



Commission Services Progress Report
on the

**EU-Japan Business Dialogue Round Table
Recommendations 2010**

*"EU-Japan business: gearing up for the next
decade"*

Brussels, February 2011

The **European Union – Japan Business Round Table** (BRT) issued in 2010 its recommendations to the leaders of the EU and Japan:

“EU-Japan business: gearing up for the next decade”.

Adopted during the BRT annual meeting held in Tokyo on 19 and 20 April 2010, those recommendations have been duly studied by the European Commission Services.

The following document outlines progress made in considering or implementing the various recommendations put forward by the BRT.

The progress report is divided into five parts corresponding to the five working parties:

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Foreword

In the foreword of the last year *Commission services progress report*, we referred to the "Europe 2020 strategy" to be endorsed by the Heads of State and Government at the European Council of June. The "Europe 2020 strategy" has been adopted in June and since then the Commission has proposed detailed and concrete policies and initiatives. As a result, the following Communications of the Commission were adopted in 2010: "*Digital Agenda for Europe*", "*Innovation Union*", "*Youth on the move*", "*Resource efficient Europe*" (followed by a Communication adopted in February 2011: "*Tackling the challenges in commodity markets and on raw materials*"), "*An industrial Policy for the globalisation era*", "*An agenda for new skills and jobs*" and the "*European platform against poverty*". Now, both the EU and national authorities have to coordinate their efforts so they are mutually reinforcing.

The members of the Business Round Table will find a reference to these important policy initiatives in many of the Commission services' replies to the BRT recommendations. Globally, the BRT concerns remain fully in line with those of the European Commission. This makes the BRT a recognised interlocutor of the Commission and its recommendations constitute a valuable input to our dialogue with Japan. This also shows how much the European Union and Japan have in common.

More specifically, the following issues, of more direct interest to the BRT have been dealt with since last year:

- In June 2010, the EU and Japan agreed upon the mutual recognition of EU and Japanese Authorised Economic Operators (AEO) programmes within the context of the implementation of the EU-Japan Customs Cooperation Agreement (EU and Japan JCC Decision No 01/2010 of 24 June 2010). The mutual recognition is intended to provide benefits to AEOs who have invested in securing their international supply chains. Work on the implementing measures is being carried out

- In July 2010, the European Commission submitted a proposal for a Directive on "conditions of entry and residence of third country nationals in the framework on an intra-corporate transferee". This scheme aims at simplifying and accelerating procedures and provides for a common definition of intra-corporate transferee. Consequently, the proposal of Directive provides for responses to longstanding Japanese requests concerning the facilitation of intra-corporate transfers of skilled non-European Union nationals both to and within the European Union. This proposal for a Directive is being discussed within the Council and the European Parliament for approval.

- In November 2010, participants in the Anti-Counterfeiting Trade Agreement (ACTA) having resolved the few issues that remained outstanding after the final round of negotiations in Tokyo, finalized the text of the Agreement. ACTA aims to establish a comprehensive international framework that will assist Parties to the agreement in their efforts to effectively combat the infringement of intellectual property rights, in particular the proliferation of counterfeiting and piracy.

- Currently, the EU and Japan are working together towards a new comprehensive and more action-oriented partnership in line with the decision taken by our Leaders at the EU-Japan Summit in 2010: "*Summit leaders decided to establish a joint High-Level Group to*

identify options for the comprehensive strengthening of all aspects of Japan-EU relations and defining the framework for implementing it,..."

Work is underway in the High Level Group to make progress on the political and economic front with a comprehensive and balanced approach. On the trade side, non tariff measures in the field of goods and services, public procurement, investments are being discussed.

- In this context, it must be underlined that the seven issues identified after the EU-Japan Summit in 2009, the so-called "paragraph 34", are now settled. At the Summit, the Parties had agreed that in order to tackle trade restrictive barriers, to increase market access opportunities and to create the best possible environment to promote bilateral direct investment flows, they should bring concrete outcomes to specific issues of their choice, in a mutually beneficial way. Four were of interest to the EU on the Japanese market (safety technology in the automotive sector, medical devices, wooden products and public procurements) and three of interest to Japan on the EU market (movement of people/intra corporate transferee, credit rating agencies and auditing). The objective was to test the ability and willingness of the two sides to work together and draw lessons for future and possibly more extensive EU-Japan cooperation in these fields.

- A public consultation on the "Future of EU Japan trade and economic relations" has been carried out and the results were made available in February. While the vast majority of respondents favour strengthened trade ties, this is subject to the major qualification that we should make progress on existing trade barriers. The period 2010/2011 has been qualified as "a year of renewal" reflecting the new political, institutional and economic context on both sides. It also reflected the challenging goal to set new foundations for the EU-Japan relationship after the "EU-Japan Action Plan") elapsed in 2011.

Ahead of us

At the EU-Japan Summit meeting which has to take place during Spring 2011, our leaders will decide on any appropriate next steps based on the outcome of the joint work carried out by the EU and Japan and the options for the further strengthening of EU-Japan political and economic relations identified by the joint High-Level Group.

Whatever the form the EU-Japan partnership will take in the years to come, the recommendations of the BRT will remain very useful to help us identifying the priorities of the business community on both sides and to look a step further.

The "Europe2020" strategy, the "New growth strategy" and the "21st Century Opening of Japan" advocated by PM Kan are promising policies towards a renewed economic and sustainable growth for the EU and Japan respectively and reciprocally.

"Trade, Investment and Regulatory Cooperation"

Working Party A

Recommendations to the EU and Japan

A-EJ-1 Strengthening the EU-Japan Economic relationship

The Working Party recommends that both authorities start negotiations on a balanced and mutually beneficial bilateral agreement, as soon as the EU and Japanese Authorities agree that the right conditions are met, in order to promote an ambitious expansion of trade and investment between the EU and Japan.

The European Commission attaches the greatest importance to the need to address barriers hindering trade and investment and remains committed to the objective of strengthening its bilateral relationship including in the trade area with Japan.

At the April 2010 EU-Japan Summit, the EU and Japan decided to establish a Joint High Level Group (HLG) to identify options for the comprehensive strengthening of all aspects of Japan- EU relations. The HLG was tasked to conduct a joint examination of all the trade issues of interest to both sides including tariffs, non tariff measures, services, intellectual property rights and government procurement. The HLG met on several occasions in 2010 and is planning to hold additional meetings in spring 2011.

Currently all options are being examined and discussed, including the one of negotiating a deep and comprehensive free trade agreement with Japan. The removal of non tariff barriers together with the improvement of access to the Japanese public procurement are of utmost importance for the Commission and are currently under review by the HLG.

The HLG will report back to the next Summit on possible ways to enhance the EU-Japan partnership. It is however still too early to say what will be the outcome of the HLG's work for the Spring Summit as the parties have not yet completed the examination of the economic impact of the different options.

A-EJ-2 Support of WTO Doha Development Agenda for fight against protectionism

The authorities of the EU and Japan should jointly seek to ensure that protectionist pressures remain in check, and advocate strict respect of WTO disciplines such as the TRIPs. The two authorities should step up efforts in concluding ambitious negotiations of the WTO Doha Development Agenda (DDA) by the end of the year. They should in particular press emerging countries including Brazil, India and China to commit to more ambitious reductions on industrial tariffs through participation in specific sectoral agreements. Further ambition should also be secured in trade and environment, services and trade facilitation.

Since these recommendations were issued, the EU has continued to make every effort to conclude the Doha Round. Following a strong political message from the G20 Summit in Seoul in November 2010, the negotiations in Geneva have intensified on all topics, and the

Round is in a phase of a serious re-launch. Recent high-level meetings have made it clear that the political positioning phase is over and that further substantive negotiations can resume.

Ministerial contacts in the margins of the World Economic Forum in Davos in the end of January 2011 reinforced the political momentum in the negotiations. An informal gathering hosted by Commissioner De Gucht for the Trade Ministers of the G7 (EU, US, China, India, Brazil, Australia and Japan) saw positive signals of openness by the main players, including China and the US. Agreement was reached to fully empower Senior Officials to make tangible negotiating progress within a matter of weeks, and narrow down issues for political engagement to only a handful. All participants confirmed the goals that they were working towards: a breakthrough and a package before the summer break, on the basis of revised negotiating texts by Easter. An intensive negotiating process will follow in Geneva at the technical and senior levels.

The EU considers that the vast bulk of the Doha modalities are duly addressed in the package currently on the table (i.e. the Chairs' texts circulated in December 2008). However, it also considers that in order to complete the package, it is necessary to pursue ambition also in Services and sectoral arrangements for industrial goods, which are "unfinished business" from 2008. Similarly, robust outcomes are needed in "rules" type negotiations, including non-tariff barriers, trade facilitation and Geographical Indications.

In this regard, while the EU shares the Working Party opinion that additional efforts should be asked from emerging economies, this should not amount to a total reopening of the negotiating package. The objective should rather be to secure additional ambition by effectively addressing the "unfinished business" from 2008. The EU continues making the strong case to its trading partners that concluding Doha would give both a significant boost to the world economy and reinforce the role of the WTO as insurance policy against trade protectionism.

The EU therefore remains firmly committed to achieving an ambitious, balanced and comprehensive outcome to the Doha Round as swiftly as possible on the basis of the progress already made. Cooperation with the government of Japan has been good, including as regards the informal Ministerial gathering hosted by Commissioner De Gucht in Davos in the end of January 2011.

A-EJ-3 Applying international standards and enhanced cooperation in the promotion of new global standards

1. *The Working Party urges both authorities to adopt international product standards and certification procedures where applicable and to*

promote harmonisation of standards and certification procedures or the acceptance of functionally equivalent regulations.

As underlined in its recent Communication on the future of trade policy, the EU is committed to promote international standardization work and achieve convergence of regulatory requirements through greater harmonization with international standards. This objective is pursued both at bilateral level (for instance, through regulatory cooperation with key trading partners such as Japan) and multilateral level (e.g. through the strengthening of the international standard-setting system, and the promotion of sectoral regulatory convergence initiatives, such as the UN ECE system for motor vehicle regulation, or the IECEE CB scheme for electrical and electronic products. With regard in particular to conformity assessment / certification requirements, the EU places great emphasis on a risk-based approach (e.g. use of supplier's declaration of conformity for low-risk products), with a view to providing flexibility to economic operators, while at the same time ensuring consumer safety. These issues are also currently discussed with Japan in the context of the High Level Group, as part of a wider exercise to tackle non tariff barriers identified by both sides.

2. *The Working Party recognises the importance of global patent harmonisation and 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 EU Member States. The main role of the European Commission is to work in order to coordinate position among EU Member States and to facilitate progress within the Group B+ (all Members of WIPO Group B, Members of the EU, the European Commission, Member States of the EPO and the EPO).

Despite WIPO's efforts to unblock the rule-making process, discussions on international substantive patent law harmonisation are not progressing. The members of WIPO Standing Committee on the Law of Patents (SCP) have tried to negotiate on a selection of issues related to patent systems for the preparation of studies that would facilitate future discussions. The future work of the SCP is not clearly defined.

In Group B+, progress has been equally slow. There has been little progress through informal consultations on the international substantive patent law harmonisation both in Europe and the USA. The last Group B+ Plenary, in September 2010, agreed to postpone the next meeting of Group B+ Working Group 1 on harmonization "until after 2010". Group B+ Working Group 1 is expected to establish a work plan for the SCP.

3. *We also believe that the two authorities should step up efforts against global counterfeiting and piracy and cooperate closely to establish a new common international legal framework for IPR enforcement. In this regard, we support the ongoing negotiation of an international anti-counterfeiting trade agreement (ACTA) and urge the two authorities to*

exercise active leadership in order to reach agreement as soon as possible.

The Anti-Counterfeiting Trade Agreement (ACTA) negotiations were launched in June 2008, based on a concept introduced by Japan in the preparation of the 2006 G8 Summit. The European Commission was actively committed in the negotiations. On 15 November 2010, participants in the negotiations¹ announced that they finalized the text of the Agreement, after the final round of negotiations in October in Tokyo.

The Parties published the finalized text of the Agreement. Following legal verification of the drafting, the proposed Agreement will be submitted to the respective capitals to undertake relevant domestic processes. For the EU this means the adoption by the Commission, the signature by the Council, the submission for consent of the EP and finally the ratification by EU member states.

ACTA is a positive agreement that will improve the international standards of IPR enforcement while including clauses to safeguard interests of other stakeholders (consumers, internet providers, developing countries). It includes state-of-the-art provisions on the enforcement of intellectual property rights, including provisions on civil measures, criminal measures, customs measures, internet enforcement measures, robust cooperation mechanisms among ACTA Parties to assist in their enforcement efforts, and establishment of best practices for effective IPR enforcement. Parties will enforce the rights as they are defined domestically.

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

This issue was already in the recommendations last year and the Commission agreed to discuss it in the Working Group on competitiveness aspects of environment policy, which is part of the Directorate General "Enterprise and Industry" - METI Industrial Policy Dialogue. The Japanese side was not too keen to go too far on this.

It was noticed that comparability was difficult because, for product policy, the Japanese Frontrunner scheme and related labelling apply at company level, while the EU Eco-design scheme applies to product categories. However, we agreed to exchange information on the new products each side intended to cover and relevant performance criteria. We also intend to pursue cooperation through the new "4E" IEA² programme to promote wider use of efficient electrical equipment.

5. *The authorities of the EU and Japan should introduce regulatory cooperation within the customs area through which, once an economic*

¹ Australia, Canada, the EU and its Member States, Japan, Korea, Mexico, Morocco, New Zealand, Singapore, Switzerland and the United States of America.

