Commission Services Progress Report

on the

EU-Japan Business Round Table Recommendations 2016

"EU & JAPAN – TAKING STRIDES TOWARDS A COMMON SUSTAINABLE FUTURE"

Brussels, June 2017

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Working Party 1

Trade Relations; Investment and Regulatory Cooperation; Financial Services, Accounting and Taxation

Recommendations from both European and Japanese industries

*WP-1 / # 01**/ EJ to EJ Strengthening the EU-Japan Economic Relationship*

Reply
The Commission has repeatedly stated its commitment to the conclusion of a highly comprehensive and ambitious trade agreement with Japan. This commitment has been confirmed more recently by Commissioner Malmström to Foreign Minister Kishida in their meeting in Bonn on 17 February 2017, as well as by President Juncker and PM Abe in the leaders' meeting of 21 March. Both the EU and Japan agreed on the objective to reach an agreement as early as possible. The negotiations are now well advanced and could potentially be concluded soon. Both EU and Japan are working with renewed commitment and efforts to reach this objective. For the EU, however, substance will prevail over speed because only an ambitious agreement could deliver real benefits to EU businesses and citizens.

*WP-1 / # 02**/ EJ to EJ Call for effective and quick implementation of WTO 'Bali Package' and work on a future WTO work program based on Nairobi Ministerial Conference Declaration*

Reply
After the successful conclusion of the 10th WTO Ministerial Conference in December 2015 with an agreement on agricultural export competition, and on other important issues, and the expansion of the ITA agreement, preparations of the next Ministerial Conference ("MC11" - Buenos Aires – December 2017) have featured prominently on the negotiations' agenda of the WTO in 2016.

At a time when protectionist tendencies around the world are putting strain on the multilateral trading system, it is important to work towards concrete results in MC11 on trade issues that matter for all stakeholders and that can bring inclusive growth, in particular for developing countries as well as for SMEs. More specifically, issues that have garnered most attention include domestic support on agriculture, fisheries subsidies, e-commerce, domestic regulation in services and an initiative to facilitate SME trade by enhancing transparency on regulatory measures.

Important progress has also been made toward the implementation of the Trade Facilitation Agreement, an outcome of the 9th WTO Ministerial Conference in Bali in 2013.
A major milestone for the global trading system was reached on 22 February 2017 when the first multilateral deal concluded in the 21 year history of the World Trade Organization entered into force. In receiving four more ratifications for the Trade Facilitation Agreement (TFA), the WTO has obtained the two-thirds acceptance of the agreement from its 164 members needed to bring the TFA into force.

WP-1 / # 03** / EJ to EJ Applying international standards and enhancing regulatory cooperation

1. General recommendations

Reply

The EU acknowledges the importance of the regulatory cooperation between the EU and Japan and its long-term role in the EU-Japan trade relations. Based on the current experience, a transparent, predictable and compatible regulatory environment is crucial for companies to conduct business successfully and to invest in foreign countries. The regulatory environment is a dynamic factor – as compared to tariff elimination – and thus it requires continuous monitoring and readjustments, if necessary. Therefore, the conclusion of a trade agreement between the EU and Japan will not put an end to the process of regulatory cooperation between the EU and Japan but rather a new beginning based on enhanced mutual understanding between the EU and the Japanese regulators as a result of the FTA negotiation process. The regulatory cooperation between the authorities after the conclusion of the FTA would be even more important in order to ensure that new barriers to trade and investment do not re-appear and undermine the benefits achieved by the FTA.

In view of that the EU has submitted a text proposal to Japan which outlines specific ways and mechanisms to facilitate the regulatory cooperation between the parties and which creates the necessary framework for it. The text proposal consists of two main parts – one on good regulatory practices and one on regulatory cooperation. The part on good regulatory practices ensures that the regulatory processes in the EU and Japan abide by the principles of transparency and effectiveness, that they involve the broad participation of the public and ultimately result in a predictable and business friendly regulatory environment. Examples of such good practices are the early information on planned regulatory measures, the public consultations, the impact assessments and the retrospective evaluations.

The part on regulatory cooperation promotes cooperation activities between the EU and the Japanese regulators through respective consultation mechanisms with the aim to reduce unnecessary regulatory differences and to achieve greater alignment with international standards. Such cooperation should ensure quality, effectiveness and adequate levels of protection of each party's regulations while facilitating trade. Regulators are encouraged to take the necessary steps to that end already before or at the outset of the regulatory process to avoid divergent and incompatible regulations and standards which would act as barriers to trade and investment.

The regulatory cooperation would not, however, limit the regulatory independence of the parties. The cooperation would remain voluntary and would take place only if both parties agree to cooperate in a specific area. In addition, even if parties engage in a regulatory cooperation activity, regulators' right to regulate will be fully preserved – regulators will be free to define their respective levels of protection in pursuit of public policy objectives.

The EU text proposal also suggests that the EU and Japan identify specific sectors and areas of cooperation and thus provide a more targeted response to the needs of the business community and the consumers. For example, the part on regulatory cooperation builds upon already existing initiatives such as the EU-Japan Industrial Policy Dialogue between METI and DG GROW and sets the framework for the establishment of other successful initiatives which would contribute to the further enhancement of the EU-Japan relations.

Sector specific recommendations

2. Create a common chemicals regulation

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

Furthermore, the two Authorities should develop a common policy on emerging issues such as endocrine disruptor and nano materials. The two authorities should also support supply chain management in developing countries in cooperation with businesses.

Reply

The EU and Japan continue bilateral cooperation on chemicals legislation under the EU-Japan Industrial Policy Dialogue and both participate in multilateral cooperation activities such as in the context of the OECD or UN. This has facilitated efficient sharing of experiences and information in matters such as risk assessment methodologies, prioritisation approaches and other practical aspects that can lead to consistent approaches to chemicals management.

The safety assessment of chemicals is largely based on the internationally harmonised OECD test methods, applicable both in the EU and in Japan, and both are Parties to the OECD Council Acts on the mutual acceptance of data (MAD). The EU and Japan regularly inform each other about substances restricted under their respective legislations, and about activities related to endocrine disruptors and nanomaterials, and about their activities related to global supply chain management, including companies activities in developing countries. Among others, information and communication about the hazards of substances relies on the harmonised Safety Data Sheets of the Global Harmonised Systems (GHS) of the United Nations. Both the EU and Japan are interested in developing tools for the communication about the presence of substances of concern in articles along supply chains.

3. Create a common resource efficiency policy

The authorities of the EU and Japan should promote the concept of energy efficiency including resource efficiency, using the right incentives, standardised methodology, criteria and the format of environmental product declaration between the EU and Japan and cooperate with each other so that such a policy will be internationally shared.

The two authorities should work together at the multilateral level to promote international harmonisation of energy conservation regulations, relevant labelling rules, and environmental and carbon footprint schemes.

Reply

The EC welcomes the idea to create a common resource efficiency policy. The EU and Japan are confronted with similar challenges in terms of resource scarcity and dependence of external providers for certain raw materials, and therefore have a common interest in promoting effective policies. The EC agrees that a multilateral effort to promote international harmonisation of energy conservation and labelling regulations, as well as environmental footprint methods, would be the most effective strategy.

4. Expand the benefits of AEOs

Reply
Mutual Recognition of AEOs including further benefits are discussed by AEO experts from both sides in their regular meetings concerning the implementation of the Mutual Recognition Decision between the EU and Japan.
The topic of expansion of the benefits under the MRA to customs simplifications (including priority at customs controls) has been discussed with Japan on various meetings over the last few years. The EU is committed to this topic and has introduced a respective proposal for the WCO SAFE Review 2018 which has been tentatively approved by the SAFE Working Group.

5. Fight against counterfeited, pirated and contraband goods

Reply
IPR customs enforcement remains a top priority for Customs in the EU. In the daily completion of their IPR enforcement-related tasks, Customs use risk analysis technics for targeting suspected shipments and available IT tools. Increased cooperation between Customs and right holders remains a cornerstone for the effective enforcement of registered rights at the EU external border. Customs are committed to cooperation with the other IPR enforcement authorities in the EU and relevant authorities in third countries in order to reduce the volumes of international trade in IPR infringing goods and its impact on global economy. The Commission, Member State experts and the European Observatory on infringements of IPR have further enhanced their cooperation in the past years. In addition to coordinating the customs activities enshrined in the yearly work programme of the Observatory, the Commission services and national customs experts participated in several events organised by the European Observatory on infringements of IPR, such as the the working groups meetings on enforcement issues and statistics.

6. Adoption of UN Regulations

In the automobile sector, the EU and Japanese Authorities should accelerate their adoption of UN Regulations to lower the cost of regulatory compliance for both European and Japanese automobile exporters by extending the benefits of mutual recognition. Also the EU and Japanese Authorities should work together to establish internationally harmonised technical requirements and testing procedures that will encourage the smooth market adoption of new environmentally friendly power-train technologies – clean diesel, electric vehicles, hybrid vehicles and fuel-cell vehicles.

Reply
The Commission services also concur with the Business Round Table that an ambitious level of reciprocal recognition between the EU and Japan is desirable. In this context, the Commission services aim to agree with Japan on ambitious provisions specifically targeted at motor vehicles in the FTA, which will, among others, aim at a high degree of alignment of regulations of EU and Japan on the basis of international standards (UN ECE Regulations) and bolster EU-Japan cooperation both bilaterally and in the context of the relevant international standard-setting body (UN Working Party 29).

WP-1 / # 04** / EJ to EJ Supporting timely development of business

1. Social security contributions (avoiding double contributions):

Reply
The Commission welcomes information that Japan has concluded 11 social security agreements with Member States and ongoing negotiations with 4 other Member States. The Commission also invites the Japanese authorities to conclude the bilateral social security agreement with the remaining Member States which express an interest in having such agreements.

However, in the EU, the Member States are in principle responsible to negotiate and conclude bilateral agreements in this field.
They also continue to be responsible for the funding and organisation of their social security systems that are the result of long-standing traditions deeply rooted in national culture and preferences. Provisions at the EU level in the field of social security coordinate, but do not harmonise, arrangements for people who exercise their right to free movement within the European Union. In particular, they ensure that people working or retiring in another Member State continue to receive various benefits (sickness, invalidity, unemployment, family, pension, etc.). These provisions have existed for more than 50 years. They have been adapted, improved and extended many times. They currently apply only to the territory of the Member States of the European Union or of the European Economic Area.

Nonetheless, Commission wishes to encourage closer cooperation between Member States in the conclusion and operation of bilateral agreements with non-EU states. Under the Framework of the Administrative Commission for the coordination of social security systems, on 5 October 2017 the Commission is organising the Fifth International Forum on the external dimension of social security. The Forum takes place annually and is a platform for discussion and exchange of experiences between Member States, as well as between third countries and Member States, in the area of the coordination of social security. The Forum will be attended by social security experts from the EU Member States. Therefore, in order to encourage the cooperation in this field, an item regarding Japan could be placed on the agenda.

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

The EU and Japan should realise far-reaching liberalisation of the movement of intra-corporate transferees within the framework of an FTA/EPA. Such liberalisation should aim at the following system:
• A framework agreement between the mother company, sending expatriates, and the host country, stipulates the maximum number of expatriates. Within the agreed limit, the mother company is free to send intra-corporate transferees to that country without further obtaining individual work permits.
• When the mother company concludes such an agreement with several Member States in which its subsidiaries or branches have operations, movement of intra-corporate transferees between those countries does not require a new work permit as long as the total number in each agreement is respected.
• Both sides should facilitate access to the labour market for accompanying family members without any limitations in regard to regular working hours.

Reply
As correctly referred, Directive 2014/66/EU on intra-corporate transfers is currently being implemented by EU Member States (deadline for implementation was 29 November 2016), with the exception of Denmark, Ireland and the UK. This Directive allows Japanese expatriates to be transferred temporarily to the territory of the relevant Member States as managers, specialists or trainees. A labour market test or economic needs test is not to be applied.
The Directive allows Member States to introduce simplified procedures for recognised entities or (groups of) undertakings. These may consist of faster procedures, as well as exemptions from providing certain documents which would normally be required as part of the admissions procedure.
The Directive already specifies that professional stays in other Member States can happen on the basis of the permit issued by the first Member State, so long as these do not exceed 90 days within any 180 day period in any single Member State. A simple notification procedure suffices in such cases, if a MS requests it. For stays exceeding 90 days, the second Member State may choose to apply the same simple notification procedure, or it may choose to issue a specific permit. In the latter case, the issuance of permits to ICTs posted by recognised entities or (groups of) undertakings can also be facilitated by that Member State.
The Directive 2014/66/EU specifies that family members have access to employment or self-employment and it does not place any restrictions as regards working hours.
As correctly referred in the question, Denmark, Ireland and the UK are not implementing this Directive and can retain national schemes.

