Commission Services Progress Report

on the

EU-Japan Business Round Table Recommendations 2012

"UNLOCKING GROWTH POTENTIAL IN EU-JAPAN BUSINESS"

Brussels, March 2013

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Trade Relations, Investment and Regulatory Cooperation

Recommendations from both European and Japanese industries

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

The BRT calls on the European Commission and the government of Japan to expedite the remaining efforts necessary to complete their scoping activities on ambitious terms. The BRT also urges the European Commission and the Council of the EU to expedite their respective work on the mandates to authorise the European Commission to negotiate an FTA/EPA and a political and cooperation agreement with Japan

The Commission agrees on the need to further strengthening the EU-Japan relationship so as to foster growth and jobs both in the EU and in Japan.
In this regard it is positive to note that the scoping exercise between the two partners was completed in July 2012 and that the Council adopted the negotiating directives on 29 November 2012. Negotiations are now to be officially launched at the next EU-Japan summit in Tokyo, on 25th March 2013.
The Commissions also fully agrees that in order to generate as much benefits as possible, this agreement will have to be deep and comprehensive and cover not only trade in goods but also issues such non-tariff barriers, public procurement, investment, harmonisation/mutual recognition of regulations and standards, or intellectual property and geographical indications.

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

The BRT is a strong supporter of the multilateral trading system, whose core functions are: trade liberalisation, rule-making and dispute settlement. However, the initial high level of ambition of the Doha Round, launched in 2001, has not been confirmed resulting in the current deadlock of negotiations. A so-called "Plan B" was abandoned in May 2011. Also the December 2011 8th Ministerial Conference in Geneva could not overcome the current deadlock which has revolved both around a lack of political will and the inability to bridge the gap of market access commitments between OECD and emerging country members. With the prospects of great uncertainty, the WTO must demonstrate its ability to deliver results for the business community. It should focus more on its core functions in the future, namely trade liberalisation and rule making. As the only international organisation creating rules and setting standards on trade at the multilateral level, the WTO must remain leader in this area and take more action. The existing legal framework provides an excellent basis but needs to be updated in order to respond to a changing global economic landscape.
Ambitious agreements on trade facilitation and non-tariff barriers should be concluded quickly. This would provide a significant boost to international trade. In addition, plurilateral sectoral agreements should be further negotiated. The WTO should also work towards clearer WTO guidelines on the coherence between bilateral / regional trade agreements and the WTO system. Finally, the WTO should explore other topical issues, such as the relationship between trade and investment, competition, energy and raw materials.
By advancing on a case by case basis the WTO should demonstrate its ability to develop new trade rules and help its members see the advantages of trade liberalisation. This should then serve to allow the restart of more comprehensive market access

negotiations. Any weakening of the multilateral trade system should be prevented by all means

The European Commission welcomes the continued interest of the business community in the Doha Round negotiations. After several years and many ups and downs in the negotiations process, the EU along with other Members of the WTO is focusing on moving forward discussions on a limited set of issues that could be agreed in the short-term, and as a first step toward the conclusion of the entire Round. In this regard, the Commission notes the importance that the business community attaches to the conclusion of an ambitious trade facilitation agreement. Although there is a clear interest on the part of all WTO Members to advance, it is important for the business community to continue to speak openly to their governments in order to express their expectations regarding the conclusion of these negotiations in the immediate future.

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

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

The EU reiterates its commitment to achieving greater harmonization between EU and Japan on the basis of international standards and the use of a proportionate, risk-based approach to conformity assessment, including the greatest possible reliance on supplier's self-declaration of conformity in lower risk sectors as a means to show compliance with mandatory requirements. The EU confirms that these will be among our objectives in the future Free Trade Agreement Negotiations for Japan in the regulatory area. This is notably the case for the motor vehicles sector, where the EU shares the view that the adoption of all relevant Regulations developed under the 1958 UN ECE Agreement, thus benefitting also from the mutual recognition foreseen therein, is the most important avenue for minimizing duplication of requirements and related conformity assessment procedures, and lowering the costs of regulatory compliance of both EU and Japanese manufacturers.

The EU and Japan have been actively working for the past years towards greater harmonization of international standards and enhanced cooperation in fields related to Health, such as Medical Devices and Cosmetics. Both are members of the IMDRF (the International Medical Device Regulators Forum, replacing the Global Harmonization Task Force) and the ICCR (International Cooperation on Cosmetics Regulation).
There are a large number of standards that relate to medical devices and cosmetics. Some of the most important include: ISO 13485 Medical devices – Quality management systems – Requirements for regulatory processes (this is a specific medical device standard based on ISO 9001); ISO 10993 Biological evaluation of medical devices; ISO 14155 Clinical investigation of medical devices for human subjects; ISO 14971 Medical devices – Application of risk management to medical devices, and, for Cosmetics: ISO 22716 – Cosmetics Good Manufacturing Practices.
Both the EU and Japan committed themselves to follow these guidelines and include the procedures as recommended at international level into their national standards processes.

2. The BRT recognises the importance of global patent harmonisation and streamlining of the patent system as a way to promote innovation, reduce costs and boost legal certainty. The authorities of the EU and Japan should take the lead in these efforts.

The European Commission supports global discussions and a future International Treaty aiming to streamline the global patent system, and considers it important to move forward. However, practically all competence for substantive patent law matters rests with the EU Member States. The main role of the European Commission is to coordinate positions among EU Member States and to facilitate progress.
Progress at WIPO Standing Committee on the Law of Patents (SCP) on international substantive patent law harmonisation continue to be blocked by divergent interests of developed and developing countries, the latter mostly interested to tackle exceptions and limitations to patent rights, technology transfer, patents and health.
In Group B+ (contracting countries of the European Patent Convention and the other members of WIPO Group B: Canada, the US, New Zealand, Australia, Japan, South Korea), progress has remained slow. However, future progress could be facilitated by the adoption in 2011 of the latest patent reform in the US, and the four studies drawn up by the Tegernsee Experts Group of the Group B+ on four key elements of global patent law harmonization: grace period, 18-month publication, treatment of conflicting applications and prior user rights.

3. Given the nature of the issue and the importance for business as well as for society in general, the two Authorities should make an effort to harmonise the regulations for energy conservation, relevant labelling rules, and carbon footprint schemes.

In the EU, work on the adoption of minimum performance requirements on the basis of Directive 2009/125/EC on eco-design continues at a brisk pace.

Eco-design measures (i.e. minimum performance requirements including maximum consumption levels) exist for some 17 product groups such as light bulbs, domestic refrigerators, washing machines and televisions. The Commission is working on new implementing measures setting out eco-design requirements for additional product groups such as computers, network stand-by appliances, heaters and water heaters, solid fuel boilers, vacuum cleaners and domestic cooking appliances. Implementing measures for these product groups are expected to be adopted in 2013.

Energy efficiency has been a regular topic on the agenda of the EU-Japan energy dialogue, where exchanges on the latest policy developments take place. Joint work is also ongoing in the context of international organizations addressing this policy issue, namely the International Energy Agency and the International Partnership on Energy Efficiency Cooperation.

4. Following the agreement on the mutual recognition of the AEOs (Authorized Economic Operators) in June 2010 between the EU and Japan, the Authorities of the EU and Japan should aim at introducing further regulatory cooperation in order to give more concrete benefits to AEOs. The BRT would in this regard like to put emphasis on simplifications of import procedures where companies are given a greater freedom while also taking greater responsibility for their imports.

Mutual Recognition of AEOs including further benefits are discussed by AEO experts from both sides in their regular meetings concerning the implementation of the mutual

recognition decision between the EU and Japan. Moreover, EU and Japanese experts will also commence working towards an automated solution for the future data exchanges. The results of those discussions are reported to the EU-Japan Joint Customs Cooperation Committee for consideration.

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

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

The European Union Customs Policy aims to facilitate legitimate trade, whilst applying the level of controls necessary for guaranteeing the safety and security of citizens and protecting public health, environment, financial and economic interests of the EU and its Member States.

The EU aims to cooperate with its trading partners to ensure end-to-end security and facilitation of the international supply chain.

DG TAXUD is interested in promoting technical solutions, including research and innovations. For this reason DG TAXUD has also a very proactive approach to encourage Member States customs administrations to participate as a potential end-users in relevant research projects for the purpose of advancing the state of the art of detecting technology applications.

7. The European Commission and the Japanese Government should support the ICT for Energy Efficiency Forum, actively participating in it and disseminating its outcome in order to encourage global collaboration.

The ICT for Energy Efficiency Forum does not exist anymore. The European Commission is currently working on a plan to set up a stakeholder group to continue collaboration at global level on promoting energy and environmental efficiency of the ICT-sector.

8. The European Commission and the Japanese Government should collaborate on achieving international harmonisation at CODEX in the description and standards for food for specified health use/functional foods.

The Commission agrees with the recommendation that calls for collaboration between Japan and the EU to enhance food safety through the application of international standards and co-operation in the standard setting process. Co-ordination takes place on a case-by-case basis in the CODEX *Alimentarius* but rather more co-operation takes place

in the WTO SPS Committee where the EU and Japan co-ordinate positions on different issues on a regular basis.

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

Enhancing the international harmonisation of technical requirements for motor vehicles is a high priority for an increasingly globalising automotive industry. The Commission fully shares the view of the BRT and would like to recall that in the EU legal system, the transposition of UN-ECE regulations into EU ones is automatic.

Review of the 1958 Agreement and IWVTA (International Whole Vehicle Type-Approval): the overall objective for the review is two-fold: 1) maintain a robust and reliable international framework to ensure sufficient level of safety and environmental protection. and 2) make the framework more attractive for emerging countries .
The process of the review is based on the belief that the 1958 Agreement needs to turn into a more extended global system. In March 2010 consensus was made at WP29 to reform and modernise this international framework in order to make it more effective in today's global market for cars. In the short term, the Agreement should be reviewed to make it more operational and attractive to countries applying type-approval system. Some 50 actions proposed by the informal group to this end were approved by WP29 in November 2011. Among them 40 actions address the reinforcement of type-approval and mutual recognition system and 10 actions target at making the Agreement more attractive to emerging countries. For the medium and long term, developing a global system attractive enough for countries applying self-certification system is considered to be the ultimate objective.
The WP29 agreed on a roadmap to carry out the 1958 Agreement review and the IWVTA establishment by the target year of 2016.

WP-A / 04 / EJ to EJ ***Supporting timely development of business***
1. Social security contributions (avoiding double contributions):
The BRT welcomes the conclusion of social security agreements between Japan and certain EU member states in the past, but regrets that no new agreements were concluded in 2011. Therefore, the BRT requests that, Japan and the Member States of the EU make further efforts to expand the network of Social Security Agreements. In addition, they should introduce an interim measure, by which a host country should either exempt contributions to pension funds unilaterally or refund the contributions in full when expatriates return to their home country.

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

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

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

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

2. Personal data protection regime:
The BRT believes that the ultimate objective of personal data protection for an individual business is to adopt and implement a reliable and cost-effective personal data protection system at the level of a corporate group, within which the flow of data should be free across national borders. In order to achieve this, the national legislation of each country should promote such a system rather than impede by creating different requirements. To realise such a business environment between the EU and Japan, the Government of Japan should make sure to build on the report of July 2011 of the Special Commission about Personal Information Protection established in the Consumer Commission with a view to realise a harmonised data protection regime between the EU and Japan. Furthermore, the EU has launched the legislative process of significantly modifying its Directive 95/46/EC. The two authorities should consult closely with each other so that the two regimes should not become more diverse.. The two governments should then launch the adequacy-finding procedure under the EU Directive as soon as feasible.
In parallel with the above process, the authorities of the EU and Japan should launch a dialogue in order to seek an international framework by enhancing cooperation with third countries and international organisations. It should eventually lead to the closer alignment of data protection regimes around the world that would enable global businesses to transfer personal data by complying with one regime.
In addition, the authorities of the EU and Japan should improve legal certainty surrounding the use of new technological tools such as cloud computing applications and services. The BRT believes that such improved legal certainty would support and enhance the application of new technological developments while maintaining the degree of data protection currently provided.

The European Commission recognises the interests of business in having reliable and cost-effective personal data protection systems at the level of a corporate group, within which the flow of data should be free across national borders. That is why the European Commission is working to simplify and expand the availability of Binding Corporate Rules (BCRs) as part of the process of the reform of EU data protection legislation. This will enable more businesses to adopt BCRs, which will enable the free flow of data across borders within a corporate group, notwithstanding any differences in national legislative regimes, while ensuring a high level of protection of personal data. The new Regulation contains several innovations to facilitate international transfers, for example clear and explicit modalities for the use of BCRs and SCCs (standard contractual clauses), eliminating cumbersome prior-authorization procedures altogether in many cases. Under certain conditions, it will also be possible to base a cross-border data transfers on non-binding instruments such as memoranda of understanding and codes of conduct. More generally, the proposal encourages the adoption of codes of conduct (which should include rules on cross-border flows) as a means to ensure proper application of the Regulation. A procedure is even foreseen empowering the Commission to declare a given code valid throughout the EU, thereby granting greater legal certainty to companies making use of them. Furthermore, the proposed new Regulation on data protection will considerably simplify compliance with personal data protection rules for businesses operating between Japan and the EU, for example due to the replacement of 27 different national laws with one single law for the whole EU, and also with the creation of the "one-stop shop", where businesses will only have to deal with one single data protection authority, as well as the "consistency mechanism", which will ensure coherent application of the rules across the whole of the EU. With regard to adequacy, as noted above, it is important to recognise that as it results in completely free flow of data between the EU and a third country without any additional rules or checks, the process for adequacy involves a very detailed, lengthy and intensive examination of a third country's laws and practices. It should be recognised that adequacy is not the only route for international data transfers: both the current Directive and, in particular, the new Regulation, provide for other ways of lawful data exchange between the EU and Japan, and businesses will see real benefits in terms of the simplification of the rules introduced by the new Regulation.

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

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

The Commission supports the BRT recommendation on deepening mutual understanding of regulatory developments. The Commission is confident that the new context for EU-Japan relations provided by the FTA negotiations will lead to enhanced regulatory cooperation, including mechanisms for cooperation at an early stage in the respective

regulatory processes, with a view to identifying potential areas for common regulatory work while also preventing obstacles to trade due to unnecessary regulatory divergences.

As part of its Better / Smart Regulation Policy, the Commission is fully committed to a transparent regulatory process that provides adequate opportunities to stakeholders, including foreign ones, to provide input at all stages of the regulatory lifecycle. The Commission shares the view of the BRT that good governance improves the quality of legislation, contributes to greater accountability of the system and ensures not only that legislation is not more burdensome than necessary to achieve its legitimate public interest objectives but also that it remains fit for purpose.

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

For further details, reference is made to the most relevant recent policy documents relating to the Commission's Better / Smart Regulation Policy:
- Commission Communication on EU Regulatory Fitness - COM(2012) 746 final of 12.12.2012
- Commission Staff Working Document – Review of the Commission Consultation Policy – SWD(2012) 422 final of 12.12.2012
- Commission Communication – Commission Work Programme 2013 – COM(2012) 629 final of 23.10.2012
- Commission Communication on Smart Regulation in the European Union – COM(2010) 543 of 8.10.2010
and, more generally, to the Commission's Better Regulation website:

http://ec.europa.eu/governance/better_regulation/index_en.htm

WP-A / 06 / EJ to EJ ***Support for SMEs***

The BRT calls on the EU and Japanese Authorities to develop measures to promote and assist SMEs to explore and seize business opportunities in each other's market. Should negotiations for an FTA/EPA begin, specific consideration should be made to establish measures for SMEs within the framework of negotiations.

The Commission considers that a SME policy dialogue would be useful, but only when it is put in a broader context of relations between for instance the Directorate General Enterprise and its Japanese counterpart, for instance in the form of Regulatory and Political Dialogue – as it is the case with China and Russia, or US (where the dialogue is put in the framework of the Transatlantic Economic Council). The SME dialogue could

be a platform providing contributions to a kind of "SME chapter" in the context of the FTA with Japan.

The Commission would like to recall that it already proposes measures to support the internationalisation of its SMEs within the EU and abroad. In Japan, the support to SMEs is one of the primary objectives of the EU-Japan Centre for industrial cooperation.

Recommendations from Japanese industry to the EU

WP-A /14 / J to E ***Europe 2020 and the Single Market Act***

The BRT expresses our continued support for Europe 2020 and in particular, the Single Market Act - the initiative of the European Commission to re-launch the single market.

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

2) The EU should make utmost efforts to realise the 12 priorities in the Single Market Act by the deadline of 2012. The BRT would like to emphasise the importance of the following priorities for the single market. - Intellectual property rights; Consumer empowerment; Services; Networks; The digital single market; Taxation; Business environment

The Commission adopted on 3 October 2012 the Single Market Act II, a Communication that sets out its strategy and twelve new key levers for the further development of the single market. The SMA II maintains the balanced political vision promoted by the SMA I that was widely welcomed by the European Parliament, Member States and stakeholders. Like the SMA I, SMA II aims to focus political attention on a restricted number of key actions fast-tracking their adoption for new growth in the single market. It announces 12 key proposals, in four key areas:

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

The Commission commits to table proposals for all key legislative actions by spring 2013. It calls on the European Parliament and the Council to adopt these proposals by spring 2014.

Regarding the Single Market Act I, by spring 2012, the Commission had presented its legislative proposals for all 12 key actions. Of these, to date, only one has been formally adopted by the European Parliament and Council. Progress is needed as a matter of urgency so that all 12 SMA I priority proposals can be agreed rapidly in line with the request of the European Council in October 2011.

