

Multilateral and Bilateral Trade & Investment, and Regulatory Cooperation

<Recommendations to the EU and Japan>

A-EJ-1 Formation of a common economic institutional environment (Joint recommendation)

In 2007 BRT in Berlin, the working party recommended a study on the feasibility of a wide-ranging bilateral agreement to promote trade and investment. Task forces were formed on both sides for that purpose and joint recommendations were presented at the BRT 2008 in Tokyo. This report outlined a number of areas of common interest where EU-Japan cooperation could be strengthened. The Working Party supports the joint statement adopted by the EU–Japan Summit in Prague on 8 May 2009 aiming notably for *“strengthening the integration of their economies with a view to better exploiting the full potential of their economic relationship”* and calls upon the authorities to work towards this goal by focussing on issues that are of Japanese and European interest and create a win-win situation for both sides.

Moreover, the Working Party believes that discussions should be initiated and pursued through respective administrations from the highest political level to ensure that the political will is translated into concrete and measurable improvements in the business and trade environment. Aiming for an ambitious removal of barriers to trade and investment, a broad range of issues should be addressed, especially harmonisation of regulatory processes, mutual acceptance of product standards and certifications, competition rules, services and procurement, in a balanced and mutually beneficial way.

A-EJ-2 Support of WTO Doha Development Agenda for fight against protectionism (Joint Recommendation)

The financial crisis and subsequent economic crisis are hitting trade flows hard around the world. The BRT is very concerned that growing protectionism will deepen and prolong the economic crisis. Protectionist rhetoric and some very real protectionist measures for instance in the US, China, Russia and Brazil have had a chilling effect on the trade and investment strategies of companies. Moreover, trade defence measures are almost certain to increase around the world as prices for energy-intensive products decrease to a low level and state subsidies flourish.

Given this background, the WTO must play a crucial role and be proactive in both preventing the closing of world-wide markets and the introduction of new restrictions on investments, market access and mobility for workers. The WTO is to be commended for its initiative of monitoring protectionist measures or new trade-hampering regulations around the world. The WTO should continue to pursue this clear objective of advocating free

trade and denouncing all protectionist measures taken by its members. Moreover, it should strengthen its stance by requesting WTO members to explain the reasoning and compatibility with WTO law of their measures to the whole WTO membership. This will mitigate the rising risk of protectionist measures and restore business confidence in the system by providing a concrete avenue to counter unhelpful protectionist tendencies. It is also critical that the WTO strongly counters any weakening of commitment to key WTO disciplines such as TRIPS. We call on the European Commission and Japanese government to jointly advocate this policy in the WTO.

The Working Party is a strong supporter of the WTO Doha Development Agenda (DDA) negotiations and continues to urge the European Commission and the Government of Japan to exert their utmost efforts in concluding ambitious negotiations, based on the current modalities, by the end of this year. The Working party is concerned, however, that the ambitious level of objectives sought at the start of the round will not be maintained in the final conclusion. We call on our leaders to press for the most ambitious deal possible.

The provisional NAMA results contained in the revised December 2008 draft will effectively lead to tariff rate cuts in OECD countries and, eventually China, but they also need to commit other emerging countries to stronger tariff reductions more explicitly. Moreover, China in particular has to show further ambition as it could still benefit from an implementation period of more than 10 years and maintain high average tariff rates despite the competitiveness of many sectors. Furthermore, it is unclear how emerging countries will make use of their flexibilities granted under the formula. There is a risk that the tariff lines which we have export interests could be excluded from tariff reductions. Finally, emerging countries have not yet shown sufficient willingness to participate in specific sector agreements and should show stronger commitment.

A-EJ-3 Applying international standards and enhanced co-operation in the promotion of new global standards (Joint recommendation)

1. The Working Party urges both governments to adopt international product standards where applicable and, in the meantime, mutually recognise products certified under similar and equivalent product standards in sectors such as Medical Devices, Construction Materials and Organic Products.
2. The Working Party recognises the importance of global patent harmonization and streamlining of the patent system as a way to promote innovation, reduce costs and boost legal certainty. The authorities of the EU and Japan should take the lead in these efforts.
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.

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 and relevant labelling rules.
5. The governments of the EU and Japan should introduce regulatory cooperation through which, once an economic operator is approved as an AEO (Authorized Economic Operator) in Japan, its status should be recognized without additional formalities in the EU, and vice versa.