In the framework of the FTA/EPA the issue of entry and temporary stay of natural persons for business purposes will be considered in what regards trade in services, providing for horizontal disciplines for several categories of natural persons. This will be complemented with a list of commitments by the EU member States and Japan. Both aspects are currently being negotiated.

WP-1 / # 05** / EJ to EJ Support for SMEs
The BRT calls on the EU and Japanese Authorities to develop measures to promote and assist each other's SMEs within their own jurisdictions.

Reply
The Commission welcomes the EU-Japan Business Round Table recommendations and the renewed focus put on the necessary support for SMEs. In particular, the Business Round Table is asking that specific consideration should be given to cross support for SMEs in the ongoing Free Trade Agreement (FTA) negotiations. This 2016 recommendation has been duly taken into account by the Commission which tabled ad hoc provisions in the EU-Japan FTA to allow SMEs of both sides to take the most out of the future Agreement. Following Japan's agreement to develop a specific 'SME Chapter' in the FTA, dedicated SME provisions have been negotiated to achieve the following objectives:
 to ensure, through information sharing provisions, transparency of all kind of import requirements in order to facilitate EU SMEs doing trade and business with Japan. Each side will put in place for information sharing purpose a public website giving a direct access for SMEs to relevant information on trading, investing and doing business in the market of the Party. A specific database should offer updated market access information about import requirements.

 to establish an appropriate institutional set-up for taking into account the needs of SMEs in the implementation of the FTA ('SME contact points' to be set up by both Parties to the FTA).
These should help SMEs from both sides to compete on the bilateral market at a level playing field with large companies so that also small companies can fully benefit from the future agreement.

In addition to the future EU-Japan FTA, the long-standing EU-Japan Centre for Industrial Cooperation remains available to provide support and information to SMEs of both EU and Japan. One of the main priorities of the Centre is to offer a reinforced support for SMEs, with a particular focus on internationalisation aspects as SMEs represent the backbone of EU and Japanese economies. The Centre already implements in a pragmatic manner a number of recommendations included in the progress report.

Moreover, the EU-Japan Centre for Industrial Cooperation is member of the Enterprise Europe Network whose aim is to help SMEs making the most out of international business opportunities. It provides support on access to market information, overcoming legal obstacles, and identifying potential business partners across Europe and in third countries markets.

Since its accession to the Network in 2015, the EU-Japan Centre for Industrial Cooperation has achieved and facilitated 10 Partnership Agreements (i.e. business deals, technology transfer agreements and/or research collaboration agreements) as well as 631 International business to business (b2b) meetings (i.e. face-to-face meetings organised between Japanese and European companies at international fairs and/or dedicated company missions).

Mutual business cooperation between European and Japanese SMEs could be strengthened through the Enterprise Europe Network: Japanese business intermediary organisations could certainly benefit from joining the Network and the business matchmaking opportunities it offers with European SMEs.

Finally, as far as recommendation 7 on "Exchanging best practices and tested solutions in industrial policy for SMEs" is concerned, it should be noted that a future EU-Japan bilateral SME Policy dialogue is envisaged at government level. A formal dialogue is currently under consideration between DG Internal Market, Industry, Entrepreneurship and SMEs of the European Commission and METI SME Agency. The dialogue on SME policy would reinforce the Industrial Policy Dialogue already set up with METI. It would allow mutual exchanges on public policies in favour of SMEs, in particular to support their internationalisation.

WP-1 / # 06** / EJ to EJ Recommendation on BEPS Action Plan and Other Tax Issues

Reply
On BEPS Action 13 (non-public CBCR):
This recommendation has been implemented at EU level via DAC4. It came into force on 5 June 2017 and first exchanges of information are expected by June 2018. The main objective of the EU was to transpose BEPS 13 without any EU specific amendments in order not to create a second layer of reporting. This should be in the interest of EU and international business community and create a level playing field.

On Mutual Agreement procedures (MAP) and binding arbitration (dispute resolution):
The EU Commission made a proposal on improving double taxation dispute resolution mechanisms in October 2016. The Directive has been discussed in Council and a general approach (agreement) has been reached at the May ECOFIN meeting. Subject to the EP report the proposal is expected to be finally adopted in July.
It will enhance tax certainty substantially and will broaden the scope of binding arbitration, clarify the timeline and provide the taxpayer with the possibility to go to national courts in case Member States do not act as they should. This is a substantial improvement for business activities in the EU internal market.

On the additional points raised:
On the other points we agree with your views. The Commission in principle agrees with the simplification of tax systems because this reduces administrative burden and enhances tax certainty, both is beneficial for the business and investment activities in the EU. Since some time the Commission is following an ambitious agenda to fight tax avoidance, increase transparency and to create a system of fair taxation. Real progress has been made in this respect over the recent years.
In addition, conclusion of bi- or multilateral Advanced Pricing Arrangement (APA) mainly in the area of transfer pricing would be an additional contribution to tax certainty.

WP-1 / # 07** / EJ to EJ Recommendation on Financial Transaction Tax

Reply
In January 2013 11 EU Member States (MS) have been authorised to establish enhanced cooperation (as provided for in the EU Treaties) between themselves in the area of setting up a common system of FTT. In February 2013 the Commission tabled its Proposal for a Council Directive implementing enhanced cooperation in the area of FTT. In the meantime one MS indicated to withdraw as a particpating MS. The first objective of this proposal is to harmonise FTT legislation between the MS participating in the enhanced cooperation.
The proposal continues to be discussed between the participating MS and in the Council. At present, the participating Member States have not decided on a final text. Among other elements, the scope of the tax and the protection of the real economy (FTT treatment of derivatives used by the non-financial industry) were also discussed. The level and structure of tax rates still has to be discussed. All these elements are carefully considered with the technical assistance of the Commission.
It has to be noted that the Commission proposal does not include the taxation of transactions in shares and bonds on primary markets. Moreover, further technical background information, among others a trend analysis on the influence of the French FTT on trading volumes, price levels and/or volatility in the taxed market segment has been added to the Commission's dedicated webpages (http://ec.europa.eu/taxation_customs/taxation/other_taxes/financial_sector/ftt_background_en.htm). 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.

Recommendations from Japanese industry to the EU

WP-1 / # 15** / J to E The importance of the Single Market

Reply

The Single Market Strategy is the European Commission's plan to unlock the full potential of the Single Market. The Single Market is at the heart of the European project, enabling people, services, goods and capital to move more freely, offering opportunities for European businesses and greater choice and lower prices for consumers. It enables citizens to travel, live, work or study wherever they wish.

But sometimes, these benefits do not materialise because Single Market rules are not known or implemented or they are undermined by other barriers. And in a rapidly changing environment, the Single Market needs to adapt to new ideas and business models.

That is why the Commission has decided to give the Single Market an important boost by taking measures that will:

Enable the balanced development of the collaborative economy

Help SMEs and start-ups to grow

Improve the opportunities for businesses and professionals to move across borders

Address restrictions in the retail sector

Prevent discrimination against consumers based on nationality or place of residence

Modernise our standards system

Create more transparent, efficient and accountable public procurement

Consolidate Europe's intellectual property framework

Ensure a culture of compliance and smart enforcement to help deliver a true Single Market.

Nowadays, the EU Single Market faces many new challenges. The Single Market is a lot bigger and much more diverse. More people want to communicate and buy online. More businesses want to go international. If we want a Single Market that allows business and consumers to make the best out of it, we need to adapt it to the 21st century. Therefore, the Commission will make proposals to:

- Fight against unfair discrimination between consumers

The Commission will take action to ensure that consumers seeking to buy services or products in another EU country, be it online or in person, get the same choice of price, sales conditions, or delivery options available.

- Open the Single Market for innovative start-ups and SMEs

We need a Single Market in which entrepreneurs can innovate and expand. More and faster access to finance, simpler VAT regulations, SME-friendly intellectual property rules and clearer company law will help small businesses in Europe thrive.

- Consider new business models emerging in the EU

The emerging collaborative economy is changing the way services are provided and consumed. On one hand, it leads to greater choice for consumers and creates new opportunities for innovative entrepreneurs. On the other hand, there are also issues related to consumer rights and safety, taxes and labour law that have to be looked at. Right now, the collaborative economy finds itself in a grey legal zone. Each EU country has a different approach, so the same business can be allowed in one city, but prohibited in another. This leads to confusion for both consumers and businesses. EU-wide guidance will clear the way for new business models, whilst making sure that consumer protection, taxation and labour law are respected.

-Unfinished business...cross border services

Companies and professionals still find it difficult to provide their services across borders. Diverging national rules and time-consuming procedures put people off expanding their businesses or looking for jobs in other EU countries. The result is less choice and higher prices for customers and also for industry - the main consumer and provider of services.

To reduce barriers in important sectors, such as business services and construction services, the Commission will propose to develop a new services passport. This document will make it easier for service providers to access markets in other EU countries. The Commission will also look at regulated professions and, together with Member States, will identify concrete reforms needed to improve access to these professions.
Bureaucracy and red tape are also a major problem for companies trying to bid on tenders in other EU countries. As public procurement in the EU represents around 19% of GDP, the strategy aims to make public procurement rules more efficient and transparent, and bring the best value for taxpayers' money.

The Strategy goes hand in hand with efforts to strengthen the EU's industrial base, boost investment, improve access to finance, ensure the free flow of energy and meet the challenges of the digital economy.

WP-1 / # 16** / J to E Revision of high customs tariffs on audio-visual products and passenger cars

Reply
This is precisely one of the objectives of the EU-Japan FTA/EPA negotiations. It is too early to say what will be the results but the aim is to agree on the total elimination of customs duties on both sides, as soon as possible and in any case within 10 years maximum

WP-1 / # 17** / J to E Chemical Regulations

17.1 REACH
The Authorities of the EU should pay more attention to the implementation of REACH. In particular:
- *There should be more opportunities to take account of the views of non-EU companies in updating guidance because a substantial part of articles on the EU market is imported from outside the EU. In this regard, the representatives of non-EU companies should be allowed to register as the stakeholders of the ECHA.*
- *If the thresholds of new SVHSs are too low, for example, in the units of ppb rather than the units of ppm, there will be practical difficulties for manufactures and importers to implement it effectively as it will be too difficult to measure correctly.*
- *The authorities of the EU should improve the enforcement of the thresholds applicable to SVHCs once they are adopted. Otherwise the increasing number of SVHCs with extremely low threshold will distort the competition between strictly complying manufacturers/importers and less strictly complying manufacturers/importers.*
- *In the evaluation of a substance allocated to a Member State in the framework of CoRAP - Community Rolling Action Plan, a private business is often requested to provide information on the substance which it holds. However, it is sometimes requested at a short notice and/or a not-well-organised manner, which is not effective. The authorities of the EU should publish the best practice for the Member States so that private businesses can help them more efficiently and effectively.*

Reply
Possibilities of non-EU companies to express views during the updating of guidance:
There are mechanisms in place which allow anyone with an interest in guidance of the European Chemicals Agency (ECHA) to make input into the update process at any stage in the consultation process (and even after the consultation has been completed and the final version of the document published). This feedback can be made via a form available on ECHA's website at: https://comments.echa.europa.eu/comments_cms/FeedbackGuidance.aspx

The form can thus also be used by companies or associations that are not based within the EU or EEA and consequently do not have the status of accredited stakeholders of ECHA and are thus not part of Partner Expert Groups (PEGs) for ECHA guidance updates. The same form also needs to be used by EU-based organisations that either fail to meet the criteria to become ECHA accredited stakeholders or have simply not applied to be stakeholders in time to participate as PEG members in a particular consultation.
The main difference between feed-back obtained via this mechanism compared to that from a formal PEG consultation (other than the fact it can be made at any time) is that individual replies to each and every comment made will not be sent by ECHA to the submitter of input made via the form. Nevertheless, there are procedures and processes in place within the guidance team in ECHA to ensure that feedback obtained via the form is addressed. This feedback mechanism was notably used by several organisations (including a Japanese industry association) during the PEG consultation on the on-going update to the Guidance on requirements for substances in articles (draft version 4.0), namely the following:

1. EWIMA (European Writing Instruments Manufacturers Association)
2. IPC – (Based in the USA) Association Connecting Electronics Industries, a global industry association, representing companies from the electronics industry, including design, printed board manufacturing and electronics assembly.
3. JEITA Japan (Japan Electronics and Information Technology Industries Association)
4. SGS TW Ltd. Taiwan (the largest independent testing provider in Taiwan)

In conclusion, there are effective mechanisms in place to take account of comments from organisations in general that are not ECHA accredited stakeholders and in particular from non-EU/EEA organisations.

