

A large, stylized yellow map of Japan is positioned in the background, showing the four main islands: Hokkaido, Honshu, Shikoku, and Kyushu.

ECONOMIC INTEGRATION: A NEW APPROACH TO REFORM

**The EBC Report on the Japanese Business Environment
2007**

**The
European Business Council
in Japan**

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A NEW APPROACH TO REFORM**

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European Business Council in Japan

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The European Business Council (EBC) is the trade policy arm of the 18 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents some 3,000 local European companies and individuals who are members of their national chambers of commerce. Around 360 of the companies participate directly in the EBC's 29 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

The EBC speaks from a platform based on member consensus, representing the common view of companies from a major economic region in the world and one of Japan's most important trading partners.

The EBC works closely with the Delegation of the European Commission in Japan and the embassies of European countries to co-ordinate policy proposals and facilitate European business in Japan.

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Economic Integration: A New Approach to Reform The EBC Report on the Japanese Business Environment 2007

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Message from the Chairman

It is my pleasure to introduce the annual report of the European Business Council in Japan (EBC) on the Japanese business environment, *Economic Integration: A New Approach to Reform*. As the title suggests, this year's report presents not only an industry analysis of developments over the past year and recommendations for future economic reforms, but also closely examines how an EU-Japan Economic Integration Agreement (EIA) could strengthen the trade and investment relationship between

Japan and the EU and vastly improve the business environment.

While notable progress on the part of the Government has been achieved, Japan's new leadership must address significant issues and critical economic reforms. In the past year, Prime Minister Abe pledged to continue the structural reforms of his predecessor and oversaw the expansion of Japan's longest economic recovery since the postwar period. A renewed commitment was made to enhancing the position of Japan as a global financial centre and Prime Minister Fukuda has embraced this reform agenda. However, political instability and turmoil has caused a stalemate in the implementation of reforms. Japan has the lowest levels of import penetration, stock of inward FDI relative to GDP, and foreign workers among all OECD countries. Crucial reforms remain frustrated by inadequate coordination, mounting bureaucracy and vested interest in the administration and industry. The progress and results of wide ranging regulatory reforms over the years are discouraging.

The current situation is critical for Japan and incentives for change could not be more compelling. An ageing society, declining birthrate and shrinking labor force threaten to overwhelm Japan's pension and healthcare systems and impose an unsustainable financial burden on both employers and employees. This is happening at a time when competition from newly emerging economies as well as industrialised economies is intensifying.

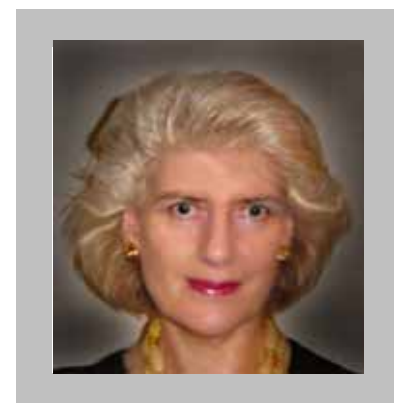
The struggle in undertaking structural reforms is not unique to Japan. Europe is also plagued by special interests trying to undermine or derail difficult but necessary changes. Economic integration in the EU, however, has provided the political leadership with a clear vision and fostered political discipline to fulfill reform commitments. In this regard, by entering into an ambitious agreement with the EU, Japan would gain a clear direction and concrete incentives to speed up reforms. Allowing for free flow of products, services, capital and people between Europe and Japan, will boost trade, innovation, and competitiveness.

The European Business Council in Japan continues to engage in dialogue on creating a thriving, successful economy in Japan for the benefit of the global economy and companies investing in Japan. Integration with the EU would build a new foundation and course that would secure Japan's future prosperity.