With the adoption of the SMA I priority measures to be completed by spring 2013, attention of the co-legislator should shift to the adoption of the key actions under the SMA II, which the Commission will have presented by then.

Consumer Empowerment

The Commission is assessing consumer empowerment in EU Member States through regular surveys and in-depth studies. In particular, it gathers relevant data in the Consumer Scoreboards, and is undertaking in-depth studies of potentially problematic markets and issues such as over-indebtedness and other vulnerability patterns in consumer markets.

The Commission is revising and updating its actions to support consumer empowerment through information, education and capacity building for consumer associations. In particular, it focuses on facilitating exchange of best practices regarding raising awareness of consumer rights and redress and regarding consumer education in schools, and on stakeholder dialogue to improve the reliability of information about products

through comparison sites, labelling or claims. Initiatives are also on-going (in particular on bank accounts and e-commerce) to ensure that consumers are better able to benefit from the increased choice of products thanks to more transparent and comparable offers and easier switching.

Digital Single Market

The Commission remains committed to removing existing barriers to the EU Digital Single Market to ensure that consumers feel as confident shopping online as in the offline world and can ripe the full benefits of e-commerce. The European Consumer Agenda, adopted in May 2012, identifies the "digital revolution" as one of the key economic and societal challenges that a comprehensive and modern EU consumer policy should address.

Two key proposals on Alternative Dispute Resolution (ADR) and Online Dispute Resolution (ODR) were tabled in November 2011 and are expected to make available to all consumers a quick and inexpensive way to resolve disputes with traders. The dedicated European platform for online dispute resolution would aim to improve consumer confidence in cross-border e-commerce.

Another key goal of the Commission is to ensure that the information consumers receive online on products and services is transparent and reliable. Through a recently launched multi-stakeholder dialogue on comparison tools, the Commission works together with consumer representatives, national authorities, traders, operators of comparison websites and other online information intermediaries to develop concrete principles, promote best practices, improve the presentation of information online and encourage cross-border comparison.

Finally, we aim at improving digital literacy, also for the more vulnerable consumers, through education and information actions. The Commission is currently developing an interactive platform for exchanging best practices and distributing consumer education materials amongst teachers and other professionals working with 12-18 year-olds. This will include, amongst others, material digital literacy and new media technologies.

WP-A / 15 / J to E Revision of high customs tariffs on audio-visual products and passenger cars

The EU is protecting some sectors of its industries by maintaining high customs tariffs, for example 14% for audio-visual products and 10% for passenger cars, even though these industries are at the forefront of international competition and need stimuli for competition rather than protection. Such protection will not help enhance international competitiveness of those sectors. Furthermore, it is only their users and consumers in the EU who unfortunately have to pay the resulting higher prices. The European Commission and the member states should abolish or drastically reduce these high customs tariffs.

Negotiations for a Free trade Agreement with Japan are due to start in coming months. The objective is to reach a deep and comprehensive agreement with the maximum coverage possible in terms of liberalisation of trade in goods while at the same time adequately taking into account the sensitivities existing in certain sectors.

WP-A / 16 / J to E Customs Classification

The BRT believes that customs classification should be done in accordance with the Harmonized System Convention rules. However, the BRT also believes it to be a fact that the rules do not provide a clear method of classification for such products as electric-

electronics products, where the technical convergence of IT and non-IT products has emerged. This situation makes interpretation and classification more difficult and complicated than ever, and has undermined transparency, predictability and promptness for businesses. It is requested that the EU acknowledges the concerns and difficulties the businesses are facing, and based on the panel reports by WTO issued on information technology dispute in August 2010, to take steps to increase predictability and improve transparency upon importation of the IT products. The improvement of the said situation will indeed contribute to the ICT industry development.
In the Netherlands, the Supreme Court ruled that toner cartridges should be classified as chemical products and thus subject to 6% customs duty. In HN classification, it is a part of copiers and thus subject to 0% customs duty. The discrepancy should be resolved without delay.

Assuring the correct and uniform classification of IT products. The EU has created the Binding Tariff Information (BTI) system as a tool by which all economic operators can obtain legal certainty about the correct classification of goods which they intend to import. The issuing of BTIs falls under the competence of the national customs administrations. Their classification decisions are based on an assessment of the objective characteristics and properties of an individual product taking into account the existing international (HS Nomenclature, HS Explanatory notes, WCO classification opinions) and European (CN, CN Explanatory Notes, classification regulations, EU Court of Justice rulings) legal framework. Every BTI is valid throughout the EU, regardless of the Member State which issued it. When Member States have divergent views on the classification of a certain product, the case is submitted to the Commission, who examines it and puts it on the agenda of the Customs Code Committee for in-depth discussion and decision

Classification of Toner cartridges:
This issue concerns two different products. The HS classification opinion only concerns ink cartridges with mechanical moving parts. These products are indeed classified as parts of a printing machine of heading 8443. The product on which the Dutch court ruled is an ink toner without any mechanical/electrical parts. For this product there is no HS guidance. In the EU, cartridges without any mechanical/electrical parts are classified as chemical products (printing ink) under heading 3215. This is supported by two EU Court of Justice court rulings (C-250/05 and C-276/00).

WP-A / 17 / J to E Fight against counterfeited, pirated and contraband goods
The BRT would like to see the EU to take further necessary steps such as a possible proposal for modification of the Enforcement Directive with a view to step up efforts in all the EU Member States to fight against counterfeited, pirated and contraband goods, both inside and outside the EU.
The BRT would also like to urge the EU to make sure to implement Council Regulation (EC) No. 1383/2003 of 22 July 2003 concerning customs action against goods suspected of infringing certain intellectual property rights and the measures to be taken against goods found to have infringed such rights. At present, several Member States have not implemented it. Due to a lack of resources, only a small part of the goods that are passing through the EU customs are checked by the authorities. A substantial part of counterfeit goods are passing through the customs as a result. With an increased cooperation by the manufacturers and importers of the authentic goods, including the provision of more information on their products and the on-site training of officials, the

customs authorities should make inspection more efficient and raise the rate of its coverage.
The importers of the authentic products have to pay for the storage, transportation and destruction costs of counterfeit goods. Some companies may, as a result, renounce the fight against counterfeit goods. However, counterfeit products raise more and more health and safety issues. In addition, there is also an obligation for the Member States to destroy counterfeit goods detained by the customs and, especially, not to release them on the EU market. The EU, through the Member States, should introduce financial support or offer free assistance.

- The Commission is continuing the on-going public consultation on the functioning of the current civil enforcement system in the EU. In November 2012 it launched a survey to gather evidence to evaluate the efficiency of existing national Intellectual Property civil enforcement systems. The survey will run for 4 months and the results be made publicly available on the IPR enforcement website.

After this round of consultation, a Commission communication to be adopted by the end of 2013 will present the conclusions and possible initiatives on how to improve the existing shortcomings

In May 2011, all the relevant stakeholders (companies, trade associations and internet platforms) signed a memorandum of understanding (MoU) on the sale of counterfeit goods over the internet. This MoU aims at developing good practices addressing online counterfeiting. It foresees a 12 months evaluation period. Following several times to discuss the functioning of the MoU, practical experiences and the expected outcomes of this initiative, the signatories acknowledged the contribution of the MoU to the good progress of their dialogue. Since the evaluation period was however extended by 6 months, the evaluation report is only expected by the end of 2012.

Regulation (EU) No 386/2012 of 19 April 2012 entrusted the Office for Harmonization in the Internal Market (Trade Marks and Designs) (OHIM) with tasks related to the enforcement of intellectual property rights, including the assembling of public and private-sector representatives as a European Observatory on Infringements of Intellectual Property Rights. The plenary session of the Observatory was held in September 2012 and the Work programme for 2013 was adopted in November 2012.

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

WP-A / 18 / J to E ***Unitary Patent***
The BRT welcomes the launch of an enhanced cooperation procedure for the creation of unitary patent protection authorised by the Council on 10 March 2011. The BRT would like to urge the EU and its Member States to adopt and implement a unitary patent protection for the greatest possible number of Member States and a unified patent litigation system as soon as possible.

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

The envisaged reform of the patent system comprises of two main elements: the creation of unitary patent protection and the setting up of a unified specialised patent court. It is

still foreseen concluding both initiatives by end 2012 and accomplishing the target of registering the first unitary patent by mid-2014.

- Unitary patent protection

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

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

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

- Unified Patent Court

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

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

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

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

Since the work on the Draft Agreement is almost finalised, its signature might happen as soon as in early 2013.

Entry into force of the agreement on the UPC is contingent on the ratification by 13 Member States (including France, Germany and UK). The ratification process would take place throughout 2013.

WP-A / 19 / J to E ***Taxation***

19.1 Common Consolidated Corporate Tax Base

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

1) Non-taxation of unrealised gains on goodwill within a group of companies that form CCCTB

2) Non-application of arms-length principle within a group of companies that form CCCTB.

3) Off-setting of profits and losses within a group of companies that form CCCTB.

The Commission welcomes the comments from BRT and confirms that the Commission remains firm on the elements of the CCCTB as proposed: an optional system with consolidation and with simple and less burdensome implementation rules. A first technical reading of the CCCTB proposal has now been completed in Council. The discussion on the proposal will continue in Council under the Irish Presidency during the first half of 2013.

19.2 Merger Directive

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

The Merger Directive 90/434 has been substantially amended several times (in particular in 2005 by Directive 2005/19) and recently codified by Directive 2009/133 of 19 October 2009. Due to the recent amendments, a revision of the Merger Directive is currently not envisaged.

19.3 EU Transfer Pricing Documentation

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

The EU and its Member States should not treat companies in good faith and companies that try to evade taxation in the same way as the imposition of penalties even when EU TPD is prepared in good faith could lead to undesirable distortions in the single market by forcing companies to adopt artificial transfer price in order to avoid penalties.

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

"7. Member States should not impose a documentation-related penalty where taxpayers comply in good faith, in a reasonable manner and within a reasonable time with

standardised and consistent documentation as described in the Annex or with a Member State's domestic documentation requirements and apply their documentation properly to determine their arm's length transfer prices".
And in Annex :
"20. Taxpayers avoid cooperation-related penalties where they have agreed to adopt the EU TPD approach and provide, upon specific request or during a tax audit, in a reasonable manner and within a reasonable time, additional information and documents going beyond the EU TPD referred to in paragraph 18.
It would appear that if there is evidence of tax evasion the requirement to "comply in good faith" will not have been met.

19.4 The fundamental reforms of VAT regime under consideration

The BRT welcomes the strategy of the European Commission to fundamentally revise the VAT system and to establish a simpler, more efficient and robust VAT system tailored to the single market as described in Com (2011) 851.
The BRT hopes that the new regime will be realised swiftly and in such a way that a business group could easily and cost effectively centralise VAT administration in the EU.

The fundamental reform of the VAT system is a longer term process which consists of several steps. The Commission intends to present in 2013 in the framework of the VAT reform a legislative proposal for a standardised VAT return. This proposal should facilitate compliance for businesses having reporting obligations for VAT in several Member States.

WP-A / 20 / J to E On the forthcoming legislative proposal on non-financial disclosure

The BRT supports the initiatives taken by the European Commission to involve stakeholders and facilitate dialogue in order to improve the transparency of companies with regard to non-financial information disclosure.
The BRT believes companies of different sizes, business sectors and organisational structures should be given the opportunity to choose the best reporting framework to express their company values. In line with the interpretation of materiality put forward by the IASB's Practice Statement for Management Commentary, the BRT strongly believes that what is material to companies is company-specific. The BRT is, therefore, in favour of a principles-based approach and have reservations about the EU endorsing any particular reporting scheme or a small number of quantitative Key Performance Indicators (KPIs).
From the perspective of an association of multi-national companies whose activities stretch across not only different European countries but also different regions in the world, the BRT strongly favours the harmonization of future requirements of non-financial information disclosure not only within the EU but also internationally. Different disclosure requirements regarding scope and content across the 27 EU Member States would create an additional administrative burden for European or multinational companies operating in different countries and regions.
The BRT believes that under a new EU regulatory framework for non-financial disclosure, companies should be allowed to report on a group or consolidated level. Such an approach would create a solid foundation for the integration of non-financial information into the management structure of a company and would be more practical than a disclosure requirement at legal entity level. Furthermore, disclosure beyond consolidated group level, for example, disclosure concerning its supply chain or value

chain, should not be mandatory because mandatory inclusion would make disclosure too burdensome for companies.

The Commission is currently preparing a legislative measure on disclosure of environmental and social information by companies across all economic sectors. This was announced in the Corporate Social Responsibility (CSR) communication adopted by the European Commission in October 2011, and previously in the SMA I. Such measure would present a balanced proposal allowing for significant progress on useful, transparent disclosure of non-financial information, but avoiding undue administrative burden for companies, especially for the smallest ones.

WP-A /21 / J to E ***EU policy on company law***

The European Commission adopted a proposal for a Council Regulation on the status for European Private Company in June 2008. According to the proposal, it was to be applicable from 1 July 2010. The Council should adopt it without delay. The statute should realize the following points.

1) Widely accessible, easy to set up and inexpensive to run

2) Allowing a great deal of flexibility to founders and shareholders to organize themselves in the way that is best suited to their activities: and

3) As uniform throughout the EU as possible.

The proposal for a regulation on the Statute for a European Private Company ("the SPE") tabled in June 2008, was designed to address the current onerous obligations on small and medium-sized enterprises (SMEs) operating across borders. It aims at offering a very flexible yet transparent company form enabling SMEs to carry out business throughout the EU, hence contributing to enhancing growth. Currently, SMEs have to set up subsidiaries in different company forms in each Member State in which they want to carry out their business. In practical terms, the SPE would allow them to set up their company in the same form irrespectively of the Member State where they carry out their business. Opting for the SPE would save entrepreneurs time and money on legal advice, management and administration..

The European Parliament adopted its report on the proposal in March 2009. Unanimity has however not yet been reached in the Council and prospects to reach an agreement in the short term appear uncertain.

The Commission will continue to explore other viable alternative means notably to improve the administrative and regulatory framework in which SMEs operate.

WP-A / 22 / J to E ***Chemical Regulations***

22.1 REACH

The BRT requests harmonization of regulation proposal in accordance with the process of REACH, especially on combined exposure of chemicals which is submitted by Member States and on denominator of concentration which could be different from Article in REACH in some Member States.

European Chemical Agency (ECHA) has been running a campaign, "Act Now ! REACH 2013" to urge prospective registrants to undertake the preparation of the joint submission in the tonnage band 100 – 1,000 t/year by the next registration deadline, 31 May 2013. New challenges are already foreseen in the SIEF operation toward 2013 registration deadline, namely, less data available, inexperienced lead registrants, mostly

SMEs in the supply chain, and heavy financial burden. The SIEF activities will stagnate due to such concerns.
In this respect, EU Competent Authorities (CA) should enhance its promotion and support to allow the registrants to make the joint submission successful and in time. Especially, we request CA to engage in arbitration to solve the disputes, for example, in the cost sharing and the lead registrant nomination, among SIEF members.

As regards SIEF formation and operation, practical solutions to the main concerns reported to the DCG have been implemented by ECHA. On the basis of the outcome of the 2010 registration deadline, the joint submission process is considered to be generally working well. However, specific problems have been identified by the Commission in the framework of the Review of REACH as regards SMEs in view of the 2013, but mainly the 2018 registration deadlines. The involvement of industry as well as ECHA is crucial in order to address those issues, namely by providing targeted guidance for SMEs on transparency, non-discrimination and fair cost sharing as well as by disseminating "best practices" in SIEFs. As problems of compliance with competition law rules as well as good practice as to the dissemination of CBI within SIEFs have also been identified, the Commission recommends in its Report on the Review of REACH that industry associations work on raising awareness on these rules and principles to the benefit of their members.

The interpretation of "Article" applied to 0.1% threshold for SVHC (Substance of Very High Concern) is still disharmonized among EU member states. The Guidance on Requirements for Substances in Articles in REACH regulation states that the 0.1% threshold should apply to an article as a whole produced or imported. Six member states, however, insist that the threshold should apply to the parts of complex articles based on the "Once an article – always an article" concept.
The BRT asks EU to soon unify the interpretation of the Article as stipulated in the Guidance document so that actors in the supply chain can avoid the fragmented compliance requirement in EU market.

As regards the interpretation of the 0.1% weight by weight threshold foreseen in Art. 7 and 33 of REACH, the existence of a divergent interpretation among MS would compromise the objective of harmonisation of the internal market. The Commission stress the importance of a harmonised implementation of those provisions and has taken appropriate action to ensure the fulfilment of this objective (infringement procedures have been launched against the dissenting MS).

22.2 RoHS

The BRT requests an early issuance of a compliance guidance of revised RoHS (RoHS II) and FAQ (frequently asked questions) which should be prepared, beforehand, in collaboration with industrial associations including Japanese ones.

The new RoHS Directive 2011/65/EU (RoHS 2) entered into force on 21 July 2011 and requires Member States to transpose the provisions into their respective national laws by 2 January 2013. The FAQ document was drafted by a Member States working group under a mandate from the RoHS/WEEE Technical Adaptation Committee and takes account of stakeholder input from a consultation on an earlier version.