² IEA: International Energy Agency. "4E": Co-operating Programme on Efficient Electrical End-Use Equipment

operator is approved as an AEO (Authorised Economic Operator) in Japan, its status should be recognized without additional formalities in the EU, and vice versa.

The European Union and Japan signed mutual recognition of Authorised Economic Operator Programmes on 24 June 2010. As of 16 February 2011, Japanese AEOs can benefit from facilitative measures in the EU.

A-EJ-4 Supporting timely development of business

1. Social security contribution

Japan and the Member States of the EU should make further efforts to expand the network of Social Security Agreements. In addition, they should introduce interim measures, by which workers should be either exempted from contributing to pension funds or should get a refund in full when returning home.

The problem of double-contributions can only be addressed by concluding bilateral social security agreements with all Member States.

It is the exclusive competence of Member States to conclude social security agreements with third countries. In this context, the Commission appreciates the fact that a growing number of bilateral social security agreements between Japan and some EU Member States have been concluded, or are being negotiated at present.

Social security agreements between Japan and a number of Member States have already been concluded (Germany, UK, Belgium, France, Netherlands, Czech Republic) or are in preparation (Spain, Italy, Ireland). Furthermore, negotiation is underway between Japan

2. Smoother and swifter movement of intra-corporate transferees(ICT)

The Japanese and EU authorities should realise far-reaching liberalisation of the movement of intra-corporate transferees.

The Japanese and the EU authorities should automatically grant spouses the same or similar rights as the holder of the entry permit upon their arrival.

Note that if the ICT concerns the moves from one Member State of the EU to another Member State, the Japanese citizens concerned are covered by the provisions of the Regulation 859/2003 extending the Regulations 1408/71 and 574/72 to third country nationals (which will soon be replaced by the new Regulation, extending application of the modernised regulations 883/2004 and 987/2009 to third country nationals), which implies that those persons do not lose the continuity of social security protection (the principles of coordination of social security applies to them).

Foreign employees are obliged to pay into the Japanese pension system but in many cases will not receive benefits or a full refund at the time of their departure from Japan. In the absence of bilateral social security agreements, benefits for departing foreign workers are calculated according to the length of their stay. It is to be expected that still considerable time will be needed at the current pace of progress before the problem of dual pension

membership and wasted premium payments will be solved for all EU citizens. In this context, the Commission calls for rapid progress and reiterates its suggestion that departing expatriates not yet covered by a bilateral agreement should receive a full refund of all mandatory pension contributions paid to date, or at least the period and the amount for the refund should be extended from 3 to 5 years. The Commission would like to point out that some additional unilateral measures on pension schemes would help to offer more flexibility to personnel management.

Prospect for implementation

At the occasion of the EU-Japan Regulatory Reform Dialogue, the Commission, together with the EU, has repeatedly stressed again the importance of concluding bilateral social security agreements with all EU Member States as soon as possible.

Given the competencies in this area, the conclusion of social security treaties between Member States and Japan has to be discussed on a bilateral basis. The Commission welcomes the efforts on exchange of information to launch negotiations with other EU countries and notes that Japan gives it a high priority.

3. *Personal data protection regime*

The WP believes that the ultimate objective of personal data protection for individual business is to adopt and implement a reliable and cost-effective personal data protection system at a level of 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 it by creating different requirements.

Currently, the European Commission works on the reform of the data protection legislation. This covers also improving mechanisms for international data transfers and streamlining cross border data flows.

The Commission intended to carry out in 2011 an analysis of the Japanese data protection legislation in order to have a complete picture of the situation in Japan and possibly launch an adequacy finding procedure.

However, at the moment, system of Japanese data protection legislation is undergoing a review. One of the contemplated goals is to establish an independent supervisory authority. The fact that the application of the legal data protection standards is guaranteed by administrative and judicial remedies and by independent supervisory authority, which is endowed with powers of investigation and intervention, and which acts completely independently is one of the important elements of the EU data protection legislation.

Taking into account the review of the Japanese legislation in progress, it might be premature to launch the in-depth study in 2011.

A-EJ-5 Integrated approach for CO2 reduction

In order to reduce CO2 emissions by vehicles it is important to adopt an integrated approach and to involve appropriately all relevant stakeholders

The main element implementing the Commission comprehensive strategy to reduce carbon dioxide emissions from new cars and vans sold in the European Union is the regulation (EC) 443/2009³ setting emission performance standards for new passenger cars.

The Regulation establishes CO2 emissions performance requirements for new passenger cars in order to ensure the proper functioning of the internal market and to achieve the overall objective of the European community of 120 g CO2/km as average emissions for the new car fleet. The Regulation sets the average CO2 emissions for new passenger cars at 130g CO2/km, by means of improvement in vehicle motor technology and its implementing measures and innovative technologies. The Regulation is complemented by additional measures corresponding to a reduction of 10g CO2/km as part of the Community's integrated approach. They include efficiency requirements for air-conditioning systems, fitting of accurate tyre pressure monitoring systems, tyre rolling resistance limits for new passenger cars, gear shift indicators, reaching 175 g CO2/km from light commercial vehicle (currently in co-decision), increased use of biofuels, consumer information, taxation and eco-driving measures .

From 2020 onwards, the regulation sets targets of 95 g CO2/km as average emissions for the new car fleet. The modalities of reaching this target are to be defined by 2013.

A-EJ-6 Better regulation⁴

In reviewing existing regulations or establishing new ones, it is extremely important that the authorities consider the relevant regulations from the perspective of competitiveness of the economy and industry.

In October 2010, the European Commission has set out plans to further improve the quality and relevance of EU legislation. It will evaluate the impact of legislation during the whole policy cycle: when a policy is designed, when it is in place, and when it is revised. The Commission will work with the European Parliament, Council and Member States to encourage them to apply "smart regulation" in their work. Finally, to strengthen the voice of citizens and other stakeholders, the Commission has decided to increase the period of its public consultations from 2012 onwards.

The financial and economic crisis has shown that regulation has a necessary role to play. It must be well designed to reach its intended objectives and to deliver sustainable prosperity and consumer protection without strangling economic operators, in particular SMEs. The new proposals are essential to deliver the ambitious objectives for smart, sustainable and

³ Regulation (EC) 443/2009 of the European Parliament and of the Council of 23 April 2009 setting emission performance standards for new passenger cars, OJ L 140, 5.6.2009

⁴ http://ec.europa.eu/governance/better_regulation/index_en.htm

inclusive growth set out by the Europe 2020 Strategy. A key part of getting legislation right is listening to the people who will be affected by it. For that reason the voice of citizens and other stakeholders will be further strengthened as the Commission will increase its public consultation period from 8 to 12 weeks."

The Communication on Smart Regulation in the EU sets out action in three areas to achieve regulation which is of the highest quality possible, in full respect of the principles of subsidiarity and proportionality:

First, the Commission will target the whole policy cycle by attaching more importance to the evaluation of existing legislation and policies. The resulting evidence will be put at the heart of the design of new or revised regulation, alongside with impact assessments. Impact assessments will continue to be carried out for all major legislative initiatives to provide evidence and transparency on all the benefits and costs of the policy choices available for political decision-making. The Commission will also include its existing actions to simplify legislation and reduce administrative burdens within its systematic review of existing legislation to ensure maximum impact of these activities.

Second, as smart regulation is a shared responsibility of all those involved in EU policy-making (the European Parliament, the Council, the Member States and other stakeholders), the Commission will continue to work with all these actors to ensure that the agenda is actively pursued by all. It will also strengthen its work on the implementation side of policies by making legislation clearer and more accessible, and will work with Member States, for strict enforcement of it. The Commission calls on Parliament and Council to make further progress on their commitment to do impact assessments on substantive amendments of its proposals.

Third, the voice of citizens and stakeholders will be further strengthened by prolonging the consultation period from 8 to 12 weeks from 2012 onwards, by carrying out a review of the Commission's consultation policy in 2011 and by increasing predictability on the Commission's planned proposals and ex-post evaluation work to allow stakeholders to prepare their engagement at a much earlier stage.

The Commission will report on progress on the smart regulation agenda in the second half of 2012.

Recommendations from Japanese members to the EU

A-E-1 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 is to be applicable from 1 July 2010. The Council should adopt it without a delay, and the statute should realize the following points.

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

The proposal on the Statute for a European Private Company (“the SPE”) was adopted by the European Commission on 25 June 2008.

This new company form would enable small and medium-sized enterprises (SMEs) to do business throughout the EU, with the aim of cutting costs and encouraging growth in this area. The SPE aims at offering SMEs a very flexible yet transparent company form.

As previously stated in the Commission progress report, the SPE has been designed to address the current onerous obligations on SMEs operating across borders, which need to set up subsidiaries in different company forms in every Member State in which they want to do business. In practical terms, the SPE would mean that SMEs can set up their company in the same form, no matter if they do business in their own Member State or in another. Opting for the SPE will save entrepreneurs time and money on legal advice, management and administration.

The proposed SPE Regulation has to be adopted by a unanimous decision of the Member States in the Council of Ministers of the European Union. The European Parliament is also required to approve the proposal. The European Parliament adopted its report on the proposal in March 2009.

Technical discussions have been completed during the Swedish Presidency (second semester 2009) however Member States could not reach a unanimous political agreement on the file in the Competitiveness Council on 4 December 2009. The Spanish and Belgian Presidencies have been looking into ways to unblock the file.

A-E-2 Japanese expatriates

The Commission announced that it would present in 2009 a proposal for a Directive setting out common procedures to regulate the entry into temporary stay and residence in the EU of intra-corporate transferees (ICTs). Such a draft Directive should include: the possibility of residence permit for self-employment; provisions for intra-EU mobility; possibilities for spouses to be automatically granted the same rights.

We would like to know the state of play as regards the transposition by member states of the Directive 2003/109/EC.

The Directive is not applicable in the UK, Ireland and Denmark. This is in the UK that Japanese nationals are the highest, the UK government should take action to enable them to benefit from the Directive.

On 13 July 2010, the Commission presented a proposal for a directive on conditions of entry and residence of third country nationals in the framework on an intra-corporate transferee. This scheme aims at simplifying and accelerating procedures and provides for a common definition of intra-corporate transfers.

By definition, intra-corporate transferees hold an employment contract with a company located in a third-country. Self-employed are therefore not covered by this scheme.

Intra-EU mobility is a key element of the proposal. For a maximum period of 3 years for managers and 1 year for graduate trainees, the proposal provides that ICTs are allowed to

work in several establishments belonging to the same group of undertakings and located in different Member States.

The proposal includes provisions aiming to facilitate and speed up family reunification. In addition, Member States may decide to apply more favourable rules to ICTs' spouses. Consequently, the EU scheme envisaged is expected to contribute to facilitate the allocation of Japanese companies' key personnel within the EU.

The proposal is currently being discussed within the Council and the European Parliament for approval.

Directive 2003/109/EC

The first report on the implementation of the Directive 2003/109/EC on long-term residence status is to be presented to the European Parliament and the Council in 2011.

A-E-3 Community Patent and Patent Prosecution Highway

- 1. We would like to urge the EU and its Member States to adopt and implement a Community Patent as soon as possible.*

The European Commission has placed the creation of a truly competitive and attractive EU patent very high on its agenda (EU 2020 Strategy and Single Market Act).

A breakthrough in the EU's endeavour to reform the patent system in Europe was achieved at the Competitiveness Council in December 2009 where the Ministers adopted Conclusions on an enhanced patent system in Europe. The patent reform package should comprise a Regulation creating the EU patent and a mixed agreement creating a specialised European and EU Patents Court (EEUPC) as well as a Regulation on the translation arrangements for the EU patent.

The Conclusions include a general approach on the proposed EU Patent Regulation. They cover the level and distribution of renewal fees and how the European Patent Office can work together in enhanced partnerships with national patent offices to allow synergies to be created to bring about more rapid delivery of patents and increase speed of access to market for innovative products and services. The European Patent Office would be responsible for the granting of EU patents.

As far as the creation of a specialised European and EU Patents Court (EEUPC) is concerned, the Council Conclusions cover major elements such as the composition of the panels of the new court, its jurisdiction and transitional provisions. The EEUPC will include local, regional and central divisions under a common appeal court. It will have jurisdiction to deal with infringement and invalidity actions relating to both European patents and to EU patent. In the initial stages, parties will be able to continue using national courts, allowing confidence in the new system to build up gradually. The central division will deal with invalidity actions, and the local and regional divisions will hear

infringement cases with flexibilities to handle cases involving both revocation and infringement.

For the time being, work on the EEUPC is being paused pending the Opinion of the Court of justice of the EU, which has been requested by the Council to assess the compatibility of the draft Agreement on the EEUPC with the EC Treaty. The Opinion of the Court of Justice is expected early 2011.

However, the creation of the EU patent will also depend on a solution to be found for the translation arrangements. The Conclusions do not reach a decision on the translation arrangements, but instead refer to a separate Regulation to be adopted by unanimity. In this context, the European Commission proposed on 30 June 2010 a Council Regulation on the translation arrangements for the EU patent (COM (2010) 350 final) on the basis of Article 118(2) TFEU.

The Belgian Presidency has launched negotiations on a proposal for a regulation on translation arrangements for the EU patent with much determination and has convened three Competitiveness Council meetings to discuss the proposal. However, so far, it has not been possible to achieve unanimous agreement among the 27 EU Member States.