A-EJ-4 Supporting timely development of business (Joint recommendation)

1. Social security contributions (avoiding double contributions):

The Working Party welcomes the fact that following the agreements between Japan and Belgium and France in 2007, the social security agreements between Japan and the Netherlands and Czech Republic have entered into effect, and those between Japan and Spain and Italy have been signed. Furthermore, negotiation is underway between Japan and Ireland, and at preparatory stage between Japan and Hungary and Sweden. 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 an interim measure, by which a host country should either exempt contribution to pension funds unilaterally or should refund in full when expatriates return to a home country.

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

- 1) The Japanese and EU authorities should realize far-reaching liberalisation of the movement of intra-corporate transferees (ICTs) . Such liberalisation could be achieved by the following systems:

- A framework agreement between the mother company, which sends expatriates, and the host country, stipulates the maximum number of expatriates. Within the agreed limit, the mother company is free to send ICTs to that country without further obtaining individual work permits.
- When the mother company concludes such an agreement with several Member States in which its subsidiaries or branches have operations, movement of ICTs between those countries should be free from obtaining a new work permit as long as the total number of the agreement is respected.

- 2) The Japanese government should abolish the system requiring foreigners with a visa additionally to obtain a re-entry permit, such that permission to leave and re-enter the country freely is automatically granted when the visa is issued. We welcome the revision of the Immigration control law under way in Japan and

urges the GOJ to implement the revision swiftly, once it has passed the parliament.

3. Personal data protection regime;

The Working Party 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 a corporate group, within which the flow of data should be free across national borders. In order to achieve this, the national legislation of each country should promote such a system rather than impede by creating different requirements.

To realize such business environment between the EU and Japan, the government of Japan should request the European Commission to launch the adequacy-finding procedure on the basis of Article 25(6) of Directive 95/46/EC.

In parallel with this procedure, the government of the EU and Japan should launch a dialogue in order to create an international framework which allows adoption and implementation of a reliable and cost-effective personal data protection system at the level of a corporate group, within which the flow of data should be free across national borders.

<Recommendations 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.

A-E-2 Japanese expatriates

1. 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;

- 1) Possibilities for intra-corporate transferees to submit an application for a work-residence permit or a residence permit for self-employment after entering the assigned country;
- 2) Provisions on intra-EU mobility;
- 3) Possibilities for spouses, to be automatically granted the same or similar rights as the holder of the permit upon their arrival.

The application of integration measures to ICTs should be voluntary.

2. More than three years have passed since the due date of the transposition into the law of the Member States of the Directive 2003/109/EC on long-term residence status. The first report required under the Directive is due by 23 January 2011. We look forward to hearing from the European Commission about the actual state of its implementation in each Member State.
3. The Directive is not applicable in the UK, Ireland and Denmark. Japanese nationals in the UK, where their number is the highest among EU countries, therefore, do not benefit from this Directive. The UK government should take action in order to enable them to benefit from the EU directive.

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.
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. Therefore the PPH is highly beneficial for patent applicants as it will expedite and improve examinations. We would like to urge patent offices of other EU member states as well as the EPO to participate in the PPH, for the benefit of patent applicants both in the EU and in Japan.

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

1. Regarding the fight against counterfeiting and piracy, it is anticipated that the Commission will issue a report in 2009. We would like to see further necessary steps such as possible proposals for modification of the Enforcement Directive with a view to step up efforts of all the EU member states to fight against counterfeited, pirated and contraband goods, both inside and outside of the EU.

A-E-5 Competitiveness of the EU economy

1. Customs Classification;

We believe that customs classification should be done in accordance with the Harmonized 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-electronics products, where the technical convergence of IT and non-IT products has emerged. This situation makes interpretation and classification more difficult and complicated than ever, and has undermined transparency, predictability and promptness for businesses. It is requested that the EU acknowledges the concerns and difficulties the businesses are facing, and to take steps to increase predictability and improve transparency upon importation of the IT products. The improvement of the said situation will indeed contribute to the ICT industry development.

2. Taxation

2.1 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 unrealised 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.

2.2 Merger Directive

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

2.3 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 an EU TPD acting in good faith and in a timely manner.

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

3. 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.