The FAQs are intended to help economic operators interpret the provisions of RoHS 2 in order to ensure compliance with the Directive's requirements. They are considered a 'living document' and may be revised again in the future.
The FAQ can be founded at the following address:

http://ec.europa.eu/environment/waste/rohs_eee/pdf/faq.pdf

22.3 CLP Regulation (Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures)

CLP regulation affects not only EU manufactures and importers but also exporters outside EU. While CLP is comparable to UN GHS, CLP does not take some of GHS classification but introduces EU own classification. As a consequence, the exporters to EU are forced to be compliant with both GHS and CLP. To alleviate a burden of exporters, we request flexibility in a way that EU accepts GHS classification and labelling at the custom clearances.

The request cannot be followed. The CLP requirements apply as they are for imports.
To note: CLP is not only 'comparable' to UN GHS, but implements it correctly. The GHS gives certain flexibilities (the so-called 'building block approach') to choose from.
The EU has made its choices through the CLP Regulation. Additional EU 'own classification' categories are (a) allowed by the GHS and (b) are gradually disappearing as the GHS evolves through the biennial revisions. Japan is invited to consider aligning its own GHS implementation – which to our understanding is more limited in scope - more with CLP.

22.4. Nanomaterial Definition

The commission recommendation on the definition of Nanomaterial (2011/696/EU) was published on 18 October, 2011. We request EU to state that a product in which the Nanomaterials are embedded shall be out of the definition scope.
This question is explicitly addressed in the Questions and Answers on the Commission´s website http://ec.europa.eu/environment/chemicals/nanotech/questions_answers.htm#13: "The Recommendation's scope covers nanomaterials when they are substances or mixtures, but implicitly not when they are final products. This limitation is equal to that introduced by ISO. This means that if a nanomaterial is used amongst other ingredients in a formulation the entire product will not become a nanomaterial."

Moreover, we expect EU to implement the prospective policy tools on nanomaterials taking into consideration the degree of exposure of nanomaterials released from the product.
This is part of the risk-based approach which is generally applied in EU policy, most notably in REACH.

Several EU member states intend to enact its own nanomaterial reporting scheme at national level. This intention incurs the manufacturers and importers of nanomaterials to make multiple reporting in each format, which shall cause inefficiency and confusion in the supply chain. To avoid such drawbacks, we urge EU commission to take an initiative to elaborate a harmonized reporting system in EU level.
The Commission will be launching an impact assessment to identify and develop the most adequate means to increase transparency and ensure regulatory oversight, including an in-depth analysis of the data gathering needs for such purpose. This analysis will

include those nanomaterials currently falling outside existing notification, registration or authorisation schemes. This will include the option of harmonised reporting system on EU level mentioned in the above comment.

WP-A / 23 / J to E ***Competition Policy***

There are guidelines in the determination of the amount of fines in case of an infringement of the competition rules. The BRT would like to see more clarity in the determination of the amount of fines so that businesses will not be unduly deterred and that the 'Europe 2020' will be achieved.

We note that Japanese industry made similar statements in its 2010 and 2011 recommendations and the Commission Services provided the following replies to the previous recommendations:

"In 1998 the European Commission published its first Guidelines for the setting of fines. These guidelines were revised in 2006. The currently applicable guidelines are designed to increase transparency by clarifying beforehand the consequences of infringing EU competition rules, thereby increasing legal certainty. The European Commission's power to set fines is only broadly defined in the relevant legislation. Council regulation 1/2003 simply determines the maximum fine as 10% of annual turnover. Fining guidelines are therefore necessary to explain how the Commission calculates its fines. However, the primary purpose of the fining policy is to provide a sufficient deterrence preventing firms from infringing the competition rules. This "signalling effect" is crucial. The European Commission's fining policy - as set out in the guidelines - is intended to convey three main messages: (i.) Do not break the competition rules, (ii.) if you do, stop immediately, and (iii.) once you stopped, do not start again. By publishing the fining guidelines and explaining how it calculates its antitrust fines, the European Commission is behaving in a transparent manner, which benefits industry. Far from being an "undue deterrent" as the Working Group seems to suggest, a competition policy regime with sufficient fining powers is an important element towards fulfilling the Lisbon Strategy. No major overhaul of the current guidelines is foreseen in the near future. However, the Commission monitors developments closely and may decide to amend the guidelines again, if called for."

The Commission Services provided the following reply to the 2011 recommendation:

The Commission Notice on best practices for the conduct of proceedings concerning Articles 101 and 102 TFEU was published on 20 October 2011.[1] The Notice provides further guidance how the Commission will act in situations where it considers the possibility of imposing fines on companies in on-going antitrust proceedings. According to the Notice, Statements of Objections will clearly indicate whether the Commission intends to impose fines if the objections should be upheld at the end of the procedure. In such cases, the Statement of Objections will refer to the relevant principles laid down in the 2006 Guidelines on setting fines. Moreover, in the Statement of Objections the Commission will indicate the essential facts and matters of law which may result in the imposition of a fine, e.g. the duration and gravity of the infringement, whether the

[1] OJ C 308/6, 20.10.2011. http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:C:2011:308:0006:0032:EN:PDF

infringement was committed intentionally or by negligence, and whether there are aggravating and/or attenuating circumstances.

The Commission services consider that the explanations provided above – in particular the 2006 Guidelines on fine-setting in combination with the increased transparency provided by the 2011 Best Practices Notice should have eliminated the concerns put forward by Japanese Industry.

WP-A / 24 / J to E ***Consumer protection***

The BRT welcomes the adoption of the Directive 2011/83/EU of the European Parliament and of the Council of 25 October 2011 on consumer rights. The BRT also welcomes the fact that the two of our recommendations are accommodated in the new directive.

The new directive, however, still maintains the discretion of the Member States to set a guarantee period longer than 2 years set in the Directive 1999/44/EC, which the BRT believes could constitute an obstacle in the single market. The BRT would like to ask the European Commission to review the advantage and disadvantage of this discretion to set a guarantee period longer than 2 years in the future review.

The Commission welcomes the BRT's endorsement of Directive 2011/83/EC on consumer rights, which will indeed improve the functioning of the internal market notably as regards business-to-consumer sales online and off-premises. It is true that the scope of the text finally agreed between the EU institutions is reduced compared to the Commission's original proposal. It was not possible to reach agreement between the Member States concerning a common period for the legal guarantee of goods. The existing Directive 1999/44/EC therefore still allows Member States to adopt longer guarantee periods in their national laws. However, BRT's attention should be drawn to the Commission's proposal for a Regulation on a Common European Sales Law adopted in October 2012. This proposal, if finally adopted by the Council and the European Parliament, will allow businesses and consumers to choose a second contractual regime for cross-border contracts that would apply instead of national laws. Under this proposal a common prescription period of 10 years will apply to the guarantee (or two years from the time when the consumer discovers the defect). So businesses making use of this optional contractual regime will be able to rely on the same guarantee rules all over the EU. This proposal is currently being negotiated in Council and Parliament."

WP-A / 25 / J to E ***Market Surveillance under the New Legislative Framework***

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

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

The BRT supports the general direction the European Commission and the Member States are taking for harmonising market surveillance. This is an important step for fair

movement of products. The BRT requests the European Commission and the Member States to disclose all the relevant information regarding the progress of this process and the implementation of the market surveillance in each Member State. The BRT also requests the European Commission and the Member States to give industry an opportunity for contributing to developing the framework of harmonised market surveillance.

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

The package includes two legislative proposals: a draft Regulation on market surveillance of products and a draft Regulation on consumer product safety. It also comprises a Communication on a multi-annual plan for market surveillance of products and a Report on the implementation of Regulation 765/2008.
As regards in particular market surveillance, the proposed package of measures aims to provide:
- more effective tools to enforce safety and other product-related requirements and to take action against dangerous and non-compliant products across all sectors through a single, coherence legal framework for market surveillance in the EU for all non-food products (both consumer and non-consumer products);
- alignment of the general obligations of all economic operators in the supply chain with clearer responsibilities for manufacturers, importers and distributors;
- improved product traceability requirements throughout the supply chain;
- strengthened cooperation among market surveillance authorities across the EU to be achieved through the implementation of the 20 actions identified in the proposed multi-annual action plan for market surveillance;
- streamlined procedures for the notification of dangerous products, and synergies between the existing Rapid Alert Information System for non-food products (RAPEX) and the Information and Communication System for Market Surveillance (ICSMS) that links together national market surveillance authorities.

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

WP-A / 26 / J to E ***Japanese expatriates***

1. The Commission presented in July 2009 a proposal for a Directive on conditions of entry and residence of third-country nationals in the framework of an intra-corporate transfer (COM (2010) 378 final). The BRT believes such a directive to expedite and facilitate the transfer of intra-corporate transferees (ICTs) is important to increase the attractiveness of the EU for multinational businesses. However, the proposal could be further improved to facilitate the transfer of ICTs and their family members.
The BRT believes a Directive should include the following measures:

1) The maximum duration of the transfer to the European Union should be 5 years for managers and specialists rather than 3 years currently set in the proposal (Article 16.3);

2) It should be possible for ICTs to submit the application for a work and residence permit after entering the assigned country based on the waiver of visa requirements;

3) It should be possible for their spouses to be automatically granted the right to work upon their arrival

4) The application of integration measures to ICTs should be voluntary.

The Commission welcomes the fact that Japanese industry finds the proposal for intra-corporate transferees' directive important in increasing the attractiveness of the EU for multinational businesses and that it will expedite and facilitate the transfer of intra-corporate transferees (ICTs) as these elements are amongst the main objectives which dictated the need for the proposal. As noted in the 2010 Progress report "EU-Japan Business Dialogue Round Table Recommendations 2010", the proposal provides for response to longstanding requests from Japan concerning the facilitation of intra-corporate transfers of skilled third country nationals both to and within the EU.
With regard to the Japanese industry's recommendations for improving this instrument, it should firstly be stated that the proposal is currently under negotiation in the European Parliament and in the Council. The legislative process may bring some changes to the current text.
Nevertheless, the Commission will not introduce new changes to the text at this stage. It is not excluded that certain amendments brought forward by the European Parliament and the Council during the negotiations could meet the expectations of Japanese industry. This may particularly be the case for provisions on the immediate access to labour market by ICT spouses. It is, however, too early to prejudge the outcome of the legislative process.
We believe that this proposal is important for EU growth and for the objective of creating favourable conditions for multinational businesses.

Regarding each of the recommendations proposed by Japan, Commission services would like to put forwards the following remarks:

1) The maximum duration of the transfer to the European Union should be 5 years for managers and specialists rather than 3 years currently set in the proposal (Article 16.3)

The proposal is an instrument regulating temporary migration - as opposed to long-term or permanent one. The proposal on ICTs is about movements of managerial and specialised staff of multinational companies, temporarily relocated for short assignments to the EU, where a three year period was considered as sufficient. ICTs are not intended to settle permanently in the EU. Should the skills need be permanent, other instruments of legal migration could be relevant, which could imply additional eligibility criteria, for instance that a work contract should be signed with the EU entity and that Member States could possibly apply the labour market test.
In addition, the proposal builds on certain aspects of the specific EU-25 commitments under the GATS and bilateral trade agreements, where the 3-years constitute a typical time-frame for a transfer. The proposal thus complements and facilitates the implementation of these GATS commitments.
Moreover, there is nothing in the proposal which would prevent an ICT from remaining on the territory of the EU following the completion of the 3-year transfer on the basis of another authorisation to work and reside. Finally, there is nothing in the proposal which would a priori prevent an ICT from re-applying for an ICT status. The relevance of temporary status in such cases could be questionable.

(2) It should be possible for ICTs to submit the application for a work and residence permit after entering the assigned country based on the waiver of visa requirements.

The whole set of the relevant provisions in the proposal aims at safeguarding – to the extent possible - the expediency and efficiency of the admission and ICT permit issuance procedures. In addition, a change to this requirement would imply an overhaul of the design of the proposal. The ICT scheme in the proposal is about temporary detachments of third country managers, specialists and graduate trainees from third-country companies to the EU.
Given this context, the ICT scheme is based on the existing employment relationship with the entity in the third country; prior employment in the relevant entity in the third country in the period immediately preceding the transfer (if required by the Member State concerned), and on the ability to be transferred back to the entity in the third country at the end of the ICT assignment to the EU. To facilitate and expedite the admissions, the proposal sets out a short (in principle, 30-days long) period for the assessment of the application.
Moreover, the proposal recognises that there are situations where visa applications or visas are not required and an application for an ICT permit is therefore sufficient.
In those cases in which a visa will be required the proposal advocates that the Member State concerned shall grant third country national whose application for admission has been accepted every facility to obtain the requisite visa. Furthermore, in the event of ICT's intra-EU mobility, the proposal does not require for an ICT to leave the territory of a Member State in order to submit relevant visa or residence permit application. This would partly address the Japanese industry's recommendation.
Finally, there are other provisions of the migration *acquis* which can appropriately address situations of legally residing third country nationals.

(3) It should be possible for the spouses of the ICT's to be automatically granted the work upon their arrival.

The Commission recognises the importance of setting out attractive conditions for the family members of the ICTs to enter and reside in the EU. As a result, the proposal derogates from the existing legislation in the field and extends the benefit of the Directive 2003/86/EC to ICTs and their family members, despite the fact that they are temporary migrants without reasonable prospects for a permanent residence in the EU.
In addition, the proposal contains further advantageous provisions than these laid down in the Directive 2003/86/EC (eg. faster procedures). The maximum period where the Member States may limit access of family members to labour market is 12 months. At this stage, it is not clear how and if the Member States would make any recourse to this possibility and effectively limit market access of ICTs' spouses.
Finally, it should be noted that the provisions of the proposal in the context of family reunification (Article 15) constitute only a required minimum starting point. In accordance with Article 4 of the proposal, Member States may decide to apply more favourable rules to ICTs' spouses than the ones laid down in the proposal.

(4) The application of integration measures to ICTs should be voluntary

The proposal does not impose any integration measures on the ICTs. The only situation where the integration measures could be applied is in the case of ICTs family members. However, this is only an option which could be exercised by the Member States. The extent, to which such a requirement would be applied by the Member States, if at all, is currently difficult to estimate.

Secondly, if any integration measures would be required towards the family members of ICTs, they could only be imposed after the family reunification has been granted and not as a pre-condition of to enter the EU. This flexibility constitutes another attractive derogation from the standard rules applied in the case of family reunification.
The current provisions of the proposal on integration measures and their potential scope are already very favourable both towards the ICTs and their family members.

2. Long-term residents
The BRT welcomes the report from the Commission on the application of Directive 2003/109/EC concerning the status of third-country nationals who are long-term residents (Com (2011) 585). The BRT has noted that the numerous issues pointed out in the report in the implementation of the directive including the weak impact of the Directive in many Member States.
The BRT welcomes the intention of the Commission to increase its efforts to ensure that the directive is correctly transposed and implemented across the EU.
The Directive 2003/109/EC is not applicable in the UK, Ireland and Denmark.
Japanese nationals in the UK, where their number is the highest among EU countries, therefore, do not benefit from this Directive. The UK government should take action in order to enable them to benefit from the EU directive.

As pointed out by the recommendation, on 28 September 2011, the Commission adopted a report on the application of Directive 2003/109/EC concerning the status of third-country nationals who are long-term residents. The report gives an overview of the state of implementation of the Directive by Individual Member States and identifies possible problematic issues.
As to the recommendation of the BRT to extend the application of the Directive 2003/109/EC to the UK, please note that according to Article 4 of the Protocol 21 on the Position of the United Kingdom and Ireland in respect of the Area of Freedom, Security and Justice - which is annexed to the Treaty of the EU - the UK has the right to opt-in into the migration acquis any time after the adoption of the relevant measure. Therefore such a decision is a matter of national competence of the UK.

Working Party B

Life Sciences and Biotechnologies, Healthcare and Well-being

Recommendations from both European and Japanese industries

General Issues

WP-B / 01 / EJ to EJ Enhancement of bio-venture activities

In both the EU and Japan, bio-venture activities should be enhanced further and dynamically integrated with each other. BRT members call for government support to expand these networks of activities through such measures as bio-conferences or the establishment of cluster centres. It is also necessary to support bio ventures financially under the current economic recession. Strong governmental (METI and MHLW) financial support is essential.

The Commission has no comment.

Healthcare

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

The regulatory harmonization and further extension of "Mutual Recognition Agreement" should be proceeded in order to avoid redundant inspections of manufacturing facilities. In addition to oral dosage forms, API, Sterile and Bio products are being requested to apply to the MRA. The new initiative of PIC/S> PIC/S stands for "Pharmaceutical Inspection Convention and Pharmaceutical Inspection Co-operation Scheme, jointly refers to PIC/S". Compared to last year a strong MHLW's initiative on PIC/S has been seen. This is an agenda point for the European industry (15 countries), EFPIA and PMDA.

The Commission supports the recommendation to extend the scope of the mutual recognition agreement. Contacts have been established and work is on-going.

WP-B / 03 / EJ to EJ Balance between prevention and treatment in healthcare

Seek balance between prevention and treatment. Thus, confirm inclusion of vaccination programs and include contraception in the scope of public funding.

Developed countries worldwide are facing an epidemic of chronic diseases. Many of these are preventable by taking action on risk factors and on health determinants. Investing early in health promotion and disease prevention is therefore key, and it is indeed disappointing that only about 3% of health care budgets is being invested in prevention.
Regarding the specific points raised in the recommendation:
The European Commission has funded and continues to fund projects related to vaccines and vaccine preventable diseases. Examples include EUVAC.NET (http://www.euvac.net), VENICE (http://venice.cineca.org), VACSATC (http://www.vacsatc.eu), ECIIS (http://www.smi.se/eciis), HPROIMMUNE (http://www.hproimmune.eu), PROMOVAX (http://www.promovax.eu). The European

Commission cannot fund vaccination programmes directly, since the organisation and delivery of healthcare is a Member State competence.