2. *The Patent Prosecution Highway (PPH) aims to facilitate, and enhance the quality of patent examination at a participating IP office, by utilizing and sharing the result of examination at another participating IP office. We would like to urge patent offices of other EU Member States to participate in the PPH as well as the EPO which had started a trial of the PPH from January 2010, for the benefit of patent applicants both in the EU and in Japan.*

The European Commission is concerned about the situation of the patent offices worldwide and their performance. The European Commission thus welcomes initiatives aiming at improving the efficiency and speed of the patent granting process, such as the Patent Prosecution Highway (PPH). However, the PPH and other utilisation schemes would be considerably more efficient if there were more "global" substantive patent law harmonization and the same "claims' patterns" for the patent applications worldwide.

The European Commission notes that Austrian, Danish, Finnish, German, Hungarian, Spanish and UK national patent offices have joined the PPH pilot project. In addition, the European Patent Office (EPO) and the Japan Patent Office (JPO) launched a bilateral Patent Prosecution Highway pilot programme in January 2010. The EPO and the JPO will evaluate the results of this programme to determine whether and how it should be fully implemented after the trial period.

The European Commission continues to believe that efforts should be invested in rectifying the deficiencies inherent in the PCT framework. The European Commission would mainly support proposals that will not undermine the current PCT system or will not hamper its future development as a work-sharing tool.

A-E-4 Fight against counterfeited, pirated and contraband goods

We 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. And we would 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.

The European Commission aims to ensure a highly efficient, proportionate and predictable system of enforcement of intellectual property rights, both within and outside the internal market. The European Commission remains committed to fighting counterfeiting and piracy by employing a balance between education and enforcement.

The European Commission will adopt early 2011 an Action Plan which will set out the main areas for future action in the field of IPR enforcement: (1) the future of the European Observatory on Counterfeiting and Piracy, (2) improving cooperation between national authorities, and (3) promoting and strengthening the current stakeholder dialogues on the sale of counterfeit goods and on-line copyright infringement. The objective of the Plan is to tie together all of our forthcoming initiatives in this area.

Alongside the Action Plan, a report on the implementation of the IPR Enforcement Directive (Directive 2004/48/EC) will be published. The report will assess the effectiveness of the Directive and the way it has been implemented in the Member States. The report will also show that albeit the Directive has provided a solid basis for the enforcement of IPR in the internal market, some of the major provisions within the Directive have lacked clarity and have led to diverging interpretations by Member States and their courts. Moreover, the analysis shows that the Directive is not fit to deal with more recent issues such as illegal up- and downloading of copyright protected content on the internet and the sale of counterfeit goods over the internet and therefore needs to be strengthened in this respect. A deeper analysis is envisaged, which might lead to proposals for amendments to this Directive.

A-E-5 Competitiveness of the EU economy

1. Europe 2020

We welcome Europe 2020 - a strategy for smart, sustainable and inclusive growth.

- *The EU should reinforce its efforts to remove the remaining obstacles and realize a fully functioning single market.*
- *As developed economies such as the EU and Japan share common values and challenges in this regard, they should be natural key strategic partners.*
- *Global harmonisation of regulatory environment as well as growth in international trade and investment should be regarded as a key contributor to the realization of the objectives of Europe 2020.*

In March 2010, the European Commission launched the Europe 2020 Strategy to prepare the EU economy for the next decade. The Commission identified three key drivers for growth, to be implemented through concrete actions at EU and national levels: smart growth (fostering knowledge, innovation, education and digital society), sustainable growth (making our production more resource efficient while boosting our competitiveness) and inclusive growth (raising participation in the labour market, the acquisition of skills and the fight against poverty). In addition, a wide range of actions at international level will be necessary to underpin these concrete actions. The single market, financial levers and external policy tools, will be fully mobilised to tackle bottlenecks and deliver the Europe 2020 goals.

In line with EU 2020, the European Commission adopted in October 2010 the "Single Market Act". The Commission put forward 50 proposals for public discussion. The Commission hopes that the re-launch of the single market will become the subject of a wide-ranging public debate for four months throughout Europe. After this discussion, the Commission will invite the other institutions to give their formal agreement to the final version of the Act.

Among the proposals, the Commission considers further developing regulatory cooperation with its main trading partners, both bilaterally, in the form of regulatory dialogues, and multilaterally, for example within the G20. The twofold objective is to promote regulatory convergence, and to push for wider adoption of international standards.

By drawing up and effectively implementing common rules, the single market must serve as a relay for structural growth. It must remain open to the world without naivety and encourage cooperation with our trading partners, in particular to ensure greater convergence of the rules and standards in force on the different world markets in order to produce mutual benefits.

"An Integrated Industrial Policy for the Globalisation Era" was adopted by the Commission on 28 October. Industry and especially SMEs have been hit hard by the economic crisis and all sectors are facing the challenges of globalisation and adjusting their production processes and products to a low-carbon economy. This initiative presents a fresh approach to industrial policy. It recognises that industry plays an essential role in facing societal challenges (e.g. climate change, ageing of population) and that its competitiveness and sustainability should be put at centre stage. It is a genuinely integrated policy as it covers the full range of EU policies, both those directly related to the competitiveness of industrial sectors (such as standardisation and innovation policies) and those which significantly impact on competitiveness (e.g. infrastructure, energy, environment, skills or trade policies). All EU policies will need to work in the same direction. The new industrial policy will entail regular reporting on competitiveness and performance policies in the EU Member States and will favour exchanges of best practices.

Key actions include:

- Improving the business environment, by implementing a smart regulation approach (competitiveness-proofing of new Commission proposals, fitness checks of existing legislation) or by improving access to finance for companies, especially SMEs

- Strengthening the Single Market, by creating a genuinely barrier-free market for business services, by improving infrastructure, by reforming our standardisation process
- Implementing an Industrial innovation strategy, by facilitating the timely deployment and commercialisation of promising technologies, notably key enabling technologies or by promoting the internationalisation of clusters and networks
- Promoting sustainability, by assisting industry's transition to a low-carbon, resource and energy-efficient economy, this will notably be the case for energy-intensive industries.
- Facilitating industrial change, by reviewing the framework for restructuring, which shall remain mainly a responsibility for the social partners, by better using our regional development funds
- On the external front, the Commission is notably committed to further develop international regulatory co-operation initiatives with a view to develop globally compatible rules and standards. In that respect, our trade agreements should also promote the use by our partners of international rules and standards, as well as of trade-friendly conformity assessment procedures.

On 9 November 2010 the European Commission also adopted its new strategy for trade, growth and jobs, as called for in Europe 2020. With the "Trade, Growth and World Affairs" communication, the Commission demonstrates the triple benefit of trade for Europe: stronger economic growth, more jobs and increased consumer choice at lower prices. Furthermore, it sets out how the Commission plans to use trade policy to create the right environment for a strong EU economy and thereby be an engine for economic growth and job creation.

The strategy sets out the priorities and objectives for EU trade and investment policy areas for the coming 5 years, as well as presents a list of actions for 2011. It proposes a strategy to reduce trade barriers, to open global markets, also in public procurement markets, and to get a fair deal for European businesses. The Commission proposes to complete its ambitious multilateral and bilateral negotiating agenda and making significant progress with our strategic partners such as the US, China, Russia and Japan, where the main focus will be on tackling non-tariff barriers to trade.

2. Revision of high customs tariffs on audio-visual products and passenger cars

The actual level of tariff protection for industrial products in the EU is among the lowest in the world. Because of historical reasons, a limited number of industrial tariff lines, including the ones mentioned in the recommendation, conserve - as an exception - some peak duties. However, it is a constant tradition of EU trade policy to advocate for further liberalisation of world exchanges. That is why a large part of the EU trade policy energy is spent on delivering balanced free trade agreements and to work towards the conclusion of the Doha Round. After finalisation of the latter, the level of protection in the products

pointed by the recommendation will be removed to a large extent. In particular, passenger cars should be subject to a much reduced 4,4% duty.

3. Customs classification

We believe that customs classification should be done in accordance with the Harmonised System Convention rules. However, we also believe it to be a fact that the rules do not provide a clear method of classification for such products as electric-electronic 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 business. It is requested that the EU acknowledges the concerns and difficulties the businesses are facing, and to take steps to increase predictability and improve transparency upon importation of the IT products.

As Japanese business correctly points out customs classification is done in accordance with the internationally agreed rules of the Harmonised System Nomenclature as set by the Harmonised System Convention. Both the EU and Japan are members of the HS Convention and bound by its rules. The EU shares Japanese business view that the rapid technical convergence of IT and non-IT products renders customs classification using the existing rules more complex. The EU would encourage Japanese business to share their concerns with Japanese authorities and support any initiative/proposal of Japanese authorities to improve the rules of the Harmonised System Nomenclature.

4. Taxation

4.1 Common Consolidated Corporate Tax Base

The European Commission should present a proposal for a common consolidated corporate tax base (CCCTB) to the Council and Parliament this year. It should include the following points to improve the competitiveness of the EU economy.

- *Non-taxation of unrealized gains on goodwill within a group of companies that form CCCTB*
- *Non-application of arms-length principle within a group of companies that form CCCTB*
- *Off-setting of profits and losses within a group of companies that form CCCTB*

The Commission services are preparing a proposal for a CCCTB which should encompass the three bullet points mentioned above. The content and the timing of this work are described in the road map for the CCCTB⁵. However, it is also obvious that any provisions of the CCCTB allowing such advantageous treatment of transferred unrealised capital gains within the group, the abolition of transfer pricing requirements or cross-border loss off-set have to be matched with a set of rules preventing unintended or undue erosion of the European corporate tax base by aggressive tax planning measures.

⁵ http://ec.europa.eu/governance/impact/planned_ia/roadmaps_2011_en.htm#taxation

4.2 Merger Directive

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

In the current work programme of the Directorate General Taxation and Customs Union there are no proposals for formal amendments of the Merger Directive. On the one hand the efforts to tackle cross-border tax obstacles in the direct tax area are focused on the CCCTB initiative and on the other hand in the current stage of the financial market crisis it appears not adequate to propose measures to the Member States which would reduce national tax revenues. In addition Member States would probably refuse to open a discussion on real estate transfer taxes. The issue of shareholding requirements is different and the opening of a discussion on reducing shareholding requirements might be justified and welcomed. However, this aspect alone does not justify the significant input on human and financial resources a formal amendment of the Merger Director would involve.

4.3 EU TPD

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 EU TPD acting in good faith and in a timely manner. On the contrary, companies that try to evade taxation should not be treated the same way.

In a Resolution of the Council (27June 2006 reference 2006/C176/01) that agrees 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, i.e. a distinction is made, based on whether or not there has been 'good faith'.

5. Competition Policy

"There are guidelines in the determination of the amount of penalties in case of an infringement of the competition rules. We would like to see more clarity in the

determination of the amount of penalties so that businesses will not be unduly deterred and that the "Lisbon Strategy" will be achieved."

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.

6. Reach

After entry into force of REACH, many of those tasks, including the provision of information on REACH to companies and the general public have been transferred to the European Chemical Agency (ECHA). We recommend that the EU Government takes further actions for education and capacity building in developing countries for compliance with REACH.

From the beginning, all efforts have been made to ensure the prompt availability of the necessary guidance documents. It must be recognised that this has been quite a task. In addition to the REACH Guidance Documents, the European Chemicals Agency (ECHA) is producing a series of shortened versions with a view to making the corresponding Guidance Documents published by the Agency more accessible for industry.

In this context, it is important to note that REACH is unique in EU (and possibly also in third country) legislation, in having available detailed guidance to meet the requirements. Of course, guidance can not answer every single question regarding the registration of every substance, but the current guidance covers all the relevant areas for industry to meet their registration requirements.

Since the WTO TBT meeting in March (23-25 March 2010) a number of guidance documents have been released by ECHA including guidance for Annex V and updated guidance on Occupational Exposure Estimation, Environmental Exposure Estimation and Exposure Scenario Format. ECHA has also announced that up to November 30, 2010 it will not issue any new guidance, to enable companies to prepare for their registration based on the current guidance.

Concerning the preparation of IT tools for CSA/CSR (Chemical Safety Assessment /Reporting), they were released on the 17 May 2010.

7. Consumer protection

The recommendations of the Japanese members mention three points in relation to the proposal for a Consumer Rights Directive, which is currently pending before the Council and the European Parliament, namely:

a) The legal guarantee should be limited to 2 years: This corresponds to the guarantee period in the Commission's proposal. However, several Member States apply currently longer guarantee periods in their national laws. The issue of harmonising the legal guarantee to 2 years is therefore controversial both in Council and Parliament. The final outcome may therefore be to maintain minimum harmonisation on this point, i.e. to allow Member States to retain their longer guarantee periods.

b) The decision whether to repair or replace a faulty product should be taken by the trader and not the consumer: The Commission's proposal provided indeed that it was for the trader to decide whether to repair or replace the faulty product. The text currently discussed in Council gives the consumer the right to choose between the two remedies. However the trader has the possibility to prove that the remedy chosen by the consumer is impossible or would cause him a disproportionate effort. The changes discussed in Council are likely to be taken over also by the Parliament.

c) The consumer should carry the burden of proof of defects that become apparent to the consumer within a period of 6 months from the date of purchase: According to the Commission's proposal, defects which appear within 6 months are presumed to have existed from the beginning. For the remaining 18 months it is for the consumer to prove that the defect was there at the time of purchase. The current Council text extends the period for the presumption to 12 months. It is not clear what the final outcome will be on this point.

8. Environment, social and governance (ESG) information disclosure

We fully support the direction taken by the European Commission on CSR, including recent efforts to improve transparency by facilitating stakeholder dialogue on Environment, Social and Governance (ESG) disclosure.

