

Commission services replies

to the

**EU-Japan Business Round Table
Recommendations 2017**

Brussels, April 2018

Table of contents

	page
Working Party 1	3
Working Party 2	23
Working Party 3	28
Working Party 4	35

Working Party 1

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

Recommendations from both European and Japanese industries

WP-1 / 02 / EJ to EJ- Call for an ambitious WTO Ministerial Conference in Buenos Aires

Reply:

In 2017, preparations of the upcoming Ministerial Conference ("MC11" - Buenos Aires – December 2017) have featured prominently on the negotiations' agenda of the WTO. Despite the EU leadership with the submission of proposals in six areas of EU priorities and Members' interest (domestic support on agriculture, fisheries subsidies, e-commerce, domestic regulation in services, transparency and good regulatory practices on regulatory measures facilitating SME access to global and transparency on horizontal subsidies), WTO Members failed to agree on any negotiated result.

Remedying the situation will require to broaden approaches and inject new flexibility in Certain groups of Members have agreed to advance work on certain issues. New approaches must support the WTO and the multilateral trading system, including by working toward multilateral outcomes through a plurilateral negotiating process. While WTO Members agreed in Buenos Aires to conclude negotiations on fisheries subsidies by 2019, a flexible multilateralism approach should gain traction among Members on a number of issues, covering notably the unfinished work of MC11.

Complimenting this track and with the objective of developing multilateral rules that address today's global trade challenges, the EU together with Japan and the US launched in Buenos Aires on 12 December 2017 a trilateral initiative to enhance cooperation in the WTO and in other forums to ensure a global level playing field and eliminate unfair market distorting and protectionist practices by third countries.

2017 also marked the entry into force of the Trade Facilitation Agreement (TFA), an agreement concluded in Bali in 2013 at the 9th WTO Ministerial Conference and the most significant multilateral trade deal since the establishment of the WTO in 1995. This agreement aims to simplify and clarify international import and export procedures, customs formalities and transit requirements. It will make trade-related administration easier and less costly, thus helping to provide an important and much needed boost to global economic growth.

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

1. General recommendations

The BRT strongly supports the joint development and application of internationally harmonised technical requirements and procedures for the testing and approval of products that are traded internationally.

The BRT recommends the authorities of the EU and Japan to enhance their regulatory cooperation and to increase communication between the two economies. The aim is to eliminate barriers to trade and investment in order to promote business and to disseminate the experience of the EU and Japan to the rest of the world.

To this end, the BRT encourages the authorities of the EU and Japan to work together in the relevant fora to develop international product standards and certification procedures. The BRT recommends that the authorities of the EU and Japan should apply such standards in as many sectors as possible.

Where international standards have not yet been developed, the BRT urges the authorities of the EU and Japan, when possible, and appropriate, to accept the mutual approval of the import, sale or use of products that have been approved on the basis of functionally equivalent requirements.

Reply:

DG GROW and the Japanese Ministry of Economy, Trade and Industry (METI) established an Industrial Policy Dialogue (IPD) in 1998 as a forum for in-depth discussion on issues of mutual interest covering competitiveness and industrial policy in Europe and Japan. The working group (WG) on standards and conformity assessment

is meeting on a yearly basis to discuss topics of mutual interest. The 20th meeting of the WG on Standards and Conformity Assessment was held on 1 February 2017 in Brussels. Both sides exchanged information on the policy evolution in the areas of technical regulations, accreditation and standardisation, as well as on circular economy and standard essential patents. The parties confirmed the value of these exchanges in reducing regulatory differences.

Sector specific recommendations

2. Create a common chemicals regulation

Reply:

DG GROW and METI regularly meet under the framework of the EU-Japan Chemical Working Group of the EU-Japan Industrial Policy Dialogue. They discuss about changes and developments in the legislation in the two areas and explore ways to strengthen the cooperation in different areas.

4. Expand the benefits of AEOs

The authorities of the EU and Japan should aim at introducing further regulatory cooperation in order to give more concrete benefits to AEOs. The BRT is aware that the two authorities are engaged in regular discussion following the agreement on the mutual recognition of the AEOs in June 2010 between the EU and Japan, but that no concrete benefits have emerged for operators. According to the progress report of the EU in 2015, the scope of this agreement is restricted to 'security and safety' only. The BRT would like in this regard to put emphasis on the simplification of import procedures where companies are given greater freedom while taking greater responsibility for their imports without an excessive administrative burden. The BRT recommends that the two authorities should consider expanding the legal base if it is necessary to realise the simplification of import procedures.

Reply:

Mutual Recognition of AEO¹s is discussed by AEO experts from both sides in their regular meetings concerning the implementation of the Mutual Recognition Decision. The topic of expansion of the benefits under the MRA to customs simplifications (including priority at customs controls) has been discussed with the Japanese authorities on various meetings over the last few years. A proposal for the WCO SAFE Review 2018 has been tentatively approved by the SAFE Working Group subject to endorsement by the WCO Policy Commission and Council in June 2018.

5. Fight against counterfeited, pirated and contraband goods

The BRT would like to see the EU and Japan step up efforts to fight against counterfeited, pirated and contraband goods, both inside and outside the EU and Japan. For example, they should better cooperate with each other and with the third country authorities to secure the closure of sites trading in fake goods. The BRT requests that the authorities of Japan should make all trade with fake goods illegal by closing the loophole by which individuals are allowed to bring in or import counterfeits for personal consumption. The BRT reiterates its support of Regulation (EU) 608/2013 of the EP and Council of 12 June 2013 on Customs enforcement of Intellectual Property rights which reflects to some extent the BRT's key recommendations such as simplifying the procedure. However, the BRT requests the authorities of the EU that they should seek ways to mitigate the financial burden of the importers of the authentic goods. The BRT would like to see an enhanced role of the Observatory on Counterfeiting and Piracy in line with the Regulation adopted by the European Parliament and Council on 19 April 2012. The BRT suggests that with increased cooperation by the manufacturers and importers of authentic goods, including the provision of more information on their products, on-site training of officials and training of officials on more effective use of the WCO's IPM (Interface Public Members), the customs authorities should make inspection more efficient and raise the rate of its coverage.

Reply:

¹ Authorised Economic Operators

Comments on the main (5) issues raised by the BRT concerning IPR enforcement at the EU border:

Issue no. 1: Mitigation of financial burden for the importers

The Commission services recall that, in line with art. 8 of Regulation (EU) No 608/2013 on customs enforcement of IPR, right holders applying for customs intervention cannot be charged any fee to cover the administrative costs resulting from the processing of the application. According to article 29 of the same regulation, it is up to the Member States customs authorities to request IPR holders for reimbursement of the costs relating to the storage, handling and, eventually, destruction of the goods incurred by the customs authorities, or other parties acting on behalf of customs authorities.

Issue no. 2: Enhance role of the Observatory

The EU Observatory on Infringements of Intellectual Property Rights is regularly invited to attend the meetings of the Customs expert group on IPR enforcement in order to ensure coordination of common customs-related activities. In addition to being associated to the customs activities enshrined in the yearly work programme of the Observatory, the Commission services are also present in most relevant meetings of the Observatory, such as the plenary session, public stakeholder meetings and the working group meetings on enforcement issues, public awareness and statistics.