The European Commission organised on 16-17 October 2012 a conference on childhood immunisation[2] to take stock of the recent initiatives on childhood immunisation taken by the EU – including the follow-up to the Council conclusions on childhood immunisation. In addition, the conference provided a platform to discuss priority areas for future EU-level action on childhood immunisation with a wide range of stakeholders. The presentations and video recordings of the conference are available online. A report with the outcome of the discussions will be published on the conference website shortly and will help guide the European Commission to define priority areas for future EU-level action (including funding) on childhood immunisation.

The ECDC[3] provides scientific support on vaccination programmes to the Member States by setting up scientific panels after requests from Member States or the European Commission. In the area of vaccine-preventable diseases, scientific panels have developed guidance on human papillomavirus vaccine[4] and diphtheria-tetanus-pertussis childhood vaccination[5], and are currently working on guidance on childhood pneumococcal vaccination.

Cervical Cancer Screening

Several Member States have introduced as part of cervical cancer control, an offer of vaccination for young women.

With the Council Recommendation of 2 December 2003 on cancer screening the EU agreed on a common approach in cancer screening. The document sets out principles of best practice in early detection of cancer. Member States are invited to implement nationwide population-based screening programmes for breast, cervical and colorectal cancer, with appropriate quality assurance at all levels. Once the Recommendation is fully implemented by all Member States it will enable all EU citizens wherever they live to benefit by the same level of quality. This also helps Member States in organising their health care systems more efficiently.

The scale of screening activities is monitored by the Commission (first report in 2008, the next planned for 2014). The first Report revealed that in 2007 for cervical cancer, only 15 Member States were running or establishing population based screening programmes. To assist the Member States with cancer screening, the Commission supported the development of the European Guidelines for quality assurance in cervical cancer screening.

The HPV vaccine offers a new, complementary tool to improve the control of cervical cancer. In 2008 ECDC produced the Guidance on the introduction of HPV vaccines in EU countries; this guidance was updated in September 2012. Since 2008, HPV vaccination programmes have been implemented in many EU countries. Coverage rates – where data are available – are lower than expected in many EU countries. Furthermore, target age, system of financing and delivery of the vaccines differ from one country to another. Moreover, at this stage the HPV vaccines cannot replace or modify current routine cervical cancer screening. It is vital that national screening programmes are maintained in place and that the impact of vaccines on screening programmes is

[2] http://ec.europa.eu/health/vaccination/events/ev_20121016_en.htm

[3] ECDC: European Centre for Disease prevention and Control

[4] http://ecdc.europa.eu/en/publications/Publications/20120905_GUI_HPV_vaccine_update.pdf

[5] http://www.ecdc.europa.eu/en/publications/Publications/0911_GUI_Scientific_Panel_on_Childhood_Immunisation_DTP.pdf

monitored closely. One of the challenges in the future will be to achieve synergy between vaccination and screening in a cost-effective way and with the maximum benefit for women.

Contraception

The provision of medical services, including contraception, is not an EU competence, but is managed and delivered at Member State level.

WP-B / 04 / EJ to EJ Mutual recognition of quality management audit results for medical devices between EU and Japan

Improve mutual recognition of quality management audit results for lower risk medical devices, e.g. those classified as Class II, ARCB under the Japanese Pharmaceutical Affairs Law, as a first step.

PMDA and MHLW should initiate to introduce a mutual recognition of quality management audit results.

Quality Management System (QMS) conformity based on ISO 13485

In principle the Government of Japan (GoJ) is now applying ISO 13485 plus minor deviations (for instance relating to sterilization unit). Too often, multiple auditors inspect the same manufacturer. In other words, a manufacturer can be audited several times per product. The Japanese law should be revised in the spirit: "One site"–"One audit"–"One third party (authority)"="One certificate based on ISO13585", (in order to avoid overlapping audits). This streamlining move could also be in the benefit of the Japanese side since it will generate savings in resources and time for the GoJ. Industry representatives agree that discussion with the Ministry of Health Labour and Welfare of Japan (MHLW) and the Pharmaceuticals and Medical Devices Agencies (PMDA) should take place at expert level (applicants/reviewers) in order to iron out the practical difficulties. On the positive side, one can note that Japan applies the GHTF classification: Class A: Notification only (to PMDA); Class B: Third party certification (possibility of PMDA if no standards are applied); Class C and Class D: Approval by PMDA. Japan has already streamlined the quality management system (QMS), by fully implementing all the agreements concerning paragraph 34, through the Administrative Notice of 30 May 2011 issued by the Surveillance/Instruction and Drug Prevention Division, Medicine and Food Bureau, Ministry of Health, Labour and Welfare, addressed to the Medicine Affairs Divisions of Prefectural Hygiene Management Departments/Bureaux, entitled “questions and answers on the conformity between the QMS Ministerial Order and ISO 13485: 2003”.

International Medical Device Regulators Forum (IMDRF)

At international cooperation level, the EU and Japan work closely in the near future in order to achieve global harmonization of QMS audit procedures at multilateral level. Indeed, the International Medical Device Regulators Forum (in which both the EU and Japan are members) has launched a public consultation on Recognition of Criteria for Medical Device Auditing Organizations on the 24th of October 2012 with the aim to define common criteria that Medical Device Regulatory Authorities represented in the IMDRF will utilize to recognize an Auditing Organization performing work under the respective medical device legislation, regulations and procedures required in its jurisdiction.

This action is part of a global commitment from Japan and the EU to streamline QMS inspection audits by refraining from carrying unnecessary QMS audits in line with international standard ISO 13485, where Japan's relevant authorities (MHLW and

PMDA) have already committed to (see the EU-Japan Free Trade Agreement currently negotiated):
- continue to work towards the simplification of the Japanese QMS requirements and will review, simplify and enhance the audit systems including through streamlining of unnecessarily burdensome administrative practices and strengthening predictability.
- ensure active and steady progress and achievements in the MHLW-industry working group (including European industry) on reducing or eliminating differences between ISO 13485 and Japan's QMS ordinance.
- regularly publish reports indicating progress towards the goal or reducing repetitive QMS audits.

WP-B / 05 / EJ to EJ Infrastructure improvement and international harmonization of regulation standards for approval of non-invasive diagnostic medicines and devices
Both governments should promote infrastructure improvement such as regulatory review process and structures to accelerate simultaneous research and development of therapeutic medicines and accompanying diagnostic medicines and devices (companion diagnostics).
Furthermore, both governments should harmonize each regulation on simultaneous development of therapeutic medicines and companion diagnostics, to support advancing science on personalized healthcare (PHC) based on global genome-cohort research.

Personalised medicine is at very early stages of development. The current EU regulatory framework on pharmaceuticals allows companies to bring also efficacious, safe and quality medicines to the market, also if the medicines are 'omics'-based. Current EU legislation on in vitro diagnostic medical devices ('IVD') allows rapid and cost-efficient market access to innovative devices and the revision of the medical devices legislation will strengthen certain aspects of the regulatory system. The objective to promote and accelerate the simultaneous development of medicines and medical devices IVDs is understandable. However, the question is whether this should be done by setting regulatory standards or whether support should be given in the form of financing research. The Proposal for a Regulation on in vitro diagnostic medical devices introduces mechanisms for cooperation between notified bodies in charge of these devices and medicinal products competent authorities. In view of the very early stages of development of personalised medicine approaches, need for prudence is needed as regards regulatory obligations so as not to unnecessarily hamper progress in the field. In order to monitor the developments in the field, this matter will be included in the regular dialogue that is taking place between SANCO/European Medicine Agency and MHLW/PMDA.

WP-B / 06 / EJ to EJ Mutual recognition of medical devices product licenses
Introduce a mutual recognition of medical device product licenses between the EU and Japan. PMDA and MHLW should introduce a mutual recognition of medical device product licenses with low risk of class II devices.

In the past years, Japan and the EU have worked together in order to eliminate the Medical Devices lag that forbids the establishment of a shared market in which both the EU and Japan could benefit. Some adjustments however still need to be addressed in order to achieve this mutual recognition of medical devices product licences.
Indeed, if Japan and the EU do have quite similar requirements for the granting of medical devices products licences, some discrepancies still need to be tackled within

Japan Law in order for the Japanese licences to be fully compatible within the EU market.

Medical devices are subject to the provisions of the Pharmaceutical Affairs Law even though their mode of action is fundamentally different from pharmaceuticals. As a consequence, the authorization procedures could sometimes be more complex than needed. The EU suggested to the GoJ that procedures for the authorisation of medical devices should not be more burdensome than necessary to address the risks posed by the different types of medical devices.

Furthermore, in order to quickly achieve mutual recognition, Japan could consider reviewing its labelling requirements and in particular the opportunity to request specific "short Instruction Manual" ("Tempu-Busyo") when the product is already accompanied by the ordinary main instruction manual.

Finally, Japan should recognise that standalone medical software can be qualified as medical device in its own right, thus aligning with American and European practices.

WP-B / 07 / EJ to EJ Mutual recognition of clinical trial results for medical devices

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

Japanese Good Clinical Practice (GCP) requirements are not fully in line with international standards (ISO 14155). Foreign clinical data are often accepted during the review process, but ad-hoc requests and requests for Japan based data and studies are often required in addition to the foreign clinical trial data.
Although Japan MHLW medical device officials participated in the revision of ISO 14155 (revised version adopted as final in 2011), and the revised standard is said by MHLW to address many of their concerns with the earlier standard, it seems that MHLW does not intend to significantly revise the existing Good Clinical Practice (GCP) guidance in Japan to more closely align it with ISO 14155:2011.
The EU invited Japan to fully apply these international standards, to which Japan answered positively and reassured the EU that the problem was now solved by the approval of foreign Medical Devices by utilizing clinical trials undertaken in the EU based on ISO 14155. Japan offered to the EU its availability to provide further clarifications on this area.
Finally, during the EU-Japan bilateral discussions towards a Free Trade Agreement, both parties committed to fully apply international standards on Good Clinical Practices including ISO 14155. Foreign clinical trial data should therefore be accepted during the review process without additional ad-hoc requests for domestic based data or studies.

WP-B / 09 / EJ to E Evaluation of innovation values for pharmaceuticals in prices.

The EU government should reinforce its innovation policy to member states and clarify

its healthcare policy, resulting in the appropriate evaluation of the value of pharmaceuticals.

In June 2011 Council adopted the conclusions "towards modern, responsive and sustainable health systems", inviting Member States and the Commission to initiate a reflection process to identify effective ways of investing in health. The reflection is articulated in five working groups; the third one coordinated by the Netherlands and dealing with "effective use of medicines". It is expected to deliver outcomes (recommendations) by 2013, on below points:

1. Can time to market be shortened without damaging the safety of pharmaceuticals?
2. Other lessons on how regulatory systems influence prices (e.g. medical devices)?
3. Effects of European Reference Price Systems on prices/availability?
4. Overall effects of reimbursement systems on prices and availability?
5. Can other parties (eg doctors, patients) take up responsibility for cost-effective use?

The Commission is actively involved in work on points 3 and 4, in relation to which two studies are currently undertaken funded through the public health programme:

- External reference pricing of medicinal products: simulation-based considerations for cross-country coordination
- Policy mix for the reimbursement of medicinal products: proposal for a best practice based approach based on stakeholder assessment" as part of the European Commission "

Points 4 of the working group's agenda (and the related study on the "policy mix") will look more specifically into how to reconcile the policy objectives of patient access and equity, budget control and rewarding high-value innovation.

And also,

Members States are systematically assessing the cost effectiveness of new health technologies including medicines, medical devices as well as surgical procedures. To support MS in this effort, the EC under the Health Programme is co funding the EUnetHTA network (www.eunethta.eu). EUnetHTA groups national and/or regional bodies responsible for HTA. Its objectives are to agree on common assessment methodologies, share information on assessment procedures as well as produce join assessments. The final aim of the Network is to contribute to better use of resource and avoid duplication of assessments.

To bring EU cooperation on HTA forward and as part of the implementing measures of the Directive on the application of patients' rights in cross border healthcare (2001/24), the Commission will set up a voluntary network between bodies responsible for HTA appointed by Member States. The network which is expected to be operational by the end of 2013, will build on the results of EUnetHTA and bring the cooperation from a project-base approach to a more "structural" approach.

Plant Protection and Biotechnology

WP-B / 10 / EJ to E Shortening review times of plant protection & biotechnology products

Shorten review times for new applications/ registrations.

Plant Protection Products and their placing on the market are regulated by Regulation 1107/2009. This legislation entered into force on 14 June 2011. The legislation lays down precise deadlines and responsibilities for every party in the approval process of active substances and plant protection products. Furthermore, the risk assessment and the underlying science are described in this legislation and in relevant implementing measures. The EU is currently in the process of adopting new legislation as regards the data which need to be submitted for the submission of an approval dossier. The whole process is transparent and with the established deadlines very transparent for applicants.

- GMOs regulatory regime

Regarding the concerns expressed by the authors in the background section, the Commission wish to underline that the GMO regulatory regime is in fact working normally as evidenced by the approval decisions taken in 2011-2012. In 2011 the Commission authorised six GMOs and renewed the authorisation of a seventh one, and in 2012 the Commission has already authorised 5 more GMOs and renewed the authorisation of a sixth one.

The functioning of the GMO regime should not be rigidly assessed purely quantitatively and in the abstract, in terms of the number of authorisations per year or time, since this is dependent on various product and case-specific elements and in particular on the quality of applications and on the time needed by applicants to answer requests from EFSA on additional scientific information. Delays are in fact frequently due to incomplete files or insufficient information from applicants.

The Commission would like to address the apparent conclusion for this recommendation which reads: 'No progress has been seen for this recommendation'. The Commission would like to point out that on the contrary, it has put in place a whole package of initiatives to reinforce the authorisation process, and in particular will propose in the coming months a Commission Regulation setting more precise requirements for the submission of authorisation applications for imported GM products for food and feed use. In addition, since the implementation of the Lisbon Treaty further time savings have been achieved through the new procedural requirements concerning the adoption of authorisation decisions which have reduced the time for risk management decisions to be taken.

Animal Health

WP-B / 11 / EJ to E Introduction of "1-1-1 concept" for all animal healthproducts

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

During the 2nd quarter of 2013 the Commission intends to adopt the legal proposal on the revision of the legislation on veterinary medicines. Decreasing administrative burden and enhancing the single market are objectives of this revision. In this light the impact is assessed of several options that would involve a change of marketing authorisation procedures.

Recommendations from European industry

Animal Health

WP-B / 19 / E to EJ Regulatory harmonization for animal health products

Further harmonization and streamlining of regulatory requirements for product registration of animal health products. MAFF should start harmonization with related countries as this is the path to the 1-1-1 concept recommended previously.

The Commission favours harmonisation of data requirements for veterinary medicines and supports in that light the activities of VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products).

WP-B / 21 / E to EJ Responsible use of antibiotics in animal health

MAFF should promote responsible use of antibiotics in animal health.

Over the past decades, irresponsible and incorrect use of antibiotics in human and veterinary medicines have accelerated the emergence and spread of resistant bacteria. This situation is worsened by the lack of investment to develop new effective antibiotics. The consequences are severe. It is estimated that each year, drug resistant infections result in 25,000 patients deaths and 1.5Bn€ healthcare costs and productivity losses in the EU. AMR is therefore a priority for the Commission with initiatives developed over the past few years in human and veterinary medicines.

To further strengthen its commitment, the Commission launched on 17th November 2011 a new 5 year Action Plan against AMR. The Plan is based on a holistic approach, in line with the "one health" initiative, taking into account all sources of resistance and all sectorial aspects of antimicrobial resistance (i.e. public health, food safety, bio safety, consumer safety, environment, research and innovation, international cooperation, animal health and welfare as well as non-therapeutic use of antimicrobial substances).

The Action Plan covers seven areas and sets out 12 concrete actions both in the human and veterinary field, identifying international cooperation as a key priority. The objective is to strengthen bilateral and multilateral commitment against AMR and encourage international partners to address AMR in all sectors.

Examples of bilateral and multilateral cooperation against AMR include the EU and USA Transatlantic Task Force against antimicrobial resistance (TATFAR) set up in 2009, the Commission's involvement in international organisations setting standards for food trade (Codex Alimentarius), animal production (OIE) and public health, including food safety (WHO).

The Commission welcome and encourage the possibility to cooperate with authorities in third countries, in scaling up visibility and awareness on antimicrobial resistance and the prudent use of antimicrobial agents.

Recommendations from Japanese industry

Plant Protection

WP-B / 27 / J to EJ Promote people's understanding of GMOs based on scientific knowledge by both the governments and the private sectors

To gain people's acceptance of GMOs, governments and private sectors should cooperate in educating people about the efficiency and safety of GMO's, based on scientific knowledge, considering world food supply and demand prospects.

On the issue of promoting the public's acceptance of GMOs, the Commission would like to point out that it is neither for nor against GMOs but bases risk management decisions on science. However, to promote a debate on the issue the Commission has organised a series of hearings, which included one on "Environmental monitoring of GM crops" held in Brussels in March 2012, after the two on "GMO risk assessment and management" (March 2011) and "Socio-economic dimensions of GMO cultivation" (October 2011). Participants at these hearings included European Parliament members, non-EU and EU national authorities, private sector stakeholders, NGOs, the scientific community and the press.