For this to happen, the respective business communities need to become more innovative and creative, breaking with the conservative traditions of the past to make bold suggestions and proposals to their governments. Progress is achieved by taking a courageous stance and not by keeping one's head in the sand. This is in line with the decision of the European and Japanese Co-Chairmen of the EU-Japan Business Dialogue Roundtable (EJBDRT) in June 2007 in Berlin, when they instructed the Working Party on Trade and Investment to work with the business communities of Japan and Europe to prepare an industry study report suggesting the content of an EU-Japan Economic Integration Agreement (EIA) to submit to the 2008 EJBDRT meeting. From this perspective, we would like to present this year's EBC report - *Economic Integration: A New Approach to Reform* - as a kick-off publication to lay the foundation for this ambitious, but worthwhile project.

Richard Collasse
Chairman, European Business Council in Japan
(President, Chanel K.K.)

Message from the Executive Director



The European Business Council in Japan (EBC) is pleased to present its 2007 report, *Economic Integration: A New Approach to Reform*. The report presents an industry analysis of developments and recommendations on key issues that constrain European business and investment in Japan.

The European Union and Japan together account for close to 40% of the global GDP, and have an annual trade turnover of around 145 billion Euros. In terms of trade volume, the EU ranks as Japan's second largest export market, and is Japan's third largest source of imports. However, despite these statistics and the fact that some European companies, especially those in niche markets, are thriving in Japan, many others struggle to build and operate their businesses due to a plethora of regulatory and non-regulatory barriers to trade that still persist.

This report comes at a crucial time in Japanese politics and reform. Following a period of political turmoil, the new administration has pledged its commitment to strengthening competitiveness in the financial sector and working to promote domestic and foreign investment. The EBC encourages the Fukuda administration to adopt a new approach to fostering economic growth and prosperity, one that builds on the existing partnership with the EU through an ambitious economic integration (EIA) agreement.

The EBC White Paper is an annual report that represents the concerns and efforts of 29 committees, 3000 stakeholders and our key stakeholders, the European National Chambers of Commerce and other business organisations represented in Japan. I would like to thank all EBC Members for their ongoing contribution to the work of the EBC's 29 sector-based committees and to the compilation of this report. Without the insight drawn from their industry experience, this publication could not have been produced. I would also like to thank the Delegation of the European Commission to Japan and the European national embassies in Tokyo for their expertise and support of EBC activities.

I am indebted to the EBC's Policy Director, Jakob Edberg, whose knowledge and professionalism have again ensured that this publication will serve as an important reference on the key issues affecting European businesses in Japan. I would also like to make special mention of Clemence Mayali, the EBC's Policy Analyst, whose contribution to the production of this report was indispensable. Finally, many EBC Members deserve recognition for their generous financial contributions towards the cost of producing this report. The EBC is extremely proud to acknowledge their help in the sponsors and supporters sections at the end of the report and on our website.

As we begin a new chapter in Japan's economic reform, the EBC looks forward to working with the new Prime Minister and his Cabinet, as well as the Japanese business community and broader public, to achieve effective regulatory reform. In order to remain competitive in the global economy, both Japan and the EU must ensure optimal conditions in which the private sector can operate more efficiently. Businesses will not flourish in a protectionist environment; rather they will thrive by opening more sectors to trade and investment opportunity. This is particularly true at a time when so many emerging countries are honing their competitiveness and taking the stage as economic powers. For this reason the EBC urges the EU and Japan to enter a dynamic economic integration agreement that will effectively promote our shared goals of improving the business environment and secure future economic prosperity for both partners.

Alison Murray
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Introduction



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INTRODUCTION

Regulatory reforms must continue

Japan has, in recent years, made enormous efforts to reinvigorate its economy. The wide-ranging reform programme of Prime Minister Koizumi was followed by further decisive action under his successor, Mr Abe. The European Business Council in Japan (EBC) greatly welcomed these developments. The EBC has long drawn attention to persistent, substantive market access problems in Japan, arguing that the removal of these obstacles would not only improve business conditions for foreign firms but, crucially, also help the many Japanese companies seeking to tap into foreign sources of capital, increase the level of competition within the Japanese market and therefore stimulate the economy as a whole. Hence the EBC particularly appreciates recent reforms that mean foreign stocks can at last be used as consideration in mergers with or acquisitions of Japanese companies, through the triangular merger scheme allowing tax deferral so long as certain conditions are fulfilled. It applauds the conclusion reached by the Council for Economic and Fiscal Policies that promoting Tokyo as a financial centre requires priority action on the long-standing problems caused by firewall regulations between securities and banking operations. It is delighted that the Government is finally addressing excessive regulation in the field of air transportation, where liberalisation of pricing and market entry would bring enormous benefits to the economy at large. And last but not least, the EBC is relieved that the Council of Regulatory Reform is now addressing the outdated requirement that foreigners holding valid visas must additionally apply for a re-entry permit if they wish to avoid losing their resident status each time they leave Japan for even the shortest business trip or family visit.