We however express concern over the potential obligation imposed on companies of different size, business sector and organisational structure to quantify and report in accordance with only one set of quantitative key performance indicators. The drivers behind value creation are company specific and can be hardly expressed in on-size-fits-all parameters.

We therefore recommend that the European Commission should:

- *create a non prescriptive approach to ESG disclosure;*

- *create an EU-wide approach in the global context; and*
- *train and educate information users, particularly investors and analysts, on how to read the ESG information.*

An initiative aiming at strengthening existing rules on company reporting about non-financial performance, such as social and environmental matters (CSR) could be part of the so called Social Business Initiative.

Current EU legislation already addresses the issue of disclosure of non-financial information. The Fourth Company Law Directive on annual accounts was amended in 2003 to require companies since 1 January 2005 to include information relating to environmental and employee matters in their annual report to the extent necessary for an understanding of the company's development, performance or position.

The EU 2020 Agenda on sustainable growth and jobs promotes corporate social responsibility (CSR) “as a key element in ensuring long-term employee and consumer trust.” This could encourage companies' management to better link sustainability issues to the company's strategy. It would also make it possible for investors to develop better company valuation models which would provide for more reliable assessment for longer-term performance. A greater transparency and awareness on sustainability matters would encourage all stakeholders to perform better in this area. However, disclosure of more non-financial information may unduly increase the administrative burden of companies, adding to the length of annual reports which are already considered by many to be too long.

It is important to achieve better transparency and comparability without unduly increasing the administrative burden for companies. The current EU programme is in favour of better regulation that aims at cutting red tape rather than adding to administrative burdens.

Thus, the European Commission is organising a public consultation in order to gather stakeholders' views on ways to improve the disclosure of non-financial information by enterprises. The consultation will start in October 2010 and will last for 2 months.

**"Life sciences and Biotechnologies,
Healthcare and well-being"**

Working Party B

Recommendations to the EU and Japan

B-EJ-1 Cooperation towards the COP10 for CBD in Oct 2010

Towards the COP10 for “Convention on Biological Diversity (CBD)” to be held in Nagoya in October 2010, EU and Japan should work together so that the international regime on CBD, especially on “Access and Benefit Sharing (ABS), can accelerate R&D and innovation to soundly develop the bio-industries, which will produce a useful products that bring social benefits, as well as secure access to those products.

The Nagoya Protocol on Access and Benefit Sharing

The adoption of the Nagoya Protocol on Access to Genetic Resources and the Fair and Equitable Sharing of Benefits Arising from their utilisation to the Convention on Biological Diversity ends a long journey that began in 2002 at the World Summit on Sustainable Development in Johannesburg.

The adopted Nagoya Protocol establishes a clear and transparent framework on how researchers and companies will in the future obtain access to genetic material for research and development. It also sets out clear obligations for states to provide that users of genetic material under their jurisdiction respect the domestic regulatory frameworks of those states where genetic material has been acquired. It will provide legal certainty and transparency about rules that apply for accessing genetic resources as well as ensure fair sharing of benefits coming from these resources.

The Nagoya Protocol does not mention patent offices as potential "checkpoints" for monitoring uses of genetic resources. It therefore does not prejudge ongoing negotiations in the World Trade Organization or the World Intellectual Property Organization on a patent disclosure requirement. Existing references to pathogens do not interfere with ongoing negotiations in the World Health Organization on benefit-sharing for access to pathogens with pandemic potential.

Access and benefit-sharing for genetic resources is a new issue for EU policy and law. As such it resonates well with efforts of greening the economy and using market-based mechanisms for financing environmental protection efforts, particularly in developing countries. EU ratification of the Nagoya Protocol will likely require the development of new Union policies or laws.

Next steps

On ABS, the Commission now needs to turn its sights towards implementation of the Protocol. A full impact assessment and a public consultation exercise are foreseen in the Commission's Work Programme for 2011. Eventual implementing measures could be proposed by the second quarter of 2012.

B-EJ-2 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.

The EU is keen to develop multiple partnerships in the field of biodiversity protection between the public sector and the private sectors as well as among the private sector. In addition, the collaboration between the private sector and civil society in this areas will also be of paramount importance. For that reason the European Commission has launched Platform on Business and Biodiversity (http://ec.europa.eu/environment/biodiversity/business/index_en.html) . The EU Business and Biodiversity Platform (B@B) is a unique facility where businesses can come together to share their experiences and best practices, learn from their peers, and voice their needs and concerns to the European Commission. The Platform aims to strengthen the link between the business sector and biodiversity conservation. It is the first initiative of this magnitude worldwide. The objective is to facilitate a business and biodiversity initiative, help businesses find solutions to adjust their activities, ensure a fair income and sustainable growth, while providing benefits for biodiversity and ecosystems; It also aims at giving visibility to business through the implementation of an award scheme, acknowledging the good practice of the best performing businesses.

In parallel some Member States, such as Denmark, are also establishing such national platforms on Business and Biodiversity. The Commission is convinced that without the full and committed engagement of business and private sector in the protection of biodiversity and ecosystem services, the EU 2020 biodiversity target will not be met.

Healthcare

B-EJ-3 Regulatory harmonization and MRA for pharmaceuticals

Proceed regulatory harmonization and further extension of “Mutual Recognition Agreement” in order to avoid redundant inspections of manufacturing facilities (delay of new drug launches)

Followings are highly prioritized items for harmonization and expansion of MRA.

- Safety measures from surveillance to vigilance should be harmonized with international standards*
- Clinical development guideline and biological preparation standards for Vaccine*
- Minimum Requirements for Biological Products*
- MRA of GMP should expand to non-solid preparations to avoid redundant inspections and testing*

The EU has a long tradition of regulatory collaboration with Japan, in particular in the context of the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) launched in 1990. The bilateral

dialogue has been intensified based on confidentiality arrangements in the area of human medicines agreed in 2007.

The Community has concluded a mutual recognition agreement (MRA) with Japan which included an Annex on Good Manufacturing Practice (GMP). The EC and Japan have exchanged diplomatic notes on 28 April 2004 confirming the completion of the preparatory work under the sectoral annex on GMP. This explicitly outlined the scope of products covered with a possibility for expansion in the future:

- chemical pharmaceuticals are covered by the GMP annex;
- homeopathic medicinal products are covered by the GMP annex as long as they are treated as drugs and subject to GMP requirements in Japan;
- vitamins, minerals and herbal medicines are covered by the GMP annex if they are considered as medicinal products in the both parties;
- medicinal gases, in-vitro diagnostics, blood, plasma and any unstable medicinal products derived from human blood or plasma are not covered as they are not treated as medicinal products or not subject to GMP requirements in the parties;
- biological pharmaceuticals, including immunological and stable medicinal products derived from human blood or plasma, and sterile medicinal products are currently not covered by the GMP annex as the equivalence of their GMP requirements has not been reconfirmed, but may be covered in the future;
- medicinal products for clinical trials and active pharmaceutical ingredients are currently not covered by the GMP annex, but may be covered in the future;

Operation of the MRA is not optimal at the moment considering that Japanese inspections in Europe have risen considerably in 2009. Moreover, Japan only recognises the fifteen States Members of the EU, prior to the enlargement of 2004; therefore not including the twelve newer Member States. The Commission will work to make the MRA with Japan fully operational within the current scope. Main issue to be tackled is the lack of recognition of new Member States. After having fixed the current issues, the Commission will re-examine the scope of the MRA as regards sterile and veterinary products (see B-EJ-7).

International harmonisation of technical requirements for medicinal products for human health is pursued through ICH which brings together the EU and Japanese regulators as well as the EU and Japanese industries.

B-EJ-4 Balance between prevention and treatment in healthcare

Seek balance between prevention and treatment. Thus, include vaccination/ programs in scope for public funding

Disease prevention and diagnostic/ screening procedures are getting a more important position in healthcare area as they allow to improve the treatment of numerous diseases but also to effectively lower the healthcare cost in mid- and long-term. Therefore, vaccine should be in scope for public funding.

Pursuant to Article 168 (on public health) of the Treaty on the functioning of the European Union, the organisation and delivery of health care is under the responsibility of the Member States. However, certain initiatives have been taken at EU level to coordinate Member State policy in this area.

As regards vaccination policy, the Council has adopted a recommendation on seasonal flu vaccination on 22 December 2009. The purpose of this recommendation is to reach the target of 75% vaccination coverage of the older age groups recommended by the WHO as early as possible and preferably by the 2014-2015 winter season. This target of 75% should, if possible, be extended to the risk group of people with chronic conditions, taking into account the guidance issued by the European Centre for Disease Prevention and Control (ECDC)⁶.¹

During the H1N1 pandemic in 2009, the Commission also published a staff working paper on vaccination strategies against H1N1⁷.

The Council adopted conclusions on 13 September 2010 on lessons learnt from the pandemic H1N1, and in these conclusions calls on the Commission to report on and develop, as soon as possible and no later than December 2010, a mechanism for joint procurement of vaccines and antiviral medication which allows Member States, on a voluntary basis, common acquisition of these products or common approaches to contract negotiations with the industry, clearly addressing issues such as liability, availability and price of medicinal products as well as confidentiality⁸.

This report is being prepared by the Commission at present, in cooperation with Member States through the EU Health Security Committee.

Plant Protection & Biotechnology

B-EJ-5 Measures against counterfeit products

Formulate concrete actions against counterfeit products

Counterfeit products do not only represent significant dangers to the consumers but also harm innovative companies. With EU and Japan together representing over 600 Mio consumers, both governments have to be world leaders in the fight against counterfeits in order to protect their population as well as their industries.

Regarding pharmaceuticals, the European Parliament has approved, on 16 February 2011, a proposal for a Directive to combat 'falsified medicines', subject to amendments. The Directive aims to prevent falsified medicines from reaching the patients by introducing harmonised, pan-European safety and control measures. These measures will ensure easier identification of falsified medicines, and improved verifications and controls at EU borders and within the EU.

New measures include:

⁶ <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:32009H1019:EN:NOT>

⁷ http://ec.europa.eu/health/archive/ph_threats/com/influenza/docs/flu_staff5_en.pdf

⁸ http://www.consilium.europa.eu/uedocs/cms_data/docs/pressdata/en/Isa/116478.pdf

- An obligatory authenticity feature on the outer packaging of the medicines : this feature will be decided at a later stage via a delegated act;
- Strengthened requirements for control and inspections of plants manufacturing active pharmaceutical ingredients;
- Strengthened record-keeping requirements for wholesale distributors;
- Strengthened rules on inspections;
- The obligation for manufacturers and distributors to report any suspicion of falsified medicines.

Animal Health

B-EJ-6 Regulatory harmonization for animal health products

Further harmonization and streamlining of regulatory requirements for product registration of animal health products.

While such global new veterinary medicinal products go through rigorous review process in Europe and the USA prior to registration, it requires additional testing in Japan under the Pharmaceutical Affairs Law before an approval is granted. Regulatory requirements for an innovative veterinary medicinal product based on biotechnology are especially stringent in Japan, and therefore, a product which is readily available to veterinarians and animal owners in Europe cannot be used in Japan. Increased harmonization of regulatory requirements would certainly improve access of animals and animal owners to innovative animal health products. Moreover, since the regulatory requirements are not harmonized, the companies are required to repeat tests on animals in Japan, even though results of identical tests are already available and are fully compliant with stringent frameworks like GLP or VICH.

It must be stressed that we do not have "regulatory" harmonisation processes. However, the International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal products (VICH), a trilateral (EU-Japan-USA) programme, is aiming at harmonising technical requirements for veterinary product registration. The VICH was officially launched in April 1996.

B-EJ-7 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.

While the studies conducted under Good Laboratory Practice or Good Clinical Practice are usually accepted by the Japanese government for inclusion in the dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Moreover, any overseas production facilities that are involved in manufacture of veterinary medicinal products imported into Japan have to be accredited

by MAFF even though their GMP status is authorized by European authorities. This process involves a large amount of administrative works.

An EU – Japan Economic Integration Agreement should aim for Mutual recognition of European and Japanese marketing authorization for veterinary products by starting off with mutual recognition of GMP certification of veterinary medicines. Harmonized regulations on animal vaccines should also be addressed under such an agreement.

The Commission will work to make the MRA on GMP with Japan fully operational and look into the scope of the MRA for veterinary medicinal products (see B-EJ-3).

Industrial Biotechnology

B-EJ-8 Strengthening activities for industrial biotechnology

To enhance the global competitiveness of the bio-based economy through increase cooperation between the EU and Japan, we suggest a number of actions that would strengthen activities in the area of industrial biotechnology:

Develop and implement EU-Japan common R&D programmes and strategies to encourage use of agro-food by-products and wastes

Support collaborative development of technologies to produce biomass based products and sustainable biofuels

Benchmark the EU and Japanese policy strategies and legislation/regulations in order to stimulate the market introduction of bio-based products from innovative technologies.

Set up a common task force to analyse which global incentives can stimulate or support the re-conversion towards a bio-based economy

The Commission attaches great importance to developing the concept of a bio-economy. Its activities have concentrated on the key areas of standardisation, labelling and communication (particularly with regard to public procurement). Encouraging Member States and private investors to set up demonstration plants for bio-refineries has been another key activity in fostering the bio-economy. The Commission is currently looking into intensifying the visibility it attaches to the topic by envisaging a Communication on the bio-economy. Apart from other initiatives this strategy paper will also highlight the international dimension and the need for intensified international cooperation in this field.