Moreover, COPIS (anti-Counterfeit and anti-Piracy Information System), the EU customs common tool managing applications for customs actions (AFA) filed by IP right holders and recording IPR infringements, is operationally connected since 2015 to the Enforcement Data Base (EDB). The EDB is the database developed by the EU Observatory on IPR infringements which assists IPR holders in the preparation of preliminary AFAs in an electronic format and allows its further electronic submission to Member States customs authorities.

Issue no. 3: Increase cooperation of manufacturers and importers on goods information

The accuracy of the information given by the holder of the decision in the AFA and contained in COPIS is key for risk analysis purposes. This is of paramount importance with regard to information permitting the identification of original and infringing goods, the existence of any security features in the goods and the distribution/supply chain of the authentic goods as well. The Commission services are aware of the need to reinforce the efforts made in this regard and do constantly encourage IP right holders the provision and update of such information and the use of the "Manual for the Completion of Applications for Action and Extension Requests".

The operational connection between COPIS and EDB will reduce the burden of multiple submissions of information and improve the quality of it. In that context, the Commission services, in collaboration with the Observatory, are engaged in the development of a trader portal for the submission, extension and renewal of an electronic AFA which will lead in future to a paperless application for custom's action.

Furthermore, the Commission services organise a dedicated yearly joint meeting with the customs authorities in the EU and stakeholders to ensure the engagement of IP right holders in the fight against IPR infringement at the EU borders. The yearly meeting has shown to be an effective forum to discuss issues of common interest.

Issue no. 4: On-site training of officials and training of officials on more effective use of the WCO's IPM

The Commission services provide Member States customs administrations with regular training actions, in particular, in its own IT system (COPIS) and promotes among Member States customs officials the IPR enforcement training actions offered by the Observatory, in particular, those organised in the shape of on line courses and webinars.

Issue no. 5: Customs inspection to be more efficient and raise the rate of its coverage

The Commission services publish a yearly report on EU customs enforcement of IPR at the border. According to the annual report covering year 2016, customs authorities detained more than 41 million products suspected of violating an IPR at the EU's external border, of a total value of more than €670 million. The number of intercepted articles has risen by 2% compared to 2015. Customs authorities are working proactively to curb the influx of counterfeit goods into the EU.

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 concur with the Recommendation of the EU-Japan Business Round Table that adoption of UNECE Technical Regulations by both EU and Japan is a key factor to reduce testing and certification costs and to improve the business environment in this sector. It is also important that new UNECE Regulations are developed in areas not fully regulated and that work progresses in view of the adoption of new or revised Regulations on power-train technologies – clean diesel, electric vehicles, hybrid vehicles and fuel-cell vehicles. DG GROW (automotive unit) meets regularly its counterpart from Japan MLIT - Ministry of Land, Infrastructure, Transport and Tourism ahead of the World Forum for Harmonization of Vehicle Regulations (WP29) meetings in Geneva, at the margins of WP29 meetings and also on technical meetings aimed at developing specific UNECE Regulations. The excellent on-going co-operation allows a co-ordinated/joint development of new or revised Regulations. Furthermore the EU-Japan Free Trade Agreement contains a robust Non-Tariff Barriers Annex on Motor Vehicles and Parts that aims at further increasing convergence with UNECE Regulations.

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

1. Social security contributions (avoiding double contributions)

Reply:

The Commission services welcome the information that Japan has concluded 12 social security agreements with EU Member States and that negotiations are ongoing with 4 other Member States. Member States are 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 EU. 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 EU or of the European Economic Area.

Nonetheless, the Commission services wish to encourage closer cooperation between the EU 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 the Commission services organise the 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 the EU Member States, as well as between third countries and the EU Member States, in the area of the coordination of social security. The Forum is attended by social security experts. The Commission services explored with Japanese authorities if Japanese government experts could participate in the 5th Forum (Oct 2017) to exchange information on the social security contributions with the EU Member States but Japan eventually did not attend the 5th Forum. The Commission services extended the invitation to the 6th Forum scheduled for autumn 2018 (a reply from Japan is pending). BRT members are invited to encourage Japan to attend the 6th International Forum on the external dimension of social security in order to facilitate information exchange between the EU MS and Japanese social security government experts.

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

Reply:

As the BRT points out, the EU has adopted an EU-wide scheme on the admission and intra-EU mobility of intra-corporate transferees and their spouses (ICT Directive, 2014/66/EU). Three EU Member States do not participate (United Kingdom, Ireland and Denmark).

The EPA with Japan will cover intra-corporate transferees. Like most agreements, it ensures intra-corporate transferees will be granted access to the EU market without any so-called labour market tests (also known as "economic needs tests") – this will apply in all EU Member States. In addition, this agreement "binds" certain advantages enshrined in the ICT Directive, but only for the 25 Member States who have adopted the Directive. It will ensure that both the intra-EU mobility rights and the rights granted to spouse transferees granted under the ICT Directive will continue to apply to Japanese citizens regardless of future EU policies.

WP-1 / 05 / EJ to EJ- Support for SMEs

Reply:

The Commission services welcome the EU-Japan Business Round Table recommendations and the continued focus put on the necessary support for SMEs. In particular, the Business Round Table is asking that specific consideration should be given "to include (...) cross support [for SMEs] in EPA negotiations". This BRT recommendation has been duly taken into account by the Commission services. Indeed, the negotiation of a dedicated 'SME chapter' in the future EU-Japan Economic and Partnership Agreement (EPA) has been achieved in 2017.

Dedicated SME provisions have been negotiated in the EU-Japan EPA in order 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 will 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 EU-Japan Centre for Industrial Cooperation is 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.

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 20 Partnership Agreements (i.e. business deals, technology transfer agreements and/or research collaboration agreements) as well as 1731 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 further 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, it should be stressed that within the framework of the overall EU-Japan Industrial Policy Dialogue, discussions on SME policy issues already took place in Tokyo with METI SME Agency in November 2017. It was considered to develop more exchanges on SME Policy experiences through the identification of a limited set of common topics: business transfer, scaling up of small businesses and SME internationalization. The issue of business transfer is particularly relevant for Japan where 2.4 M owners of SMEs are over 70. The dialogue on those three topics will allow mutual exchanges on relevant EU and Japanese public policies in favour of SMEs.

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

The BRT supports the creation of an internationally fair taxation framework and level playing field. At the same time, the BRT urges that authorities of the EU and Japan to ensure that the implementation of the BEPS Actions should not create additional administrative burden on businesses.

Reply:

On BEPS (Base erosion and profit shifting) Action 13 (non-public CBCR²):

This recommendation has been implemented at EU level via DAC4³. It came into force on 5 June 2017 and first exchanges of information are expected by June 2018. The main objective 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 the international business community and would create a level playing field.

On Mutual Agreement procedures (MAP) and binding arbitration (dispute resolution):

The Commission services made a proposal on improving double taxation dispute resolution mechanisms in October 2016. The proposal has been discussed in Council and a general approach (agreement) has been reached in May. Subject to the European Parliament 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.