With regard to the socio economic dimensions of GM cultivation, we note that the Environment Council asked the Member States on 4 December 2008 to collect and exchange relevant information on the socio-economic implications of GMO cultivation across the food chain. It also asked the Commission to prepare, on the basis of this information, a report for due consideration and further discussion. This report was published on 15 April last year and may be viewed at:

http:/7ec.europa.eu/food/plant/gtno/reports studies/index en.htm

The report is a starting point and in the next steps the Commission intends to define with the Member States a robust set of factors and indicators to capture in a uniform way the socio-economic consequences of GMO cultivation across the EU and along the food chain. A technical working group composed of Member State experts has been set up and will start working on developing these indicators and factors in January 2013

Working Party C

Innovation, Information & Communication Technologies

Recommendations from both European and Japanese industries

ICT

WP-C / 01 / EJ to EJ Execution of Growth strategy and ICT strategy

Both Authorities should implement detailed action plans with specific targets and use PDCA cycles to monitor the status of each item. ICT Strategy Progress Reports for each action should be published on the Authorities' websites. Some progress has been seen for this recommendation. The Digital Agenda for
Europe Annual progress report was released on 22nd of Dec, 2011

The EU's Digital Agenda for Europe is an annual report which gives an overview of progress on the actions of the Digital Agenda for Europe, updating the list of completed actions since the Digital Agenda Scoreboard in May 2011, and outlining the work ahead. This document is part of the efforts of the European Commission on the implementation and governance of the Digital Agenda, further to other activities in 2011 including the Digital Agenda Scoreboard and the Digital Agenda Assembly. The overall aim of the Digital Agenda is to deliver sustainable economic and social benefits from a digital single market based on fast and ultra-fast internet and interoperable applications, and is a key component of the Europe 2020 strategy to provide growth and jobs in a sustainable and inclusive manner. The last annual report issued in December 2012 is published on the Digital Agenda website.

WP-C / 02 / EJ to EJ Coordination of trading principles of ICT services

Both sides' authorities are requested to discuss trade principles of ICT services aiming at creating better environment for the business and co-operate for implementation of such principles to third countries for improving global trade conditions.

The European Commission shared the EU-US Trade Principles with the Ministry of Internal Affairs and Communications during the EU-Japan ICT Dialogue of 2011 and took note in 2012 that a similar set of principles had been signed between the US and Japan. The Principles are also being discussed between Members of WTO thus indicating that they provide a modern way of working together. The forthcoming EU-Japan FTA negotiations may provide a platform for creating a better environment for business in the ICT sector.

WP-C / 03 / EJ to EJ Building trusted and safe online environment

(1) Both authorities should establish an information sharing / exchange mechanism between EU and Japan for cyber security
1) Study on cyber-attack information sharing within closed organizations and companies.
2) Study on investigation mechanism across borders.
3) Study on reporting procedure for cyber-attack disclosure from companies to government (even if the personal data is included in the disclosure, companies can be exempted from breach of personal data protection.)
(2) Study on mechanism for joint training such as simulation exercises involving both forces against cyber attack

(3) Construction of safety network including government and defence industries.
(4) Conduct technology development for prediction and immediate responses against cyber-attack

and

WP-C / 04 / EJ to EJ Building robust critical infrastructure supported by ICT
Both authorities are recommended to share best practices, and earmark funding for R&D and give incentives for private sectors to construct robust resilient infrastructures supported by ICT, including telecom network and data centre, etc.

In line with agreement between VP Kroes and Minister Kawabata in June 2012, a workshop was held in Tokyo on 15 November 2012 in order to exchange information on a number of topics in the field of Internet Security (IS), including IS strategy development, sharing good practices on IS R&D activities, protection of critical infrastructure and information sharing, awareness raising and online privacy/data protection. The workshop was set up by MIC and included participants from MoFA, NISC, and Cabinet Secretariat; while on the EU side the participants came from DG Connect. This was a successful information exchange, allowing both sides to identify areas for potential collaboration and further exchange. Notable was the emphasis on practical activities, paving the way for best practice exchange. The forthcoming EU Cyber strategy should form the basis for further discussion.

WP-C / 05 / EJ to EJ Deployment of Next Generation Broadband Networks
(1) Regulations should provide necessary legal certainty for investors. Technologies should be able to evolve on their own merits – innovation and investment decisions should not be hampered by technology-prescriptive regulations.
(2) Both Authorities should provide the necessary stimuli to industry to encourage the provision of high-speed fixed or mobile broadband services in the areas where deployment by private sector investment is difficult (such as less-populated areas).
(3) To promote the use of ICT, both Authorities should enhance the social benefits of the next generation broadband network by encouraging education, healthcare and other government services.
(4) To permit a more efficient use of the spectrum, and to address the very rapid traffic growth in the mobile networks due to smartphones, both Authorities should free up as many frequencies as possible for use by mobile broadband. Moreover, both Authorities should strive for a harmonised use of the spectrum to ensure economies of scale and thereby lower service prices incurred by consumers. Some progress has been made for this recommendation
The European Commission proposed a growth package for integrated European infrastructure on 19th of Oct, 2011. Out of 50 billion Euro Connecting Europe Facilities, 9 Billion Euro are allocated to the telecommunication sector (from 2014 to 2020)

Key strands of current policy work focused on fostering the roll-out of broadband include the following:
- The EC is working on implementing the 12 July statement of VP Kroes on Broadband which sets out a framework to provide the legal predictability, consistency across the single market and competition needed for investment in high speed networks. This will take the shape of a Recommendation which we expect will be ready in the first half of

2013. The EC is also working on revising the relevant markets recommendation to provide more long term certainty.
- The EC is developing concrete proposals to reduce the cost of broadband deployments in Member States through focusing on reducing the 80% or so of costs that are due to civil engineering, and is planning to come forward with a proposal for a regulation in the first quarter of 2013.
- The Commission has taken initiatives to ensure that at EU level the right funding is available to ensure the roll-out of infrastructure in areas that are underserved, notably through the Connecting Europe Facility (CEF), which, as regards telecoms, entails the use of innovative financial instruments which will reduce the risk of private investment. In addition, grants from structural funds will play their role.
- The EC is also developing a wireless broadband strategy to ensure that Europe' airwaves keep pace with developments, based on the Radio Spectrum Policy Programme.
- It is also preparing a recommendation in the area of net neutrality.

WP-C / 06 / EJ to EJ Continued efforts for ICT usage towards social challenges

The BRT recommends continued efforts for the promotion of ICT use by the public sector. Both Authorities also should facilitate the convergence of ICT and other sectors, such as healthcare, education, energy and automobile etc. by budget allocation for innovative ICT demo projects. It will generate new growth service sectors for ICT industry. Where appropriate, laws and rules which could impede advanced ICT usage should be deregulated.

Some progress has seen for this recommendation

On 19th of Oct, 2011, the European Commission proposed Connecting Europe Facilities funding scheme amounting to 50 Billion Euro funding. Digital service infrastructure projects such as electronics health record, electronics identification, electronic procurement are selected for CEF grants.

The Digital Agenda for Europe continues to aim to address the big societal challenges of today by applying ICT solutions in order to achieve goals such as better and personalised healthcare (whilst at the same time delivering cost savings for patients and society at large); faster and more effective interaction for citizens and business with public authorities; the possibility for a greater part of the EU ageing population to be able to live safely and independently. ICT will also help tackling environmental issues such as energy efficiency and greener transport.
Major initiatives include the European Innovation partnership (EIP) on active and healthy ageing; the eHealth action plan; the eGovernment ation plan; the EIP on smart cities; and Intelligent Mobility.
In addition, the Commission's ICT technology research programme (FP7, Framework Programme 7, and in future Horizon 2020) aims at, inter alia, jointly tackling global societal challenges in fields such as intelligent transport, healthy ageing, smart cities, etc.

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

(1) The BRT welcomes the fact that the European Commission is proposing a Regulation as the legal instrument for aiming higher level of the harmonization of data protection within the EU. It will lead to innovative new online services across Europe. The BRT also welcomes the inclusion in the proposal of a consistency mechanism for ensuring coherent implementation among Member States and of the explicit legal recognition of Binding Corporate Rules (BCRs)

(2) However, the current proposal contains several clauses that are difficult to implement and that increase administrative burden for businesses. The European Commission is requested to discuss with global businesses a practical implementation ensuring innovation and privacy protection and that will finally create benefit for consumers in Europe. Further clarification is required for the definition of personal data, modality of consent, data portability, right to be forgotten, data breach notification procedure and sanctions. Introduction of penalty amounts to the maximum 2% of company's worldwide turnover is excessive comparing the gravity of breach. Further simplification of BCRs should also be considered.
(3) The Government of Japan is reviewing its Personal Data Protection law in its Consumer Commission. The two authorities should consult closely with each other so that the international data transfer regime between the EU and Japan should become streamlined so as to develop a better environment for businesses.
Both Authorities should then launch the adequacy finding procedure to enable data transfer from the EU to Japan as soon as feasible.
(4) Both Authorities should review regulations prohibiting applications from using cloud computing. When reviewing regulations, proper utilization of big data should be considered.
(5) The EU and Japanese Authorities should begin a cloud computing dialogue to harmonise regulations on cloud computing and thereby facilitate cross border transactions and international data transfers within the EU and between the EU and Japan while enhancing the balance of privacy, information security against cyber-attack, data protection and the free flow of information.

The European Commission welcomes the BRT's support for greater harmonisation of data protection rules in the EU through the new Regulation. The European Commission believes that the new Regulation will enable businesses to achieve significant cost savings. The European Commission agrees that it will lead to more innovative online services across Europe, and that the consistency mechanism and simplified BCRs will bring benefits to business. The European Commission is in regular and valuable dialogue with stakeholders on innovation and privacy protection to hear views on issues such as the clarity of definitions in the Regulation, modalities of consent, data portability, right to be forgotten, data breach notification procedure and sanctions. The European Commission is interested to note that there are similar discussions taking place in Japan on the protection of personal data and is open to dialogue with Japan. With regard to adequacy, it is important to recognise that it is only one of the tools for international data transfers provided in the new Regulation. It is noted that since adequacy results in completely free flow of data between the EU and a third country without any additional rules or checks, the process for adequacy involves a very detailed, lengthy and intensive examination of a third country's laws and practices. It should be recognised that both the current Directive and, in particular, the new Regulation, provide for other ways of lawful data exchange between the EU and Japan. The new Regulation facilitates and simplifies several alternative means of transferring data between the EU and third countries, e.g. binding corporate rules, standard contractual clauses, memoranda of understanding and codes of conduct. This will greatly facilitate the international transfer of data in the context of cloud computing, while continuing to ensure a high level of protection of personal data, which is crucial for citizens and businesses to have the necessary trust to make full use of the potential of cloud computing. More specifically on cloud computing, the European Commission's strategy launched in September 2012, "Unleashing the potential of cloud computing in Europe" outlines actions to promote, speed up and increase the use of cloud computing across the economy. Key actions of the strategy include: cutting through the jungle of technical standards so that cloud users get

interoperability, data portability and reversibility; support for EU-wide certification schemes for trustworthy cloud providers; and development of model 'safe and fair' contract terms for cloud computing contracts, including Service Level Agreements. The proposed data protection Regulation will also support the uptake of cloud computing by enhancing trust in innovative computing solutions and boosting a competitive digital economy where Europeans feel safe.

Cloud computing: The second EU-Japan workshop on cloud computing was held in November 2012 in Tokyo. During the 2012 EU-Japan ICT Dialogue, also held in Tokyo, both sides presented an update of the respective policies promoting cloud computing services and discussed the way in which they could further enhance cooperation in areas of mutual interest and concern.
The EU side proposed to work together on standardisation issues and on service level agreements (contracts). While no clear reply was given by the Japan side, the possibility to work together on these items needs to be explored with the Japan mission in Brussels.

WP-C / 08 / EJ to EJ ***ITA expansion***

The BRT recommends that both Authorities ensure that the current ITA is reviewed at the earliest opportunity and that additional electronic goods be granted duty-free status in addition to those that already have that status. The broadest possible expansion (including large portions of Chapters 84, 85 and 90) of the scope is needed so that current and future innovative technological developments should not cause product classification uncertainties.

(1) The EU should complete its implementation of the WTO panel in the ITA dispute without further delay to avoid new convergence technology of ITA products being reclassified as dutiable.
(2) The geographical coverage of the ITA should be expanded by encouraging more countries to join the ITA. Membership should be promoted as a means of boosting efficiency and productivity, improving the investment climate, helping bridge the digital divide and enabling the move to a more energy-efficient and climate-friendly society.
(3) Effective mechanisms (such as fora for industry to explain state of the art technology to government) are needed to ensure the ITA is kept up to date and reflects technological developments.

The EU concurs that expansion of the ITA is an important objective for this year and a possible deliverable for the ITA-Ministerial. However, a distinction has to be made between a wider sectoral agreement on electronics, as previously proposed in NAMA by Japan and some other countries and an expansion of the existing ITA. Not all electronic products are necessarily ITA-related and including domestic appliances and all audio-visual products in an expanded ITA is not convincing. The first half of this year is the window of opportunity for the expansion of the ITA and insistence on sensitive products such as televisions would be counterproductive, as there is a trade-off to be made between timing and the level of ambition of the expansion.

1) The EU has by 1 July 2011 duly implemented the WTO ITA panel ruling and the implementing measures were accepted by the complainants.

With regard to point 2, it should be noted that the EU is making a big effort to help increase the geographical coverage of ITA by outreach meetings with countries such as Chile, Mexico, Kenya, South Africa and Qatar and encourages Japan to support these efforts. Also, the EU is engaging in outreach with existing members of ITA who have not

yet joined the review process, including Indonesia, India and the countries of the Gulf Cooperation Council.

With regard to point 3 the Commission agrees that mechanisms to keep the ITA up-to-date also after the review are important and could benefit from industry-input.

From the EU side, the negotiations are led by DG Trade, whereas DG TAXUD provides technical support (mainly by assisting in obtaining correct, exact and for customs purposes manageable product descriptions). Currently, the negotiations are on-going and it is expected that the negotiations could be concluded in time for the WTO Ministerial Conference in December 2013.

WP-C / 9 / EJ to EJ Balancing of trade facilitation and security

The BRT recommends that both Authorities should cooperate and lead the international harmonisation of rules and operations to achieve efficient public and private sector operations, balance trade facilitation and the assurance of safety and security. Both Authorities should drive aggressively an initiative to remove barriers to realising a balance between trade facilitation and the ensure security. In particular:
Security regulations that have been tightened despite the existence of the MRA on AEOs should be examined and considered for deregulation. (e.g. In case of trade transaction between AEO program certified companies, several security requirement will be relaxed.)

We would like to point out that the EU and Japan already act to strengthen trade facilitation and security. The Customs Cooperation and Mutual Assistance Agreement between the EU and Japan contains a provision (article 9) on developing and strengthening cooperation on topics of common interest with a view to facilitating discussions on customs matters in the framework of relevant international organisations, such as the WCO and the WTO.

WP-C / 10 / EJ to EJ Harmonization between the EU and Japan for M2M communication and ITS

Both Authorities should cooperate and lead the international harmonisation of M2M (Machine-to-Machine) communication and ITS (Intelligence Transport Systems) including standardization for technical specifications.

The EU has sought international cooperation in the field of ITS in order to benefit consumers and industry and the public sector, to reduce developments costs, avoid duplication, and to get better access to global markets. What we focus on is aspects such as global harmonisation of standards, core applications and test tools, access to data from field trials and probe data (data collected by road vehicles).
DG Connect signed in 2011 a Memorandum of Cooperation with the Ministry of Land, infrastructure, Transport and Tourism (MLIT). This has led to the establishment of a working structure for trilateral cooperation between DG Connect, the US Department of Transportation (DoT), and the MLIT. The parties share results of ongoing research and trials, and each party participates as an observer in trilateral meetings.

WP-C / 11 / EJ to E Fundamental Reform of the Private Copying Levy System (Compensation System for Private Copying)

(1) The EU and Japan should cooperate / have a dialogue to reform fundamentally the private copying levy system and thereby promote the lawful use of licensed digital content.

(2) Any review for reform should consider, in a comprehensive manner, alternative methods – including new content distribution practices – available to secure compensation for rights' holders and creators from private copying as well as the development of licensed cloud-based content streaming models. Increasing the availability of lawful digital content will require a reform of the existing copyright regime in the EU as well as in Japan. The aim of the reform should be to; promote open and competitive markets in licensed digital content, with the aim to increase availability of more legitimate digital content, at prices which appeal to consumers and hereby promote innovation and growth of digital creative market. The goal should be to enable the establishment of a system which is transparent, fair and equitable to consumers, rights' holders, service and equipment providers, etc.

(3) The EU and Member-State Authorities should ensure that reform of the private copying levy system remains a priority issue for the wider copyright debate on the European digital economy agenda. EU-level action is required if transparency and legal certainty is to be achieved.

EU Member States enjoy a large discretion on how to provide right-holders with fair compensation for acts of private copying. In view of the variety of national practices, the Commission has been working with all relevant stakeholders to consider a more coherent approach. In the Communication of 24 May 2011 on a single market for intellectual property (the "IPR Communication"), the Commission stated that the proper functioning of the internal market requires reconciliation of private copying levies with the free movements of goods and services. In order to achieve this, the Commission appointed a high level mediator to open a dialogue with stakeholders, and to explore new licencing opportunities in the digital environment as well as possible approaches with a view to improve the administration of levies, in particular in cross-border situations. At the end of 2011, Commissioner Barnier announced that Mr. Antonio Vitorino, former EU Commissioner, had been asked to act as the mediator on private copying levies. In spring 2012, Mr Vitorino invited stakeholders to send written contributions, followed by stakeholder meetings before and after the summer. The mediator is expected to issue recommendations to Commissioner Barnier before the end of 2012. Mr Vitorino´s recommendations will serve as a basis for the Commission´s further actions.