Recommendations only to the EU

Plant Protection & Biotechnology

B-E-1 Shortening review times for products by Plant Protection & Biotechnology

Shorten review times for new applications/ registrations

Research and development of innovative and beneficial Plant Protection & Biotechnology products requires high input costs. Therefore, timely access to the markets

is crucial for the R&D-intensive companies Establishment and maintenance of science-based, predictable and timely regulatory systems free from undue political influence and the appropriate protection of proprietary data are therefore key requirements for sustainable and innovative research.

The EU regulatory system with regard to the applications for the authorisation of GMOs is science-based, making the distinction between risk management and risk assessment and provides for specific timelines for the assessment and the decision-making procedures. More particularly, the submission of the authorisation is the starting point of the authorisation procedure and the European Food Safety Authority (EFSA) in its quality as risk assessor, as well as the competent national authorities, have specific deadlines for each step of the assessment procedure. Furthermore, once the Commission receives the opinion of EFSA on the safety of a specific application, it should submit within specific timelines a proposal on the decision to be taken as regards this application to the Member State representatives.

Additionally, the regulatory framework for the authorisation of GMOs also provides for a 10-year period of data protection from the date of authorisation. Regulation (EC) No 1829/2003 on genetically modified food and feed regulates data protection and confidentiality by similarly worded provisions. The scientific data of an application can not be used for the benefit of another applicant for 10 years following the authorisation. Notably, genetic modifications are also patented under national laws and normally last for 20 years. In case patent-protected data is used after the 10-year data protection period, the conflict would be taken at national level for breach of patent law."

Animal Health

B-E-2 Introduction of “1-1-1 concept” for all animal health products

Introduction of 1-1-1 concept for all products (one dossier – one assessment – one decision on marketing authorization)

This goal has yet to be achieved for the animal health industry, with the exception of centrally authorized products. In line with the concepts already existing in the EU the animal health industry in Europe is seeking a systemic change based on the one, one, one concept (“1-1-1 Concept”) for all products.

In the context of the review of the legal framework for veterinary medicinal products several options to simplify authorisation procedures will be assessed.

B-E-3 Responsible use of antibiotics in animal health

Promote responsible use of antibiotics in animal health

As a responsible industry, the animal health industry seeks to work with veterinarians, farmers and the feed industry to dispel the myths about the use of antibiotics in animals and promote their responsible use.

The initiative of the animal health industry to promote the responsible use of antibiotics in the animal health domain is very much welcomed.

"Information and Communication technologies"

Working Party C

Recommendations Supported by European and Japanese Members

New Path for Growth by Adoption of ICT

C-EJ-1 Sustainable Growth towards Low Carbon Society

At the COP15 Conference, the EU leaders also offered to increase the EU's emissions reduction to 30%, on condition that other major emitting countries in the developed and developing worlds commit to do their fair share under a global climate agreement.

To achieve these goals, authorities should prioritize the role ICT can play in achieving a low-carbon society.

The European Commission asks the ICT industry to even exceed the overall 2020 reduction targets by 2015. In response, the ICT sector has announced the creation of an ICT for Energy Efficiency (ICT4EE) Forum. It is supported by four key industry associations of the sector (Digital Europe, GeSI, JBCE and TechAmerica). Green IT Promotion in Japan also has signed a MOU with ICT4EE.

When it comes to this kind of initiative, Japanese and European authorities should play the role of a facilitator, e.g. regarding the dialogue between the ICT sector and other sectors. GHG emission reductions by ICT in other areas are known around the world, so we recommend that the EU and Japan act as aggressive regions on environmental activities to conduct a campaign for enlightenment.

In order to expedite the introduction of solutions, we continue to request the governments of both the EU and Japan to support the development of common metrics and processes for the measurement of GHG reduction by ICT, such as the ongoing efforts in ITU which visualize reduction effects in terms of the environmental burden, thus improving persuasiveness in the market.

The Green IT Promotion Council is creating the new index "Datacenter Performance per Energy (DPPE)" covering overall productivity, including IT equipment. We propose to use this index for environment-related institutional settings.

ICT-enabled infrastructure such as smart grids has a huge potential for the reduction of greenhouse gases. To accelerate investment in this area, authorities could start a dialogue with industry with regard to the harmonization of meter features, data protocol, data privacy, and data security.

The Commission has addressed the potential role of ICT for the development of a low carbon society in its Communication of March 2009 (Mobilising ICT to facilitate the transition to an energy-efficient low carbon economy").

The Digital Agenda for Europe adopted by the Commission in May 2010 wants to ensure that the ICT sector leads the way on sustainable growth, a low carbon society, and reduced energy consumption. Digital technologies have enormous potential to tackle social challenges such as this. To this end, several of the 100 or so concrete action points for the Commission and Member States in the Digital Agenda focus in this area, including the following:

- Assess by 2011 whether the ICT sector has complied with the timeline to adopt common measurement methodologies for the sector's own energy performance and greenhouse gas (GHG) emissions and propose legal measures if appropriate.
- Support partnerships between the ICT sector and major emitting sectors (e.g. buildings and construction, transport and logistics, energy distribution) to improve the energy efficiency and greenhouse gas emissions of these sectors by 2013.
- Assess by 2011 the potential contribution of smart grids to the decarbonisation of energy supply in Europe and define a set of minimum functionalities to promote the interoperability of Smart Grids at European level by the end of 2010.
- Publish (Commission) in 2011 a Green Paper on Solid State Lighting (SSL) to explore the barriers (for the wide deployment of SSL technology) and to put forward policy suggestions; it will in parallel support demonstration projects using the CIP.
- Member States to agree by the end of 2011 common additional functionalities for smart meters.
- Member States should: by 2012 include specifications for total lifetime costs (rather than initial purchase costs) for all public procurement of lighting installations.

The Commission is also supporting R&D to promote further innovation both in ICTs themselves as well as in their application aiming to bring about efficiency gains.

In this context the European Commission and the Ministry of Economy, Trade and Industry of Japan are in the process of agreeing to establish a close research cooperation on Intelligent Transport Systems, including in research on the methodology to assess the impact of ITS for environmental energy issues.

C-EJ-2 *Knowledge-Based Growth*

Both the EU and Japan are establishing a long-term growth strategy plan for growth not only as a short-term response to recover from the economic crisis. The ICT industry should play a strategic role in economic growth, job creation, and innovation. ICT is functioning as social infrastructure of all industries and strategic use of ICT is effective in the economic policy for each industry. Thus, ICT strategy should be consistent with growth strategy.

The Commission agrees with the importance of knowledge based growth, and the concept of "smart growth" is an important part of the EU's 2020 strategy approved by the European Council in June 2010.

The EU aims to boost smart growth in particular through three flagship initiatives: firstly implementation of the Digital Agenda for Europe (notably to ensure better access to higher speed broadband); secondly the Innovation Union (this aims to refocus R&D and innovation policy on major societal challenges and strengthen all the links in the innovation chain, from "blue sky" research to commercialisation); and thirdly the initiative Youth on the Move, which focuses on education and training for young people.

Since cloud computing may play an important role in smart growth, and since it does not recognise borders, the Commission is also interested in a number of international aspects, including the importance of robust, predictable and transparent regulatory frameworks in third countries in order to handle cloud computing.

New Regulatory/Institutional Framework that paves the New Path for Growth

C-EJ-3 *Taxation System that Supports the New Path for Growth* (Applying reduced VAT rate to eBooks)

In the EU, the long-standing application of a reduced VAT rate on culturally worthy products has helped to spread fine culture widely and rapidly at lower prices, and has highly contributed to the development of rich culture and improvement of the quality of life.

The latest innovation provided us with the new option of reading books by electronic means, i.e. eBook, rather than on paper. In light of the lower price, availability of contents, search performance, and resource saving, this new method provides even better access to fine culture than the original method. Consumers, however, are obliged to bear a higher cost to enjoy the benefits of the latest technology due to the fact that the eBooks are subject to the standard VAT rate in the EU. Respecting the spirit of a reduced VAT rate for “culture” and in order to end the unnecessary discrimination against eBooks compared with paper books, we urge that eBooks be taxed at the reduced VAT rate in the EU, and at most at the same rate as paper books.

This issue will be tackled among other issues in the framework of the future revision of the current VAT system. As a first step in this revision, the Commission intends to table a Green Paper towards the end of this year. The aim of this Green Paper is to launch a broad debate involving as wide a number of stakeholders as possible on an evaluation of the current VAT System and how best to create a simpler, more robust and efficient VAT system within the single market. This Green Paper and subsequent public consultation will form an important element of a forthcoming new VAT strategy.

This industry will have the opportunity to express its view and send us the appropriate studies to show that a reduction of VAT would also reduce the final price and not increase the publishers' benefits, within the framework of the above mentioned consultation.

(Greenhouse Gas Emissions of Data Centers)

Regulations have been introduced in the UK and Tokyo to make it obligatory to reduce the total amount of CO₂ at each facility in an effort to reduce greenhouse gas emissions. We request governments to recognize the contribution of data centers to a low carbon society. These must be taken into account when considering additional requirements for operators of data centers, which would hamper their competitiveness in relation to general offices.

See reply under C-EJ-1

C-EJ-4 *Data Protection, Utilization, and Security in the Cloud Computing Era*

The significance of cloud services is not only the efficient use of IT infrastructure, but the crossing of business and industry borders. The social system as a whole can promote the integration and sharing of vast amounts of information and knowledge. Consequently, an "information society" with the participation of all individuals and companies can be realized.

Along with the expanded use of ICT, accelerated information storage are enabling new value-added services through cloud computing. In the near future, new services with cloud computing that handles enormous data process such as real-time stream data can be deployed as a new infrastructure for our businesses.

The connected society and cloud computing are crucial elements in that process.

On the technology side, high dependability must be ensured to deploy cloud computing as an infrastructure for businesses of the EU and Japan. Government support is expected for the promotion of R&D and standardization of the basic technologies that underpin operational continuity, security, data storage, and the process of stream data. A technology for anonymizing the large amount of data can convert the data into highly value-added services, and is critical in promoting the use of cloud computing.

Last but not least, governments should foster a secure feeling in the market about cloud computing by deploying it for their e-Governments and presenting successful cases.

The governments of both Japan and the EU should stimulate the introduction of mechanisms where the cloud and its services can request and get a different quality of service from the underlying network (NGN).

Cloud computing is a high priority in the EU's Digital Agenda for Europe and the need to develop an EU-wide strategy on cloud computing is therefore highlighted in various action points of the digital Agenda.

Relevant policy areas of the Digital agenda include:

- Data protection
- Governance, Privacy and security, including consumer concerns
- Standardisation and interoperability
- Green IT
- Communication infrastructure (broadband)
- International cooperation, including the development of an EU-wide strategy on cloud computing

It can be seen, then, that there are a number of questions that need to be answered to make cloud computing happen in practice, and happen more smoothly and quickly. These concern legal, technical and commercial issues, where there is a strong public interest, given that almost all organisations today use databases or networks, which may be "in the cloud".

The Commission is aware of the need to ensure that European achievements, such as effective data protection and the EU's Single Market, do not clash unnecessarily with cloud computing.

For instance, as regards data protection, the European Commission works on the reform of the data protection legislation. The objective is to update and modernise a well-tested legal framework and to encourage trust in the internet as a medium and in emerging technologies such as cloud. This should include deploying the Privacy by Design principle, but also require the operators to be more transparent, providing its users with comprehensive information on how the service works and how the information a user provides is handled.

The Commission therefore aims to work on an EU-wide cloud computing strategy, including three broad areas covering the legal framework, technical and commercial fundamentals, and market aspects of cloud deployment.

The deliverable of the strategy will be a document combining analysis and a plan of future actions by 2012, based on intense consultation, both in the EU and with third countries such as Japan.

C-EJ-5 *The Right Regulatory Environment for Investment in NGN*

High-speed broadband networks are the decisive input factor for achieving all other ICT-related policy objectives since they provide the basic underlying infrastructure needed to make nearly all other services and applications of the future information society a reality. High-performance fixed and mobile telecommunications infrastructures have thus become a decisive factor for the global competitiveness of modern knowledge-based economies. Hence, social development as well as future growth and jobs will largely depend on the ability to provide for an innovation- and investment-friendly regulatory framework. When regulating, authorities should take into account the investment risks companies are willing or not willing to take and come up with differentiated regulatory responses targeted to the amount of investment risks companies are willing to take. On top of that, regulation should provide for the necessary legal certainty for investors.

Due to different subscriber density and demand in different regions and over time, different technologies and topologies are best suited for different scenarios. Therefore the principle of technology neutrality in any regulation is crucial. It is also important to let different technologies evolve on their own merits and not to stifle innovation and hamper investment by making regulation prescriptive on technologies.

Superfast broadband is at the heart of the Digital Agenda. Dramatically increasing access to such networks will take a mix of players and mix of technologies and requires industry to play a full role.

The Commission's NGA (Next Generation Access) Recommendation⁹ sets out key principles of how to promote the roll-out of superfast broadband, focusing on protecting

⁹ Com (2010) 6323 and COM (2010) 472

the competitive process, while accepting that it is also necessary to incentivise fibre investment.

C-EJ-6 *ITA & Trade Security (ITA)*

The expansion of the Information Technology Agreement (ITA) is crucial for Japan's and Europe's future, not only as a factor of development of a major industrial sector in its own right, but also as a driver of productivity, innovation, job creation, improved competitiveness, and service quality in virtually all other industrial sectors and public services. Japan and the EU should drive not only maintenance of the current ITA but should jointly strive for a review of the ITA as soon as possible.