It is unfortunate that recent political turmoil has put these and other essential reforms on hold. However, the EBC is pleased to note that newly elected Prime Minister Fukuda has committed himself to continuing the reform process, and trusts that remarks he has made about correcting the so-called adverse effects of regulatory reform do not imply backtracking - something that Japan simply cannot afford.

Overall, the EBC believes that the new Japanese government can do far more to ensure that conditions for doing business within Japan support and stimulate competitive enterprise, at the same time as promoting social welfare and safeguarding the environment. In particular, the approach taken to regulation will influence whether or not Japan is seen as an attractive place to do business, boosting the prospects of local firms and drawing in new capital and investment from abroad.

Implementing the recommendations provided in this report would substantially increase the business opportunities both for European and Japanese companies and what currently is simply a strong trade relationship could be transformed into a great one, benefiting both national economies and individual companies.

However, current instruments for enhancing cooperation between Japan and the European Union are largely confined to dialogues that yield, at best, a harvest of understandings, goodwill and piecemeal improvement, of little help to companies battling structural barriers, constant red tape and competitive pressure. The EBC therefore argues that a new approach is needed, which will lead the European Union and Japan towards integration of their respective rules and regulations, offering the prospect of greatly increased market access and mutual trade, while respecting shared concerns for economic, social and environmental "balance". The EBC has expressed this new approach in terms of an Economic Integration Agreement (EIA) and in this report identified issues we believe should be addressed within such an accord.

EU – Japan Economic Integration Agreement

The Economic Integration Agreement envisaged by the EBC would entail Japan and the European Union working together towards the abolition of obstacles to mutual trade. Member States of the European Union long ago realised the benefits that could be created by cooperating on these issues and have invested hugely in the establishment of a

Single Market, characterised by the free movement of goods, people, services and capital. Given the equal level of economic development, the EBC believes that an ambitious EU-Japan agreement addressing issues beyond the WTO framework is not to the detriment of the multilateral system, but to the benefit of each side.

This is not to suggest that the EU and Japan should embark on the very extensive programme of integration that has been achieved by EU Member States, but recommends that they should focus on achieving the benefits of much closer cooperation in the economic arena. The motivation for doing so is strong. The European Commission has estimated that, thanks to the Internal Market, EU GDP in 2002 was 1.8% or 164.5 billion euro higher than it otherwise would have been. Benefits for consumers include a wider choice of quality goods and services, in many cases at lower prices, and the opportunity to move across borders for work without foregoing welfare protection. Benefits for business of having a single set of rules and unified certification schemes are obvious, especially to small and medium-sized enterprises, which might previously have been deterred from entering new markets by the costs and difficulties involved

The effort and commitment required to achieve the EU Single Market should not be under-estimated. Yet many years' work by committees and expert groups from across the Member States have led to balanced agreements on numerous issues that, without compromising on efficiency, are sensitive to the technical, social and cultural concerns of all parties. The inclusive approach has favoured outcomes that are acceptable to all and thus more likely to prove successful than a unilateral approach to rule-making. The result is a body of singularly robust rules and regulations, adopted and supported by 27 Member States, that have boosted trade within the EU. Why, then, not use this work to inspire – and even give substance to – a body of rules and regulations of even greater significance, also for an agreement between EU and Japan?

Europe and Japan share many of the same concerns and challenges at the global trade level. Both have a co-operative, inclusive and sensitive approach to solving socio-economic issues. The sheer size of their combined economies - EU and Japan account for 40% of Global GDP - means that each offers huge potential to the other. Yet our mutual economic and trade relationship currently suffers from endless wrangling over differences in respective rules and regulations. The EBC believes that this is the time to work together to create a shared set of rules and regulations. The greater the consistency in rules and standards, the better for business - provided of course that the rules and standards are founded in real business experience, rather than pure politics.