Thresholds for SVHCs

SVHCs listed in the candidate list do not have, as such applicable thresholds for these substances in articles which would limit the placing on the EU market of such articles containing them. Articles 7 and 33 of REACH do establish requirements for notification and communication in the supply chain for SVHCs present in articles, included in imported articles, but these apply only if the concentration of the substance in the article is above 0.1% (i.e.1000 ppm).
In relation to restrictions defined in Annex XVII to REACH, where often concentration limits for restricted substances apply, the ECHA Forum has recently published guidance "Forum methodology for recommending analytical methods to check compliance with REACH Annex XVII restrictions" which, among other matters, provides recommendations regarding the relation between the limit imposed in the restriction and the limits of quantification and of detection of the analytical methods to be used in its enforcement. https://echa.europa.eu/documents/10162/13577/methodology_analytical_methods_en.pdf

Enforcement of REACH provisions

The enforcement of REACH provisions, including those on restrictions, authorisation or compliance with Article 33 communication obligations, remains the exclusive responsibility of Member States, which do so by means of their market surveillance authorities. However, REACH has created the Forum for Exchange of Information on Enforcement, where the relevant authorities from the Member States inform each other about their activities and agree on common priorities and enforcement projects. Forum will start this year the first European enforcement project on SVHC in Articles.

CoRAP and cooperation between companies and the evaluating Member State

It is worth noting that the CoRAP is published annually but covers a 3-year period. Therefore, generally companies often have a 3 year pre-warning about the intentions of Member States as to which substances they plan to evaluate. The "good practice" guidance that you encourage ECHA to draft in order to allow the process to run more smoothly was published by ECHA in 2014, following extensive discussion between ECHA, stakeholders

and the Commission. Please see the document "Interaction between the evaluating Member State and the Registrants under Substance Evaluation – Recommendations" https://echa.europa.eu/documents/10162/13628/interaction_ms_reg_sev_en.pdf/c5ba2af8-eadc-4830-9dfb-389a4bf8f637

17.2 Appropriate approach to Endocrine disruptor

The authorities of the EU should regulate endocrine disruptors not by using the categorisation like CMR (carcinogenic, mutagenic or reprotoxic), but by using the risk assessment based on sound science because endocrine disruption is not the endpoint of toxicity. The hazard assessment should be conducted by identifying adverse effect based on the endocrine mode of action defined by the WHO, and characterising with taking into account of potency, lead toxicity, severity and irreversibility.
The BRT is concerned that the European Commission has already sent a draft decision to the WTO that applies to DEHP, DBP, BBP and DiBP without waiting for a communication on the categorisation due to be published in July 2016.

Reply:
On 15 June 2016, the European Commission presented two draft legal acts in the context of the Biocidal Products Regulation (BPR) and the Plant Protection Products Regulation (PPPR) to define criteria for the identification of Endocrine Disruptors (EDs). Information on the draft legal acts as well as on the state of play can be found on the Commission's website . The rationale of the amendments is explained in a Communication to the European Parliament and the Council . The proposal does not foresee a categorisation similar to those for CMRs. The European Commission proposed to identify endocrine disruptors using hazard assessment based on scientific data, and the WHO/IPCS definition of EDs and of adverse effects . The following elements need to be present for identifying a substance as ED:

- Adverse effects
- An endocrine mode of action
- A biological plausible link between adverse effects and the endocrine mode of action.

The proposals are now undergoing the adoption procedures foreseen in the two legislations (BPR, PPPR). It is currently not possible to specify the point of time of adoption, but it is assumed that this will happen during this year.
The proposed legal acts amending the BPR and PPPR are not directly applicable to other legislations, e.g. REACH. However, REACH is already now identifying EDs as substances of very high concern following the same principles (i.e. using the WHO/IPCS definition and a science based hazard assessment).
Procedures to identify substances as SVHC due to endocrine disrupting properties are already well established under REACH. The four phthalates (DEHP, DiBP, BBP, DBP) were identified as EDs for human health following those procedures. The Member States agreed in the responsible Committee (REACH Committee) in February 2017 on the identification, and the adoption of the relevant Decision is expected to be finalised soon. The draft Decision had been notified to the WTO under the TBT agreement and the Japanese industry had provided comments TBT/WTO to which the European Commission has responded.

17.3 RoHS

The BRT recommends that the identification and assessment of substances for RoHS inclusion should be done based on a robust and consistent methodology by taking account of the most appropriate risk management option. Going forward, the principles of "REACH and Directive 2011/65/EU (RoHS) - A Common Understanding should be duly applied and implemented to avoid overlap in regulation.
The BRT requests that all new regulatory initiatives should provide the necessary level of legal certainty, transparency and predictability to allow for timely implementation with regard to restriction, substitution and exemption requests.

Reply
"We take note of the views expressed in the recommendation and would reassure the BRT that the identification and assessment of substances for RoHS inclusion is based on a robust and consistent methodology." Firstly, the EU would like to refer to the Explanatory Memorandum of the notified draft, which explains the procedure for restricting substances under RoHS1 in detail and addresses BRT's concerns. The Explanatory Memorandum of the notified draft explains the procedure for restricting substances under RoHS1 in detail and addresses the BRT's concerns.
In connection with the Explanatory Memorandum, the EU would also like to draw attention to the following points:
Relationship between REACH and RoHS
The Explanatory Memorandum provides a detailed explanation of the relationship between REACH and RoHS. In general, although REACH and RoHS establish different scientifically based procedures, overlaps are avoided and the two procedures are meant to work in synergy.

17.4 CLP Regulation

To alleviate burden on exporters, the authorities of the EU should accept GHS classification and labelling at the custom clearances.
In addition, the authorities of the EU should take GHS into consideration from ATP (Adaptation to Technical Progress) stage.

Reply*:*
Importers of chemicals in the European Union are required to comply with Regulation (EC) No 1272/2008 on the classification, labelling and packaging of substances and mixtures (the 'CLP Regulation'). The CLP Regulation is largely aligned to the classification and labelling rules under GHS. It is therefore not correct that "CLP introduces the European Union's own classification", but the European Union is implementing GHS through the CLP Regulation in accordance with the Building Block approach, as defined in GHS Section 1.1.3.1.5:
"Countries are free to determine which of the building blocks will be applied in different parts of their systems. However, where a system covers something that is in the GHS, and implements the GHS, that coverage should be consistent".
Accordingly, CLP Annex I on classification follows closely the structure and content of the GHS (including the numbering) and applies most GHS hazard classes and their related labelling elements. The CLP Regulation carries forward some additional elements from its predecessor legislation (such as a limited number of additional hazard statements).
The European Commission regularly adopts Commission Regulations amending the CLP Regulation for the purpose of its adaptation to technical progress (ATP) in order to implement revisions of GHS. Most recently, Commission Regulation (EU) No 2016/1179
aligned the CLP Regulation to the fifth revision of GHS; an alignment to the sixth and seventh revision of GHS is foreseen.

17.5. Nanomaterial

1. Definition
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.

Reply:
The Commission Recommendation on the definition of nanomaterial (2011/696/EU) is the reference for determining whether a material should be considered as a 'nanomaterial' for legislative and policy purposes in the European Union. This definition, based only on the size of a material, covers natural, incidental or manufactured materials. However, regulatory action under EU legislation setting out restrictions on nanomaterials takes into consideration possible exposure.

2. Standardisation of measurement method

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

Reply:

The wide variability of nanomaterials does not allow to consider only one measurement method for their identification, because no single measurement method can be applied to all materials. Development of guidance is ongoing which will provide a tiered approach on how to use effectively available measurement methods on the identification of nanomaterials according to the EU definition. The EU is in the process of providing standardised methods: in the frame of the standardisation mandate given to the European standardisation body CEN, particular focus is on the development of standards/technical specifications for the measurement of the dustiness of nanomaterials and the efficiency of filters to capture nanoparticles. As the definition of nanomaterial in the EU differs from the ISO concept, there is currently no activity from by CEN to develop internationally harmonised standards for the identification of nanomaterials.

3. Reporting scheme

The authorities of the EU should take an initiative and establish a harmonised reporting system at the EU level.

Because the above 1 and 2 are not progressing, some Member States have started their own reporting schemes. The EU should move more quickly on a harmonised reporting system.

Reply:

The European Commission has undertaken an impact assessment on possible transparency measures on nanomaterials (available on http://ec.europa.eu/DocsRoom/documents/20427) and come to the conclusion that an EU reporting scheme on nanomaterials would not be justified taking into account its costs and benefits. This is because nanomaterials are very widespread in the economy, and there are no indications for the majority of nanomaterials of risks that would require urgent action or full information on all products containing nanomaterials. Rather, the European Commission prefers a combination of clarifying information requirements for nanomaterials in the REACH Annexes and the set-up of a European Union Observatory on Nanomaterials (EU-ON) at the European Chemicals Agency (ECHA), that will be formally launched in summer this year (a delegation agreement with ECHA was signed on 7 December 2016). This is without prejudice to initiatives at the level of Member States which may take their own actions, provided they are compatible with EU Internal Market rules.

17.6. Biocide Product Regulation

The BRT asks the authorities of the EU to evaluate, in due course, the effectiveness of measures for treated articles under the Biocide Product Regulation (BPR) in reducing the risks posed to humans, animals and the environment by biocidal products, and ensure that such measures are fit for purpose.

As the BPR is conceptual and not necessarily easy to understand, the BRT asks the authorities of the EU to issue a practical and easy-to-understand FAQs for the importers of active substance, biocide products or treated articles which illustrate proper procedures for actual cases.

Reply:
In relation with the provisions on treated articles in the Biocides Products Regulation (EU) No 528/2012 , some guidance exists and have been developed with Member States and stakeholders representatives. The guidance gives general elements to be considered by economic operators and a case-by-case assessment must be made by them for each treated article they place on the EU market. Information is also made publicly accessible to all stakeholders on the European Chemicals' Agency website (https://echa.europa.eu/regulations/biocidal-products-regulation) in order to facilitate the compliance of EU and non-EU economic operators, like the list of active substance which may be used in treated articles.
An assessment of the pros and cons of the provisions on treated articles was made at the time of elaboration of the measures in the proposal for the Biocidal Product Regulation in 2009 (proposal COM(2009) 267 final and document SEC(2009) 773 final), and it was considered by EU Council and the EU Parliament that the measures on treated articles are needed in particular to ensure safety for human, animal health and the environment in the EU, looking at the inherent hazardous properties of biocidal products and intoxications or impacts to the environment identified in the past. The Biocidal Product Regulation only entered into application in 2013, and part of the measures on treated articles entered into application only on 1st March 2017. An assessment of the effectiveness and efficiency of the provisions on treated articles would be done in due course when experience will be acquired on the implementation of the Biocidal Products Regulation as a whole, and when the legislation will have to be reviewed.