The EC proposal for review of the ITA presented in WTO in 2008 and described in the last progress report includes a call for expansion not only of the product coverage but also of the geographical coverage and removal of non-tariff barriers and prohibition of new non-tariff barriers.

The EU has on several occasions and latest in end of 2010 before the ITA Committee again expressed its willingness to commence negotiations on an update of the ITA and invite Japan along with other ITA members to respond positively to the proposal of negotiations.

The WTO panel on certain disputed ITC products have issued the final report which should be seen as an important signal that negotiations could start. The EU as one of the original signatories attaches great importance to the ITA and will continue to stress the importance of a much needed update of the agreement.

Striking a Balance between Security and Facilitation of Trade

Amid a global trend of stricter security measures, the multinational companies which build the international supply chain have been taking action to pursue supply chain security by striking a balance between security and the facilitation of trade. However, neither Authorized Economic Operator (AEO) programs nor the advance cargo manifest declaration rules developed around the world based on the WCO SAFE Framework on Standards are necessary the same, and excessive tightening of regulations such as Importer Security Filing and Additional Carrier Requirements (U.S. "10+2" Program) is enforced. The multinational companies of the EU and Japan share concerns about further burdens on businesses and unwanted hindrances to smooth trade as a result of such regulations.

In such an environment, we repeat that the EU and Japan must lead the international harmonization of trade institutions to strike a balance between security and the facilitation of trade, and to realize efficient public-private operation.

More specifically, governments are expected to:

Implement the mutual recognition of AEO programs between the EU and Japan as soon as possible, and exempt from the application of the EU advance cargo manifest declaration rules, just like the case admitted by the mutual recognition of AEO between the EU and Switzerland;

The European Union and Japan signed mutual recognition of Authorised Economic Operator Programmes on 24 June 2010. As of 16 February 2011, Japanese AEOs can benefit from facilitative measures in the EU.

The EU rules on advance cargo information follow the WCO SAFE Framework of Standards. This shows the EU's commitment both to trade facilitation and to international standardisation i.e. to the reduction of diverging practices.

The case of Switzerland, Norway and Andorra (being either geographically in middle of the EU, or having a special relation with the EU) and thus integrated in the EU security zone and applying the same supply chain security legislation as the EU, is unique.

C-EJ-7 Fundamental Review of the Copyright Levy System and the Compensation System for Audio and Video Private Copying

In order to promote further lawful use of digital content, it is necessary to implement dialogue/cooperation between the EU and Japan concerning a fundamental review of the compensation system for private copying. Currently compensation is paid by means of copyright levies, a system which dates back to the analogue era (at least in Europe). Copyright levies are a way of compensating for revenue loss caused by private copying, but they are not intended to fight piracy.

Furthermore, the rules of the current levy system vary enormously across Europe. There is no European benchmark for determining what products are subject to levies, or what amount is to be charged.

In reviewing the systems, we should take into consideration in a comprehensive manner the methods available, to secure compensation for private copying for right holders and creators. The goal should be to enable the establishment of a system which is transparent, fair, and equitable to such interested parties as consumers, right holders, service providers, and equipment providers.

This increased transparency and legal certainty can be achieved only through the application of objective European criteria by a political and legislative intervention at the European level. The European Commission and member states must therefore ensure that private copy compensation remains firmly on the agenda as a priority in the wider copyright debate on the European digital economy agenda.

EU Member States enjoy a large discretion on how to provide right-holders with a fair compensation for acts of private copying, in line with the 2001 Directive on Copyright in the information society. In view of the variety of national practices, the Commission has been working with all relevant stakeholders to consider a more coherent approach.

An EU stakeholder platform on private copying levies has met regularly since July 2008 to discuss trade-related aspects of private copying levies. The aim of the platform is to reach a comprehensive stakeholders' agreement on both trade aspects and tariff methodology; this agreement should thereafter be supplemented by a Commission recommendation. The role of the Commission in this stakeholder-driven process is limited to that of a facilitator of discussions.

In December 2008, an interim agreement was reached on cross-border trade, refund schemes and electronic commerce in goods subject to levies, with a view to bringing

major reductions in trade barriers currently caused by the territorial application of levies. However, this interim agreement was conditional on the outcome of the result of the issue of rate-setting and methodology for selecting products subject to levies.

The ICT Industry made clear that more predictability as to rates and products chosen for levies is essential to ensure planning security when launching new products. Following intense debates in 2009, the ICT Industry deemed that no sufficient progress was made on rate-setting and methodology and decided in early January 2010 to abandon the stakeholder platform.

The issues raised by levies are practical matters that require practical responses. The stakeholders themselves are therefore well-placed to identify and develop mutually acceptable solutions in this area. In light of this it is in the interests of both parties to resume the dialogue.

Japan and the EU pursue their dialogue on intellectual property rights; the most recent dialogue took place in Tokyo on 18 March 2010. Copyright in Internet age and cooperation on the fight against piracy were on the agenda.

Recommendation Supported only by Japanese Members

C-E-1 International Transfer of Personal Data in the Cloud Computing Era

The international harmonization of regulations and international data transfer regime between EU and Japan should be streamlined so as to develop a better environment for businesses to mutually provide highly value-added services. The objective should be to build and implement a reliable and cost-effective regime for businesses in the EU and Japan. In this regard, the European Commission should consider granting the adequacy status to Japan on condition that data importers in Japan have obtained the Japanese Privacy Mark.

The European Commission welcomes initiatives enhancing protection of personal data such as a voluntary system of Privacy Marks in Japan.

In its 2010 November Communication on a comprehensive approach on personal data protection in the EU (COM (2010) 609 final), the European Commission encouraged self-regulatory initiatives and announced to explore the feasibility of establishing EU certification schemes in the field of data protection and privacy.

A Privacy Mark may be taken into account when considering the adequacy of the level of protection afforded by a third country, as it contributes to ensure that a processing activity is performed under particular conditions which may provide safeguards for the rights of individuals. However, a privacy mark in itself is not sufficient and has to be considered in the light of different elements surrounding a privacy mark.

**"Financial services
Accounting and Tax Issues"**

Working Party D

Recommendations to the EU and Japan

Financial Services

D-EJ-1 Progress in the financial market reform since the financial crisis

In response to the global financial crisis, the G20 countries have agreed to the common principles for financial market reform, which are: (1) strengthening transparency and accountability, (2) enhancing sound regulation, (3) promoting integrity in financial markets, (4) reinforcing international cooperation, and (5) reforming international financial institutions. The G20 countries are now taking actions for their implementation.

Specifically, under the G20 framework the Basel Committee of Banking Supervision (BCBS) has made proposals regarding bank's capital requirements, leverage regulation and liquidity regulation in order to enhance the soundness of the bank's management. And the Financial Stability Board (FSB) has presented the international principles for the compensation practices in the financial institution. Now it seems that a new regulatory order based on the untraditional way of thinking is about to be built, including such measures as imposing additional regulations on the "systemically important financial firms," which are large and complex financial institutions.

We agree in general that these financial reforms will stabilize the financial system and enhance the transparency and accountability of financial institutions, financial markets, and financial products, while ensuring their fairness and integrity. The stabilization of the financial market and financial system is important for market users including the companies that raise capital.

The EU has taken a leading position in shaping the international response to the crisis and establishing the basis for recovery and renewed growth. In Seoul in November 2010, the G20 leaders pledged to continue coordinated efforts and to act together to generate strong, sustainable and balanced growth. The Seoul Summit deliverables include the Seoul Action Plan as well as core elements of a new financial regulatory framework, including bank capital and liquidity standards, and measures to better regulate and effectively resolve systemically important financial institutions, complemented by more effective oversight and supervision.

The European Commission is committed to endorse all the agreements reached at the G20/FSB level and ensure their timely and consistent implementation. This includes inter alia the new Basel III rules on capital and liquidity, the FSB policy recommendations on Systemically Important Financial Institutions and compensation standards.

The European Commission will propose, in the first quarter of 2011, the necessary legislative texts to transpose the principles of Basel III into European law. This legislation will take the form of a revision of the directive on capital requirements (CRD IV).

The European Commission has set out its orientations for a crisis management framework in October 2010. The proposed framework covers early intervention, recovery and resolution, including the financing of resolution, and will include measures to ensure adequate preparation by firms and authorities, and effective coordination in cross-border cases. On this issue, in the G20 context, the Commission supports exploring the idea of a binding international agreement.

The EU has transformed the FSB-principles for compensation practices into binding legal requirements through the third revision to the Capital Requirements Directive (CRD III) and will continue along these lines by introducing remuneration rules in other areas, such as insurance and investment funds.

The European Commission considers that the implementation of the reforms should be fully consistent with the objective of enhanced financial stability and should not negatively impact economic activities.

D-EJ-2 Issues to be mindful of when proceeding with reform

At the same time, we point out that there are several issues we should bear in mind as we proceed with regulatory reform. Innovation in the financial market is important and a careful balance must be struck between innovativeness and regulation.

When the regulation is discussed in the global context, the characteristics of each country and region should be fully considered. We believe that we should build harmonized regulations through multilateral discussions on a global basis.

Since the beginning of the crisis in 2008, the Commission and EU governments have taken the necessary urgent action to safeguard the stability of the financial system. A safer, sounder, more transparent and more responsible financial system, working for the economy and society as a whole and able to finance the real economy, is a precondition for sustainable growth.

Recent market turbulence has confirmed the need to advance swiftly to complete the necessary reforms at the European and global level. Regulation of financial services needs to be complemented by an ambitious reform agenda for growth, based on the internal market. The European Commission will actively contribute and push for solutions that are consistent with the Single European Market and therefore do not favour a particular group structure.

The Commission will present the vast majority of the remaining regulatory reform proposals to the Council and European Parliament by the end of the year and the last proposal will be delivered by spring 2011. According to better regulation principles, the proposals are being prepared after stakeholder consultation and impact assessments. The cumulative effects of the various measures on the financial sector as well as on the real economy must be fully taken into account. Such considerations will be fully reflected in the impact assessment and in the calibration of the various measures. In this context, the outcome of the work already underway in the Financial Stability Board and the Basel Committee on the cumulative effects of financial sector reform will be fully taken into account.

Accounting

D-EJ-3 Accounting Issues in EU and Japan

Working Party D has recommended enhancement of the governance of the accounting standard setting bodies and the convergence of accounting standards. The Financial Stability Board (FSB) is going to undertake a strategic review of the policy development work of international standard setting bodies, and the IASB has established an external Monitoring Board, members of which include the International Organization of Securities Commissions (IOSCO), the European Commission, the US Securities and Exchange Commission, and Japan's Financial Services Agency. In addition, IASB and FASB have established the Financial Crisis Advisory Group (FCAG). FCAG will advise the IASB and FASB on the standard-setting implications of the global financial crisis and on potential changes to the global regulatory environment. Since its inception, FCAG has announced the wide-ranged report on the activities of Accounting Standard Board. We support these trends and look forward to further developments. We also support the progress towards the IFRS introduction in Japan and look forward to further discussions on the convergence.

While the purpose of financial accounting is to provide financial information to a company's outside stakeholders such as shareholders and creditors, we strongly point out that the view of a company's management is also important when setting standards. Changes in accounting standards have impact on corporate activities and thus on the economy. We believe that net income with recycling arrangement is useful as accounting information. Companies set the prices for goods and services they sell based on cost. If items not recycled such as the actuarial gains and losses in the pension accounting are expanded and thus profit and loss not reflected in the net income are expanded too, we are concerned that underlying business activities such as cost management and selling price formation could be disrupted.

IASB is in the process of revising its financial instrument accounting standard and we support the approach to recognize the net unrealized gain on available-for-sale securities as other comprehensive income (OCI). However, it is also proposed that if the net unrealized gain is recognized as OCI, the dividend is recognized as net income but the realized gain is recognized as OCI, not as net income. We cannot agree with this approach.

The net realized income has been described by some as a kind of income manipulation, but we believe that the sale of the securities is one way of showing the management's decision, and thus recognizing the net realized income as net income gives more useful accounting information. In the insurance context, assets held by insurers are managed consistently with the asset liability management and the risk management of the company in order to back insurance liabilities and to meet insurers' commitments toward policy holders and not in the interest only of the shareholders (and so not for "managing earnings" over time). Furthermore, the removing of the available for sale (AFS) category is inconsistent with the business model approach on which the IFRS 9 is based: the long term business model of insurance should be recognized through the AFS.

As part of the process to strengthen the immediate recognition in the accounting standards for employee benefits, the actuarial gains and losses may be recognized immediately upon accrual as OCI. The immediate recognition of the actuarial gains or losses coming from short term financial market fluctuations could cause the pension plans, which are long term promises between employers and participants, to give

excessive fluctuation to net income. We support the approach to recognize the actuarial gains and losses as OCI and not as net income. On the other hand, we believe the actuarial gains and losses should be recycled for the above mentioned reason.

We ask IASB to discuss the revenue recognition criteria with careful consideration of the actual business practices in countries around the world. It is necessary to recognize the possibility that changing the accounting standards affect the business practices. We believe that accounting standard reform is necessary when there are concrete problems that may hinder investor's decision making, but if not, the established accounting practices should not be overruled.

With regards to the IASB's financial statement presentation project, in addition to OCI issues and the removing of the two separate statements (income statement and statement of comprehensive income) we are concerned about the requirement for the use of direct method in cash flow statement. The users of financial statements are able to acquire sufficient useful information from disclosures with indirect method. Based on the fact that companies will incur large amount of cost, we do not see any overriding benefit coming from the requirement of direct method.