WP-C / 12 / EJ to E Applying reduced VAT rate to e-Books

To end the unnecessary discrimination between e-Books and paper books, the BRT recommends e-Books should also be liable for the reduced VAT rate applied in the EU to "culturally-worthy" items and the rate charged should not exceed the rate applied to printed publications.

The Commission is in the process of a review of the current VAT rates. A public consultation, which raises notably the issue of equal treatment of comparable products such as e-books and printed books, was made at the end of 2012. This review should result in a legislative proposal from the Commission by the end of 2013.

INNOVATION IN GENERAL

WP-C / 13 / EJ to EJ Enhanced Cooperation between the EU and Japan on 21st Century societal challenges

(1) The BRT recommends that both sides' Authorities support flagship demo projects and innovative solutions to common societal challenges through deregulation, easing of investment, notably for SMEs, and inviting expertise from EU and Japanese industry.
(2) The BRT recommends further enhancement of joint R&D projects between the EU and Japan. Work towards international standardisation should gain particular attention for such projects.
(3) The EU, Member-States and Japan should continuously allocate strategic budgets to innovation investment particularly on education in science, technology, engineering and mathematics fields, and on developing competent human resources in S&T, as well as to R&D Infrastructures in national laboratories and universities. Strong ties with business should leverage this investment.
(4) Tax credits for R&D should be expanded to encourage private sector investment in R&D.

Japan has high technological strength and innovation capacity and is a leader in ICT research, so it is therefore a strong partner for the EU in the field of ICT research. There are currently around 17 projects with the participation of partners from Japan in FP7. But in a way this is not indicative of the extent of our cooperation, as we also have over 90 projects which are taking or have taken place in FP7 involving European subsidiaries of Japanese companies. These projects cover a wide range of topics, including cognitive systems; robotics; Internet of things; Digital libraries; FET Open, etc. From a more strategic point of view, as opposed to the bottom-up nature of participation in FP7, the following activities should be mentioned:

- Coordinated call on Future Internet/New Generation networks mobilising 9mn Eur from the European side
- Memorandum of Cooperation on Smart Mobility signed with the Ministry of Land, Infrastructure and Transport (which is being boosted by the hosting of an official from that Ministry)
- cooperation on e-Science data infrastructures (high speed research networks) in the Asian region
- active and healthy ageing projects.

The coordinated call mentioned above has been published this year in line with the description contained in the Work Programme ICT FP7 2013. This call has been planned over the last three or four years, backed by EU companies and research institutes, through the holding of annual conferences on Future Internet to which Japanese entities were invited. The activity was given political blessing during the 2011 ICT Dialogue, and at a 2012 meeting between VP Kroes and Minister Kawabata. It takes place in the overall context of the EU-Japan S&T agreement.
There are six topics targeted by this coordinated call:

a) Optical Communications
b) Wireless Communications
c) Cyber-security for improved resilience against cyber threats
d) Internet of Things and Cloud Computing services
e) Global scale experiments over federated testbeds, FIRE
f) Green & content centric networks

WP-C / 14 / EJ to EJ Business cooperation between EU and Japanese Clusters

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

In view to reinforce more practical cluster cooperation between the EU and Japan, DG Enterprise and Industry organised the first EU-Japan Cluster Match-making event from 12 to 15 November 2012 in Tokyo. This was the first time that such an international cluster mission was organised at EU level. The event focused on green materials and clean technologies and was held at the occasion of the Green Innovation Expo 2012 at Tokyo Big Sight exhibition centre.

The event was co-organised with the EU-Japan Centre for Industrial Cooperation as part of the Memorandum of Understanding on cluster cooperation signed with the European Cluster Collaboration Platform and was facilitated by a consortium led by the Fondation Sophia Antipolis (France). The 4 day-mission allowed a delegation composed of 18 representatives from clusters & SME members from 7 European countries (incl. Germany, France, Sweden, Poland, Denmark, Spain, Italy) to initiate strategic partnerships and business cooperation with Japanese clusters and enterprises.

All in all, over 14 Cluster-to-Cluster meetings and 16 Business-to-Business meetings have been organised which generated great interest and scope for cooperation. Some cooperation agreements are concretely envisaged between European and Japanese clusters and numerous BtoB partnerships are being considered in distribution, storage, technology and knowledge cooperation which could be concretised through further exchanges including visits of Japanese companies in Europe in 2013.

Further cluster matchmaking events in Japan might be envisaged in other fields of mutual interest in 2014 by the EU Japan Centre and the European Cluster Collaboration Platform explores the possibility to facilitate the organisation of an incoming mission of Japanese clusters in Europe in 2013 with the support of the EU Japan Centre.

INNOVATION IN AERONAUTICS, SPACE AND DEFENCE

Aeronautics

WP-C/ 15/ EJ to EJ Government-Led Industrial Cooperation in Aeronautics

The Authorities of Japan and the EU should significantly upgrade the scale of E Japan industrial cooperation in aeronautics, stimulated by government funding.
As shown in the GOJ's Progress Report, recent years have seen real progress in Research & Technology cooperation. The programmes involved, however, remain far below EU-Japan potential. Full-scale industrial cooperation remains scarce.

WP-C / 16 / EJ to EJ Environmental Issues in Aeronautics Technology
The Authorities of Japan and Europe should establish broad bilateral cooperation on environmental issues.
We do not see much recent progress. A small Japanese participation in initiatives under the EU Commission's Framework Programme budget, however, is a first but potentially important collaboration.

WP-C / 17 / EJ to EJ Cooperation in aircraft certification
Cooperation between Japanese and European aircraft certification authorities should be upgraded. Specifically, EU-Japan cooperation should be upgraded at the level of a full bilateral agreement. The use of English for all relevant documents should be permitted.

WP-C / 18 / 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.

January 2009 marked a turning point in EU-Japan aviation relations, when representatives of Japan's Ministry of Transport (MLIT) and the EC signed a "Record of Consultations", laying down the process for restoring legal certainty to bilateral air services agreement between Japan and EU Member States. This process is practically completed.

At the EU-Japan Summit in May 2011, President Barroso suggested exploring the possibility of a comprehensive EU-Japan air transport agreement, in parallel to a future EU-Japan FTA. The EC has thus offered Japan to share in more depth the EU approach to international air transport liberalisation and our positive experiences with market opening and to hold informal exploratory consultations with MLIT about the potential benefits of an open aviation agreement between Japan and the EU.

Given the improved aviation relationship between Japan and EU, it is in our mutual interest to make progress on concrete dossiers like safety, security, environment and ATM (cooperation in the latter field established through a Memorandum to coordinate EU's SESAR programme and Japan's equivalent system CARATS).

Progress has also been made in the air safety area. Based on the July 2011 conclusions of the EU-Japan Transport Dialogue and following a Japanese proposal to open negotiations for an Agreement on civil aviation safety (the so-called 'BASA'), preliminary discussions at technical level took place in Cologne in January 2012 between EASA, the Civil Aviation Bureau of Japan (MLIT-JCAB) and the European Commission (DG MOVE- E3 Air Safety Unit). The aim of discussions was to explore the possible evolution of the EU-Japan relations towards a BASA as a next step in the cooperation in the area of aviation safety.

The EU delegation and JCAB agreed to focus next technical discussions on the area of Airworthiness (Certification, including Environment, and Production) and Maintenance. For the EU side, the proper development of this process should help the Commission to obtain a mandate from the Council of the EU to start formal BASA (Bilateral Aviation Safety Agreement) negotiations with Japan with the technical assistance of EASA. Technical teams from EASA and JCAB will need to present to each other their complete and detailed regulatory frameworks in the certification and maintenance domains and organise technical sessions in that sense in Japan as a next step in the process.

A follow-up meeting involving representatives from the EC, EASA and JCAB took place during the June 2012 US/Europe International Aviation Safety Conference. From the JCAB side the willingness to proceed was reiterated, adding a wish to explore the (flight crew) licensing to a future BASA. The EC took careful note of this request, and reiterated from its side the willingness to proceed, noting however that progress on a comprehensive aviation agreement had not progressed in parallel, which it indicated could impact the progress towards a BASA.

A third meeting (in Brussels) with the Japanese (aviation) representative to the EU took place on 21 June 2012. The message was clear that Japan did not want to proceed with talks on a comprehensive aviation agreement, but were strongly in favour of proceeding with a BASA.

The EC responded by conditioning progress towards a BASA on progress towards a comprehensive agreement in parallel. This is more logical as it would be difficult to reconcile the status as privileged partner on aviation that a BASA would give to Japan without establishing a solid relation in terms of mutual market access.

A positive development has been the set-up of the High-Level Aviation Dialogue on 30 October 2012 between the Director of Air Transport of the Commission and the Director General of civil aviation of Japan.

- The EC is satisfied with EU-Japan aviation safety cooperation. There is a smooth dialogue and technical sessions have been organised involving the EC, EASA and JCAB.

- The EC is very aware of the benefits that could be achieved through the establishment of a bilateral aviation safety agreement with Japan

- We believe this is a good time for EASA and JCAB to define and exchange information on technical elements that need to be assessed within each party's oversight system.

- To this end the EC has repeatedly indicated its willingness to progress this issue through informal contacts and mutually beneficial confidence building activities with the possibility/desirability that these initial steps could lead to negotiations for a BASA with the EU.

- We nevertheless believe broader cooperation would be in mutual interest. For this reason, at the EU-Japan Summit in 2011, Commission President Barroso suggested that we should look at the conclusion of a comprehensive air transport agreement.

- On this basis the EC has been very clear in its indications that an activity towards the development of a bilateral aviation safety agreement is clearly linked to progress made as regards an overarching EU/Japan comprehensive aviation agreement, where unfortunately it remains to be seen how and when both sides will agree on how to progress.

- The High-Level Aviation Dialogue between the EC and Japan started on 30 October 2012 at the level of Directors. The Commission believes it is of the essence to upgrade aviation relations with Japan and place it as a privileged partner. This status should be reflected in the establishment of a comprehensive aviation Agreement between the EU and Japan.

- A positive agreement in that sense may accelerate the discussions towards a BASA.

Space

WP-C / 19 / EJ to EJ Government-Led Industrial Cooperation in Space.
The Authorities of Japan and the EU should significantly upgrade the scale of EU-Japan industrial cooperation in space, stimulated by government funding. Constructive work continues between METI and the European Commission, although the scope of cooperation is still very limited. Japanese companies have been involved in a small European Commission Framework Programme Call

The Commission considers with great interest the recommendations of the BRT in this area. Closer links will need to be developed to achieve more concrete results in the long term.

WP-C / 20 / EJ to EJ Civil Purpose Satellite Technology
In the civil satellite technology field, Japanese space Authorities (at Cabinet level) and European space Authorities (EU Commission, European Space Agency, and Europe's national space agencies) should establish a common mechanism for a formal and permanent dialogue with the purpose of identifying further mutually beneficial subjects of cooperation. Of particular interest to both the EU and Japanese industries are advanced broadband and mobile communications services that would be applicable, among other cases, to the rescue of populations hit by a natural disaster.
There has been no progress on this issue. We welcome the GOJ's intention to consider this Recommendation internally and consult with European space Authorities.

EU and Japan have an advanced space science and technology sector and a strong space industry.
Europe's priorities in Space lay in developing space related services for the civil society like Earth observation (GMES), Satellite navigation (Galileo) and Space science and technology for the exploration of the solar system and the Universe.

The Commission would welcome a stronger involvement of Japanese scientists in our programme. There are a number of promising areas for EU-Japan Space cooperation:
- o Earth observation and Climate change
- o Oceans monitoring
- o Support for the management of natural disasters
- o Securing space assets and the Earth from debris or Near Earth Objects like asteroids. Japanese expertise is welcome (Hayabusa Mission successfully touched down on an asteroid and brought material back to Earth)
- o Exploration of the Solar system and robotics in Space

There were 7 Japanese participations in the 5th call for proposals, from which 2 were successful (evaluations in Feb. 2012) in the technology field (good success rate; e.g. from the 30 US participations only 3 were successful).
The last call ended on 21 November 2012:
- Integration of satellite communication and satellite navigation solutions with space-based observing systems
- Research into reducing the vulnerability of space assets
- Security of space assets from in-orbit collisions
- Debris removal/mitigation concepts
- Processing and analysis of data obtained from space missions

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Japan's participation is the highest since the start of 7th framework-programme - 20 organisations participate in proposals. The evaluation is ongoing.

WP-C / 21 / EJ to EJ Mutual Backup of Government Satellite Launches

Japanese and EU Authorities should bring about a mutual backup cooperation scheme of all government launches using their respective satellite launcher fleets. There has been no progress on this issue. The commercial arrangement between Mitsubishi Heavy Industries, Ltd. and Arianespace can be used in theory but is inadequate by itself in the case of government programs.

No progress has been made at this stage but the Commission is ready to reconsider the case should the issue continue to exist.

WP-C / 22 / EJ to EJ Cooperation on Satellite Navigation Systems

EU and Japan Authorities should establish a close cooperation between Galileo and the Quasi-Zenith Satellite System. This should include frequency management, handset technology (receiver chips) development, and cooperation in GNSS meetings to set up service standards. Furthermore, the EU and Japan should develop cooperation on GNSS downstream applications.

Japan is developing its own regional satellite navigation system called QZSS, which is intended to cover East Asia. It is a civilian system and their first satellite was launched in 2010. The initial plan was to have a 3-satellite constellation, but there are plans to extend this to 7 satellites. Full operational status with at least 4 satellites is expected by 2020.
The Commission is pleased to have a technical agreement to ensure radio frequency compatibility between the first QZSS satellite and Galileo. This agreement on technical compatibility was signed within the framework of the International Telecommunications Union (ITU). The agreement ensures radio frequency compatibility between the first QZSS satellite and Galileo. It was signed by the Japanese Space Agency JAXA and the European Commission.
We would wish to continue cooperation to guarantee compatibility and if possible interoperability between the full QZSS constellation and the deployed Galileo constellation.

WP-C / 23 / EJ to EJ Cooperation on Active Space Debris Removal

EU and Japan Authorities should lead a global effort to remove space debris from low and geostationary Earth orbits. Near-term bilateral cooperation should include defining debris removal standards (or code) and developing debris removal technologies.

The Commission considers with great interest the recommendations of the BRT in this area. Closer links will need to be developed to achieve more concrete results but this is a long term objective.

Defence

WP-C/ 24/ EJ to EJ Defence Purpose Satellite Technology and Services

The BRT recommends that the Authorities of Japan and EU Member States should establish a regular dialogue aimed at sharing experience on defence purpose satellites.

This should also include dialogue on the delivery of secure communications services (as PFI is evolving as a growing subject in the new economic environment).

The Commission welcomes measures to improve defence trade between EU Member States and Japan. Both the EU and Japan are facing a number of security challenges and have to meet these challenges at a time when defence budgets are under severe pressures. The Commission is supportive of an industry policy dialogue which could be invaluable not only in building contacts and identifying barriers to collaboration; but could also help build a framework of mutual confidence and trust which is so important in defence trade. The extent to which the Commission can be involved in taking forward this proposal will depend on the nature of the dialogue. The Commission will discuss this idea with the AeroSpace and Defence Industries Association of Europe and assess to what extent it can provide support.

Recommendations from only European Industry

INNOVATION IN AERONAUTICS, SPACE AND DEFENCE

Aeronautics

WP-C / 29 / E to EJ Level Playing Field in Civil Aeronautics Markets

The Authorities of Japan and Europe should encourage competition and facilitate the entry of each other's aircraft on their respective domestic markets on the basis of reciprocity. Airlines and other major customers should be encouraged to diversify their sources of supply. Cooperation in aeronautics should not be biased towards US industry, but should be significantly increased between the EU and Japan.

See reply under WPC- 15, 16, 17 and 18

Defence

WP-C / 35 / E to EJ Internationally recognized procurement processes for defence equipment and services

The following should be applied to all defence procurement processes. (1) Clear statements of requirements, communication of any changes (2) Advising of timelines and adherence to them (3) Notice of evaluation criteria and the weightings given each criterion (4) Acceptance of English-language documentation (5) Application of NATO standards (6) Full public disclosure of the basis of awards (7) Opportunities to appeal award decisions, without the requirement to withdraw from the competition.

The Japanese MOD should perform the selection of the equipment independently from the existence of local manufacturing capabilities. If a foreign company is selected, then the Japan MOD should separately select the local industrial partner based on a licenced production and modification package made available by the selected foreign company.

Defence and sensitive procurement in the EU is subject to the rules of Directive 2009/81/EC. The Directive introduces at European level fair and transparent rules to help companies to access defence and security markets in other EU countries. It also guarantees flexibility for contracting authorities to negotiate in detail all features of complex contracts and to require safeguards that are necessary in the fields of defence and security, in particular on the protection of classified information and on security of supply.

The Directive covers contracts for military equipment, related works and services as well as for sensitive security equipment, works and services which involve access to classified information.

The deadline for transposition was August 2011. There have been delays in the transposition process. However, by January 2013 all Member States but one have notified to the Commission transposition of the Directive into their national legislation. The Commission is now committed to ensure that the Directive is correctly implemented and applied.

As regards third countries economic operators, the Directive leaves to Member States and their contracting authorities the choice whether to allow them participation in their procurement procedures under the Directive.