WP-1 / # 18** / J to E Resource Efficiency Policy

18.1 Circular Economy

The BRT would like to stress the need for a greater harmonisation and simplification of existing legislation and policies at EU level to overcome barriers posed by diverging interpretation and implementation at Member State level. In this context, consistent definitions of waste and end-of-waste criteria would be needed in order to ensure free movement of secondary raw materials within Europe or globally. In particular, the BRT requests the authorities of the EU to closely monitor national implementation of such criteria in order to identify potential barriers to the Circular Economy.
BRT represents industries with highly complex and global supply chains. The authorities of the EU and Japan should keep this in mind and therefore contribute to regulatory harmonisation at global level. Such harmonisation can be achieved through the development of technical standards in line with ISO standards and help industry to better implement circular models in the supply chain whilst creating a level playing field for all market actors. In parallel, the authorities of the EU and Japan should consider incentives for manufacturers to increase the use of recycled materials in products and for producers of secondary raw materials to provide them in higher quality and quantity. These would be necessary steps for the creation of a global and functional secondary raw materials market.

Reply:
Identifying potential incoherencies and hurdles at the interface of EU legislation on waste, chemicals, and products, or in their implementation is essential to achieve a smooth transition to a more circular economy, where the value of products, materials and resources is maintained in the economy for as long as possible, and the generation of waste is minimised. Before the end of 2017 the Commission intends to deliver a Communication with policy options to address the main problems at the chemicals, product and waste interface that will have been identified by then. This document will then be subjected to public consultation before final decisions are taken.

On 27 January the Commission published a roadmap on the intended work related to the chemicals, products and waste interface which was open for consultation until 28 March 2017. The initiative will address the traceability of substances of concern in products and their presence in recycled materials, as well as difficulties in the application of EU waste legislation. Four issues have been identified hindering the transition of recycled materials from waste to new products:
(1) Insufficient information about substances of concern in products and waste;
(2) Presence of substances of concern in recycled materials and in articles made thereof;
(3) Uncertainties about how materials can cease to be waste;
(4) Difficulties in applying and implementing EU waste classification methodologies and impacts on the recyclability of materials.
The European Commission would like to invite the BRT to submit its views on the issues identified in the Roadmap.

18.2 Ecodesign Product Lots

The BRT asks the authorities of the EU to uphold the Energy Related Products (ErP) principle of setting Minimum Energy Performance Standard (MEPS) at the level of Least Life Cycle Cost (LLCC) so that consumers can buy affordable and efficient products.
The BRT also asks that the authorities of the EU should carry out comprehensive impact assessments before deciding to include components integrated into products into the ErP product Lots scope and hence avoid inefficient "double" regulation measures. It is essential that optimum efficiency is pursued at the level of the final product not at the component level where there are no tangible benefits to the consumers.
The BRT suggests that "repair as produced" principle should be applied to spare parts under ErP as it is the case in the RoHS Directive In order to avoid disposing off usable parts prematurely and considering the resource efficiency aspects.

Reply*:*
The EC welcomes the recommendations on Ecodesign policy and reassures the BRT that the least life cycle cost principle is enshrined in the EU framework legislation guiding the establishment of product specific measures. The question of the apparent double regulation for some products has been discussed at length with EU based as well as Japanese manufacturers. The EC considers that there are no effective ways to exempt products from applicable regulations, which are supposed to be used as components within other products also regulated under the Ecodesign Directive, while agreeing to the fact that energy efficiency should be optimised at the level of final products. Every proposed Ecodesign regulation is subject to an impact assessment before it is accepted by the EU co-legislators.

18.3 Energy Labelling

With respect to the ongoing Energy Labelling directive revision, the BRT urges the authorities of the EU to avoid leaving the top energy classes empty as this will confuse consumers and discourage innovation on the producers' side to come up with more energy efficient products. The rules for rescaling the energy label should also be tailored to the characteristics of the products in scope and generally speaking should only take place when more than 50% of products on the market move to the top classes. The BRT also cautions against setting a costly database for products' information as this will not substitute market surveillance in each Member State and risks that confidential data are leaked to third parties.

Reply:
The proposed revision of the Energy Labelling Directive into a Regulation has been discussed extensively by the EU co-legislators, as well as with stakeholders. The prevailing view to deal with saturated top energy classes is that the least bad solution is to leave the two top classes empty at the time of rescaling. Based on this principle, clear rules for the

rescaling of existing Energy Labels have now been agreed by the European Institutions. Equally, it has been considered that the benefits of implementing a product database, in terms of more effective market surveillance, outweigh the potential initial costs for affected economic operators.

WP-1 / # 19** / J to E Taxation

19.1 Common Consolidated Corporate Tax Base

Reply
In October 2016, the Commission proposed the re-launch of the CCCTB through a two-step process. Member States should negotiate and agree the common base first, before converging on the consolidation element. The new proposal makes the CCCTB mandatory for all multinationals with a turnover of more than €750 million, to ensure that it covers companies with the greatest tax planning capacity. It also includes new growth-friendly elements, such as incentives for Research and Development and equity financing. As such, the CCCTB offers the advantages of being a simple, stable and robust corporate tax system for the entire EU, that would benefit both EU and non-EU businesses operating in the Single Market. Member States have now started to negotiations on the common base.

19.2 Merger Directive

Reply
After the publication of the Company Tax Study and the accompanying Communication, COM (2001)581, the Council adopted a new recast of the Directive concerning indirect taxes on the raising of capital (Council Directive 2007/7/EC of 12 February 2008) whose article 6 provides that the Member States may charge transfer duties on the transfer of immovable property situated within their territory.
Concerning the request by some Member States to hold shares received in exchange for an asset contribution during a number of years, the Commission services have not received any individual complaint raising this issue as a potential infringement to the Merger Directive and there has not been any case before the European Court of Justice about it. In any case, any company may introduce such a complaint and request our services to consider the case under EU Law.
Finally, the risk of double taxation on dividends paid by European subsidiaries to Japanese parent companies is an issue outside the competence of the EU Institutions and should be ruled by the bilateral relations between the concerned EU Member State and Japan.

19.3 The fundamental reforms of VAT regime under consideration
The BRT welcomes the strategy of the European Commission to fundamentally revise the VAT system and to establish a simpler, more efficient and robust VAT system tailored to the single market as described in Com (2011) 851. The BRT also welcomes the publication by the Commission of options for simpler and more robust future VAT regime. Furthermore the European Commission announced in its Work Programme 2016 to publish a Communication setting out the definitive VAT regime.
The BRT hopes that the new regime will be realised swiftly and in such a way that a business group could easily and cost effectively centralise VAT administration in the EU.

Reply
-The Commission will present a proposal for a VAT definitive regime in September this year.
-Under the definitive system proposed taxable persons will have to register only in the Member State in which they are established and will have to comply with their tax obligations only in that Member State. A One Stop Shop mechanism will be put in place that

will allow taxable persons to pay, in the Member State where they are established, the VAT due in other Member State. This will reduce considerably the complexity of the current VAT system and the costs for taxable persons.
-Since the definitive regime will require several years to enter into force, the proposal will further introduce certain harmonization and simplification provisions regarding the current VAT system. The aim is to make sure that Member State apply rules uniformly regarding certain transactions for which at present different practices are followed. That will reduce the risks currently experienced by businesses trading in different Member State.

19.4 Country by country reporting (CBCR)

Reply
BRT recommends that information on a country-by-country basis should be exchanged between tax administrations (as recommended by the OECD in BEPS Action 13 and implemented in the EU via DAC4) but not be published. The Commission argues that the purpose of public and non-public CBCR is different:
The Commission takes the view that transparency in this area should go beyond the exchange of information between tax administrations. Public reporting does not serve the same purpose as information sharing and reporting between tax authorities. According to the proposal for public CBCR EU tax authorities will receive more details and more granular data for all third countries in which an EU company is active than the public.
When it comes to public disclosure, it is important that EU citizens get information about where in the EU companies are paying taxes. The ultimate aim of public country-by-country reporting is to enable public scrutiny on multinational companies' tax strategies. This is different from the aim of the exchange of information between tax authorities, which need to enter into the details of compliance with tax laws and potential business secrets. That is why it would not be appropriate to require exactly the same set of comprehensive information submitted by multinational companies to their tax authorities. Moreover, following the consensus developed within the G20, tax administrations are bound by their commitment to keep some parts of this information confidential, as they contain business secrets. The Commission proposal on public CBCR should therefore be seen as an initiative that has a different purpose than the OECD recommendation.

Background:
The Commission proposed a public Country-by-Country Reporting (CBCR) by any big multinational company operating in the EU on 12 April 2016. The European Commission proposes an amendment to the Accounting Directive to introduce a public country-by-country reporting requirement for very large (i.e. turnover >€750 million) EU multinational enterprises, and non-EU multinational enterprises operating in the EU.
This reporting would be made available on a public website and filed within business registers. The information to be disclosed by them on a country-by-country basis would include income tax paid and accrued as well as the nature of activities, number of employees, turnover and profit before tax. The information would be given for each EU Member State and each tax haven where the group has operations, and aggregated as regards non-EU operations.
For multinational group established in a third country, the obligation would impinge on its major subsidiaries / branches in the EU to ensure that an EU subsidiary/branch publishes it on behalf of the ultimate parent, unless that parent posts its CBCR on its web site. EU banks will continue to publish the CBCR in accordance with CRD4 – the content of which is more detailed than, but not so far from this proposal.
The proposal is unlikely to be agreed this year. In the European Parliament, a joint opinion at ECON and JURI level is expected mid June 2017. The rapporteurs propose to reduce the size threshold below €750m in order to bring more companies in the scope. They strongly support the full disaggregation of information per each tax jurisdiction whereas the Commission proposed, for various reasons, an aggregation of data ad regards third countries.

Council also lacks a position to start trilogues at the moment. The Council legal service gave a negative opinion on the legal base of the proposal i.e. Article 50 TFEU requiring qualified majority. It is unlikely that Member States will unanimously agree to change the legal base that requires unanimity (Article 115 TFEU), and yet there is currently no qualified majority to accept the Presidency compromise on the proposal (DE). The Commission and the EP defend the proposed legal basis.

WP-1 / # 20** / J to E Company Law / Corporate social responsibility

20.1 A new strategy on CSR Policy

Concerning a new strategy on CSR policy that the European Commission is currently updating, the BRT recommends as follows:

(1) Highlight innovation: The European Commission should articulate the proactive nature of CSR that leads to innovation and opportunities.

(2) Take a flexible, principle-based approach: The European Commission should take a "principle-based" approach for evaluation and reporting. This approach will allow each company to meaningfully express their business in a dynamic and changing environment.

(3) Build an open platform: The European Commission should take a proactive role in creating an open platform.

(4) Create incentives to foster leadership for change: The European Commission should create incentives for companies that take leadership in identifying, preventing and mitigating the negative impact of businesses

(5) Articulate policy linkages across the European Institutions

Reply:

On the basis of the main principles and policy approach of the 2011 EU CSR Strategy, the Commission is currently intensifying its work on the effective implementation of a number of voluntary and legislative initiatives included in such Strategy, in particular the Non-Financial Information Disclosure Directive and the revised Public Procurement ones. Furthermore, some more recent and innovative measures in this area have just been adopted, like the Shareholders Rights Directive, or will be adopted soon, like the Conflict Minerals Regulation.

The Commission continues to encourage EU Member States to adopt National Action Plans on Corporate Social Responsibility and on Business and Human Rights.

Two important and strategic Communications have been adopted last autumn by the Commission on the Sustainable Development Goals (SDGs)/2030 Sustainability Agenda and on the Capital Markets Union.

As foreseen in the SDGs Communication of November 2016, a Multi-Stakeholder Platform is being established by the Commission, under the Chairmanship of FVP Timmermans. It will ensure, in a shared responsibility effort, a comprehensive monitoring of the implementation of this ambitious agenda by the EU, its Member States and the private stakeholders (business, Trade Unions, Civil Society NGOs and Academia). This Platform will develop an improved coordination and cooperation between all these public and private stakeholders for the implementation of EU legislation, programmes and policy initiatives in the sustainability field.

At the last November 2016 meeting of the WG on CSR in the framework of the EU/Japan Business Dialogue, the Japanese government and Commission services showed great openness, willingness and support for strengthening cooperation on matters governing CSR/responsible business conduct in the framework of the global agendas, such as the Sustainable Development Goals.

Both the EU and Japan share common goals and challenges relating to CSR/responsible business conduct. Both parties agreed for next meetings of the CSR WG to focus on more concrete issues such as sustainable investment, business and human rights, including sharing

good practices on both, and the promotion of public/private partnerships, governments and businesses sharing the same goals.