The European Commission attaches great importance to the International Accounting Standards Board (IASB) governance and to the global convergence of accounting standards. More and more jurisdictions are in the process of ensuring convergence between their national Generally Accepted Accounting Principles (GAAP) and IFRS or adopting IFRS directly. Japan committed to make a decision regarding the mandatory use of IFRS in or around 2012.

The European Commission follows very closely developments on IASB governance. The implications of the global financial crisis on standard-setting led to important steps forward in the governance of the IASB. We are involved in the IASB governance working group of the Monitoring Board established in early 2009, which is chaired by Mr. Kono, Vice-Commissioner of the Japan Financial Services Agency. The task of the group is to look into issues related to IASB governance and the broader objectives of financial reporting. A report is expected beginning of 2011. As a member of this Monitoring Board, we have been involved in the search for the successor of the IASB chairman (as from July 2011 Hans Hoogervorst will replace Sir David Tweedie).

The EU Commission shares the view that many of the IFRS standards under development have a broader economic impact. The IASB thus needs to develop high quality standards that need to be understandable and practicable. In addition, we expect standard setters to consider all potential impacts of new standards and require proper impact assessments. We believe that new accounting standards should not impact well established and successful business models.

The European Commission closely follows the IASB work on revising the accounting requirements for financial instruments. The European Commission has decided not to endorse Phase 1 of IFRS 9 on the classification and measurement of financial assets via fast track procedure, because we believe together with key Member States that there are still issues that need to be improved. Recycling of gains and losses is one of them and very relevant for the financial industry, including the insurance industry. We therefore expect

that the IASB will have a second look at Phase 1 before IFRS 9 is finalised including Phases 2 (impairment) and 3 (hedging).

The short-term revision of IAS 19 Employee Benefits may bring about some other substantial changes, which are also controversial, e.g. the treatment of risk-sharing plans. The European Commission has been asked to make sure that an amended standard is accompanied by an appropriate impact assessment in order to address the potential socio-economic side-effects. Regarding the treatment of actuarial gains and losses the IASB may allow for the OCI and P&L solution. The project is currently under discussion by the Board and expected to be finalised by the end of 2010.

The European Commission is concerned about the potential impacts of the proposed changes to IAS 11 and IAS 18 in the area of revenue recognition. The business model of some industries, e.g. in the telecom and construction industry, might be fundamentally impacted in a way that does not reflect the real activity performed by the companies. We believe that the IASB should carefully consider comments received and carry out an impact assessment since we are concerned that a new standard might increase complexity too much.

The European Commission takes the view that the change of presentation of financial statements should not be introduced at the same time as some major accounting standards are under review. The use of the direct method in the context of cash flow statements is only one example for the changes discussed which are controversial. However, recent discussion at IASB and FASB suggest that the project might be delayed.

The European Commission intends to continue and intensify policy and technical dialogue with Japan in order to make sure that there is an ongoing 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.

Tax

D-EJ-4 Tax Issues in the EU and Japan

The governments of Japan and Europe should ensure that dividend payments from subsidiaries to parent companies and royalty and interest payments between related parties are, to the greatest possible extent, exempted from withholding taxes in the source country. While there have been some improvements with respect to the dividend taxation between Japan and some EU member countries, we believe that the removal of double taxation is still an important issue, and we hope that all the EU Member States and Japan will conclude tax treaties. In order to reduce the risk of economic double taxation, furthermore, it is important to ensure an arena for wide-ranging dialogues between the tax authorities. In particular, they should introduce clauses that will enable corresponding adjustments and arbitration in tax treaties. In addition, they should harmonise and simplify documentary requirements in transfer pricing taxation and promote and facilitate the conclusion of bilateral and multilateral APAs.

With the progress of convergence of Accounting Standards, new deviations arise between corporate accounting and tax practice. We ask that the Governments of Japan and Europe respond flexibly to the deviations.

When companies conduct their businesses on a global basis, transparent and fair taxation in countries are extremely important. If the taxation on some specific industry or sector is introduced, it could distort the resource allocation and damage the sound growth of companies and economies. We hope that transparent and fair tax reform and implementation are continued.

Transfer pricing reply is addressed in Working Party A (A-E-5/4.3)

Promoting and facilitating bilateral and multilateral APAs is an area of work addressed by the EU Joint Transfer Pricing Forum¹⁰. That work resulted in a Communication that included guidelines for Advanced Pricing Agreements within the EU (COM (2009) 472). 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.

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.

Recommendations only to the EU

Financial Services

D-E-1 Solvency margin regulation

The solvency margin regulation of insurance companies has been discussed on global basis and we support the Japan and EU governments' approach towards regulation, which acknowledges the dialogue between public and private sectors. When the equivalence assessment of its regulations is conducted between the EU and external parties, such process should be conducted in a constructive manner.

The political negotiations on the Solvency II Directive led to split the equivalence assessment process into two phases. The first phase relates to the general criteria for the equivalence assessment. The Committee of European Insurance and Occupational Pensions Supervisors (CEIOPS) published a draft methodology for equivalence

¹⁰ http://ec.europa.eu/taxation_customs/taxation/company_tax/transfer_pricing/forum/index_en.htm

assessments in April 2010. The second phase relates to individual third country assessments. In August 2010, CEIOPS provided the Commission, after consultations, with a final advice on which third country supervisory regimes should be included in the first wave of equivalence assessments.

In October 2010, the European Commission asked CEIOPS to assess whether the supervisory regimes of a selection of first wave third countries satisfy the general criteria for assessing third country equivalence; Japan is included in this list (in relation to re-insurance only) together with Bermuda and Switzerland. CEIOPS should examine the legislation in place, supervisory practices, implementation and application of that legislation within the third country's supervisory regime. CEIOPS final advice should include both an analysis of the extent to which the criteria are fulfilled and an assessment of whether it is possible for the Commission to adopt a positive equivalence. This work should be completed by the end of September 2011; decisions should be taken before Solvency II becomes applicable.

The European Commission and the Japan Financial Services Agency will continue their dialogue on insurance. The 3rd insurance dialogue took place in April 2010 in Tokyo. The agenda focused on regulatory developments, equivalence under Solvency II and insurance guarantee schemes in Japan and the EU.

Tax

D-E-2 Tax Issues in the EU

Many Japanese companies in the EU are implementing integration and rationalization of their European business organizations. Examples are the centralization of such functions as sales support and accounting. The relation between intra-group transactions and taxation is an important element in decision making in a business. We ask the EU and the Member States to establish a tax system that will enable companies conducting business in the EU to enjoy the benefit of the Single Market to its full extent. In particular, taxation on unrealised gains as a result of a goodwill transfer within a group should be deferred; transactions within a group should be exempted from the application of the arms-length principle; and the off-setting of profits and losses within a group should be allowed.

Currently, cross-border transactions between associated companies are commonly adjusted, according to transfer pricing rules, to comply with the arm's length principle. Further, transfers of assets between such companies are taxable, since they qualify as a sale, which commonly gives rise to a capital gain or loss, as the case may be. A gain may be treated as unrealised in the context of a transfer only if the asset is moved to another Member State within the same company (e.g. from a Head Office to a Permanent Establishment and vice versa). Finally, the possibilities of cross-border loss offsets are of a limited scope, especially in the aftermath of recent jurisprudence of the ECJ.

The introduction of a Common Consolidated Corporate Tax Base (CCCTB) would have a significant impact on all these matters. Companies would no longer be required to comply with transfer pricing obligations in intra-group transactions because those would not give rise to any profit or loss. What is more, intra-group asset transfers would be made available free of tax and cross-border loss offsets would be an automatic result of consolidation.

**"Innovation, Environment and Sustainable
Development"**

Working Party E

Recommendations to the EU and Japan**1. Global warming and water problems**

It is forecast that due to the effects of global warming and climate change, glaciers will melt, sea levels will rise, desertification will occur due to drought, and increased damage will be caused by torrential rain, floods and tidal waves resulting from changes in the amount of precipitation. The temperature rise over the last 50 years amounts to 0.13 degrees per decade, corresponding to double the rate seen over the last 100 years as a whole. Over the 20th century, sea levels rose by an average of 17cm, and it is forecast that by the middle of this century, while rivers' annual water volume and useable water volume will rise by 10-40% in high altitude zones and some humid and arid zones, it will decrease in most medium-altitude zones and some arid/semiarid tropical zones.

While this development poses a huge risk for potential conflicts and human misery, there will also be enormous business opportunities worldwide. All predictions come to the conclusion that the international water market will increase significantly over the next decades. The worldwide turnover in 2007 was estimated to amount to around €360 billion and estimates see the turnover in 2020 at around €805 billion. Nearly all countries around the world need to invest, either in modernisation of, new technologies or in gaining access to new and additional resources of freshwater.

- E-EJ-1 Recommendation for Japan and the EU to intensify cooperation on water problems as one of the most important issues relating to global warming and climate change.**
- E-EJ-2 Recommendation on supporting the establishment of mechanisms to enable sustainable use of water through forming consensus with stakeholders in watersheds, in order to ensure the conservation of water sources and safe, useable water.**
- E-EJ-3 Recommendation on further developing water purification methods to reduce the cost of water.**
- E-EJ-4 Recommendation on the need for raising the accuracy of technology and to standardize technology for observation/prediction of groundwater storage potential distribution and water quality inspection technology, and put these to use in drawing up plans for the establishment of water re-use/flood control systems.**
- E-EJ-5 Recommendation on the need for Japan and the EU to cooperate in the field of human resource development in the water sector utilizing instrument such as ODA to developing countries.**
- E-EJ-6 Recommendation on developing methods and technologies to reduce the amount of water used for irrigation and to avoid the negative consequences of irrigation like increasing the salinity of land.**
- E-EJ-7 Recommendation on developing and promoting methods and technologies to reduce the enormous losses in water distribution in many countries,**
- E-EJ-8 Recommendation on developing and promoting methods and technologies to improve the sanitation situation, which is critical in**

- many countries with respect to human dignity and negative health implications.**
- E-EJ-9 Recommendation on developing and promoting methods and technologies to provide “Point of Use” water treatment technologies for the many human settlements, which will not have access to treated and piped water within the next 30 years.**
- E-EJ-10 Recommendation on developing and promoting methods and technologies to improve the technology for water recycling to be more generally used in the cities of the future and arid countries.**

These sets of recommendations are still all valid. The importance of the water management, water saving and access to water was recognized again as a priority area of cooperation by both sides, during the last EU-Japan High Level Dialogue on Environment, held in Tokyo last 9 September 2010.

2. Fossil Energy and Raw Materials

Given the limited resources of fossil energy and raw materials in Europe and Japan, combined with the growing recourse of some fast growing countries to strategic pricing and acquisition of limited raw materials and fossil energy, the EU and Japan should foster cooperation in pursuing common strategies to keep fossil energy and raw materials markets open, undistorted and stable. This would also be in the interest of sustainable development of most developing countries and emerging economies.

- E-EJ-11 Recommendation on accelerating the introduction and spread of utilizing new and renewable sources of energy to replace fossil energy wherever feasible. Japan and the EU should lead in developing new standards and adapting international standards for energy related equipment and systems.**

Promotion of new and renewable sources of energy is one of the main policy priorities for the EU and will remain so in the years to come, as highlighted by the Commission Communication on "Energy 2020: A strategy for competitive, sustainable and secure energy." The EU continues to work toward implementation of the new Directive on renewable energy which set ambitious targets for all Member States, such that the EU will reach a 20% share of energy from renewable sources by 2020 and a 10% share of renewable energy specifically in the transport sector. Under the Directive, the EU Member States submitted national renewable energy action plans in 2010, showing how they intend to reach their targets. By setting a longer term regulatory framework, it can be expected to deliver a significantly higher rate of increase in the consumption of renewable energy and create investor confidence.

Following the adoption of the recast Directive on the energy performance of buildings (Directive 2010/31/EU) in May 2010, the European Commission has asked the European Committee on Standardisation in December 2010 to devise new standards for buildings. These new standards should replace and complement the existing standards on the basis of the old Directive on the energy performance of buildings of 2002.

Similarly, as regards eco-design and energy labelling, mandates for devising new standards for energy related products and appliances are issued as need be. The EU and Japan are discussing eco-design issues within the DG Enterprise and METI Industrial Policy Dialogue but approximation is not always easy due to legislation differences.

E-EJ-12 Recommendation on supporting the development of business concepts and ideas on how to profitably contribute to mitigation and adaptation to climate change through adequate usage of fossil energy and raw materials.

The Intelligent Energy-Europe programme is the tool of the European Union for funding actions to improve market conditions that help to save energy and encourage the use of renewable energy sources in Europe, so as to move society towards a more energy intelligent Europe. The projects are designed to help achieve the key climate change and energy targets that the EU has set for itself by 2020. Until today, well over 400 innovative projects for a more energy intelligent Europe have been supported. In 2009, the EU's budget for these projects mounted to €65 million.

We agree on the importance of new Business concepts on how to contribute profitably to mitigation and adaptation to climate change. In this respect, another new interesting initiative is the Japanese Bilateral offset project. The EU, is also examining the possibility to engage in the new Global Superior Energy Performance initiative, of which Japan is already part.

The Commission has also issued a mandate for the EU standardisation institution CEN with a view to measuring, testing and quantifying GHG emissions from sector specific sources. Standardisation organisations of 3rd countries and ISO will be associated.

E- EJ-13 Recommendation on raising awareness on access to raw materials.