In this annual EBC Report, we have identified some of the key issues that should be addressed if a properly integrated basis for trade between the European Union and Japan is to be achieved. The issues are arranged according to the EU's "four freedoms" below.

Free movement of goods between the EU and Japan

There are no physical barriers to the movement of goods across the borders between EU Member States. The absence of customs documentation requirements reduces both delivery times and costs. More technical barriers to trade between countries are also considerably reduced, either by allowing products legally sold in one Member State (i.e. in compliance with national rules) to circulate freely throughout the Union; or, in more complex cases, by harmonising national rules in the form of single EU Directives.

Recognising how the EU approach has eased cross-border trade, the EBC believes its benefits should be extended to EU-Japan trade, and calls on the European Union and Japan to initiate discussions on mutual acceptance of standards and certification schemes in product areas such as Construction Materials, Medical Equipment, Medical Diagnostics, Animal Health and Vaccines, as well as all products sold on retail markets where certification schemes exist.

How would mutual acceptance work? It helps that both European Union standards (EN) and Japan Agricultural Standards (JAS) / Japan Industrial Standards (JIS) are scientifically-based and highly sensitive to issues of human and environmental safety. In the case of products such as machinery, industrial installations, toys, electrical

equipment, electronics, domestic appliances, pressure equipment, personal protective equipment, recreational craft, refrigerators and sawn timber, standards exist in both the EU and Japanese systems and are basically the same, so it should be easy for each side to agree on direct and unconditional acceptance of the others' standards.

Certain other products are covered by EN standards but not JIS/JAS - Medical Devices and Medical Diagnostics being prime examples. In these cases, however, Japan employs a policy of certification per product (or what would be called "market authorisation" in the EU context) based on the same requirements as the EN standards, as set out under Good Clinical Practice (GCP), Quality Management System (QMS) and Good Manufacturing Practice (GMP) regulations. Furthermore, both the EU and Japanese approaches are built on ISO requirements, albeit these have been slightly modified by Japan. Given their common foundations, it should be possible to establish mutual acceptance of EN standards on the one hand and Japanese certifications on the other in respect of Medical Equipment and Medical Diagnostic products, and also of respective market authorisations of Pharmaceuticals, Animal Health, Vaccine and Cosmetic products. The EBC would therefore expect mutual acceptance of all these products to be included in the first phase of any EU-Japan Economic Integration Agreement.

It will also be important for Japan and the European Union to agree on systems for ensuring human and environmental safety where this is not linked to specific product certifications or standards - for example, the positive lists used respectively in the European Union and in Japan concerning ingredients in cosmetics and residues in food; acceptable food additives; the quarantine list of pests acceptable in cut-flowers without requiring fumigation; and authorised chemicals. From a business perspective, mutual acceptance of each party's lists would be the most practical solution, as it would enable companies to enter the foreign market by simply following home jurisdiction regulations. From the regulators' perspective, however, agreeing to this could be problematic since substantial differences exist between the two sides and could even increase in the future. The EBC therefore believes that the European Union and Japan should aim to create a set of common standards in these fields.

The potential benefits of mutual acceptance and common standards cannot be over-stated. Both the European Union and Japan would gain from reduced administrative costs and from increased trade. Moreover, the benefits to consumers could be vast. For example, the current certification procedure delays the introduction of foreign, new life- and cost-saving medical devices and vaccines onto the Japanese market. After having cut re-imbursment prices over the line for many years, the Government of Japan now seems to be realising that such products are actually capable of reducing social costs and boosting economic performance over the longer term, as the population gains access to better therapeutic and preventative healthcare. Circumventing the lengthy national certification procedure and being able simply to accept products already certified in Europe would be a cost-efficient and safe way of improving access for Japanese consumers. It would also allow Japan to increase competition within its home market, and by doing so, improve the competitiveness of domestic industry. Moreover, the reciprocity of a mutual acceptance approach would lower entry barriers for Japanese manufacturers wanting to enter EU markets and so could boost their performance: certification in Japan would be sufficient to allow access to the whole of Europe!

