

**The EU-Japan Business Round Table
Working Party 1**

“Creating an open environment for trade and investment”

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<Recommendations to the EU and Japan>

1-EJ-1 Dialogue on the formation of a common economic institutional environment

The current bilateral framework to promote two-way trade and investment has not delivered satisfactory results. The EU-Japan Regulatory Reform dialogue has been instrumental in identifying and defining barriers hampering trade and investment, but not efficient enough in finding solutions. Similarly, the 10-year Action Plan for EU-Japan Cooperation, which started in 2001, has promoted political interaction and people-to-people exchange, but is not addressing trade related issues in a straight forward manner. Given this background in 2007, the EJBRT recommended the study of the feasibility of an EU-Japan Economic Integration Agreement.

The Working Party is recommending continued discussion on an ambitious bilateral framework to set new standards for global trade. Such a framework initiated and pushed through respective administrations from the highest political level is the most feasible way to deliver real solutions for business. The Authorities should not surrender to endless discussions but establish a mechanism that can take the EU-Japan relationship to a new level.

Any future EU- Japan framework should not undermine, but be complementary to the WTO and DDA negotiations underway. It should include harmonisation of regulatory processes, mutual acceptance of product standards and certifications, building as much as possible on existing international standards. Moreover, short-, medium-, and long-term trade issues of importance to both sides should be addressed.

1-EJ-2 Supporting timely development of business (Joint recommendation)

1. Social security contributions (avoiding double contributions):

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 application procedures for obtaining work and residence permits:

The two authorities should conclude an agreement to simplify and accelerate the procedures to obtain work and residence permits for intra-corporate transferees between the EU and Japan. The procedures should include the possibility of submitting an application for work and residence permits after entering the assigned country as well as automatic granting of the same rights to spouses of the permit holders. Regarding the Commission proposal for a directive setting out common procedures to regulate the entry into, temporary stay and residence in the EU of intra-corporate transferees, which has been anticipated to fall of 2008, it should include the aforementioned measures.

The Government of Japan 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.

3. Personal data protection regime;

The two authorities should work together to ensure an internationally equal, transparent and secure data protection regime between the EU and Japan. The European Commission should consider launching a detailed study to assess the adequacy of the level of protection afforded by the Japanese Data Protection Act and its implementation measures.

1-EJ-3 Enhanced co-operation in the promotion of new global standards (Joint recommendation)

1. The EJBRT recognizes the importance of global patent harmonization and streamlining of the patent system, as a way to promote innovation. The Authorities of the EU and Japan should take the lead in the creation of a harmonised international patent system.
2. 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..

3. Given the nature of the issue and the importance for business, the two governments should make an effort to harmonise the regulations for energy conservation and relevant labelling rules.

<Recommendations to the EU>

1-E-1 EU policy on company law

1. Regarding the Statute for European Private Company ("the SPE"), the European Commission has finalised the regulatory impact assessment and is currently preparing the legislative proposal for the SPE. We recommend that it should be introduced as soon as possible.

1-E-2 Japanese expatriates

1. The deadline of the transposition of Directive 2003/109/EC on long-term residence status has expired. We look forward to hearing from the European Commission about the actual state of its implementation in each Member State without delay.
2. 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.
3. The Commission announced that it would present 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. 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.

1-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.

1-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.

1-E-5 Competitiveness of the EU economy

1. Customs Classification;

We understand that the classification must be done in accordance with the Harmonized System Convention rules. However, we 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 continues efforts to take this initiative towards a substantive solution.

2. 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. EJBRT supports this approach.

3. 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 EJBRT supports the initiative of the European Commission for Better Regulation.

4. 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 >

1-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 13 have been approved in five and a half years. The government of

Japan should seek to immediately approve the remaining 33 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 widely used, 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, and streamlining of accreditation procedures for foreign testing institutes.
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.

1-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 and the accountability of regulators, including as regards the development of new regulations, 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 implemented between the expiration of the public comment period and the submission or release of the final law, regulation, guideline or agency recommendation, in order to give officials time to consider the comments received.

1-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; harmonising Good Clinical Practice (GCP) and Quality Management System (QMS) requirements with international standards. Foremost, GCP-related requirements need to be modified, since they currently impose an unsustainable burden on applicants in terms of work and application fees.
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.

1-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 to:

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.

1-J-5 Eliminating unnecessary bureaucracy for foreign residents

The Government of Japan 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.

1-J-6 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.