Following the establishment of its "Defence Task Force" in November 2011, the Commission will adopt in 2013 a Communication on a comprehensive strategy to strengthen Europe's defence sector. The main objectives of the Communication are to strengthen the internal market for defence; support the competitiveness of the EU defence industry; promote synergies between civil and military research; and promote the efficient use of all relevant EU policies to strengthen the defence sector. The Communication will represent a significant Commission's contribution to the overall debate leading to the European Council dedicated to defence matters now scheduled for December 2013.

WP-C/ 36 / E to EJ Greater emphasis on life cycle life costs in awarding contracts
The BRT recommends that Life Cycle Costs should form the basis of all relevant defence contract awards.

Article 47(1)(a) of Directive 2009/81/EC of the European Parliament and of the Council of 13 July 2009 on the coordination of procedures for the award of certain works contracts, supply contracts and service contracts by contracting authorities or entities in the fields of defence and security, and amending Directives 2004/17/EC and 2004/18/EC, explicitly provides for lifecycle costs as award criterion for the MEAT (most economically advantageous tender).

Working Party D

Financial Services, Accounting and Tax Issues

Recommendations from both European and Japanese industries

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

- Regulation on the financial sector should be implemented looking ahead the broader economic implication

- An excessive 'ring-fencing' in each jurisdiction and duplication of regulations have to be avoided with effective supervision and international coordination

- Consider local specificities of each country and region when discussing regulation in a global context.

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

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

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

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

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

across the EU are managed in a way which avoids financial instability and minimizes costs for taxpayers.

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

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

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

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

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

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

WP- D / 03 / EJ to EJ ***Liquidity in secondary markets***

Maintain liquidity in secondary markets

It seems to be too early to assess the final impact of liquidity rules on the real economy.

At the international level, discussions are still on-going regarding the final calibration of the short term (LCR – *Liquidity Coverage Ratio*) and long term (NSFR – *Net Stable Funding Ratio*) liquidity ratios introduced by Basel III. The observation period for LCR will end in mid-2013, while for the NSFR, it will end in mid-2016 and, especially for the LCR, some issues are still under discussion.

At European level, the texts implementing these Basel liquidity rules, included in "the CRD IV package" (made up of a *Capital Requirements Directive* and a *Capital Requirements Regulation*), are still under negotiation in the framework of the co-decision legislative procedure (discussions between the Council and the European Parliament on the basis of the Commission proposal). The final version of the text is not available as of now, but one of its aims is to take full account of the observation period to define an

appropriate calibration of the ratios (i.e. high quality liquid assets, inflows and outflows for the LCR). As a consequence, the definition of liquidity rules is not yet finalised and data gathered during the observation period on, for example, certain categories of equities will contribute to the final outcome.

The Commission is fiercely committed to introducing new liquidity rules, as it recognises the impact of the lack of such rules during the last crisis. However, it is necessary to take fully into account the potential unintended consequences of these new rules on the real economy. At the end of the observation period, taking into account the data gathered and the international developments, it will be possible to design an appropriate calibration of the LCR and the NSFR to avoid any potential negative consequence on the real economy, especially for countries that do have specific financial systems.

WP- D / 04 / EJ to EJ ***Accounting Issues in EU and Japan***

- Net unrealised gain on available-for-sale securities recognised as other comprehensive income (OCI), dividend recognised as net income but realised gain as OCI, not net income.
- Actuarial gains and losses on employee benefits should be recycled.
- Operating and finance leases should be treated separately.
- The use of direct method in cash flow statement would not add benefit.

The Commission attaches great importance to the global convergence of accounting standards. More and more jurisdictions are in the process of ensuring convergence between their nationally Generally Accepted Accounting Principles (GAAP) and IFRS or adopting IFRS directly. The preferred approach focus on the adoption of IFRS rather than on gradual convergence. Japan is therefore encouraged to take a positive decision regarding adoption of IFRS. Major economies like the US or Japan should demonstrate their strong commitment towards full adoption of IFRS, paving the way to establish IFRS as the global accounting language.

Many of the IFRS standards under development have broad economic impact. The IASB thus needs to develop high quality standards that need to be understandable and practicable. The IASB should consider all potential impacts of new standards and require proper impact assessments. The slow progress achieved towards the completion of the convergence programme between the IASB and the FASB poses some concerns. The effort to achieve convergence between the IASB and the FASB should not further delay the delivery of the major outstanding standards, in particular accounting for financial instruments. The IASB should therefore complete its work promptly to respect the G20 timing (mid-2013) and consider that convergence could be achieved with each board (the IASB and the FASB) issuing separate but consistent standards (same approaches but maintaining specificities in the final content of their respective standards).

On the four key projects (financial instruments, revenue recognition, leases and insurance):

1. The Commission closely follows the IASB work on revising the accounting requirements for financial instruments. The Commission considers all three phases of IFRS 9 (classification and measurement, impairment and hedging) need to be completed before a decision on the endorsement of IFRS 9 can be taken.

2. The IASB is working on the revision of the requirements for the accounting of leases. Previous proposals have not been supported in the EU. The general view is that the IASB should make an effort to better explain the overall objective of the project.

3. The Commission is concerned about the potential impacts of the proposed changes to the requirements in the area of revenue recognition. The business model of some industries, in particular the telecom industry, might be impacted in a way that does not reflect the real activity performed by the companies. The IASB should carry out thorough effect studies before the standard is finalised.

4. On the revision of IFRS 4 Insurance Contracts, the Commission is awaiting the revised proposal by the IASB.

The EU continues to timely adopt the IFRS standards issued by the IASB. In 2012, EU Member States voted in favour of adoption of the new rules on consolidation (IFRS 10, 11, 12), IFRS 13 Fair Value Measurement and amendments to IAS 32 and to IFRS 7 (offsetting).

The Commission intends to continue policy and technical dialogue with Japan in order to make sure that three is an on-going debate and exchange of views, e.g. regarding the issue of further convergence of accounting standards and necessary improvements regarding the governance of international standard setting bodies.

WP- D / 05 / EJ to EJ ***Tax Issues in the EU and Japan***

All EU Member States and Japan to modernise tax treaties. Tax treaties should ensure to the greatest possible extent that dividend, royalty and interest payments are exempted from withholdings taxes and provide for corresponding adjustments and arbitration.

The Commission is in favour of a modernisation of the Tax Treaties. However, it is up to

Member States to re-negotiate their Double Tax Conventions.

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

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

Moreover, in its Communication on Double Taxation in the Single Market (COM (2011) 712), the Commission recognises that the existing instruments are insufficient to address many of the double taxation situations not covered by the EU legislation (such as the Interest and Royalties Directive and the Parent-Subsidiary Directive) or by the Arbitration Convention of 23 July 1990 on the elimination of double taxation in connection with the adjustments of profits of associated enterprises. The Commission services are therefore considering possible solutions to the unsolved cases of double taxation within the Single Market. One of the possible policy options could be the recommendation to re-negotiate the Double Tax Conventions between Member States in order to include in the Mutual Agreement Procedure (MAP) the arbitration mechanism as foreseen in the new version of article 25 of the OECD Model.

Harmonise and simplify documentary requirements in transfer pricing taxation and promote the conclusion of bilateral and multilateral Advanced Pricing Agreement (APAs).

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

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

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

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

Introduce participation exemption and exempt dividends and capital gains received from business investment from further corporate taxation.

The Commission is aware that taxation of capital gains and dividends is problematic for business as it may result in a double taxation or trigger administrative burdens to recover the taxes paid. The Parent-subsidiary Directive is aimed at eliminating these risks for the corporate dividend distribution in the EU, but it requires at least a 10% shareholding. For portfolio dividends, as well as for capital gains, there are currently no provisions at EU level.

The current 2013-2014 Commission's plan does not envisage specific legislative proposals to tackle the taxation of capital gains and the 10% threshold in the Parent-subsidiary Directive.

However, the plan contains the announcement of a broader initiative for the treatment of portfolio dividends in the Single Market.

Avoid introducing tax regulation focusing on specific industry or category of business, such as a Bank Tax, which could lead to distortion in the allocation of resources and economic activities in the private sector

The Commission has adopted its proposal for a Council Directive establishing a common system of financial transactions tax (FTT) in the EU on 28 September 2011; two of the aims of the proposal were to ensure a level-playing field from a taxation point of view and to recoup a part of the costs related to the recent financial and economic crisis. Having in mind that the financial sector currently enjoys a favourable tax treatment (compared to other sectors) in the framework of VAT (estimated to around EUR 18 bn. per year in the impact assessment accompanying the Commission's proposal) and that the financial sector has benefited from support measures worth around EUR 1.6 tn. between 2008 and the beginning of 2012, the Commission has decided to direct this tax to the financial sector, i.e. making financial institutions liable to pay the tax.

Discussions on the FTT are continuing in the framework of the enhanced cooperation procedure.

Japan and the EU have to work together to convince the United States to prevent the negative aspects of the Foreign Account Tax Compliance Act which is applying to foreign countries as well.

The European Commission has been following very closely the developments concerning the US Foreign Account Tax Compliance Act (FATCA) both within the EU and in third countries.
It has been in touch with Japan to exchange views on this issue.
The Commission welcomes the move made by the US to implement FATCA through administrative cooperation at governmental level. In particular, it welcomes the development of the Model 1 Agreement to Improve International Tax Compliance and to Implement FATCA which the US has elaborated in cooperation with five EU Member States. The Model simplifies the application of FATCA by financial institutions, addresses the legal issues raised by FATCA and is also a step forward in combating cross-border tax evasion. Two EU Member States (UK and DK) have already signed a bilateral agreement with the US, along the lines of this Model, and many other Member States are expected to do so in the coming months.
The Commission is aware that the US has also developed an alternative Model for facilitating the implementation of FATCA (Model 2) and that Japan intends to sign an agreement with the US along the lines of this Model. The Commission has noted with interest that Model 2 includes a provision which would allow countries to renegotiate a Model 2 agreement to convert it into a Model 1 agreement at some future date, should they wish to do so.
The Commission is interested in exchanging views and experience with the Japanese business on the technical issues related to the implementation of FATCA

Recommendations from both European and Japanese industries to the EU

WP- D / 11 / EJ to E ***Issues to be mindful of when proceeding with reform***

Amongst the prevailing credit crisis in Europe the trend to tighten the regulations on financial institutions and to decrease the fiscal debt might be useful to avoid the foreseeable future's possible financial crisis. However, in the perspectives of coping with today's crisis, it might not only be least effective, but worsen the current situation.
The European governments should cautiously make a decision when and how to introduce tighter regulations in order to minimize potential economic slowdown.

The European economy is still facing difficult challenges. It is therefore essential for the EU to make every effort to rapidly implement measures to re-launch growth, investment and employment. The Commission works with a view to safeguarding the integrity and stability of the single market, to improving the functioning of financial markets and to breaking the feedback loop between sovereigns and banks.

The crisis exposed serious inadequacies**,** such as regulatory gaps; inadequate supervision; poor corporate governance; opaque markets and overly-complex products. Experiences during the crisis have clearly demonstrated that we need common EU rules, growth-friendly fiscal consolidation and further financial governance. The Commission is committed to pursue its reform programme on regulation and supervision of the financial sector, in line with G20 commitments. The EU is approaching the end of its largest ever programme of financial services reform. Around thirty targeted measures have been proposed after comprehensive impact assessments and consultations.

These reforms are based on a two-pillar approach: firstly we need to stabilise the financial sector and re-establish confidence; secondly, we need to put in place measures to ensure the financial sector supports healthy growth and investment. Each proposal is carefully calibrated to be bearable for the financial sector and to support the real economy.

The June 2012 European Council agreed on significant measures to address Europe's challenges. It agreed to a single banking supervision mechanism in the euro area,, increasing budgetary integration and achieving a genuine Economic and Monetary Union. In October 2012, the European Council reiterated its firm commitment to take resolute action to address financial market tensions and restore confidence. It welcomed progress made so far, and also called for swift, determined and result-oriented action to ensure the full and rapid implementation of the Compact for Growth and Job.

WP- D / 12 / EJ to E ***Solvency margin regulation***

- With respect to "Reinsurance" among three areas to be assessed, Japan received equivalence determination from the European Insurance and Occupational Pensions Authority (EIOPA).
- In the meantime, concerning the remaining areas, "Group supervision" and " Group solvency", assessment procedures expected to continue until 2015 should be conducted constructively

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

The implementation of Solvency II has been delayed by the on-going discussions on the Omnibus II Directive. This means that the European Commission's decision on the equivalence of the Japanese solvency regime will not now be taken in 2013, as previously envisaged.

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

WP- D / 13 / EJ to E ***Tax issues in the EU***

Establish a tax system which will enable companies conducting business in the EU to enjoy fully the benefits of the Single Market. In particular,

- *Introduce a common consolidated corporate tax base as soon as possible.*

See comment under WP-A 19 (1) above

- *Amend the Merger Directive (Directive 90/434/EEC) to cover the transfer of real estate and other intangible assets in reorganisation and to abolish the requirements in certain Member States to maintain the holding of shares received in exchange of contributed assets for a specified number of years*

The holding period issue under the Merger Directive was brought up in the past by the Commission. However, since no agreement on abolishing the holding period requirement could be achieved, no action in this direction is envisaged by the Commission in its next legislative plans

- *Exemption from penalties related to non-compliance with documentation requirements and transfer pricing adjustments, and from interest related to a company submits an EU TPD in good faith and in a timely manner*

See comment under WP – A: 19 (3) above

- *Simplify and harmonise the VAT system to enable centralised VAT accounting in a cost-efficient manner.*

See comment under WP – A: 19 (4) above

WP- D / 14 / EJ to E ***Tax on Financial Transaction***

The BRT insists that EU should not introduce tax on financial transactions. If EU

might introduce the tax on financial transactions, it would not only harm the potential growth rate of GDP, investors may execute its transactions on bonds/ equities/derivatives in the non-EU countries, instead of EU member countries.
EU governments should also bear in mind that the tax on financial transaction may cause a lot of burden in the transaction through IT system, which could give a similar bad effect in the markets. As this could reduce the market liquidity, it is likely that market volatility would rather become bigger.

The Commission's services are aware of the difficulties of introducing a financial transaction tax, but do not agree with the BRT's recommendation. The Commission has already published its proposal for a Council directive establishing a common system of FTT in the EU on 28 September 2011 in which such difficulties are taken into consideration. In a parallel proposal in November 2011 the Commission has proposed that two thirds of the FTT revenue obtained by using the minimum tax rates would go to the EU budget as an own resource. It was estimated that around EUR 57 billion would be collected in the whole EU.
After intense discussions during the Polish and Danish Presidencies, during the Council meetings of June and July it was ascertained that no agreement is foreseeable in the future on the basis of the Commission's Proposal. Between 28 September and 23 October 2012, 11 MS have sent official letters to the Commission, indicating that they are willing to work together, under the enhanced cooperation procedure, for establishing a common form of FTT. On 23 October 2012, the Commission has published its proposal for a Council decision authorizing enhanced cooperation in the area of FTT, which was has already received the consent of the European Parliament on 12 December and is now on the table of EU finance ministers.

Working Party E

Energy, Environment and Sustainable Development

Recommendations from both European and Japanese Industries

Natural Disasters and Safety Measures

WP-E / 01 / EJ to EJ Identification and prevention measures for natural risks
The EU and Japan should put in place appropriate mechanisms to identify the potential risks of natural disasters and the probability of their occurrence, and objectively verify their impact.

WP-E / 02 / EJ to EJ Facilitating international support in case of disaster
International support is indispensable in times of a major natural disaster. The necessary measures need to be adopted to facilitate the swift acceptance of support from overseas.

WP-E / 03 / EJ to EJ Strengthening international collaboration for "Post crisis" management
The EU and Japan should improve the sharing of know-how and expertise in specific fields for "post crisis" management. Such joint efforts will significantly speed up the recovery of the concerned population and area.

The European Commission would firstly draw the EU-Japan business community's attention to the recent agreement between the European Commission's Humanitarian Aid and Civil Protection department (ECHO) and Japan's Ministry Land, Infrastructure, Transport and Tourism on cooperating on managing disasters which would seem to address a number of these concerns.

In so far as there may be additional expectations and difficulties experienced by the EU-Japan business community, the European External Action Service draws the Business Round Table's attention to its competence and capabilities in the areas of crisis response and crisis management following technological incidents or man-made and natural disasters and its willingness to discuss these topics with any and all relevant Japanese stakeholders. It is possible, however, that given the complex, fast moving and at sensitive nature of cooperation in these fields that fora other than the EU-Japan Business Round Table might be the most efficient for making progress on these topics.

Alternative and Renewable Energies

WP-E / 04 / EJ to EJ: Enhancing high-level EU-Japan dialogue on energy
The EU and Japan should enhance their dialogue on energy policy, including the setup of a dedicated high-level dialogue on nuclear energy.

Energy cooperation has for a long time been on the agenda of bilateral cooperation between the EU and Japan. The two sides have established a regular energy dialogue at the level of Directors General following the commitment of the 2006 EU-Japan Summit. In 2012, the regular energy dialogue was held for the first time at the Ministerial level, between Commissioner for Energy Gunther Oettinger and Minister of Trade, Economy and Industry Yukio Edano. They reaffirmed commitment to reinvigorate energy cooperation and agreed to enhance cooperation in several areas, including on nuclear

safety and regulatory frameworks. Additionally, they agreed to strengthen cooperation in areas of reform of electricity markets, energy-related research and energy security.

