turkey, Russia, Taiwan, Japan, South Korea, South Africa and Brazil.

The European Commission is now holding discussions with some of these countries, e.g. Armenia and Turkey, regarding possible peer review of their stress tests.

The EU continues to support the improvement of nuclear safety in Ukraine under its Instrument for Nuclear Safety Cooperation (in particular in the areas of nuclear regulation and nuclear waste management). Progress has been made for granting Euratom and EBRD loans to Ukraine.

In April 2013, on invitation by the Taiwanese nuclear safety regulator, the Atomic Energy Council (AEC), the European Commission and the European Nuclear Safety Regulators' Group (ENSREG) have done an expert peer review of the stress tests of the Taiwanese nuclear power plants, conducted in 2012.

***WP-E / # 13 / EJ to EJ Promoting involvement of international institutions to finance capacity-building actions nuclear safety and more generally nuclear investment in the best conditions of safety and security***

*To facilitate nuclear investment and achieve a high level of safety, Japan and the EU should encourage the World Bank, the European Bank for Reconstruction and Development (EBRD), and the European Investment Bank (EIB) to consider loan and loan guarantees on nuclear investments and to allocate funds for, and to promote the establishment of, dedicated nuclear safety programmes.*

Throughout 2013, the EU Instrument for Nuclear Safety Cooperation continued to provide financial support for measures for improving nuclear safety in non-EU countries, particularly in terms of regulatory framework or management of nuclear plant safety (design, operation, maintenance, decommissioning), the safe transport, treatment and disposal of radioactive waste, remediation of former nuclear sites, protection against ionising radiation given off by radioactive materials, accident prevention and reaction in the event of an accident, or also the promotion of international cooperation. The financing takes the form of projects or programmes, grants to fund measures, contributions to guarantee funds and national or international funds, or even human or material resources.

**WP-E / # 15 \*\* / EJ to EJ Fostering international harmonization for EV safety and charging infrastructure**

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

In January 2013, the European Commission organised an international conference on smart grid standardisation achievements. The conference aimed at disseminating the achievements of smart grid standardisation work, notably on charging electric vehicles. The conference was open to an international audience and results were discussed of the work carried out by the European standardisation organisation in the frame of the mandate they had received from the European Commission concerning the charging of electric vehicles.

**WP-E / # 18 / EJ to EJ Further promoting demo projects of smart cities and smart grids**

*The EU and Japan should continue promoting demonstration experiments of smart cities and smart grids, furthering exchanges on:*

- *Energy storage*
- *Energy efficiency and construction techniques for smart cities*
- *Communication standards*
- *Other key aspects/components of smart grids: power electronics, control and automation, information and monitoring systems, etc.*

*The EU and Japan should provide open access to allow each other's industry to participate in such experiments.*

Further promoting demo projects of smart grids and smart cities: Through the last calls of the 7<sup>th</sup> Framework Programme for RTD and the first calls of the new programme Horizon 2020, a considerable number of demonstration projects on smart grids and smart cities are supported.

The European Commission promotes knowledge exchange between the smart grid demonstration projects in the frame of the European Electricity Grid Initiative.

International exchanges are promoted through the involvement of the European Commission and several EU demonstration projects in the activities of the International Smart Grid Action Network (ISGAN). This will lead to the publication of a global casebook on 'Active Demand Management' in Spring 2014.

The funding for smart cities demonstration projects under Horizon 2020 reflect the priorities discussed in the frame of the Smart Cities and Communities European Innovation Partnership, which intends to pool resources to support the demonstration of energy, transport and information and communication technologies in urban areas.

To support dissemination, replication and analyses based on the European smart cities demonstration projects the European Commission launches a Smart Cities Information System, which should act as a one-stop shop for information on smart cities, energy-efficient buildings and sustainable energy district projects.

**WP-E/ # 21 / EJ to EJ      Facilitating transfers of green technologies**

*The EU and Japan should assist emerging economies in developing the necessary human resources and infrastructure so that they can smoothly absorb advanced technologies. To facilitate the transfer of technologies on a commercial basis, the EU and Japan should support the recipient countries in putting in place an appropriate regulatory framework and enforcement tools to ensure the protection of intellectual property rights.*

The EU supports the objective of having an appropriate regulatory framework to ensure the protection of IPR. Regulatory convergence is often part of agreements that the EU negotiates or concludes with the third countries. It entails at least the references to international standards and conventions in this field and in some cases encourage regulatory convergence towards EU standards. Particular attention should be paid to the enforcement of such rules, and measurable monitoring of technology transfer, capacity building and technical assistance in general. Follow-up and monitoring, based on measurable achievements, is desirable. Clear control of the technology transfer, capacity building activities and technical assistance in general is needed for awareness-raising of our efforts in this field and effective monitoring of these activities.