20.2 Conflict minerals

The BRT acknowledges that the proposal for a Regulation has taken up certain feedback from businesses such as the promotion of internationally recognised frameworks, the voluntary approach of self-certification and the publication of a list of responsible smelters and refiners. The BRT also acknowledges that two expert groups have been formed to define the list of minerals and metals within the scope of the Regulation and to clarify the meaning of conflict and high risk areas. The BRT requests that their work should be carried out in a transparent manner.

Without a well-established traceability scheme such as the iTSCi (ITRI Tin Supply Chain Initiative), it would be extremely difficult to implement the conflict-free accreditation for smelters. The BRT thus requests that hasty expansion of the geographical scope without reliable implementation of the existing traceability scheme should be avoided.

In order to effectively stimulate responsible sourcing, The BRT suggests that incentives focusing on upstream operations should be further considered. Concentrating on upstream supply chain operators and on facilitating the transmission of quality information in the supply chain leverages the appropriate point in the supply chain, is consistent with the OECD guidance and with industry initiative. Beyond the pinch point of smelters/refiners, it becomes exponentially more difficult to identify the origins of metals.

The BRT further requests that clear criteria for the certification of Responsible Importers, Smelters and Refiners should be set under a reliable, well-governed and functioning certification system. In order to avoid confusion in certifying importers, the BRT calls for the EU to set clear criteria for importers to become 'responsible'. Such criteria should make use of the existing criteria such as CFSI (Conflict Free Sourcing Initiative)'s Conflict Free Smelter Program and LBMA (London Bullion Market Association).

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

Reply:

The European Commission takes note of the EU-Japan Business Roundtable's recommendations on Conflict Minerals.

The EU Regulation on Conflict Minerals has now been adopted by the European Parliament and the Council, and will enter into force in June 2017.

As set out in the Regulation, the European Commission is currently drafting a handbook for economic operators explaining how best to apply the criteria for the identification of conflict-affected and high-risk areas. During this process, the European Commission is consulting relevant stakeholders, as well as Member States experts. The Commission will also call upon external expertise to provide an indicative, non-exhaustive, regularly updated list of conflict-affected and high-risk areas based on the external experts' analysis of the Handbook and existing information of, inter alia, academics and supply chain due diligence schemes.

Regarding existing industry initiatives on responsible sourcing, such as those of the iTSCi, CFSI and LBMA, the EU Regulation will recognize existing industry schemes which are aligned with the OECD Due Diligence guidelines. This will allow us to benefit from the work of these relevant industry associations.

Concerning the incentives set out in the Joint Communication, the new Public Procurement Directive allows for the use of social and ethical selection criteria. We are looking into the use of such criteria to use this instrument for the European Commission's purchases of, for instance, computers or other IT equipment.

20.3 Non-financial disclosure

Concerning the non-binding guidelines for the reporting of non-financial information under the Directive 2014/95/EU on disclosure of non-financial and diversity information by certain large undertakings and groups, the BRT recommends as follows:

1. Be flexible and principle-based

Non-financial reports are a vital communication tool when reporting company retain ownership in determining whom it intends to tell and what is material. Materiality differs for each company, depending on the nature of business, the perspective of top management and corporate culture. Due to the subjective character of materiality, the imposition of a specific and harmonised KPIs does not accurately reflect the ongoing efforts of companies faced with complex challenges at a local level. Therefore, a principle-based approach is the only viable way for companies to meaningfully express their business in a dynamic and changing environment.

2. Emphasise on dialogue

The guidelines should recognise dialogue as equally valuable means for companies to strengthen the trust of their investors and stakeholders, and leverage the improvements of companies' internal practices by making it part of the PDCA management cycle. Dialogue is a powerful tool to foster a culture of risk management and innovation, whereby companies can exchange views on potential future risks as well as explore collaborative opportunities. Many private initiatives are in the making at the international level to forge cost effective and meaningful collaborative dialogues.

3. Foster innovation and growth

Global companies are motivated to integrate CSR into daily business to become more innovative and competitive in the global context. Such innovation is fostered through open exchanges among stakeholders, partner countries or regions, governments and suppliers. From this perspective, the guidelines should not push for compliance mind-set, but foster meaningful channels for companies and investors to discuss value creating processes.

4. Promote existing international reporting frameworks

The EU should promote internationally recognised frameworks that take a process based approach, therefore give companies enough flexibility to take meaningful actions without becoming an outcomes based tick-box exercise. Such frameworks include the UN Guiding Principles on Business and Human Rights and OECD Due Diligence Guidance.

Reply:

The Directive on disclosure of non-financial information (2014/95/EU) requires around 6000 large companies listed in EU markets, or operating in the banking and insurance sectors, to disclose relevant environmental and social information in their management report, with the first reports to be published in 2018 (on financial year 2017). The Directive requires as well the Commission to prepare non-binding guidelines on methodology for reporting non-financial information.

The Commission services have taken note of your recommendations.

These guidelines are being developed on the basis of extensive public consultation, including:

- A public consultation conducted in the spring of 2016 (355 responses);
- 16 interviews with experts in the non-financial reporting field over the summer 2016;
- Two stakeholders' workshops organised in September 2016 and February 2017, each attended by around 80 stakeholders;
- An exchange with the High Level Expert Group on Sustainable Finance in January 2017.

The non-binding guidelines will be adopted by the Commission by the end of Q2 2017.

20.4 Responsible Supply Chain Management

The BRT welcomes the European Commission's commitment to support the implementation of internationally recognised frameworks such as the UN Guiding Principles on Business and Human Rights.

The BRT suggests that the authorities of the EU should take the following approach:

1) It ensures flexibility as well as global harmonisation;

2) It is compatible and does not conflict with existing initiatives and legal instruments not only in the EU but also in other regions;

3) It does not create unnecessary administrative burden and incur supplementary costs for companies which are not effective in solving the fundamental problem; and

4) It is globally comprehensive and encourages all governments (not only national but also local governments), business, and civil society to foster responsible supply chains.

Reply:

The European Commission is advancing on responsible supply chains through different external and internal EU policies - using a so-called 'smart mix approach'. As mentioned above, the Commission has introduced recent legislations such as the new provisions on public procurement which focus on environmental and social considerations and the non-financial disclosure Directive which requires large companies to disclose information on policies, results and risks concerning environmental aspects, social and employee-related matters, respect for human rights, anti-corruption and bribery issues.

The Commission has also developed capacity-building and outreach programmes to help developing countries and all relevant stakeholders address sustainability challenges. This is done both in the context of the EU international cooperation policies as well as in support of its trade agenda.

The Commission is engaged in several dialogues with producing countries and other partners to continue to encourage public authorities and relevant actors to address responsible supply chains issues.

WP-1 / # 21** / J to E Product Safety/Market Surveillance

21.1 Product safety and market surveillance package proposal

The BRT recommends that the authorities of the EU should amend the Article 7 of the proposal for a Regulation on consumer product safety (COM(2013) 78) by which the indication of the country of origin would become mandatory because according to the final report on the 'Implementation of the New Regulation on Market Surveillance: Indication of Origin' dated 6 May 2015, the mandatory indication of the country of origin does not add much value. The BRT believes that the mandatory indication of the country of origin would not necessarily improve safety for consumers but that it would place substantial administrative burden on manufacturers and/or importers. The BRT therefore believes the mandatory indication of the country of origin should not be included in the Package.

Reply:

The indication of the country of origin is expected to usefully supplement the basic traceability requirements and therefore to facilitate the task of market surveillance authorities in tracing the product back to the real place of manufacture.

21.2 Market Surveillance under the New Legislative Framework

The BRT supports the general direction the European Commission and the Member States are taking for harmonising market surveillance. This is an important step for fair movement of products. The BRT requests the European Commission and the Member States to disclose all the relevant information regarding the progress of this process and

the implementation of the market surveillance in each Member State. The BRT also requests the European Commission and the Member States to give industry an opportunity for contributing to developing the framework of harmonised market surveillance.
The BRT would like to thank the Directorate General of the European Commission concerned for the involvement of the industry and requests that it should continue to consult stakeholders widely – preferably through public consultation when draft guidance for the New Legislative Framework is ready.

Reply:
Updated guidance on the new legislative framework and the implementation of EU product rules (the so-called 'Blue Guide') has been issued in July 2016 and is available at: http://ec.europa.eu/DocsRoom/documents/18027/
In the context of the fourth priority policy areas to be tackled under President Juncker's Agenda for Jobs, Growth, Fairness and Democratic Change, i.e. a deeper and fairer internal market with a strengthened industrial base, the Single Market Strategy, Upgrading the Single Market: more opportunities for people and business, adopted by the Commission on 28 October 2015, envisages measures to be taken to ensure a culture of compliance and smart enforcement to help deliver a true Single Market.

The Commission will launch a comprehensive set of actions to further enhance efforts to promote compliance and to keep non-compliant products from the EU market by strengthening market surveillance and providing the right incentives to economic operators - 'Internal Market for Goods - Enforcement and Compliance' initiative. The general objective of this initiative is to improve the functioning of the Single Market and to achieve a higher level of consumer protection through the reduction of the number of non-compliant products on the EU Single Market, while the specific objectives are: (a) Facilitating compliance on the single EU market for products, in particular by helping businesses to comply with EU legislation on non-food products and exploiting digital technologies; and (b) Detecting and taking action against non-compliant products, in particular by allowing market surveillance authorities to more effectively detect and punish non-compliance by those businesses unwilling to abide by the rules, to deter businesses from evading the rules, and hence to establish a level playing field and fair competition between economic operators.
The inception impact assessment report of this initiative has been published in May 2016, and an online public consultation conducted in the period from June to October 2016. The Commission is currently preparing the full impact assessment which will be followed by a proposal before the end of 2017.

21.3 Consumer protection

Reply
On 23 May 2017, the Commission adopted the report on the "Fitness Check of EU consumer and marketing law" as well as on the evaluation of the Consumer Rights Directive 2011/83/EU. Both reports are publicly available under the following link: http://ec.europa.eu/newsroom/just/item-detail.cfm?item_id=59332.

With regard to Directive 1999/44/EC on certain aspects of the sale of consumer goods and associated guarantees, the Commission adopted on 9 December 2015 a proposal for a directive on online and distance sales of goods (COM/2015/635) which proposes to introduce fully harmonised rules on legal guarantees for the online sector (with a legal guarantee period of 2 years). On this point, the Fitness Check evaluation confirms the need coherent rules applicable to both the online and offline sales, as is the case under the current Directive 1999/44/EC. The Commission is assisting Parliament and the Council in their discussion on possibly expanding the scope of its December 2015 proposal to cover all sales channels.

WP-1 / # 22** / J to E Access of third countries goods and services to the EU's Procurement Market

Concerning the amended proposal for a Regulation on the access of third-county goods and services to the Union's internal market in public procurement COM(2016) 34, and any other public procurement related legislation, the BRT recommends the following:

1. Non-legislative policy measures should be pursued in order to achieve the objective of opening procurement markets internationally;

Reply:
In its impact assessment on the proposal for a regulation 'International procurement instrument', 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. However, the EU believes that ultimately, negotiations and dialogues with third countries remain the preferred option to ensure reciprocal market openness.

2. An effective mechanism to prevent the EU from arbitrarily excluding third-country goods and services from its procurement market and to ensure legal stability and predictability for businesses should be incorporated into the legislation;

Reply:
The amended Commission proposal does not provides for an exclusion of third country bidders but provides for price adjustment measures in the evaluation process of the tenders of products and services originating in targeted third countries. In addition, in the revised proposal, the decentralised pillar, i.e. the possibility for a contracting authority to decide autonomously on the application of restrictive measures, has been deleted.

3. Clear and transparent criteria for the scope and conditions of the application of the legislation based on an appropriate and balanced analysis should be included in the legislation.

Reply:
In the revised proposal, price adjustment measures would be limited, reasoned and based on the existence of restrictive and discriminatory policies and practices in the access to the procurement market of the third country concerned. Where the EU has concluded an international agreement on public procurement, the adoption of price adjustment measures would only be possible where the goods and services concerned are subject to a specific market access reservation. Price adjustment measures would be adopted following a Commission investigation and consultations with the targeted third country. The finding of the Commission investigation shall be made publicly available.