² CBCR: Country By Country Report

³ The 4th Directive on Administrative Cooperation (DAC4)

On the additional points raised:

The Commission services in principle agree 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 services are 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 E- Recommendation on Financial Transaction Tax

The BRT maintains its serious concern over the EC's proposed financial transaction tax (FTT), particularly with respect to its wide range of application. If imposed, the FTT will result in reduced volume of financial transactions and decreased liquidity. It will also lead to a significant increase in funding costs and impairment of legitimate hedging activities by parties including non-financial corporations. The decreased liquidity in secondary markets is also likely to cause impacts on primary markets eventually.

Impact on liquidity, funding costs and hedging costs should be carefully considered in the ongoing discussion on scope of transaction, country of taxation and tax rate in one harmonised tax regime so as to develop and integrate capital markets in the EU.

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. 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 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 services.

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_backgroun_d_en.htm

In its impact assessments the Commission services have 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 / 18 / J to E- The importance of the Single Market

In improving the Single Market, the EU and its Member States should not only aim at the harmonisation of national rules at the EU level. They should also aim at better regulation by eliminating duplicative legislative framework and aim at the liberalisation and deregulation.

The BRT would like to emphasise the importance, however, that the EU should make a policy through Regulations in the areas in which the uniform application of policy throughout the EU is crucial.

The BRT would like to point out, moreover, that, when a rule is introduced at the EU level, not only its implementation but also its uniform compliance and enforcement in all the Member States is increasingly important. The BRT, therefore, welcomes the package of measures to enhance compliance and practical functioning of the Single Market published on 2 May 2017 as a step forward.

Reply:

Improving the Single Market for goods will reinforce trust of consumers in the products they buy, create a level playing field for businesses and bring economic benefits. A recent study on "The Costs of Non-Europe in the Single Market" shows that a reduction of trade barriers could lead to an increase of intra-EU trade by more than €100 billion per year.

On 19 December 2017 the Commission adopted two legislative proposals to make it easier for companies, especially SMEs, to sell their products across Europe, and to strengthen controls by national authorities and customs officers to prevent unsafe products from being sold to European consumers.

The proposal for a new Regulation on the Mutual Recognition of Goods aims at making the principle of "mutual recognition" which ensures that products not subject to EU-wide regulation can, in principle, move freely within the Single Market if they are lawfully marketed in one Member State, faster, simpler and clearer in practice.

Non-compliant products endanger consumers and put compliant businesses at a competitive disadvantage and therefore the proposal of a Regulation on Compliance and Enforcement aims at creating a fairer internal market for goods, through fostering more cooperation among national market surveillance authorities. This will include sharing information about illegal products and ongoing investigations as well as helping national authorities to improve checks on products entering the EU market.

These proposals complement other initiatives already put forward to deliver on the 2015 Single Market Strategy: measures for improved protection of intellectual property rights, proposals on e-commerce, guidance on the collaborative economy, steps to modernise the EU's standardisation policy, a Start-up and Scale-up Initiative, measures to give a fresh boost to the services sector and steps to enhance compliance and practical functioning of the EU Single Market.

WP-1 / 19 / J to E- Chemical Regulations**19.1 REACH**

1. The BRT requests that the Authorities of the EU should pay more attention to the implementation of REACH.

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 same as the EU companies.

Reply:

The majority of ECHA guidance documents include a public consultation where all parties can comment. ECHA has developed a certain procedure to nominate 'accredited stakeholders'. We will forward this request to ECHA to examine this issue and reply to this demand from non-EU companies. Nonetheless, ECHA accredited stakeholders represent company associations not individual companies.

If the thresholds of new SVHCs 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.

Reply:

The limit values, for example laid down in restrictions, are set according to the risk. It is often the case that analysing very low levels is more difficult and more expensive. However, the Forum for the exchange of information on Enforcement developed a compendium of analytical methods where they provide guidance to enforce many REACH restrictions. More information in the ECHA website

<https://echa.europa.eu/about-us/who-we-are/enforcement-forum/enforceability-of-restrictions>

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.

Reply:

Member States are the main responsible for enforcement and they are carrying out enforcement activities to decrease the number of non-compliances in the market. Enforcement is identified as a priority in the just adopted REACH Review in order to ensure level playing field. More information on enforcement campaign results is available in ECHA website and some of them controlling imports in collaboration with customs

<https://echa.europa.eu/about-us/who-we-are/enforcement-forum/forum-enforcement-projects>

2. The BRT requests that the Authorities of the EU should further improve the PACT-RMOA.

Reply:

The REACH Review (Communication published on 5 March 2018

https://ec.europa.eu/growth/sectors/chemicals/reach/review_en

identified opportunities for further improvement, simplification and burden reduction. Regarding specifically the authorisation process, the Communication contains actions for improvement such as simplification of the process of applying for authorisation or a more consistent use of the available socio-economic information at the RMOA stage. Moreover, SMEs have been extensively considered in the recent REACH review.

The ECHA process foresees public consultation as well as call for evidence. More information in <https://echa.europa.eu/public-consultations>.

3. The BRT requests to the authorities of the EU to mitigate the effect of the withdrawal of the UK from EU on the implementation of REACH.

Reply:

The REACH Regulation is very clear in this regard. According to its Article 8, "Only Representatives" shall be legally established within the EU. After the UK withdrawal, this will mean the territory of the EU-27/EEA. The manufacturer having appointed an "Only Representative" will need to involve an "Only Representative" based in one of the EU-27 Member States or the three EEA Member States. The "Only Representative" will also need to be changed in REACH-IT.

The European Chemicals Agency has developed some useful material related to the UK withdrawal from the EU which is available on the Agency's website:

<https://echa.europa.eu/uk-withdrawal-from-the-eu>

19.2 Appropriate approach to Endocrine disruptor

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

Reply:

Scientific criteria to identify endocrine disruptors under the biocidal products Regulation were adopted on 4 September 2017 and published on 17 November 2017 as Regulation (EU) 2017/2100. The criteria entered into force on 7 December 2017 and they will be applicable from 7 June 2018, including for substances still under evaluation at that time. Scientific criteria to identify endocrine disruptors under the plant protection products Regulation – similar in content to the criteria under the biocidal products Regulation – were endorsed by EU Member States in December 2017. They are under scrutiny of the

co-legislators until the 9th of April 2018 and will be eventually adopted by the Commission if there are no objections from any of these institutions.

The scientific criteria are based on the WHO definition of an endocrine disruptor, for which there is wide consensus. A technical Guidance document to implement the criteria is currently being developed by the European Chemicals Agency and the European Food Safety Authority. It is expected to be finalised by June 2018 and a public consultation on a draft document was open until 31 January 2018.

Information to WTO members on the latest developments on endocrine disruptors was circulated in form of a communication on 20 December 2017. Further relevant information on the matter is available on the Commission's website

http://ec.europa.eu/health/endocrine_disruptors/next_steps_en.

19.3 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.