Free movement of services between EU and Japan

EU companies have the right to establish themselves in other Member States, and to provide services on the territory of a Member State in which they are not established. To reinforce these rights, specific legislation has been enacted in fields such as financial services, telecommunications, broadcasting and the recognition of professional qualifications. A more general Services Directive will eliminate remaining obstacles and discriminatory barriers, cut red tape, and modernise and simplify the legal and administrative framework, with a view to improving the competitiveness not just of service enterprises, but also of European industry as a whole.

The EBC argues that such benefits could be extended across the EU-Japan trade relationship and suggests that work should focus particularly on establishing common competition rules and common standards for service providers in the financial, legal, telecom, and construction sectors.

At present, differences in the views of European and Japanese regulators on basic principles relating to risk management and handling conflicts of interests make it inherently difficult for financial services firms to integrate their Japan and EU businesses. Indeed, Japanese firewall regulations prevent integration of the Japan business into global operations and are also, at times, in conflict with European home regulator requirements. Hence, firms active on both markets would have much to gain if the EU and Japan could agree on how to ensure good governance in the financial sector under a principles-based system. This would reduce administration, and allow true integration and seamless development of innovative products for both markets. It would also take Japan a significant step nearer to being able to realise its potential as a global financial centre.

Crucially, it is foreign lawyers working in Japan who have provided many of the services essential to introducing new corporate and financing techniques to the country. They consistently play a key role in the integration of the Japanese and EU economies, interfacing between European and Japanese firms on cross-border investment. Lawyers are, however, restricted in the extent to which they may exercise their profession since legal qualifications are currently not recognised across jurisdictions and, in some cases, their activities are circumscribed by local rules. The EBC therefore believes that an EU-Japan Economic Integration Agreement should aim to deliver mutual acceptance of legal qualifications and of engagement by lawyers in the scope of activities permitted by their home jurisdiction.

In the area of telecom carriers, it is most important that the European Union and Japan should work to develop common rules that will ensure free and fair competition and inspire confidence in the market. The rules should include guidelines on funding Universal Services and calculating connection fees. Governments should implement measures that guarantee transparent costs, ensure that charges to competitors are cost-based, and monitor anti-competitive behaviour in relation to the price and non-price terms of supply.

Competition

Establishing common rules for competition would also be crucial in other services sectors. At present, the EBC has serious concerns about the so-called privatisation of Japan Post, which seems to be enjoying special treatment from the Government (still its only stockholder) with a view to securing future profitability. A special section has been created within the FSA to deal with the Japan Post Insurance and Japan Post Bank companies, instead of subjecting them to the same regulatory department as their competitors. The need for strengthened compliance and risk management functions within the Japan Post Life Insurance Company, Kampo, is not being given sufficient priority and there are doubts whether a level playing field for all issuers of insurance will be guaranteed. The impact is also being felt by European carriers and forwarding companies in Japan. They already struggle with high costs and insufficient infrastructure at international airports, rigid custom clearance procedures and outdated restrictions on foreign-owned companies engaging in domestic freight forwarding business. Now Japan Post's plans to expand, for example in the international express market, while still benefiting from preferential regulatory treatment, are posing a serious threat to the functioning of the market and the ability of competitors to provide services to the Japanese public.

Procurement

Both Japan and the EU are party to the plurilateral WTO agreement on government procurement (APG) and have implemented WTO-plus provisions aiming to open up as much of this business as possible. Nevertheless, participation of European companies in public works in Japan remains very low, in part because, while transparent procurement procedures are in place, they are often simply not used, and also because contracts are so sub-divided that they none meets the threshold to be covered by the WTO agreement. The EBC therefore considers that an EU-Japan Economic Integration Agreement should seek to secure reciprocal market access with binding rules and simplified, yet more effective compliance measures than those of the WTO APG, guaranteeing equal treatment of foreign and domestic suppliers; transparency of information on and notice of government procurement opportunities; relevant brand neutral specifications; the process for bid evaluation; the award challenge procedure; and concrete enforcement mechanisms.