4. Furthermore, the authorities of the EU and its Member States should increase their efforts to facilitate better access to the respective public procurement markets. In particular:

- ***The authorities of the EU and its Member States should make more information available in English.***
- ***The use of English when submitting tender proposals should be allowed or at least partially allowed, especially for the technical specifications and communication.***

Reply:
A machine translation for all notices in Tender Electronic Daily (TED) is now available for free on line.

Working Party 2

Life Sciences and Biotechnologies, Healthcare and Well-being

Recommendations from both European and Japanese industries

General

WP-2 / # 01** / EJ to EJ Implementation of the Nagoya Protocol on Access to Genetic Resources and Benefit Sharing under coordination with industries

Reply:
"Following a wide and inclusive consultation process the Commission has issued guidance on the scope of application and core obligations of the Regulation http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A52016XC0827%2801%29

Healthcare

WP-2 / # 02** / EJ to EJ MRA of GMP for Pharmaceuticals
Further extension of the "Mutual Recognition Agreement" (MRA) of GMP should be proceeded in order to avoid redundant inspections of manufacturing facilities. In addition to oral dosage forms, API, Sterile and Biotechnology products are being requested to apply to the MRA. Full support is requested to expand the MRA of GMP to liquids, sterile forms and API, as well as biotech products in order to avoid redundant inspections and testing.

Reply:
In the area of pharmaceuticals, the expansion of the Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) to all Member States and its update to current legislation was adopted in May 2016. This was a milestone in enhancing the bilateral relations in this area. The inclusion of all Member States has been a longstanding objective of the EU. In terms of the expansion of the product scope of medicinal products, EU and Japanese medicinal authorities have reached an advanced state of agreement.
We are now entering into the phase of finalising the equivalence assessments by the regulators and the launch of the official procedure to finalise this agreement. This can be expected in the near future.

WP-2 / # 03** / EJ to EJ Mutual recognition of quality management audit results for medical devices between EU and Japan
The EU and Japanese governments should establish a mutual recognition scheme for Quality Management System (QMS) audit results. In June 2015, the Japanese government announced it would officially join the Medical Device Single Audit Program Pilot (MDSAP) to share QMS audit results between United States, Canada, Australia and Brazil. Improvement in efficiency and reduction of workloads for both authorities and the industry are expected. We call for a similar regulatory harmonisation approach between the EU and Japan for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical and Medical Device Act (J-PMD Act).
As a result of the implementation of the J-PMD Act in November 2014, the ISO13485 audit report is accepted for the QMS process in Japan. However, the Japanese original

requirement still remains. For a real regulatory harmonization, submission related formats / standards also need to be harmonized. We would like to request a clear direction towards a product-based and rationalized annual audit.
The EU side requests a complete harmonization by eliminating Japan's deviations on top of ISO13485. As a next step, mutual recognition of medical device products for lower risk classes should be introduced as soon as possible. Further improvements are desirable when introducing a new ISO revision. If the ISO revision differs per country (for example: ISO 60601 rev2 and rev3), the workload for manufacturers is very heavy. Therefore, the introduction schedule of new ISO standards should be harmonized, including a grace period. The EU side would also like to suggest the necessity of disseminating information on QMS ministerial ordinances in English, for the purpose of MDSAP rationalization of investigation pursuant to Chapter 3, Production and Marketing.

WP-2 / # 04** / EJ to EJ Mutual recognition of medical devices product licenses

Mutual recognition of medical device product licenses between the EU and Japan should be introduced. Regulations of low risk class II devices are similar in the EU and Japan. Therefore, mutual recognition of this category of products may be realized earlier. After a basic agreement on the Trans Pacific Partnership (TPP), the Japanese government is revising the law proceeding convergence of approval conditions of medical devices. A similar approach is needed between the EU and Japan. PMDA and MHLW should introduce mutual recognition of medical device product licenses with low risk of class II devices by taking the difference of classification of medical devices between Japan and the EU into account. By harmonizing QMS and classification it should be possible to introduce new products within the same time frame and in one process. It is desirable that this issue is solved quickly.
The EU will pursue MDR, but not enough information is communicated to Japan. We would like to suggest that the EU communicates with the Japanese government about the new MDR implementation.

Reply:
Regulatory cooperation between Japan and the EU in the medical devices area is well established both at bilateral level as well as at multilateral level via IMDRF (International Medical Device Regulators Forum). In IMDRF, Japan and the EU are key partners of specific working groups developing e.g. a uniform medical device identification system or defining a common table of contents for medical device regulatory submissions (a first step in defining a common data set).

The Medical Devices Single Audit Programme (MDSAP) Pilot, one of the working items of IMDRF, is intended to allow MDSAP recognized Auditing Organizations to conduct a single audit of a medical device manufacturer quality management system (QMS) that will satisfy the relevant requirements of the medical device regulatory authorities participating in the pilot program. In 2015, Japan joined the MDSAP adding to the original members United States, Canada, Australia and Brazil. The EU is participating as observer. Several EU notified bodies or their subsidiaries have been recognized as Auditing Organizations under MDSAP.
Under the existing EU legislation only audits conducted by Notified Bodies designated by EU Member States can be accepted. Certain tasks may be delegated by Notified Bodies to subcontractors but not the full quality management system (QMS) audit. Thus, EU recognition of audits carried out by MDSAP recognized auditing organisations not designated as EU Notified Bodies are currently not possible. Such situation shall not

change under the new two Regulations on medical and in-vitro diagnostic medical devices.

To achieve a reciprocal recognition of the quality management system (QMS audits) between Japan and the EU it would be necessary to align the legal requirements on the intensity and frequency of the regular and unannounced audits and the qualification requirements for the auditing personnel in both economic areas. Joint work to be done in the future by the two jurisdictions under the MDSAP within IMDRF could constitute a positive opportunity for further regulatory convergence and building of mutual trust, which is however only a pre-requisite amongst others for mutual recognition to work in practice.

Regarding the communication with the Japanese government, in July 2015 DG GROW exchanged letters with the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) of Japan establishing a confidentiality arrangement to exchange regulatory information including advanced drafts of legislation and/or regulatory guidance documents as well as information related to the authorisation and supervision of medical devices. The Commission services have regular exchanges with PMDA both bilaterally and in the multilateral IMDRF context.

WP-2 / #05** / EJ to E Mutual recognition of clinical trial results for medical devices

Mutual recognition of clinical trial results for the development of new medical devices should be accelerated. At present, the standards of clinical trials in the United States, EU and Japan are seen to be almost equivalent and there are several cases where clinical trial results are mutually recognized between EU and Japan. EU Japan BRT members request to both governments in the EU and Japan to accelerate mutual recognition of clinical trial results by increasing such cases and showing clinical trial conductors implementing guidelines.

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

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

Japan GCP (J-GCP) has been harmonized with ISO14155, but the EU side requests Japan to improve the actual operation of J-GCP. The clinical trials performed in EU countries according to ISO 14155 should be easily accepted and if not accepted, an explanation with a scientific background is a must. In addition, the Japanese government should prepare a clear definition for accepting/preparing clinical trial reports.

While the harmonization between GCP and ISO14155 for medical devices in Japan has made progress, we hope for early disclosure of a clear guidance for judgment on the need for clinical studies, conditions for acceptance, etc. in order to make the actual operation of GCP smoother. Regarding the guidance for the preparation of the

Clinical Evaluation Report, we request the Japanese Government to issue the guidance as early as possible.
We expect that the standard for deciding whether clinical trials are necessary or not will be clearly established. The Government should publish guidelines for creating clinical evaluation reports as soon as possible.

Reply:
In June 2016, the EU published the fourth revision of guidance 'Clinical evaluation: A Guide for Manufacturers and Notified Bodies under Directives 93/42/EEC and 90/385/EEC (MEDDEV 2.7/1 revision 4)' . The guidance focuses much more on the applicability of the clinical data rather than its origin. In general foreign clinical data are accepted in the EU for conformity assessment by Notified Bodies if certain criteria are met, such as e.g. an analysis whether data generated outside the EU are transferable to the EU population.
It seems however, that factors such as differences in the population, local practice, and requirements in many jurisdictions around the world often outweigh the possible benefits of reduced duplication of clinical trials. Similar to the issue of mutual recognition of quality management audit results (point 1 above) DG GROW therefore rather see this as an issue that could benefit from development of international principles in the multilateral IMDRF context.

<u>Plant protection and Biotechnology</u>

WP-2 / # 06** / EJ to EJ Shortening review times of plant protection & biotechnology products
Shorten review times for authorization to place novel plant protection products in the market and approval of importation of commodities treated with novel plant protection products and/or derived from biotechnology by the harmonization of safety dossier and risk assessment as well as streamlining the review process.

Reply
The issue of chemical Maximum Residue Levels (MRLs) has been addressed by the EU to Japan in the free trade agreement negotiations context.
The EU was requesting Japan to align with international standards for chemical MRLs and to set timelines for assessment.

Japan has informed of its current procedure as follows:
Japan has committed that when there is an existing international standard (Codex Alimentarius) applied to certain chemicals, Japan would not further require residue study data on crops if the theoretical Maximum Daily Intake does not exceed the ADI (acceptable daily intake). Concerning the timelines Japan undertook to review the times taken for the assessments and to notify in an administrative notice the normal evaluation times.
In case there would still be concerns and especially if Japan meanwhile would have required residue study data on crops in these cases where international standard exists, business is invited to be in contact with the Commission in order to flag it up to Japan and to see that the commitments are undertaken."

Animal Health

WP-2 / # 08* / EJ to EJ Mutual recognition of GMP and marketing authorization for animal health products
With regard to the mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products, MAFF and the European agency should accept GMP certification of the other party where the GMP requirements are similar or equivalent.

Reply
In the area of pharmaceuticals, the expansion of the Mutual Recognition Agreement (MRA) on Good Manufacturing Practices (GMP) to all Member States and its update to current legislation was adopted in May 2016. This was a milestone in enhancing the bilateral relations in this area. The inclusion of all Member States has been a longstanding objective of the EU. In terms of the expansion of the product scope of medicinal products, EU and Japanese medicinal authorities have reached an advanced state of agreement.
We are now entering into the phase of finalising the equivalence assessments by the regulators and the launch of the official procedure to finalise this agreement. This can be expected in the near future.

Healthcare

WP-2 / # 09** / EJ to E Evaluation of innovation values for pharmaceuticals in prices
The EU government should reinforce its innovation policy to member states and clarify its healthcare policy, resulting in the appropriate evaluation of the value of pharmaceuticals. If member states introduce healthcare technology assessment (HTA) for their reimbursement system, they should carefully adapt appropriate methods and processes so as not to impede patient access to new pharmaceuticals and discourage innovations.

Reply
In June 2016 the EU launched a new Joint Action which is financed under the Public Health Programme and foresees concrete steps towards improved cooperation of national HTA bodies. The Joint Action is called EUnetHTA 3 and runs until 2020. The aim of the Joint Action is inter alia to facilitate early dialogues on HTA between industry and HTA bodies, to carry out a significant number of HTA assessments jointly and to improve the quality of joint work. Efforts are also made to increase the uptake/use of joint work at national level.

In addition, in September the Commission launched a new initiative to prepare for improved HTA cooperation in Europe for the period beyond 2020 (ie when the current joint action comes to an end). This new initiative is mentioned in the Commission Work Programme for 2017 and the preparatory work for the initiative is ongoing. A public consultation was launched (currently the results are summarised in a report to be published in Q2 of 2017) and three studies are ongoing which will inform the impact assessment process. A proposal is currently expected for Q4 of 2017.

Animal Health

WP-2 / # 10 / EJ to E Introduction of "1-1-1 concept" for all animal health products*

Reply
As indicated in our reply last year, the European Commission published its draft proposal for a new Regulation on veterinary medicines in September 2014. The Commission included the proposal to widen the scope of the centralised procedure to include any type of product including generics of nationally authorised products should applicants wish to obtain a centralised marketing authorisation. The proposal is currently being discussed by Member States (MSs) and from the comments made thus far by both MSs and the European Parliament, no objection has been raised on this point. Once discussions have been finalised and the new regulation is in place, it would be for the applicants to decide whether to obtain a centralised authorisation valid across the EU or other routes of authorisation - thus going in the direction of the recommendation.