Reply:

A study has been launched by the Commission services in January 2018 to support the review of the list of restricted substances that inter alia focuses on an update and further enhancement of the existing methodology for identification and assessment of substances for a possible future restriction under RoHS. This study will be accompanied by several stakeholder consultations as well as the existing substance review expert group, where a broad range of stakeholders is also represented. Any related legal initiative will follow the Better Regulation principles.

Results are expected in Q2 2019. The RoHS/REACH Common Understanding paper continues to be relevant.

19.4 CLP Regulation

The BRT requests that, to alleviate burden on exporters, the authorities of the EU should accept GHS classification and labelling at the custom clearances.

Reply:

When the GHS was implemented, the objective was not to lower the level of safety in the EU. The existing EU Regulation was aligned as much as possible with the UN GHS, only few elements have not been taken into account. This is in line with the UN GHS agreement: building block approach. In any case, the differences between the EU system and the UN GHS are very marginal and they should not represent a big issue for Japanese business.

19.5 Nanomaterial

1. Definition

2. Standardisation of measurement method

3. Reporting scheme

Reply:

1. Definition

The Commission services have prepared the proposal for changes in REACH Annexes concerning the information requirements on nanoforms of a substance and transparency in the registration dossiers to ensure clarity on how nanomaterials are addressed and safety is demonstrated in registration dossiers. Currently this proposal is discussed with Member States in the REACH Committee. The changes concern:

- the characterisation of the nanoforms of a substance (particle size distribution, shape, surface area and coating) in Annex VI,
- the triggers for data waiving in Annex VII-X where the triggers used for classical substances don't work,

- introducing of the new physico-chemical properties such as dissolution rate and dispersion stability,
- stressing the importance of the inhalation route of administration in toxicological studies,
- extended use of toxicokinetic studies and
- long term (eco) toxicological studies.

In addition, in a parallel process the definition of nanomaterials is being revised and its update will be included in Annex VI.

2. Standardisation of measurement method

The Commission activities in this area include:

- M461 mandate given to CEN to develop European standards for measurement of dustiness, efficiency of filtration workplace exposure and other guidance, in total CEN will provide 16 deliverables;
- financing projects via frame work programs focused on the measurement methods applicable on nanomaterials, outcomes from these projects can be further used for standardisation;
- Involvement in the development and acceptance of the OECD test guidelines for nanomaterials

3. Reporting scheme

The Commission services have assessed all pros and cons for the harmonised reporting system at the EU level, and despite of the existence of such systems in some EU countries, it has been concluded that this system would bring disproportional financial burden for involved stakeholders. Instead of this, we are pursuing the development of the Nano-observatory information system, which is being developed by ECHA and will become the universal source of information on nanomaterials for experts, authorities and the general public.

19.6 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.

Reply:

In relation to the provisions on treated articles in the Biocides Products Regulation (EU) No 528/2012, some guidance has 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. In 2020 Member States have to report to the Commission services on the implementation of the Biocidal Product Regulation in their territory. On the basis of the reports of the Member States, the Commission services shall report to the European Parliament and the Council, including on the provisions on treated articles.

WP-1 / 20 / J to E- Resource Efficiency Policy

20.1 Circular Economy

A truly circular economy requires the involvement of actors in all stages of the ideal economic cycle and should be based on life-cycle thinking. The BRT therefore recommends the authorities of the EU to assess environmental benefits at the design stage from the perspective of scientific evidence and to take into account trade-offs between energy efficiency, resource efficiency, safety and performance of products.

Reply:

The services of the Commission welcome the recommendations on Circular Economy. As part of its continuing effort to transform Europe's economy into a more sustainable one and to implement the ambitious Circular Economy Action Plan, in January 2018 the European Commission adopted a new set of measures, including:

- A Communication on options to address the interface between chemical, product and waste legislation that assesses how the rules on waste, products and chemicals relate to each other. This initiative aims to ensure coherence between the different legislations and to strengthen a coherent and systemic regulatory response in promoting circular economy.
- A strategy on plastics in the circular economy to transform the way plastics and plastics products are designed, produced, used and recycled. By 2030, all plastics packaging should be recyclable. The Strategy also highlights the need for specific measures, possibly a legislative instrument, to reduce the impact of single-use plastics, particularly in our seas and oceans.
- A Monitoring Framework on progress towards a circular economy at EU and national level. It is composed of a set of ten key indicators which cover each phase – i.e. production, consumption, waste management and secondary raw materials – as well as economic aspects – investments and jobs - and innovation.
- A Report on Critical Raw Materials and the circular economy that highlights the potential to make the use of the 27 critical materials in our economy more circular.

The proposed actions will contribute to "closing the loop" of product lifecycles through greater recycling and re-use, and bring benefits for both the environment and the economy.

The revised legislative proposals on waste set clear targets for reduction of waste and establish an ambitious and credible long-term path for waste management and recycling. Key elements of the revised waste proposal include A common EU target for recycling of municipal waste; for recycling of packaging waste; Binding landfill target to reduce landfill; ban on landfilling of separately collected waste; Promotion of economic instruments to discourage landfilling; Simplified and improved definitions and harmonised calculation methods for recycling rates throughout the EU; Concrete measures to promote re-use and stimulate industrial symbiosis - turning one industry's by-product into another industry's raw material; Economic incentives for producers to put greener products on the market and support recovery and recycling schemes (eg for packaging, batteries, electric and electronic equipment, vehicles).

The EU works actively in multilateral fora such as the G7 Resource Efficiency Alliance or the G20 Resource Efficiency Dialogue as well as on a bilateral basis with Japan and other governments to promote international exchanges and cross fertilisation in addressing resource efficiency.

Regular exchanges on resource efficiency policies take place through the "Climate Change & Environment Working Group" that convenes within the framework of the Industrial Policy Dialogue established between the Ministry of Economy, Trade and Industry (METI) and DG GROW.

These measures provide clear signals for businesses worldwide and promote greater harmonisation and simplification of existing legislation in the EU. The transformation of the world economy towards sustainability and circularity has the potential to be a major source for growth in the future. The EU policy for circular economy applies the same principles for businesses within and beyond the EU and helps to create growth and jobs within a more sustainable and more adequately protected environment.

The BRT correctly states that in the transition to a Circular Economy, there is a role to play for actors in all stages of the production cycle. It is precisely for this reason that the Circular Economy Action plan is a cross-cutting strategy, considering all life-cycle phases from design to end-of-life and covering and connecting all relevant sectors.

The BRT further recommends the EU to ensure coherence in following up the action plan, and to assess whether existing and/or future legislation and policies pose obstacles to the circular economy. In this context the recommendations mention various strands of EU policy relevant for products, as well as specific policies related to waste.

Ensuring policy coherence is standing practice in the EU, and there are several safeguards in place to achieve this, including the impact assessment which precedes new legislation. More details can be found in the better regulation package.

Specifically as regards circular economy, the action plan provides a common policy context in which policy tools addressing different sectors can be developed. It is therefore expected to further increase policy coherence rather than diminish it, and take away obstacles to a circular economy rather than creating new ones. A recent example of how policies are being adapted to better support the transition to a circular economy is the revision of the waste legislation, which i.a. addresses streamlining and clarifying definitions, improving harmonisation and providing a level playing field.