WP-E / 05 / EJ to EJ Leadership role to establish world safety standards

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

Ensuring and continuously improving nuclear safety in the Union and globally is a priority of the EU. The Euratom Community is a Contracting Party in the main instruments governing nuclear safety through the IAEA, in particular the Convention on Nuclear Safety (CNS), and the Convention on the Early Notification of a Nuclear Emergency. The extraordinary meeting of the Convention on Nuclear Safety in August 2012 agreed to set up a working group tasked with reporting in 2014 on a list of actions to strengthen the Convention and on proposals to amend it, if necessary, in which the Commission is actively participating.

On 25 January 2013, a new cooperation mechanism was established between the EU and the International Atomic Energy Agency (IAEA). The cooperation between the IAEA and the EU institutions has grown significantly over the last years, with the EU being a major contributor to the activities of the IAEA, both in terms of financing and technical expertise. While traditionally the cooperation has focused more on non-proliferation and ensuring that all nuclear material is used only for peaceful purposes, after the Fukushima accident, nuclear safety has gained more momentum. The new mechanism should help enhance cooperation in all areas relating to nuclear technologies, including safety and security of nuclear energy production and research activities.

WP-E / 06 / EJ to EJ Nurturing skilled independent nuclear safety authority

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

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

One of the key lessons learnt from the Fukushima accident is that the effective independence of the national regulatory authorities must be ensured. The EU Nuclear Safety Directive adopted in 2009 foresees that EU Member States establish and maintain a competent regulatory authority in the field of nuclear safety of nuclear installations. The competent regulatory authority has to be functionally separate from any other body or organisation concerned with the promotion, or utilisation of nuclear energy, including electricity production, in order to ensure effective independence from undue influence in its regulatory decision making.

In March 2011, following the Fukushima accident, the European Council mandated the European Commission to review existing legal and regulatory framework for nuclear safety and propose any improvement that may be necessary. Taking account of the findings of that accident, the views of various stakeholders, and the findings of the EU comprehensive risk and safety assessments of nuclear power plants, implemented in the EU following the Fukushima accident, the Commission proposes to strengthen the regulatory requirements. Amongst other proposals, it indicates that the current provisions on regulatory separation and the effectiveness of nuclear regulatory authorities need to be

strengthened to ensure the effective independence of these authorities and guarantee that they have the appropriate means of action. The Commission is currently working on a revision of the Nuclear Safety Directive, which will be presented in 2013.

WP-E / 07 / EJ to EJ Cooperation on renewable energy development

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

The regular energy dialogue between Ministry of Trade, Economy and Industry and the European Commission in 2012 provided an opportunity to discuss the latest developments in the field of renewable energy and respective policy frameworks. In the context of the new EU programme for research and innovation Horizon 2020 and the energy policy review in Japan, consideration is being given on how to take forward cooperation on research and innovation, building on the successful research cooperation on photovoltaic which is already underway.
The Japanese research and industry community is invited to develop international cooperation with the European Energy Research Alliance, the alliance of the leading EU energy research centres, in particular on wind, energy storage, smart grids, bioenergy and photovoltaic.

WP-E / 09 / EJ to EJ Sharing best practices for safety and regulation with emerging nuclear power countries

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

The Commission continues to encourage all EU neighbouring countries to strengthen its safety culture and emergency preparedness. In 2012, the European Commission held several meetings with representatives of EU neighbouring countries which operate or own nuclear installations or which have plans for the development of nuclear power – Armenia, Republic of Belarus, Republic of Croatia, Russian Federation, Swiss Confederation, Republic of Turkey and Ukraine. These countries agreed to undertake voluntary safety assessments taking into account the EU specifications and methodology, including the principle of peer reviews. Two of these countries – Switzerland and Ukraine – were fully integrated in the EU stress-test process. A Euratom loan is currently being considered for Ukraine, in order to speed up the implementation of its comprehensive safety upgrade programme.

WP-E / 10 / EJ to EJ Promoting involvement of international institutions to finance capacity-building actions nuclear safety and more generally nuclear investment in the best conditions of safety and security

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

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

WP-E / 11 / EJ to EJ Ensuring fair competition in exports

The EU and Japan need to create equally competitive fields for export industries, including fulfilment of world safety standards, and strictly adhere to the OECD's Arrangement to Officially Support Export Credits. The EU and Japan should request other countries to make every effort to also adhere to these provisions.

The European Commission agrees on the importance of strictly adhering to the OECD's arrangement to officially support exports credits or to any equivalent set of disciplines which the EU and Japan might negotiate in the future with the other major international providers of export credits . The European Commission also agrees with the need to try to engage other countries to make efforts to adhere to provisions on export credits. In this context the Commission welcomes the creation last year of a new International Working Group to negotiate a new international agreement on export credits which should also include non-OECD countries.

WP-E / 12 / EJ to EJ Fostering international harmonization for EV safety and charging infrastructure

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

WP-E / 13 / EJ to EJ Cooperating on pre-commercial development of batteries

The EU and Japan should seek opportunities for partnerships between governments and research institutes to develop pre-competitive technologies for next-generation batteries (e.g. for lowering cost, improving battery life, enhancing safety, and raising energy density).

WP-E / 14 / EJ to EJ Sharing best practices for reuse and recycling of batteries

The EU and Japan should share best practices with respect to the reuse and recycling of rechargeable batteries to enhance their secondary use.

Regarding electric vehicles and batteries the European Commission informs that the regulatory authorities of Japan and the EU, together with those of the US and other parties, have launched specific work on these issues under the UNECE framework, based on the decision to closely cooperate on convergence of regulatory obligations related to electric vehicles in the global context. This work is expected to lead to cost savings through economies of scale for automotive manufacturers. Under the cooperating agreement two informal working groups on electric vehicles were set up under the 1998

Agreement on Global Technical Regulations. The initiative was taken by the European Commission, the National Highway Traffic Safety Administration (NHTSA) and the Environmental Protection Agency (EPA) in the United States and the Ministry of Land, Infrastructure, Transport and Tourism of Japan. The working groups are open to all countries that are contracting parties to the relevant UN Agreement.

The first group is addressing the safety aspects of electric vehicles and their components, including the battery, covering the safety of occupants against electric shocks in-use, while recharging as well as after an accident. The second group is focusing on environmental aspects of regulations applied to electric vehicles.

WP-E / 15 / EJ to EJ Further promoting demo projects of smart cities and smart grids
The EU and Japan should further promote demonstration experiments of smart cities and smart grids with respect to rechargeable batteries and related products and should provide open access to allow each other's industry to participate in such experiments.

On 10 July 2012, the European Commission launched the Smart Cities and Communities European Innovation Partnership. The partnership proposes to pool resources to support the demonstration of energy, transport and information and communication technologies (ICT) in urban areas. The energy, transport and ICT industries are invited to work together with cities to combine their technologies to address cities' needs. This will enable innovative, integrated and efficient technologies to roll out and enter the market more easily, while placing cities at the centre of innovation. The funding will be awarded through yearly calls for proposals: €365 million for 2013. This Innovation partnership will be fully operational under "Horizon 2020", the new research and innovation funding framework under the next Multiannual Financing Framework (MFF 2014-2020).

The Stakeholder Platform for Smart Cities and Communities was launched in 2011. This Platform constitutes a forum for business, public authorities and the research community to engage in international and cross-sector cooperation.

Global-Warming Issues

WP-E/ 16 / EJ to EJ Establishing in the near future a new, fair, and effective international framework
The EU and Japan should promote a post-Kyoto framework that engages all major emitters of greenhouse gases to take a fair share of the burden of global CO2 emission stabilization and reduction.

The European Union, like Japan, was instrumental to the success of the Climate Change Conference of the parties in Qatar in 2012. The Doha conference (COP18) implemented the achievement of the UN climate conference in Durban in 2011, paving the way for a future legally binding agreement with mitigation commitments by all Parties to be adopted by 2015 and be implemented from 2020.

The outcome of the Climate negotiations in Doha includes:

- Adoption of a second commitment period of the Kyoto Protocol from 2013 to 2020 and. closure of the negotiations cycle started in Bali in 2007 (the Bali Roadmap).

- Agreement on the next steps towards adoption of the 2015 Agreement as well as on how to raise mitigation ambition before 2020 in the framework of the Ad Hoc Working Group on the Durban Platform for Enhanced Action (ADP).

Since 2010 the international community has recognized the scientific evidence that global warming needs to be held below 2°C above the pre-industrial temperature in order to prevent climate change from reaching dangerous proportions. However, international action taken to date is still not sufficient to prevent this ceiling from being exceeded. Scientific evidence indicates that a temperature rise of more than 2°C could have irreversible and potentially catastrophic environmental consequences with high costs in human and economic terms.

The EU is successfully reducing its emissions of greenhouse gases, but worldwide emissions are continuing to grow. Global energy-related emissions of carbon dioxide (CO2), the main greenhouse gas, reached a record (30.4 gigatonnes) in 2010. The concentration of CO2 in the atmosphere is increasing annually and is at its highest level for 650,000 years, scientific research shows.

The EU is leading by example through its domestic action to tackle climate change. Despite economic growth of almost 40% since 1990, the EU-15 is well on track to achieve and exceed its 8% emissions cut under Kyoto. Taking all 27 EU Member States together, GHG emissions in 2010 were 15.5% lower than in 1990 while GDP was 41% higher. Full details can be found in the European Commission's annual progress reports.

The EU hopes that Japan will also maintain ambitious climate policies, including through maintaining is 25% emission reduction pledge by 2020.

The EU and Japan hold regular bilateral dialogues to further exchange views on these issues.

WP-E/ 17 / EJ to EJ Setting CO2 emission targets in a fair and transparent way

The EU and Japan, when setting national targets, should take into account their international fairness, feasibility, and social impact on citizens. The setting of such targets should be done with a high level of transparency and in consultation with stakeholders.

In 2007, EU leaders - recognizing the benefits in terms of stimulating innovation, economic growth and jobs - committed the EU to becoming a highly energy-efficient, low-emission economy. Since then binding legislation has been put in place to cut emissions to 20% below 1990 levels by 2020. The EU has also inscribed this target in the second commitment period of the Kyoto protocol adopted at the Doha Climate Change Conference in 2012.
The EU is offering to increase this reduction to 30% if other major economies commit to take on their fair share of global action. In the longer term, the EU is committed to cutting its emissions by 80-95% below 1990 levels by 2050 as part of the effort required from the developed world as a whole. In March 2011 the European Commission published a roadmap that charts a cost-effective pathway for making the necessary transition to a competitive, low carbon European economy by mid-century.
This ‘climate and energy package’ was agreed by the European Parliament and Council in December 2008, after extensive, inclusive and transparent consultations with all stakeholders, and taking into account domestic circumstances. It then became law in June 2009. Future climate legislation will continue to be based e.g. on open consultation and full transparency, ands answering the findings of science.

WP-E/ 18 / EJ to EJ Facilitating transfers of green technologies
The EU and Japan should assist emerging economies in developing the necessary human resources and infrastructure so that they can smoothly absorb advanced technologies. To facilitate the transfer of technologies on a commercial basis, the EU and Japan should support the recipient countries in putting in place an appropriate regulatory framework and enforcement tools to ensure the protection of intellectual property rights.

The EU supports the objective of having an appropriate regulatory framework to ensure the protection of IPR. Regulatory convergence is often part of agreements that the EU negotiates or concludes with the Third countries. It entails at least the references to international standards and conventions in this field and in some cases encourage regulatory convergence towards EU standards. Particular attention should be paid to the enforcement of such rules.

Developing Energy Efficiency and Energy Savings

WP-E/ 20 / EJ to EJ Continuously improving incentives and regulations to promote the adoption of energy-efficient technologies and processes
The EU and Japan should continue to refine their regulations and incentives to promote the efficient use of energy (energy efficiency as well as energy savings). Setting mandatory principles for standards for building and house insulation plays a major role in reducing energy consumption and dependency and in achieving a significant reduction in CO2 emissions. Japan and the EU should also share best practices to implement energy efficiency regulations, Innovation processes, trainings, experimental programmes of construction and renovation regarding products and services.

The EU adopted the Directive 2012/27/EU on energy efficiency on 25 October 2012; it entered into force on 4 December 2012. This Directive establishes a common framework of measures for the promotion of energy efficiency within the European Union to contribute to the achievement of the EU's headline target for energy efficiency of 20% by 2020 and paves the way for further energy efficiency improvements beyond that date. It lays down rules designed to overcome market failures that impede efficiency in the supply and use of energy, requires Member States to adopt indicative national energy efficiency targets for 2020 by April 2013. Member States are also required to take key decisions on the design of energy efficiency obligations, or alternatives, by October 2013; to adopt long-term strategies for mobilising investment in the renovation of the national building stock, including policies and measures to stimulate "cost-effective deep renovations", by April 2014; to assess the potential for improving energy efficiency in gas and electricity infrastructure by June 2015; and to assess the potential for district heating and cogeneration by December 2015. Member States must renovate 3% (by floor area) of their central government buildings each year, or adopt measures that achieve equivalent energy savings in these buildings. Moreover, central government purchasing under the public procurement directive should (with exceptions) be limited to products, services and buildings with high energy efficiency performance. The Directive also includes new obligations regarding energy audits, metering and billing, grid and demand response issues, and energy services.

Energy efficiency has been a regular topic on the agenda of the EU-Japan energy discussions. Joint work is also ongoing in the context of international organizations

addressing this policy issue, namely the International Energy Agency and the International Partnership on Energy Efficiency Cooperation.

Securing Supply of Raw Materials

WP-E / 21 / EJ to EJ Promoting adhesion and enforcement of EITI
The EU and Japan should work closely with other governments, industrial bodies, and NGOs to enable resource-producing countries to fulfil the EITI's "Principles and Criteria" and to advance from candidate to compliant EITI countries.

Recent European Commission Communication on security of energy supply and international cooperation has called for increasing focus on the promotion of good governance in all EU's energy dialogues.

The EU is an official supporter of the EITI Initiative of the World Bank and its principles. In addition to the financial contributions of some EU Member States, the EU contributes financially to the EITI Multi-Donor Trust Fund (EITI MDTF). The European Commission also participates in the work of the EITI Board and in the Management Committee (MC) of the EITI Implementation Support Facility Trust Funds (EITI MDTF).

In October 2011, the Commission put forward a legislative proposal requiring the disclosure of payments to governments on a country and project basis by listed and large unlisted companies with activities in the extractive (oil, gas and mining) and forestry sectors. The proposed review of the Accounting Directive with a system of country-by-country reporting (CBCR) would apply to EU privately-owned large companies or companies listed in the EU that are active in the oil, gas, mining or logging sectors. Reporting taxes, royalties and bonuses that a multinational pays to a host government will show a company's financial impact in host countries. This more transparent approach would encourage more sustainable businesses. The proposal is currently under negotiation between the European Parliament and the Council.

WP-E/ 22/ EJ to EJ Promoting action to minimize commodity price *volatility*
Japan and the EU should strive to reduce excessive price volatility in commodity markets and should accordingly identify common actions to take in international fora.

The European Commission has actively participated in the G20 work on commodity market transparency and oversight. The relevant G20 experts groups have addressed issues of improving the transparency of physical markets, in particular through the JODI-Oil database, assessing the functioning of oil Price Reporting Agencies, strengthening the producer-consumer dialogue on oil markets, and extending the work on physical oil market transparency to physical markets for gas and coal.

In October 2011, the European Commission has put forward legislative proposals for a review of the Markets in Financial Instruments Directive (MiFID) and the Market Abuse Directive (MAD) on 20 October 2011 that include further targeted measures to improve the functioning of derivatives markets, with a particular emphasis on commodity derivatives. The measures will increase transparency of trading activity in commodity and other derivatives and ensure that relevant data on the activities of all key market participants will be more readily available. It will also prevent the abusive behaviour of

markets participants by covering all kinds of venues and transactions by pan-EU rules. The proposal is currently under negotiation between the European Parliament and the Council.

Annex

Recommendations for which no reply is provided

WP-A-03-(5). The two Authorities should create a framework between the EU and Japan in the development of practical application of new technologies, such as RFID and biometrics authentication technologies. This will enable and enhance cooperation among companies in the EU and Japan, and will also promote new international standardisation and lead to its dissemination.

WP-B /08 / EJ to EJ. Enhancement of cooperation with industry and academia. Enhance international cooperation in the development of plants with new beneficial traits/Promotion of industry & academia cooperation .

WP-B / 20 / E to EJ Mutual recognition of GMP and marketing authorization for animal health products. Mutual recognition of European and Japanese marketing authorizations and recognition of GMP certification for veterinary products. MAFF should work out harmonized regulations leading to the 1-1-1 concept.

WP-B / 28 / J to E Shorten the approval time to register new micro-organism and introduce new technology for producing seasonings and amino acids. Shortening the approval time needed for registration of new materials and introduction of new technologies which aim for product expansion, cost reduction, environmental concerns or diversification of the fermentation material. Clarification of the approval process is also requested.

WP-E /08 / EJ to EJ Promoting reciprocal access to R&D facilities. The EU and Japan should support joint R&D activities or mutual access to unique, capital intensive R&D facilities located in either the EU or Japan.

WP-E/ 19 / EJ to EJ Cooperation on long-term innovative R&D projects to reduce GHG emissions. The EU and Japan should cooperate on joint R&D efforts by industry, academia, and government to develop innovative technologies to reduce greenhouse gas emissions. They should also allow access by their industries to their domestic pre-competitive, government-funded research projects because highly innovative technologies require lengthy timelines and very large budgets for basic research and development.

WP-E/ 23 / EJ to EJ Supporting R&D for recycling and material substitution. Japan and the EU should encourage the recycling of raw materials in developed countries through R&D, industrial policy, and international cooperation as well as promote research aimed at the substitution of critical raw materials.