4. Integrated approach for CO2 reduction:

The European Commission's CO2 Communications of February 2007 calls for technical improvements of passenger cars to the level of an averaged CO2 emission of 130 g/km in order to achieve the EU objective of 120 g/km in 2012. On 19 December 2007, the Commission has further proposed legislation to reduce the average CO2 emissions of new passenger cars to 120 grams per kilometre by 2012. For CO2 reduction, various measures including improvement of road systems and traffic flow, improvement of fuel quality, education of drivers toward eco-driving and fiscal incentives to encourage the purchase of more fuel efficient cars are important. So, combining the efforts of all relevant parties involved: auto industry, fuel sector, policy makers and drivers to achieve the objective of CO2 reductions, which is called an integrated approach, is the most balanced and realistic way to achieve this goal. The BRT supports this approach.

5. Better Regulation;

In reviewing the existing regulations or establishing new ones, it is extremely important to consider the relevant regulations from the perspective of competitiveness of the economy and the industry. In this connection, the agreed processes of Stakeholder Consultations and Impact Assessment should be duly implemented. Moreover, the Integrated Approach, a concept of appropriate burden sharing by the entire society, is important. The BRT supports the initiative of the European Commission for Better Regulation.

6. REACH

The EU regulation of Registration, Evaluation, Authorization and Restriction of Chemicals (REACH) has been put into effect since June, 2007. 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 Chemicals Agency (ECHA). We recommend that the EU government takes further

actions for education and capacity building in developing countries for compliance with REACH. We also request consideration by the EU government to establishing certain lead-times or grace periods for compliance in cases involving developing country parties in supply chains.

< Recommendations to Japan >

A-J-1 Recognizing and applying international standards

The Working Party recommends the Japanese Government to place particular emphasis on:

1. Food Additives The Ministry of Health, Labour and Welfare submitted a list in December 2002 of, in its own words, “unauthorized food additives whose safety is globally confirmed and are widely used outside Japan.” Out of this list of 46 “priority additives”, only around half have been approved in five and a half years. The government of Japan should seek to immediately approve the remaining food additives on this list and then prepare a new list, in close consultation with the EU Authority, on any remaining additives that are officially recognized as safe and in wide use, and seek to have these approved as soon as possible, and certainly by the end of 2009.
2. Construction Products The Government of Japan should work together with the EU Authorities towards mutual recognition of all JAS/JIS and EN standards for all building materials. Procedures for foreign testing institutes seeking accreditation under JAS/JIS should be streamlined. Mere reference to ISO standards within JAS/JIS, has proved to not be adequately helpful in facilitating the process.
3. Organic Products With the implementation of the new organic JAS law in April 2006, the mutual recognition agreement between EU and Japan on organic product certification and labelling ceased to be valid. The Government of Japan should work together with the EU Authorities to achieve mutual recognition of Organic Food Products labelling.
4. Labelling rules The Household Product Quality Law and accompanying voluntary labelling guidelines “hyojikitei” prescribe in extreme detail how household products should be labelled when sold in Japan. The Government of Japan should issue clarifying orders to provide retailers with flexible alternatives for providing Japanese consumers with globally sourced products while taking full responsibility for the quality and safety of the products.
5. Cosmetics The Government of Japan should establish a mechanism enabling swift acceptance of ingredients widely used or recently recognised in Europe and the U.S.
6. Medical Equipment The Government of Japan should intensify the work to simplify and harmonise the regulatory processes in the field of Medical Devices with that of the EU. In particular, mutual acceptance of regulatory practices and standards concerning principles of safety and performance, marketing authorisation, clinical trials and on-site

audits of manufacturing facilities should be promoted.

A-J-2 Improving regulatory transparency and accountability

<Summary of recommendation>

The Government of Japan should reinvigorate its efforts to improve transparency and consistency in all areas of regulation, including the development of new regulations, and the accountability of regulators, in order to facilitate business in Japan for both foreign and domestic firms. The Government of Japan should ensure that:

1. All Ministry-proposed laws, regulations, guidelines and agency recommendations are made available for public comment, by enforcing and monitoring compliance with existing public comment requirements.
2. Complete draft laws are made available for public comment, rather than mere summaries, before bills are submitted to the Diet for deliberation.
3. A 30-day waiting period is actually implemented between the expiration of the public comment period and the submission or release of the final law, regulation, guidelines or agency recommendation, in order to give officials time to consider the comments received.