Plant Protection & Biotechnology

WP-2 / # 11 / EJ to E Maintenance of Import MRLs into the EU to allow free trade of food commodities*

Reply
Regulation (EC) No 1107/2009 concerning the placing of plant protection products on the market introduced hazard based criteria related to human health for the approval of active substances used in plant protection products. Following such "cut-off" criteria, active substances cannot be approved or renewed if they are classified as carcinogenic, genotoxic, toxic for reproduction or with endocrine disrupting properties following Regulation (EC) No 1272/2008, and if they do not benefit from the derogations for the compliance with these criteria.
Regulation (EC) No 396/2005 on maximum pesticide residues in food and feed allows for the setting of import tolerances even for substance not approved in the EU, on the condition that the risk to consumers is acceptable. This Regulation follows a risk assessment approach and does not mention the "cut-off" criteria since it was adopted before the approval of Regulation (EC) No 1107/2009.
The Commission is carefully considering the possible effects of the "cut off" criteria of the plant protection products legislation not only on the EU agricultural market but also vis-à-vis the EU's trading partners. The setting of import tolerance for active substance falling under the "cut-off" criteria will be considered on a case by case basis, keeping in mind the objectives of consumer protection of the pesticide legislation but also the EU's international obligations arising from the WTO Agreement on the Application of Sanitary and Phytosanitary Measures.
An evaluation process of the pesticides legislation (Regulation (EC) No 1107/2009 and Regulation (EC) No 396/2005) is planned in 2017 and will tackle this issue. Your comments and further additional inputs will be taken into account in the context of this evaluation via a comprehensive stakeholder consultation.

Working Party 3

Innovation, Information & Communication Technologies

Recommendations from both European and Japanese industries

WP-3 / # 01** / EJ to EJ Concerns on Emerging FLMs and Market Access Improvement in Third Countries

The BRT has serious concerns that some countries are implementing Forced Localization Measures (FLMs). Those measures could become a real threat to digital trade. Maintaining the business environment to realize an adequate "cross-border data flows" is imperative for multinational companies and for citizens who consume services offered by global players.

The BRT requests both sides' Authorities to lead global rule making by incorporating provisions to restrict digital protectionism such as FLMs into EPA negotiations respective parties are engaged or TiSA negotiation, and jointly approach the abolishment of such regulations.

Reply:

The European Commission shares concerns expressed by the EU-Japan Business Round Table. EU and Japan have met in 2016 to discuss those market issues with certain Third Countries. The G7 ICT Ministerial meeting held in Takamatsu adopted a Joint Declaration in which internet openness and cross-border information flows is promoted. The Joint Declaration explicitly oppose to "data localization requirements that are unjustifiable taking into account legitimate public policy objectives."

Similarly an EU-Japan Joint Press Statement was issued at the occasion of the CEBIT tradeshow in March 2017 in which the development of the data economy is encouraged "*including through the promotion of the free flow of information, taking fully into account the respective legislation and measures related to the protection of personal data*."

WP-3 / # 02 ** / EJ to EJ Balancing Privacy Protection and Innovation

Reply

As reflected in their 20 March 2017 Joint Press Statement, the EU and Japan have intensified their dialogue on data protection and data flows. In particular, they consider that the recent reforms of their respective privacy legislation offer new opportunities to further facilitate mutual data flows, including through finding an adequate level of protection.

WP-3 / # 03** / EJ to EJ Cybersecurity of Critical Infrastructure

The BRT welcomes the EU's adoption of the Network Information Security Directive. The Cybersecurity Basic Act was adopted in Japan, and the GoJ established the Cybersecurity Strategy Headquarters and National centre of Incident readiness and Strategy for Cybersecurity. The EU and Japan share their views on the importance of cybersecurity measures for critical infrastructure.

Cloud computing services, being digital services, are under the scope of the NIS Directive. Detailed provisions will be specified by EU Member States. As there are several types of service provision of cloud operators, the BRT asks the Commission to encourage EU Member States to release obligations for operators.

International cooperation is effective in coping with high-level attacks. The BRT requests to actively conduct educational activities such as public-private joint seminars. A sharing scheme should be created between the national contact points designated in each Member States based on the NIS directive on the one hand and Japan on the other hand.
The BRT also requests that both sides' Authorities enhance the quality and volume of human talent in the cybersecurity area.

Reply:
Requested information on detailed provision for cloud computing services will be provided when EU Member States have transposed the NIS Directive into national law, i.e. secondary legislation. EU Member States have until May 2018 to do so.
The European Commission welcomes EU-Japan Business Round Table recommendations for actively conducting educational activities such as public-private joint seminars, sharing scheme between EU and Japan national contact points and enhancing quality and volume of human talent in the cybersecurity area. These proposals should be considered at the occasion of the coming EU-Japan Dialogues.

WP-3 / # 04 / EJ to EJ Fundamental Reform of the Private Copying Levy System (Compensation System for Private Copying)
The EU and Japan should cooperate to thoroughly reform the private copying levy system taking into account the evolution of technology and distribution channels for lawful digital contents. Expansion of the current levy system to new devices or cloud services should be avoided prior to the fundamental reform of the system.
Any review for reform should consider, in a comprehensive manner, alternative methods – including new content distribution practices – available to secure compensation for rights' holders and creators from private copying as well as the development of licensed cloud-based content streaming models. Increasing the availability of lawful digital content will require a reform of the existing copyright regime in the EU as well as in Japan. The aim of the reform should be to promote open and competitive markets in licensed digital content, with the aim to increase availability of more legitimate digital content, at prices which appeal to consumers and hereby promote innovation and growth of digital creative market. The goal should be to enable the establishment of a system which is transparent and fair to consumers, rights holders, service and equipment providers, etc.

Reply:
The European Commission has recognised in the Copyright Communication (10 December 2015 – COM (2015) 626) that national levies' systems may create obstacles to the Single Market. Some issues have been mentioned (link between compensation and harm to right holders, relation between contractual agreements and sharing of levies, double payments, transparency towards consumers…) but there is no decision whether any action is to be taken. It is to be expected though that if anything is to be done, it will remain limited to specific issues raised and not be an overhaul of the whole levies system. The European Commission is also monitoring developments at national level and considers positively changes that take into account new realities and make use of licensing instead of levies which indeed are more appropriate in many cases where content is accessed and not owned.

WP-3 / # 05 / EJ to EJ Expansion of membership of Expanded ITA agreement

Reply:
The European Union implemented the results of the ITA-2 on July 1st 2016 as agreed in Nairobi. Implementation by Japan ran into considerable delays and was finally completed only in May 2017. Japan has now fully eliminated tariffs in the 6 tariff lines concerned. The EU implements the biggest tariff elimination (around €2 billion of duty is concerned) of all participants except China. This elimination of tariffs takes place according to a carefully negotiated schedule with staging periods of 3, 5 and 7 years. This schedule will not be renegotiated. However, for close to 80% of lines tariffs were fully eliminated already last year on 1 July. The EU works actively together with Japan to sign up more members for ITA-2. So far only Macao has joined the original participants and Georgia has indicated its intention to join, but a number of other countries have shown an interest in signing up.

WP-3 / # 06 / EJ to EJ Cooperation to Maintain an Open and Transparent Internet (Internet Governance)
The BRT highly appreciates that at the United Nation WSIS+10 High level meeting in December 2015, participants confirmed that an open and transparent online environment involving multiple stakeholders is effective, and agreed to extend IGF activities for 10 years and organize another high level meeting in 2025. However, there are different views on internet governance and differences are not resolved.
The BRT believes that the current mechanism is appropriate for the digital economy to contribute to the global economy, and requests the EU and Japan to continue cooperating for the maintenance of the multi-stakeholder system at all discussion occasions, for example at the meeting of United Nations Commission on Science and Technology for Development (UNCSTD) to be held in May 2016.

Reply:
The EU and Japan have a similar position on internet governance and continue to cooperate on this matter at various multilateral events. The coming DG CONNECT-MIC Dialogue on ICT should be held in October 2017 in Tokyo and should address, as one of its items, internet governance.

WP-3 / # 07 * / EJ to EJ Work towards International Standardisation at Joint R&D Programmes
Both sides' Authorities should specifically favour joint R&D programmes that are geared towards international standardisation such as standardisation in advanced manufacturing, the Internet of Things and Cybersecurity. Regulatory cooperation between the EU and Japan for facilitating digitalization will accelerate creation of innovation through the deployment of new services and products in both regions.

Reply:
The European Commission pays specific attention to standardisation issues in domains (IoT, cybersecurity, advanced manufacturing) mentioned by the EU-Japan BRT Recommendations and related joint research work between EU and Japan took place under the European Horizon 2020 programme.
In addition, at the CEBIT tradeshow on 20th March 2017, a Memorandum of Understanding for IoT industrial cooperation was signed between the Japanese IoT

Acceleration Consortium and the European Alliance for Internet of Things Innovation. Cooperation in standardization activities related to IoT is explicitly mentioned in the document.

WP-3 / # 08 * / EJ to EJ Sharing Vision and Roadmaps for a Better Coordination of R&D Projects/Programmes

To make the programmes even more effective to manage and accessible from the industry, the procedure for preparation, launch and evaluation of coordinated calls should be well discussed by both parties and standardised. Especially, transparency should be enhanced throughout the application and evaluation processes. Clearly mentioning correspondences between European and Japanese calls would greatly facilitate the identification of opportunities for cooperation. If possible, synchronized publication of such calls would be desirable. Both sides' Authorities should increase matchmaking activities between European and Japanese industry to find out common themes. The role of National Contact Points (NCP) should be reinforced. Japanese NCP should work more closely with European NCPs and both should coordinate their efforts. For sharing the vision and working on the common roadmaps, the industry-led activities of European Technology Platforms (ETPs) can be a model.

To increase participation in the respective R&D projects of each region, the BRT recommends authorities to promote the services offered by the National Contact Point in Japan for Horizon 2020 and other relevant instruments (including the EEN) to widely circulate R&D call notifications and support the formation of partnerships. The BRT hopes that initiatives under Horizon 2020 and Japan's 5th Science and Technology Basic Plan will lead to further EU-Japan strategic R&D cooperation.

Reply:

In Horizon 2020, 4 coordinated calls have been launched: 2 in Work Programme (WP) 2014-2015 in ICT and aeronautics, and 2 in WP 2016-2017, in the field of ICT and Health. Participants from the private sector have been active in these calls. The preparations and launch of the above-mentioned coordinated calls are in general always well discussed and coordinated between the EU and the Japanese counterpart. More coordinated calls are planned in WP 2018-2020.

Besides these co-ordinated calls, we implement in Horizon 2020 WP 2016-2017 a co-funding scheme with Japan's Science and Technology Agency (JST), which is applied in two call topics (NMBP-02-2016 – Advanced Materials for Power Electronics and NMPB-03-2016 – Innovative and sustainable materials solutions for the substitution of critical raw materials). These call topics have been discussed and agreed by authorities on both sides, and it is planned that the scheme will expand to other areas in Horizon 2020 WP 2018-2020.

An important instrument we have in our policy dialogue with Japan is the Joint Science and Technology Coordination Committee (JSTCC) under the framework of the EU-Japan S&T agreement, which are organised in average every 18 months. At these meetings, priorities for future cooperation between the EU and Japan are discussed. The third such meeting was in May 2015 in Brussels, and the next is planned in November 2017 in Tokyo. Since 2014, there have also been 3 EU-Japan Task Force meetings on S&T Cooperation. The 3rd Task Force meeting was held in Brussels in October 2016, where senior officials from Japanese authorities and the European Commission assessed cooperation achievements and discussed further S&T cooperation activities as a preparation for the next JSTCC meeting.

In the Commission's multiannual roadmap on S&T cooperation with Japan (the second was published in October 2016), we identify key priority areas in our R&I cooperation and other areas with potential for strengthened collaboration.
The Horizon 2020 NCP for Japan provides important activities and services in relation to the dissemination of opportunities offered by Horizon 2020 for Japanese researchers and research organisations, in order to strengthen cooperation between the EU and Japan in R&I, and to support the EU-Japan policy dialogue and coordination activities. We agree with the recommendation that these services are promoted in order to increase the participation in the respective R&D projects of each region. A new Service Facility has been launched in Horizon 2020 WP 2016-17 to support the strategic development of international cooperation in R&I. Services will include awareness raising and training activities to enhance international cooperation activities in Horizon 2020, support to NCPs and other multipliers, organisation of meetings and events, and analysis and monitoring activities.