One action contained in the action plan specifically addresses coherence of policy, stating that "The Commission services will examine options and actions for a more coherent policy framework of the different strands of work of its product policy in their contribution to the circular economy". Work on this action is ongoing and first results are expected at the end of 2018. Naturally, any actions that (in the longer term) would lead to new policies or legislation would be subject to aforementioned better regulation approach.

Finally, the BRT recommends the EU 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. In 2018 the Commission published its plastics strategy, which inter alia addresses this issue.

20.2 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.

Reply:

The services of the Commission welcome the recommendations on Ecodesign policy and reassure the BRT that the least life cycle cost principle is guiding the EU in the formulation 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. 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 energy efficiency should be optimised at the level of final products. The 'cascading' principle make sense: an energy efficient component is integrated into a product and helps this product to become more efficient. This more efficient product is in turn integrated into a more efficient final

product, also helping to make it more efficient. This also results in increased production volumes – and thus lower prices – of energy-efficient components. It creates a level playing field among producers of components and of end-products. It helps the manufacturers of these components to amortise their investments in the development of energy-efficient components. It facilitates market surveillance and reduce the risk of circumvention. In short, it creates a framework by which the performance of components and the products in which they are incorporated progressively improves with time. We believe that consumers benefit from the application of these principles. This is to be verified on a case-by-case basis in each relevant impact assessment. Every proposed Ecodesign regulation is subject to an impact assessment before it is accepted by the EU co-legislators.

Regarding the repair as produced principle, the EC is attempting to introduce gradually, on a case by case basis, requirements in Ecodesign regulations which facilitate that products are repaired, such as the availability of spare parts, the ability to disassemble components and the availability of firmware versions in ICT products. Furthermore, a reparability index for products is also under development, with a view to including it in new and existing Energy Labels from 2020 onwards.

20.3 Energy Labelling

Reply:

Article 11.8 of Regulation (EU) 2017/1369 lays down that "Where a label is introduced or rescaled, the Commission shall ensure that no products are expected to fall into energy class A at the moment of the introduction of the label and the estimated time within which a majority of models falls into that class is at least 10 years later".

Article 12 of Regulation (EU) 2017/1369 lays down that the European Commission shall establish and maintain a product database. The product database shall not replace or modify the responsibility of the market surveillance authorities.

The services of the Commission hold meetings with the Ecodesign Consultation Forum to define the details of the database. The discussion is driven by the provision in Regulation (EU) 2017/1369 to minimise the administrative burden for the supplier and other database users, to have a user-friendly and cost-effective database and avoid redundant registration (art. 12.7). The Ecodesign Consultation Forum is composed by representatives from all the EU Member States governments and 60 European-level stakeholders (from industry, NGOs, consumers associations, etc.).

WP-1 / 21 / J to E- Taxation

21.1 Common Consolidated Corporate Tax Base

Reply:

In October 2016, the Commission services 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 started the negotiations on the common base.

21.2 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.

21.3 The fundamental reforms of VAT regime under consideration**Reply:**

As set out in its Action Plan on VAT: "Towards a single EU VAT area - Time to decide", the Commission proposed a far-reaching reform of the EU VAT system on 4 October 2017.

This reform envisages a future VAT system whereby the place of taxation of intra-Union supplies of goods between taxable persons will be the Member State of destination of the goods. The full details of the definitive VAT arrangements will be contained in a further proposal to be made before the summer of 2018.

Once agreed by the Council, the new rules of the VAT definitive regime would ensure that the intra-Union supplies of goods between taxable persons are taxed at the rate of the Member State in which the goods arrive, and would end the current exemption for the intra-Community supplies of goods.

Whilst the Commission services acknowledge the view of the BRT regarding the timeline for the adoption of the definitive system, the Commission will propose that the changes in legislation to support the definitive system be operational on 1 July 2022.

WP-1 /22 / J to E- Company Law / Corporate Social Responsibility**22.1 A new strategy on CSR Policy****Reply:**

The Commission services are actively engaged to promote CSR/RBC⁴ and to foster the development of networks of expertise, exchanges and the uptake of responsible business practices by European and Japanese business in the context of the EU-Japan trade relations. For instance, the EU-Japan FTA includes dedicated CSR/RBC provisions in the EU trade and investment agreements with reference to international instruments such as the OECD MNE Declaration. In line with the Trade for All strategy, a 9 million euros pilot project on responsible supply chains funded by the EU and implemented by the OECD and ILO has also been initiated. This project will promote CSR/RBC in all its dimensions such as the respect of the environment, the promotion of decent work and the respect of human rights. A wide-range of activities will be covered

⁴ CSR/RBC: Corporate Social Responsibility/Responsible Business Conduct

by the programme including the creation of platforms for exchanges of best practices, trainings and workshops for business as well as in country-conferences and research studies. Japan will be one of the partner countries

22.2 Conflict minerals

Reply:

The EU Regulation on Conflict Minerals entered into force in June 2017 and sets out due diligence obligations that EU importers of tin, tungsten, tantalum and gold will have to comply with as of 1 January 2021.

As set out in the Regulation, the Commission services are drafting guidelines for economic operators describing how best to apply the criteria for the identification of conflict-affected and high-risk areas. During this process, the Commission services consulted relevant stakeholders, including Member States experts. These guidelines are expected to be published in the first half of 2018.

The Commission services, in the course of 2018, will call upon external expertise to provide an indicative, non-exhaustive, regularly updated list of conflict-affected and high-risk areas, based on this Handbook and existing information of, inter alia, academics and supply chain due diligence schemes.

Regarding the EU list of global responsible smelters and refiners, it will take into account those covered by supply chain due diligence schemes which have been recognized by the Commission services and will be updated regularly.

WP-1 / 23 / J to E Product Safety / Market Surveillance

23.1 Product safety and market surveillance package proposal

Reply:

The European Commission awaits the initiative from the Council presidency on the Product safety and market surveillance package proposal from 2013. If the Council and European Parliament decide to continue the discussion on this package the Commission services will ask them to take into account the new proposal on compliance and enforcement adopted on 19 December 2017.

23.2 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.

Reply:

There are still too many unsafe and non-compliant products sold on the EU market: as many as 32% of toys, 58% of electronics, 47% of construction products or 40% of personal protective equipment inspected do not meet the requirements for safety or consumer information foreseen in EU legislation. This endangers consumers and puts compliant businesses at a competitive disadvantage. Therefore, on 19 December 2017 the European Commission tabled the proposal for a Regulation on Compliance and Enforcement. Once adopted, the Regulation will help create a fairer internal market for goods, through fostering more cooperation among national market surveillance authorities. This will include sharing information about illegal products and ongoing investigations so that authorities can take effective action against non-compliant

products. The Regulation will also help national authorities to improve checks on products entering the EU market. Since 30% of goods in the EU are imported, the Commission services further proposes to reinforce inspections of ports and external borders. The draft Regulation has been sent to the European Parliament and Council for adoption. Once adopted, they will be directly applicable.