EU and Japan should identify actions to be taken in international fora such as the OECD and WTO, and promote a coherent set of rules on access to raw materials in their bilateral relations as well as WTO accession negotiations. Especially both sides should work on further supporting the “EITI Principles and Criteria” and actively encourage other countries and international companies to commit themselves to the “EITI Principles”.

We are supporting the work at the level of the OECD, WTO and EITI as well as working directly on raw materials and development issues with the African Union and the ACP.

EU and Japan will continue cooperation in international fora such as OECD and WTO. A workshop was cosponsored by the EU and Japan in the OECD on 30 October 2010 in Paris. The main objective of this workshop was to increase awareness of the issue of sustainable supply of raw materials amongst both OECD and non-OECD members, through an exchange of views on economic and policy implications. The EU will keep promoting a coherent set of rules on access to raw materials in its bilateral relations, bilateral and multilateral negotiations.

In relation to the OECD, apart from trade-related issues, there have been discussions ongoing on conflict minerals since 2009. In December 2010, the OECD finalised its guidance material on due diligence in the mining sector in conflict zones.

In relation to the EITI, the Commission organised a meeting with Member States on 9 September 2010 during which the issue of transparency in payments to governments in the extractive sector, as promoted by organisations such as the EITI, was discussed. A presentation was also made on the passing of binding extractive transparency legislation in the US in July (as part of the 'Dodd-Frank' act). The EC also hosted a series of meetings of the EITI from the 8-10 November 2010 in Brussels. It was agreed that the European Commission should become a member of the EITI board.

The Communication on the Raw Materials Initiative (COM (2011) 25) contains a text outlining the EC's support to the EITI and related activities in the area of revenue transparency in the extractive sector. It also identifies initial areas of action for the promotion of good governance, investment and infrastructure as well as geological knowledge and skills within the EU-Africa co-operation on raw materials (see next point E-EJ-14 for full scope of co-operation)). Finally the Communication also refers to ongoing work to assess the feasibility of country-by country reporting for companies involved in the extractive sector. This work includes the anticipated completion of an Impact Assessment in early 2011 and a Communication by September 2011.

E-EJ-14 Recommendation on promoting a level playing field for raw materials through their respective development policies. Improvements in governance should be obtained through specific commitments on natural resources management in Governance Action Plans and strict enforcement of budget support criteria.

In June 2010 in Addis Ababa the European Commission and African Union (AU) Commission agreed to launch a bilateral co-operation on raw materials which would focus on 3 themes: (i) governance (including support of EITI), (ii) infrastructure/investment and (iii) geological knowledge and skills. On 9th September, the Commission hosted a Member State meeting on Raw Materials Initiative and development with the aim of an exchange of views on a possible EU contribution to this co-operation with the AU. Common actions to be taken with the AU were subsequently agreed at the EU-Africa summit held in Libya on 29-20 November 2010. These form part of the EU-Africa Joint Strategy for 2011-2013.

In addition, with regard to relations with the ACP, following a meeting of ACP Minerals Ministers held in Brussels held on 15th December, the ACP agreed to work closely together with the EU on raw materials and development issues.

3. Promote specific cooperation in industrial and research development

Joint programs enhancing EU-Japan research projects on next-generation technologies should be designed in cooperation between European and Japanese academia and the private sector. Developing and sharing energy efficient technologies worldwide is critically important. Whilst political will, public management, sensible regulation and

pricing of energy are most crucial, technology can often provide cost effective solutions to many environmental and developmental problems.

E-EJ-15 Recommendation on developing common standards

Recommendation on developing common standards for new environmentally friendly products and technologies as early as possible in close consultation with the industries concerned. However, such standards should not hamper the search for alternative solutions or technological advancements and thus may not be applicable in all industries.

Please see E-EJ-11 above

E-EJ-16 Recommendation on the development of common standards for electro-mobility and related infrastructure.

Such standards as well as taxation incentives would greatly facilitate the introduction and worldwide dissemination of this new technology.

Although the Commission can share the recommendation of the WP 's members, the development of common standard will require to overcome numerous hurdles.

Electro-Mobility is currently promoted by several Member States, notably France, Spain, Germany, Portugal and Denmark, although there still remains a number of issues to be addressed. Actions are required in each of the following areas:

- ensure that alternative propulsion vehicles are at least as safe as conventional ones
- foster education and training practices to ensure the transition of the workforce through new green jobs
- promote common standards that will allow all electric vehicles to be charged anywhere in the EU
- encourage installation of publicly accessible charging points
- ensure the development of smart electricity grids
- update the rules and promote research on recycling of batteries

High-level discussions among all relevant stakeholders are ongoing in Europe with a view to foster an “integrated approach” that will enable to achieve the expected results in terms of competitiveness and employability of workforce.

E-EJ-17 Recommendation on widening the cooperation mechanism for environmental technology.

Recommendation on widening the cooperation mechanism for environmental technology currently undertaken in the fields of photovoltaic, power storage, and carbon capture and storage (CCS). Promote cooperation and exchanges between Japan and EU.

The international dimension is an inherent part of all European research activities. Participation is open to international organisations and legal entities established in third countries after the minimum conditions laid down in the ‘Rules for participation’ have been met, as well as any conditions specified in the specific programmes or relevant work programmes. Within the bilateral EU-Japan cooperation on research, energy is considered

as one of the priority areas for cooperation, with photovoltaic, power storage and CCS having been identified as the topics for joint EU-Japan work.

E-EJ-18 Recommendation on promoting and intensifying exchange programs of Japanese and European students;

Especially in technical and research areas. In particular, develop student exchange programs with a mandatory internship component in European and Japanese industries such as the Vulcanus programs.

The European Commission is convinced of the crucial importance of developing a pool of talented young engineers and scientists able to work both in Japanese and European business environment. This is key to fostering the development of EU-Japan industrial and research cooperation, as well as enabling EU and Japanese companies to exploit the full potential of bilateral trade and investment opportunities. For these reasons, the European Commission and Japan's METI have established the "Vulcanus" programmes in 1996/1997, following a 1995 recommendation of the EU-Japan Industrialists' Round Table, the predecessor of the EU-Japan Business Round Table. Since then, the "Vulcanus" programmes have demonstrated their value for both EU and Japanese industries, and created a pool of highly successful young people with an impressive record in developing EU-Japan business relations. The European Commission and METI, as well as private EU and Japanese companies, have therefore been steadily increasing their financial contributions to the "Vulcanus" programmes, enabling participants numbers to reach a peak of 46 EU students and 25 Japanese students in 2009-2010. Unfortunately, budget constraints on both sides are obliging us to reduce these numbers in 2010-2011. However, current discussions between the EU and Japan on the future of the bilateral relationship put a lot of emphasis on people-to-people exchanges, in particular for EU and Japanese engineering and scientific students. The European Commission will certainly try to promote the development of such exchanges, including through the "Vulcanus" programmes, in the years to come.

4. Continuous cooperation on global warming

E-EJ-19 Promoting the efficient use of energy

Industry has been a forerunner in energy-efficiency improvements because lowering energy costs is a prerequisite for competitiveness. In addition, industries in the EU and Japan have been developing energy-saving products. To decrease greenhouse gases (GHG), it is important to diffuse higher efficient equipment and products as well as fuel-efficient vehicles by using a front runner approach. This is based on the 3Rs (reduce, reuse, recycle) which minimize energy consumption of products through their total life cycle of procurement, usage and recycling.

A range of policies and legislation at the EU and national level already foster resource efficient and eco-friendly products. Eco-design aims to improve the environmental performance of products throughout the life-cycle by systematic integration of

environmental aspects at a very early stage in the product design. Following the recast of the Ecodesign Directive, the scope of the Directive was extended from energy-using products (products which consume, measure, generate or transfer energy during use) to all energy related products (not only energy-using products, but also products which do not consume energy, but have an impact on energy consumption during use, such as windows or insulation materials).

Energy labelling is also an important driver for manufacturers to produce products and appliances that are as energy efficient as possible.

Buildings are another important target for energy efficiency measures as its energy saving potential is considerable. See also under E-EJ-11 above.

E-EJ-20 Promoting the reduction of reliance on fossil fuels

a. The spread of existing technologies

From a mid-term point of view, it is indispensable to spread existing technologies such as nuclear energy and renewable energy so that they replace fossil fuels. This is necessary not only for low carbon emissions but also for energy security. Spreading the use of nuclear energy more than at present requires the restoration of trust and the establishment of a consensus by citizens from the aspect of safety. In promoting renewable energy, such as solar, wind, and biomass energy, challenges still exist regarding cost and stability of energy supply.

The central goals for the EU energy policy include security of supply, competitiveness and sustainability and have been underpinned by ambitious goals (reduction of greenhouse gas emissions by 20%, rising to 30% if the conditions are right, increase of renewable energy to 20% and a 20% improvement in energy efficiency). These goals have been incorporated into the Europe 2020 Strategy for smart, sustainable and inclusive growth, adopted by the European Council in June 2011, and into its flagship initiative "Resources efficient Europe". Additionally, the EU has also committed to reach, in 2020, a 10% share of renewable energy in the transport sector – a sector that is highly dependent of fossil fuels. This target can be achieved by increasing the use of biofuels, hydrogen or renewable electricity in transport. It should be noted that the EU set up a mandatory sustainability scheme for the biofuels to be counted towards the Member States' 10% target and to be eligible for financial support.

The EU Member States are free to choose their energy mix, including the use of nuclear energy. To role of the EU is to develop in the interest of all Member States the most advanced legal framework for nuclear energy, meeting the highest standards of safety, security and non-proliferation. An EU-wide legal framework was enacted through the adoption of the EU Nuclear Safety Directive in 2009, and solutions for nuclear waste management, in particular geological disposal, are partly entering the phase of practical implementation. In 2010, the European Commission has proposed a Directive which sets safety standards for disposing spent fuel and radioactive waste from nuclear power plants as well as from medicine or research. With the Directive internationally agreed safety standards become legally binding and enforceable in the European Union.

b. *Development of innovative technologies*

The development of innovative technologies such as clean coal, carbon dioxide capture and storage (CCS), hydrogen energy, nuclear fusion, advanced energy storage and fuel cells require long-term efforts to reduce GHG. It is also essential to increase Governments' expenditure on research and development and to promote international public-private cooperation.

Low carbon technologies will play a crucial role to achieve EU's energy and climate policy objectives. The EU energy policy's technology pillar – the European Strategic Energy Technology Plan (SET-Plan) aims to accelerate energy technology development. To make best use of investments the EU has been developing several European Industrial Initiatives, namely wind, solar, bio energy, smart grids, nuclear fission, and CCS.

It has been estimated that to fully implement the SET-Plan to grasp the potential of technology, the investment needs to be increased from the current level of investment of € 3 billion per year to €8 billion per year. This means a net increase of €50 billion for the next ten years period, both public and private. The actions of the SET-Plan would take the form of 'public (MS) - public (EC) - private alliances' in a decentralised, open architecture, which would share objectives, planning, monitoring and reporting tools and, when appropriate, implementation instruments'.

E-EJ-21 *Diffusing environmental and energy-saving technologies in developing countries*

To advance the reduction of GHG emissions on a global scale, it is critical to initiate measures in developing countries. Deploying energy-saving technologies in such countries that are expected to increase their use of energy, such as China and India, is an especially big challenge. Together with European and Japanese businesses providing technical cooperation to these countries, the governments should establish an environment that stimulates financial cooperation and private investments. Protection for intellectual property rights is essential in this regard.

The EU over the last several years has established or enhanced cooperation dialogues with the world's major energy players, including the developing countries. Energy cooperation with EU's partners is typically comprehensive in scope, encompassing issues from regulatory cooperation and technical cooperation to promotion of sustainable policies and technology cooperation.

It is very important to deploy energy-saving technologies in developing countries, especially fast-growing economies, so as to curb their increase in energy use. In this sense, it will be indeed essential for EU and Japanese businesses to provide technical cooperation to these countries and establish an environment that stimulates financial cooperation and private investments. The EU has initiated a new capacity building program for climate change in cooperation with UNDP to this end, which contains a private sector capacity building component. It will focus on addressing barriers to diffusion of low carbon technologies, and on facilitating the dialogue between relevant institutions and industry to support mitigation actions. 5 recipient countries and four energy intensive sectors have been identified for the moment.

We think the new technology mechanism being negotiated at the UNFCCC could also be a good way to encourage technology diffusion. In this respect, the engagement of the private sector will be key. Also the Global Superior Energy Performance initiative could be promising in taking this forward.

Work is also ongoing in the context of international organizations, dealing with various aspects of energy and technology policy such as the International Energy Agency, the International Renewable Energy Agency, the International Partnership on Energy Efficiency Cooperation, as well as others. Both the EU and Japan are now involved in the elaboration of the Low Carbon Energy Technology Platform, proposed by the G8.

We agree that the protection of intellectual property rights is essential in spurring innovation and investment in third countries.

E-EJ-22 Continuation of “green policy”

Many countries have expanded fiscal expenditure on “green policy” programs and governments’ efforts towards a low-carbon society/economy are highly appreciated. In current and future “green policy”, reduction of GHG emissions from the view point of the total life-cycle basis must be promoted.

The central goals for the EU energy policy include security of supply, competitiveness and sustainability and have been underpinned by ambitious goals (reduction of greenhouse gas emissions by 20%, rising to 30% if the conditions are right, increase of renewable energy to 20% and a 20% improvement in energy efficiency). These goals have been incorporated into the Europe 2020 Strategy for smart, sustainable and inclusive growth, adopted by the European Council in June 2011, and into its flagship initiative "Resources efficient Europe". A key element of it will be taking account of the life-cycle of products and promoting a circular economy.