Free movement of people between EU and Japan

Ensuring free movement of people is crucial to the successful operation of the EU's Single Market. So, with a few (temporary) exceptions, citizens of the European Union have been granted extensive rights to travel freely and settle in any Member State, study or seek work there (while retaining entitlements to unemployment benefit for up to three months), practice a profession or set up a business, and ultimately retire to any Member State and be paid their statutory pension in their new country of residence. Similarly, any attempt at achieving greater economic integration between the EU and Japan will depend on the ability to make it easier for people to move between the two. This will entail substantial revision - and in some cases abolition - of current visa and work permits for EU citizens in Japan and Japanese citizens in Europe, and should also facilitate participation in respective education and academic programmes, such as Erasmus. The Agreement should also ease obstacles in the form of national social security procedures, and eliminate the need for individually brokered arrangements between each Member State and Japan on issues such as reimbursement of compulsory state pension contributions.

Free movement of capital between EU and Japan

Free movement of capital is an essential condition for the proper functioning of the EU's Single Market, facilitating trade across borders and enabling workers' mobility. It is also essential for the cross-border activities of financial services companies. Recently, the legislative phase of an action plan aimed at developing a true European-wide market in financial services was completed, which will eventually provide consumers with a wider choice of financial products – such as loans, insurance, saving plans and pensions – which they will be able to buy from anywhere in Europe, and will also make it easier and cheaper for companies to borrow money, bringing down the cost of capital, goods and services for everybody. These are strong arguments for working towards the free movement of capital between the European Union and Japan. Besides the issues already addressed concerning the financial services industry (see above), an Economic Integration Agreement would need to focus on tax issues, eliminating double taxation between the EU and Japan and the withholding tax on dividends, royalties and interest. It should also enable employers' and employees' contributions to social security systems within the EU and Japan to be tax deductible on a mutual basis, and establish joint guidelines on interpretation and harmonisation of documentary requirements for transfer pricing assessments.

Intellectual Property

In addition to working towards establishing the free movement of goods, services, people and capital, an EU-Japan Economic Integration Agreement would need to address a number of broad issues fundamental to any effort to boost mutual trade, to ensure free and fair competition, transparent investment rules and shared policies on intellectual property rights and enhanced institutional cooperation on rules and enforcement. It would need to go beyond the limitations of current WTO discussions and agreements, but could ultimately provide a lead for future WTO negotiations. For example, both Japanese and EU companies are leading benefactors of strict international intellectual property protection and their respective Governments have indicated that the WTO TRIPS agreement is inadequate, particularly in the area of enforcement. An Economic Integration Agreement between the EU and Japan should therefore take TRIPS as a starting point and seek to build on a proper enforcement regime. It should contain ambitious undertakings on the protection of intellectual property, establishing identical protections for right-owners in both markets; mutual recognition of geographical indications, copyrights, and patent protection and licensing systems; and common rules and principles for penalties applying to counterfeiting and patent infringements on the Internet. A forward-looking Economic Integration Agreement could particularly help to safeguard innovation, research and development in areas such as new drugs, by harmonising rules on the data protection period and selection of brand names.

To sum up, given the challenges of the global economic landscape, the strength of bilateral relations between the European Union and Japan, the importance of their mutual trade and their shared interest in fostering competitiveness, the EBC believes the time is right for further, faster economic integration. Cooperation on the development of a formal EU-Japan Economic Integration Agreement, that builds on, complements, and goes

beyond WTO, would accelerate the reduction of non-tariff barriers and could provide the impetus for a step change in EU-Japan trade and investment. It could also enable leadership in the development of future rules and standards for use not only at home, but in markets across the world. Surely that is a prize worth working for?

How this report is organised

This report consists of 31 chapters covering a wide range of sectors and business areas. Each chapter addresses the concerns of a specific EBC sector committee and derives from the collective first-hand experiences of committee members doing business on the ground in Japan. Chapters consist of a series of recommendations for further regulatory reform with a section on prospects for economic integration highlighting the priorities of each sector of the industry. We trust this report will prove to be a positive contribution to the thinking of the Japanese Government and other authorities seeking to improve the environment for business and investment in Japan.