The Commission services propose the following:

- A European Union network of market surveillance authorities – the network will help authorities better coordinate their controls and work more efficiently. It will allow them to pool knowledge, support each other, develop a common intelligence picture, and devise efficient methods for more targeted and risk-based controls. The network will give market surveillance the common European perspective necessary in a common European market.
- Commission support – the Commission services will be able to channel more administrative and financial support to top priority cross-border joint investigations and assist authorities with joint procurement of product testing capacity. It will also invest much more in common knowledge gathering among enforcement authorities and linking-up of different IT tools, such as RAPEX and ICSMS (Information and Communication System on Market Surveillance), used by market surveillance authorities and customs to inform each other about dangerous goods.
- Shared evidence – use of another Member State's evidence, test reports and decisions will be made easier. If a product is found not to comply with EU product rules in one Member State, the evidence and decisions can be transferred to another, to facilitate enforcement across the EU. Enforcement authorities will be able to coordinate better and to share more information about investigations and illegal products through regular meetings and common IT tools.
- Collaboration with businesses – closer collaboration between businesses and authorities will be fostered. All businesses selling products in the EU will have to designate a person in the EU who can be easily contacted when authorities have a question about compliance of their product. This person can be the manufacturer, importer or a natural or legal person with an appropriate mandate from the manufacturer.
- Transparency – authorities will more systematically publish their findings, especially when restricting the marketing of certain products.
- Single contact point – a single liaison office will have to be set up in each Member State. This will facilitate the coordination of cross-border enforcement and channel requests quickly and efficiently to the right people.

23.3 Consumer protection – legal guarantee period

Reply:

The BRT recommends what had been already proposed. Hence we take note of the recommendation and we would refer the BRT to the ongoing negotiations on the Sales of Goods proposal which aims for fully harmonised rules on legal guarantees for the sale of goods. DG JUST is now negotiating this in Council on the basis of an amended proposal, the scope of which covers both online and offline sales (COM(2017)637 final of 31 October 2017 - <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2017%3A637%3AFIN>)

WP-1 / 24 / J to E- Access of third countries goods and services to the EU's Procurement Market

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 Commission services have 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 provide 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 services investigation and consultations with the targeted third country. The finding of the Commission services 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

HEALTHCARE

WP-2 / 01 / EJ to EJ- Mutual Recognition Agreement for Pharmaceuticals GMP should be extended

Reply:

The expansion of the operational scope to include biological pharmaceuticals (including vaccines), active pharmaceutical ingredients, and sterile products was agreed at the technical level following equivalence assessment by DG SANTE. This scope expansion has to be formalized through a Joint Committee Decision. The internal processes necessary to adopt this JC Decision are ongoing (on the EU side, we need a COM Decision, after consultation with MS +translations) and can hopefully be finalized in April 2018.”

WP-2 / 02 / EJ to EJ- Mutual recognition should be improved for Medical Devices

(i) Mutual recognition of quality management audit results for Medical Devices

should be established between EU and Japan

(ii) There should be mutual recognition of Medical Devices product licenses

(iii) There should be mutual recognition of clinical trial results for Medical Devices

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 does 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.

As regards clinical trials, 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 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 DG GROW therefore rather sees this as an issue that could benefit from development of international principles in the multilateral IMDRF context.

PLANT PROTECTION & BIOTECHNOLOGY

WP-2 / 03 / EJ to EJ- Acceleration and dissemination of scientific knowledge on new plant technologies by both the governments and the private sector.

Reply:

Public awareness on new techniques

The Commission services have implemented concrete actions to increase public awareness on biotechnology, in particular as regards new techniques in agriculture. On 28 September 2017 a high-level conference on modern biotechnologies in agriculture was organised, to promote informed public debate on how the EU can benefit from modern biotechnologies and innovation in the food and agricultural sector while maintaining high safety standards.

Global harmonization on GMO risk assessments.

On one hand, the WTO Sanitary and Phytosanitary Agreement allows countries to introduce and maintain measures on food safety, animal and plant health, which result in a higher level protection, compared to the relevant international standards/guidelines/recommendations. Such measures must be based on science, should be applied only to the extent necessary to protect human, animal or plant life or health and should not be more trade restrictive than necessary.

On the other hand, EU legislation and practices in the area of GMO risk assessment are consistent with the agreements, principles and guidelines developed at international level, i.e. the Cartagena Protocol on Biosafety and CODEX guidelines. The Cartagena Protocol, which focuses on the protection of the environment and human health from risks related to Living Modified Organisms (LMOs) that are traded internationally, lays down general principles and guidelines to carry out risk assessments of LMOs. CODEX developed principles for the risk analysis of foods derived from modern biotechnology, and specific Guidelines for the conduct of food safety assessment of foods produced using recombinant-DNA plants and microorganisms.

Global Low Level Presence Initiative

The EU applies a zero tolerance policy for non-authorised GMOs. GMOs can be placed on the EU market only after having been authorised by the EU based on a risk assessment demonstrating their safety for human and animal health and for the environment. This risk assessment is performed by the applicant and evaluated by the

European Food Safety Authority (EFSA) and the EU Member states' competent authorities.

The services of the Commission are aware of the international discussions on Low Level Presence issues, and welcome getting knowledge of those discussions, but cannot engage in any discussion aiming at policy agreements on acceptable low level presence of non-authorized GM crops in traded food and feed.

Status of new plant breeding techniques.

The Court of Justice of the European Union will render a ruling on whether the Genetically Modified Organisms (GMO) legislation applies to organisms produced by targeted mutagenesis techniques and on whether Member States can regulate organisms which fall under the exemptions set out in that legislation. The conclusions of the Advocate General were published on 18 January 2018, and the ruling is expected later this year. The interpretation of the Court of Justice of the European Union will provide clarity on the legal status of organisms produced with genome editing technologies and will be binding for all EU Member States.

PLANT PROTECTION & BIOTECHNOLOGY

WP-2 / 06 / EJ to E- Regulations governing import Maximum Residue Limits (MRLs) into the EU should be clarified so as to allow free trade of food commodities.

Reply:

The EU regulations on food safety aim at ensuring the highest degree of consumer protection. The hazard based criteria laid down in Regulation 1107/2009 on the authorisation of plant protection products fully correspond to this principle. An evaluation of the Regulations for authorisation of plant protection products and for pesticides residues in food and feed is currently ongoing in the EU. Existing inconsistencies between the two pieces of legislation arise from the fact that the Regulation on pesticides residues came into force years before the one on authorisation of plant protection products. The EU will carefully evaluate the results of the study (expected at the beginning of 2019) and then decide about any further steps.

Working Party 3

Digital Innovation and Mobility

Recommendations from both European and Japanese industries

WP-3 / 01 / EJ to EJ- Cooperation for Global Digital Trade Rule Making

Reply:

The Commission services share concerns expressed by the EU-Japan Business Round Table regarding Forced Localisation Measures (FLMs) and considers it as an important issue. Consequently chapter 8 of the EPA (Trade in services, investment liberalisation and electronic commerce) contains an article which will allow EU and Japan to reassess the need for inclusion of an article on the free flow of data within three years of the entry into force of the EPA.