A-J-3 Creating a more efficient product approval process in the human and animal health sectors

Japan needs to reduce the time and costs associated with introducing innovative new treatments in the human and animal healthcare markets in Japan and to bring Japanese rules in line with global standards. The Government of Japan is therefore urged to create more efficient product approval processes, in particular by:

1. Shortening the medical equipment certification process: accepting clinical trial data generated overseas and harmonising Good Clinical Practice (GCP) and Quality Management System (QMS) requirements with international standards. The Working Party recommends that in the meantime, both governments should officially recognise that either ISO 14155:2003 (and as subsequently amended) or Japan GCP is, in principle, generally acceptable to either party for all medical device clinical investigations and that, in principle, a QMS audit conducted by responsible authorities in Japan (PMDA or third party testing organisation) or by Notified Bodies in the EU is generally sufficient as evidence of compliance with quality management system requirements when applying for market authorisation on either market.
2. Eliminating differences between Japanese GCP and the GCP established by the International Conference on Harmonisation; and increasing the number and quality of

staff working on consultation and approval review in the Pharmaceutical and Medical Devices Agency (PMDA).

3. Improving the product approval process for animal health products by adhering to the standard administrative review period of one year. This could be achieved by streamlining and accelerating administrative procedures and eliminating unnecessary and scientifically unjustified requirements.

A-J-4 Ensuring free and open competition in services

The Working Party urges the Government of Japan to tackle the lack of free and open competition in Japan's services markets. In particular, the Government should:

1. Remove obstacles to integrating the operations of financial groups. In particular, the initiated reforms of firewall restrictions should be implemented fully to allow financial groups to structure their organisations in Japan in the same way as they do in the rest of the world.
2. Implement the privatisation of Japan Post so as to ensure a level playing field. This means that the *Kampo* insurance business should be subject to the same capital, solvency margin, tax and policyholder protection funding requirements as private sector insurers. Limits are needed on its expansion until competitive safeguards have been established to prevent cross-subsidies from its existing dominant position. Similarly, the insurance business of cooperative societies (*kyosai*) should be subject to the same requirements as private sector insurers.
3. Exempt securities issued by governments and government agencies of major countries, including European governments, as well as securities listed in the exchanges of European markets that have appropriate disclosure requirements, when implementing the proposed revision of disclosure rules within the Financial Instrument Exchange Law (FIEL), the amendment of which is currently under discussion in the Japanese Parliament.

A-J-5 Promoting foreign direct investment

The Government of Japan should promote growth through further participation of Japanese firms in the global economy and of foreign firms in the domestic economy. To this end, and in line with the treatment applied to stock swaps involving purely domestic companies, it should consider allowing tax deferrals for capital gains stemming from direct cross-border mergers and re-organisations.

The Government should also ensure that rules of fundamental importance to foreign companies are not altered without prior notice and consultation. In this context, the Working Party calls on the Government to use all means available, including revision of Article 821 of the Corporation Law, to ensure legal certainty for foreign companies

established as branches in Japan.

A-J-6 Promoting EU-Japan cooperation in commercial aircraft development and production

Historical circumstances have created practices that have distorted the market mechanism in the field of large (more than 100-seat) commercial aircraft procurement. As a result, Japanese airliners buy almost exclusively from one supplier. The Japanese Government should promote fair competition by providing similar support to European – Japan Cooperation programs in the field of commercial aircraft development as is currently given to the cooperation between Japanese manufacturing and their U.S. counterparts. European companies can offer technology, know-how, and production and management techniques that can benefit Japanese manufacturing companies and capitalise on their strengths, for the benefit of both Japan and the EU.

The Japanese government should set a positive example to the private sector of the advantages of sourcing from more than one aircraft manufacturer by buying large aircraft for official government use from an alternative supplier.

Similarly, the Japanese aerospace and defence industry is at times reluctant to work with European companies, due to the long-standing relationship with North American companies, and limited awareness of the European aerospace sector.

European aerospace and defence companies are ready to consider joint development of new products and willing, within such programs, to transfer to the Japanese aerospace and defence companies advanced technology and know-how. The improved capacity and global competitiveness of the Japanese industry following such a cooperation should be increasingly important, given the acute need to cut procurement costs and the current discussion in Japan of a re-interpretation of the current very strict export ban.

Co-operation with Europe will also allow final Japanese users of equipment such as fighter air-crafts to directly manage configuration control, not possible through the “black box approach” employed by current partners.