Space

WP-3 / # 12 / EJ to EJ Regulatory Cooperation in Space Operations
Japanese and EU Authorities should use their new EU-Japan Space Policy Dialogue to discuss regulatory cooperation in space operations.

Reply
EU and Japan will indeed use the EU-Japan Space Policy Dialogue to advance cooperation in the field of space "

WP-3 / # 13 / EJ to EJ Mutual Backup of Government Satellite Launches
Japanese and EU Authorities should bring about a mutual backup cooperation scheme of government launches using Japanese and European launcher fleets.

Reply
As far as the commission is concerned, it is not envisaged any launcher cooperation with Japan in the context of Copernicus, and, for security reasons the launch of Galileo satellites must exclusively take place from EU territory.

Defence

WP-3 # 14 / EJ to EJ / EU -Japan Cooperation in Defence Equipment
Potentially momentous changes have been occurring in Japan's defence equipment sector. Cooperation between the Japanese and EU defence industries shows signs of budding as a result. Taking note of the fact that most of the progress being made is between Japan and individual EU Member States, we urge a steady continuation of this fruitful bilateral process while also recommending discussions between Japan and both the European Commission and the European Defence Agency.

WP-3 / # 18 / E to EJ Internationally Recognized Procurement Processes for Defence Equipment and Services

Reply*:*
The Commission welcomes the developing trade between the EU and Japan in the field of defence. Moves to strengthen industrial co-operation are important for both sides and it is also welcome that the bilateral discussions between Japan and Member States are leading to concrete results. However, in the area of defence the Commission does not have competence as external defence trade is largely a matter for Member States. Nevertheless, the Commission would examine options to provide support in this area if requested by Member States.

Railway
WP-3 / # 15 / EJ to EJ Railway Market Access
Both sides' authorities should continue their efforts to ensure that their commitments, such as on procurement transparency and non-discrimination, are fully implemented to result in much more tangible improvements in actual market access. Especially, both sides' authorities should establish their respective open description of compliance requirements as well as validation processes. The certification procedures for railway rolling stock and equipment should be made fully transparent to the interested parties of both sides and should be further simplified.
The BRT takes note that both sides' authorities are now discussing the removal of the Japanese operational safety clause from Japan's GPA Annex III as well as the EU's notes against Japan from the EU's GPA Annex III in the context of EU-Japan EPA/FTA negotiations.
In addition, the European Railway Agency and the Japanese Ministry of Land, Infrastructure, Transport and Tourism should look into the possibility of harmonizing their respective mandatory technical requirements by assessing the equivalence of these mandatory technical requirements.
The BRT believes that win-win solutions can be found through such development. This will help both the EU and Japanese railway operators to increase their capabilities to respond to their customers' expectations as well as both the EU and Japanese railway manufacturers to strengthen their competitiveness in and outside the two regions.

Reply:
The EU and Japan continue to explore concrete modalities to improve their regulatory cooperation on railways technical standards, in particular in view of possible recognition of equivalent mandatory technical requirements. The work of the Technical Expert Group with the participation of experts from both sides is focused on exploring the feasibility of such recognition.
The discussion on technical standards in the various areas of the railway sector continues to be held also in the EU-Japan Industrial Dialogue on Railways where both public authorities and private sector representatives participate.

Aeronotics

WP-3 / # 16** / E to EJ Weight Restrictions on Haneda Airport D Runway
Haneda D runway weight restrictions are an obstacle to the use of European-made aeroplanes and an obstacle to further development of international traffic at Haneda. These weight restrictions should be re-examined to allow the operations of new and larger airplanes such as Airbus-made A380 and A350. We request both sides' Authorities in charge to cooperate in making the necessary verifications. Additionally,

for the newest mid-size A350 aircraft, operation could be possible with the re-verification of the withstand load with regards to part of the construction.

Reply

We understand that the problem raised by the BRT has been solved in the meantime. However, we have been made aware of another problem related to the restriction imposed on A380 day-time operation at Haneda Airport which is based on a claim by JCAB that operating the A380 would reduce airport movements at peak times because of the wake vortex separations the aircraft imposes.

A new wake vortex separation standard has been certified by EASA (RECAT-EU) which reduces the A380 wake signature. JCAB should be encouraging airlines to use the A380 at Haneda through the implementation of RECAT-EU to increase movements and passenger throughput. The wake vortex restriction is only applied at Haneda Airport, but not at Toyo's second airport, Narita.

Haneda airport would welcome the A380. It has anticipated the adaptation of ground infrastructure with two A380 gates ready to host A380s. Runways and taxiways are also A380 compatible (so called Code F airport in ICAO terminology) and A380 taxi routing is even identified in the Airport official document (AIP).

As both Narita and Haneda airports are now reaching their capacity limit, allowing the A380 at Haneda during day time will ensure the most optimal use of slots in a congested environment.

For these reasons we understand that it is essential that RECAT-EU be implemented in Haneda, helping lifting the A380 restriction.

The Commission line is that this has been the object of demarches locally by the EU Authorities in Tokyo and has also been raised as part of the overall aviation dialogue between the DG MOVE and their Japanese counterparts. The Commission will continue to encourage work on this issue.

Working Party 4

Energy, Environment, Sustainable Growth

Recommendations from both European and Japanese industries

WP-4 / #01** / EJ to EJ Change and harmony in the areas of energy and the environment
Japan and the EU are committed to working together to stabilize resource prices and implement energy mix policies suitable for regional needs that will enable companies to continue their business activities in a stable manner.

WP-4 / # 02** / EJ to EJ Basic energy policies
Harmonization of supply stability, economic efficiency, the environment, and safety standards:
The governments of Japan and EU countries should carefully consider the resumption of nuclear power generation, which can be an effective measure for reducing greenhouse gas emissions.
Japan and the EU must promote a framework for a more comprehensive collaborative alliance from the viewpoints of energy and the environment.
Short-, medium-, and long-term energy strategies:
All of the countries participating in COP21 have affirmed their commitment to controlling carbon dioxide emissions as a countermeasure against global warming.
The key to this will be to balance economic growth with the reduction of CO2 emissions.
And while the decision to engage in global efforts to cut CO2 emissions was made at COP21, it will be essential to ensure that these efforts are paired with economic growth to make it possible to move forward with them in a sustainable manner.
Going forward, it will be important for governments, industries, and citizens to develop a solid understanding of the current energy situation and consider which changes are temporary or cyclical, and which are permanent. In addition, it will be necessary to determine what kinds of risks and chances are conceivable for the future, identify what can be done to make our energy systems more secure, reliable, and sustainable, and consider short-, medium-, and long-term energy strategies.
A multi-layered energy supply structure capable of functioning not only during times of peace but also in emergencies should be established.

To ensure the stable and adequate supply of energy, Japan and the EU must share best practices for the construction of an energy value chain capable of achieving the prescribed energy mix and consider the upgrading of old equipment and facilities to improve t

WP-4/#11*EJ to EJ Promotion of global investments and nurturing of long-term Relationships

Reply
In the frame of the implementation of the Energy Union Framework Strategy, the EU has developed an integrated view on energy security and the transition to the low-carbon economy. In this policy framework, the role of 'energy efficiency as an energy source in its own right' and of renewables for energy security is recognized, as well as the importance of secure gas supplies for the energy transition. The EU is committed to implement policies based on the objectives of this overall framework. As part of the external dimension of the Energy Union framework, The Directorate General "Energy"

(DG ENER) organises energy dialogues with major energy consuming and producing countries, with a view to support the Energy Union's objectives as well as to contribute to global energy supply security and price stability and to a positive international investment climate for the energy sector. To further these objectives, the European Commission DG ENER is also fully committed to work closely with Japan's METI and other international partners in the frame of multilateral organisations and fora.

WP-4/#03*/EJ to EJ Fossil fuels
Advantages and disadvantages of coal, oil, natural gas, and LP gas:
Japan and the EU should contribute to countermeasures against global warming by supporting the introduction of coal-fired thermal power characterized by high efficiency and low CO2 emissions, such as ultra-supercritical coal-fired power, and the development of new technologies, such as carbon capture and storage (CCS).

Reply
With respect to supporting the introduction of high efficiency coal-fired thermal power, the EU is committed to the OECD framework for export credit support for such power plants.

WP-4/#04**/EJ to EJ Nuclear power

Reply
While the Commission recognizes the importance of a well-balanced energy mix to address the challenges of decreasing the energy sector's environmental load and of ensuring stable supply at competitive rates, in the EU's institutional framework, decisions on the energy mix are the competence of EU Member states. As such, it is to the EU's Member States to decide whether nuclear power generation will be part of their energy mix. The EU is committed to ensure that, when and where nuclear power generation is deployed in its Member States, it is done in a safe and secure way. The EU wants to cooperate with Japan to internationally promote nuclear safety.

WP-4/#05**/EJ to EJ Renewable Energy
Renewable energy is expected to play a major role in countermeasures against global warming, and there have been recent signs of improvement in the cost aspect, which had been considered an issue against the use of renewable energy. At the same time, thorough discussions regarding the economic, efficiency, and stability aspects must also be continued.

Reply
The Commission would welcome close collaboration with Japan on storage batteries.

WP-4/#06**/EJ to EJ Effective use of biomass resources

Reply
Several streams of work from the COM relate to this recommendation:
- The COM proposal for a recast of the Renewable Energy Proposal (COM(2016) 767) adopted in Nov. 2016 and currently discussed in EP and Council, and its specific articles on bioenergy;
- The follow-up to the Circular Economy Action Plan, in particular as it relates to using biomass in its most efficient way, with the preparation of COM non-binding guidelines on biomass cascading use.
- the follow up work to the COM Bioeconomy Strategy (eg stakeholders panel, observatory) also touches upon the issues mentioned in the recommendation.

WP-4/#07**/EJ to EJ Energy conservation & energy efficiency

Reply
The recommendations of the BRT seem to take a rather conservative approach to the current and future role of renewable energy, of energy efficiency (although to a lesser extent) and of smart system management and to the energy transition in general. Its recommendations give the impression that it is not convinced about the enormous business opportunities that are entailed by the Paris agreement and the evolution to a low-carbon economy. The Commission has stressed these opportunities on the occasion of the publication of the 'Clean energy for all Europeans' package on 30 November 2016.
This shortcoming in the BRT's recommendations might be due to the composition of its energy sector group in which case it would be recommended that it would be reviewed to include all segments of the energy sector.

WP-4/#08*/EJ to EJ Energy research and international cooperation

Reply
Liquefied natural gas (LNG) is a crucial energy resource to Japan and of increasing importance to the EU in the light of its energy diversification and security policies. Internationally, important developments are taking place in the global LNG market, with implications/opportunities for EU and Japan business. LNG seems however to be absent in the BRT's recommendations.

WP-4/#09**/EJ to EJ Efforts toward the prevention of global warming following the Paris Agreement reached at COP21

Reply
The Paris Agreement established an enhanced transparency framework for climate action by countries as well as support provided and received. Work on a programme to decide on detailed rules implementing the Agreement are currently ongoing with the agreed aim of concluding in 2018. Fit for purpose transparency and accountability rules to help track progress against countries' commitments are a priority for the EU. The EU is also strongly engaged in establishing robust rules for international market mechanisms under Article 6 of the Paris Agreement (such as bilateral offset mechanisms), in particular to avoid double counting. The EU and Japan collaborate closely in the negotiations.

WP-4/#10*/EJ to EJ Promotion of resource efficiency and the circular Economy

Reply

"The Commission has given high priority to the transition to a Circular Economy and earlier this year reported on the implementation of its 2015 Circular Economy Package (http://ec.europa.eu/environment/circular-economy/implementation_report.pdf)

In the context of G7 the European Commission has been actively supporting work in the context of the G7 Resource Efficiency Alliance. In 2016 the European Commission actively contributed to the discussions leading to the adoption of the Toyama Framework on Material Cycles by the G7 Environment Ministers' Meeting. At bilateral level the issue of Resource Efficiency was discussed at the most recent EU-Japan High Level Dialogue (March 2017).