WP-3 / 02 / EJ to EJ- Privacy Protection and Innovation towards Digital Economy

Reply:

GDPR implementation

The Commission services attach a great importance to the fact that the guidelines prepared by the WP29 (and after May 2018 the European Data Protection Board) are subject to public consultation before finalisation. The final responsibility for those guidelines remains with the Article 29 Working Party and the future European Data Protection Board, and the data protection authorities will refer to them when enforcing the Regulation.

The Commission services have been working very closely with the Member States to support their work during the transition period between the entry into force of the GDPR in May 2016 and its entry into application in May 2018. The Commission services' objective is to ensure the highest possible level of consistency. To this end, the Commission services have set up an Expert Group to accompany the Member States in their effort to prepare for the Regulation. The services are also engaging in bilateral meetings with Member States' authorities to discuss issues arising at national level. The Commission services will continue working with Member States to promote consistency and limit fragmentation in the application of the Regulation, taking into account Member States' room for specification under the new legislation.

After May 2018 the Commission services will closely monitor the application of the Regulation in Member States and take appropriate actions as necessary.

It is also important to recall that, where questions regarding the interpretation and application of the Regulation arise, it will be for courts at national and EU level to provide the final interpretation of the Regulation.

Rulemaking for the facilitation of cross border transfer of personal data

As it was already stressed in the Commission's Communication "Exchanging and Protecting Personal Data in a Globalised World", the Commission services attach great importance to the facilitation of personal data exchange between our economies. In this regard, we would, in particular, stress the novel and unique nature of the possible adequacy decision currently being discussed with Japan. The objective of this work is to complement the trade agreement with – for the first time ever - simultaneous adequacy findings by the EU and by Japan. The Commission services agree of course with the BRT on the usefulness and the commodity of use of the new "toolkit" of mechanisms for personal data transfers under the GDPR. Developing such tools (in particular certification) is a prominent share of the ongoing Commission services' work on the

implementation of the data protection reform. However, an (hopefully imminent) adequacy decision will elevate the data exchange between the EU and Japan to a new, different dimension, as there will be no more need for extra authorisations. Indeed, when the ongoing process is concluded, both our economies will benefit from fully free data flows in both directions, from the EU to Japan - in the same way as this is the case between two EU Member States – but also from Japan to the EU. It will be excellent news for citizens on both sides, whose data will benefit from a high level of data protection, and businesses that will benefit from consumer trust and substantially cheaper and easier data transfers.

ePrivacy Regulation

As regards the relationship between the proposal for the ePrivacy Regulation and the General Data Protection Regulation (GDPR) that becomes applicable on 25 May 2018, the proposal seeks to update the current rules to make them fully consistent with GDPR. To this end, the proposal removes overlaps (e.g. the data breach notification requirement has been removed as it is already included in the GDPR) and ensures consistency regarding fines (aligns their maximum with the GDPR ones). Last but not least, the proposal aligns the supervisory authorities with those of the GDPR (like the GDPR, the proposal designates Data Protection Authorities as competent authorities).

Regarding the machine-to-machine communications, the proposed ePrivacy Regulation covers the transmission of machine-to-machine communications data when carried out by an electronic communications service provider, just like the ePrivacy Directive currently does. The reason for this is that machine-to-machine communications data may relate to a natural person or may constitute business information, just like communications exchanged by natural persons or legal persons.

If the transmission of machine-to-machine data were not required to be confidential, such a situation may lead to an interference with the right to respect for private life and communications of the natural or legal person the data relates to.

So if the data are shared via an electronic communication service (for instance a telecommunications company), the confidentiality of machine-to-machine communication is protected. Conversely, machine-to-machine communications which are not operated by an electronic communications service provider or an electronic communications network provider are not in the scope of the proposal.

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

Reply:

Harmonised implementation of the NIS (Network and Information Security) Directive in EU Member States cannot be assessed for the moment as EU Member States have until May 2018 to transpose the NIS Directive into national law, i.e. secondary legislation.

The Commission services welcome 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. 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)

Reply:

In the EU copyright framework, the private copying exception or limitation is optional for the Member States. However, if Member States decide to implement this provision, they are obliged to provide for fair compensation to right-holders. In many Member States this is done by means of a levy.

In the view of the Commission services it is an important objective that when Member States impose such levies for private copying to compensate right holders, their different systems work well in the single market and do not raise barriers to the free movement of goods and services. The Commission services have in the past undertaken a variety of initiatives to foster this and continue to actively monitor the situation while at the same time taking note of the clarifications on a number of open issues that the Court of Justice has provided in the recent past in various judgments in this field.

At this stage, there is no cooperation envisaged with Japan on this topic and the recent EPA concluded between Japan and the EU does not provide any measures as regards exceptions to copyright except a 3-step test reminder.

WP-3 / 05 / EJ to EJ- Cooperation Towards Digital Economy

Reply:

The Commission services consider the digitising of the industry as a key issue for the future of our economies. EU and Japan organised a dedicated seminar, in the margin of the last BRT in Brussels addressing the data economy. In addition, since 2015, the Commission services and the Japanese authorities are regularly organising workshops in Japan and Europe involving industry that addresses priority topics for the EU Japan cooperation like data, platforms, blockchain, etc. The next workshop will be held in Tokyo on 18th April 2018 and the following one in Brussels end of 2018.

WP-3 / 06 / EJ to EJ- Skill Development for Digital Economy

Reply:

The Commission services are promoting various initiatives aimed at increasing training in digital skills for the workforce and for consumers; modernising education across the EU; harnessing digital technologies for learning and for the recognition and validation of skills; and anticipating and analysing skills needs. On 10 June 2016 the Commission services published a new Skills Agenda for Europe, working together to strengthen human capital, employability and competitiveness. It presents a number of actions and initiatives with the ambition to tackle the digital skills deficit in Europe. The new agenda sets out to improve the quality and relevance of skills formation, to make skills and qualifications more visible and comparable and advancing skills intelligence, documentation and informed career choices. Digital Skills and Jobs Coalition is the new flag ship initiative among a number of other initiatives that were presented.

The mid-term review of the Digital Single Market strategy, published in May 2017, focuses on digital skills oriented actions, aiming to manage digital transformation of our society and economy.

On 28 September 2017, the Commission services launched the second European Digital Skills Awards. Companies and other organisations are invited to submit projects they have implemented to improve digital skills in Europe for the awards. The best 4 projects designed at improving the digital skills of citizens, the labour force, ICT professional and in education will receive an award. A fifth award will go to the best project which also address the needs of women and girls.

WP-3 / 07 / EJ to EJ- Building Connectives for Digital Society (5G)

Reply:

The Commission services and the Japanese government have a strong cooperation on 5G: an EU-Japan MoU on 5G was signed in 2015, under the EU research programme H2020 four joint calls on 5G were set-up, regular conference calls are organised to discuss spectrum and 5G events are organised to promote international cooperation.

The 7th EU-Japan Symposium on ICT Research and Innovation covering 5G will be organised in Brussels end of 2018.

WP-3 / 08 / EJ to EJ- Seamless Approach Towards Digital Society

Reply:

Open innovation was discussed during the last Dialogue between DG CONNECT and METI last October in Tokyo. At this occasion it was agreed to set-up a workshop on open innovation to define cooperation priorities. This workshop took place on 19 March in Brussels.

Research cooperation between EU and Japan is very strong with 4 joint calls under the H2020 Programme.

Aeronautics

WP-3/ 09/ EJ to EJ- Government-Led Industrial Cooperation in Aeronautics

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

WP-3 / 10 / EJ to EJ Cooperation in Aircraft Certification

Cooperation between Japanese and European aircraft certification authorities should be upgraded. Specifically, the BRT recommends the signature of a Bilateral Aviation Safety Agreement (BASA) between the JCAB and the EASA that would cover both type certification and maintenance activities.

Reply:

The Commission services are indeed engaged with Japan on Bilateral Aviation Safety Agreement

Negotiations - the second round of negotiations was completed recently. The EU side is eager to sign the agreement

WP-3 / 11/ EJ to EJ- Cooperation on Navigation Regulations for Helicopters

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

Reply:

A memorandum of cooperation in the field of Air Traffic Management modernisation has been signed. This should facilitate the cooperation between EU and Japan on ATM, including on Navigation Regulations for Helicopters.

WP-3 / 12 / EJ to EJ- Regulatory Cooperation in Space Operations

Europe and Japan should not lose the momentum and continue to cooperate closely on regulatory matters in the space sector.

Reply:

There is an excellent cooperation with Japan on Earth observation in several areas of common interest, e.g. CO2 monitoring, marine environment, as well as a great EU's interest in pursuing and fostering this cooperation;

In the field of Satellite Navigation:

- the Commission services are happy to see the good progress made by QZSS;
- there is a very good uptake of Galileo in consumer devices, most notably in smartphones with all major producers now offering Galileo enabled smartphones.

In Space Research, Japanese entities participated in 2014-2017 Horizon 2020 space calls, but there is room to improve their participation. Potential areas for cooperation are: space exploration, scientific data exploitation, and space weather.

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

WP-4/02/EJ to EJ- Basic energy policies

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

WP-4/05/EJ to EJ- Renewable Energy

WP-4/06/EJ to EJ- Smart Grid and convergence of Electric distribution networks with ICT

WP-4/07/EJ to EJ- Effective use of biomass resources

WP-4/08/EJ to EJ Energy conservation & energy efficiency

WP-4/09/EJ to EJ- Energy research and international cooperation

Reply:

DG Energy welcomes the report and recommendations on energy by the EU – Japan Business Round Table.

The report reflects that EU and Japan business think of future opportunities and development in the frame of the Paris agreement and the possibilities offered by innovative and low-carbon energy technologies..

WP-4/03/EJ to EJ- Fossil fuels

Reply:

DG Energy has a sceptical remark regarding this recommendation 3 on fossil fuels.

While the important role that natural gas can play in the energy transition is recognised as well as back-up for variable renewable energy, this recommendation underestimates the potential of renewable energy to provide cost-effective power supply (given the recent decreases in costs of RES production), as well as the possibilities of new smart grid technologies and improved functioning of the electricity market to integrate and balance renewable energy production (such underestimate is however not found in the rest of the report). The last sentence of this paragraph seems to imply that the BRT recommends that the EU would actively support unabated coal-fired thermal power generation, which would be counter-productive in the light of the EU's energy and climate policy targets.

WP-4/10/EJ to EJ- Efforts toward the prevention of global warming following the Paris Agreement reached at COP21

Reply:

The EU remains fully committed to being a global leader in the fight against climate change. On 26 February 2018, the EU Foreign Affairs Ministers stressed the need for the swift implementation of the Paris Agreement and reaffirmed the crucial role of multilateralism.

The EU must continue to build on this momentum throughout 2018, in order to conclude the important work at COP24 the EU needs to complete governance rules within the time frame agreed in Paris. This is essential to build trust among stakeholders and

ensuring that implementation of the Paris Agreement is effective and fair, while sending strong market signals to spur low-emission and climate resilient innovation and investment by the private sector and action by states, cities and other governments.

Action by governments, subnational level, and non-state actors will be key to achieve the Paris Agreement's objectives. Industry and business in particular, being at the forefront of innovative solution, have the potential to be important part of delivering climate action on the ground. But the climate and energy objectives of the countries' targets are also an important opportunity for industry and business. Climate finance and the implementation of the national commitments create market opportunities for businesses. The full implementation of the pledges made under the Agreement will require the energy sector alone to invest an annual average of USD 840 billion.

The EU shares the view that major economies- together accounting for over 80% of GHG emissions- have particularly important role to play in driving the global transition to low carbon economise. This is why we are strengthening our bilateral climate policy dialogues and technical cooperation with those strategic partners, including Japan.

Commission services thank the BRT for its proposals on low-carbon technologies. This is certainly a vast field for private sector initiatives, as the ones mentioned in the text. From the public side, the EU intervenes on climate technology and transfer mainly through the institutions foreseen under the UNFCCC and the Paris Agreement, such as the Climate Technology Centre and Network (CTCN) for which the European Commission is a major donor, the Technology Mechanism and the Technology Executive Committee (TEC).

WP-4/11/EJ to EJ- Promotion of resource efficiency and the circular economy

Reply:

The international dialogue on resource efficiency and circular economy has witnessed an increasing attention to the challenges and opportunities linked with plastics. With the support of enabling policy frameworks, business leaders are key players to improve plastic products by instilling the principles of circularity and sustainability throughout each steps of the plastic' value chain from design to recycling.

In January the European Commission presented a new set of measures to implement the EU Circular Economy Action Plan. These measures include an EU Strategy for Plastic to transform the way plastics and plastics products are designed, produced, used and recycled. The Strategy recognises the importance of international cooperation and wishes to capitalise on the international developments on resource efficiency and marine litter, especially in the G7 and G20. In this light, the Environment Directorate-General and the Ministry of the Environment of Japan have organised a G7 Plastics Workshop in the context of 2030 Agenda implementation and towards G7 collaborative activities. Gathering policy makers, experts, business representatives and other key stakeholders, the workshop aims to provide a platform for discussion and reflection to take forward the G7 Bologna Roadmap plastics aspects and deliver the strategic direction of the Kobe 3R Action Plan and the Toyama Framework on Material Cycles in relation to the resource efficiency of plastics, including the realisation of related climate change benefits. This will also contribute to the G7 Alliance on Resource Efficiency and to the objectives of the G7 Action Plan to Combat Marine Litter.

This year there is also an abundance of opportunities to promote resource efficiency and circular economy at the international level: the World Circular Economy Forum (Yokohama, Japan on 22-24 October 2018), and the 23rd Plenary Meeting of the UN Environment's International Resource Panel taking place back-to-back.

The EU looks forward to closer cooperation with Japan in the context of the Canadian G7 Presidency and G20 Argentinian Presidency.