Business Fundamentals

**Human resources
Intellectual property
Retail & wholesale
Legal services
Tax**

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HUMAN RESOURCES

Regulatory Developments

Immigration policies in Japan have yet to enable efficient cost-effective transfer and employment of foreign staff. For Japanese companies and foreign-owned businesses relying to a significant extent on foreign expertise, the full mobility of foreign labour in and out of the country is crucial to their success.

Japan is the only advanced industrial nation to regulate the movement of foreign residents through a dual visa and re-entry permit system. In addition to a standard visa system, the Immigration Bureau under the Ministry of Justice, administers a unique re-entry permit system that requires all foreign residents, including permanent residents, to acquire special permission if they wish to leave the country without losing their residency status. In 1999, a revision of the Immigration Control and Refugee Recognition Act enabled an extension of the maximum period during which re-entry is permitted, from one year to three years. The revision made it easier for foreign residents to enter and leave Japan, but only after a multiple re-entry permit has been obtained and as long as the visa remains valid. Restrictions on work permits also pose a challenge for businesses to employ foreign staff. Under the current system, work visas for special skilled workers that do not have a university degree are only granted if proof of ten years' work experience is demonstrated.

Recent revisions to labour laws have been successful in granting employers greater discretion in terms of working hours, compensation, pension schemes and contracts, but continue to support the long-term employment system. The Labour Standard Law was amended in June 2003 to permit employee dismissals only if the employer met stringent criteria for economic hardship. This amendment did not set out specific criteria for what would be considered reasonable compensation for severance.

Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees, however, there are yet to be amendments that would enable expanding refunds of mandatory Japanese pension fund contributions for expatriate workers leaving Japan. Refunds for pension payments are covered by social security agreements currently in the process of being concluded with Belgium, France, the UK and Germany. A comprehensive economic integration agreement between the EU and Japan would have to streamline the process of brokering multiple individual agreements on social security pension reimbursement.

Prospects for EU-Japan Economic Integration

Economic globalisation and current demographic trends in Japan including an acute shortage of skilled labour, an ageing population, and a declining birth rate present significant challenges for domestic and foreign-owned businesses and the long-term vitality of the Japanese economy. Companies are forced to streamline their management, improve working conditions, enhance operational efficiency and find new sources of labour from abroad. In light of these challenges, it is critical that labour regulations and human resource management practices facilitate international commercial transactions and provide the best means of acquiring and retaining a high-skilled competitive workforce. In order to meet the evolving demands of today's fast-paced global economy, the Government of Japan must deregulate obstructive regulations on immigration, pension schemes, and employment tenure in line with international standards and practices.

Priorities

- **Create a single EU-Japan labour market**
- **Abolish or substantially revise all visa and work permit requirements between the EU and Japan**
- **Facilitate the inclusion of Japanese universities and students into Erasmus and other Intra-European educational co-operation schemes**

Key Issues and Recommendations

■ Immigration: re- entry permits and work permits

Yearly status report: limited progress. The Council for Regulatory Reform of Japan has recommended that the re-entry permit system be reformed before the end of fiscal year 2007. The process for applying and renewing such permits remains bureaucratic and time-consuming, with cost implications for both applicants and employers. Furthermore a re-entry permit does not appear to provide additional measures for controlling immigration. Foreigners possessing a visa have already been screened and found eligible to stay in the country. Immigration officials are able to monitor exit and entry of foreigners through their visa, which can be cancelled at any time should the holder be found to engage in activities other than those permitted under the terms of the visa. Restrictions on work permits also pose a challenge for businesses and companies that seek to employ foreigners with a specialized skill set. Currently, young professionals (with no university degree) applying for a visa are required to prove their “special skills” on the basis of a proven record of 10 years’ professional experience.

Recommendation:

- The Government of Japan should abolish the re-entry permit system.
- Immigration policies can improve access to skilled labour by relaxing the criteria for obtaining work permits.
- Regulations should allow foreign experts to practice their professions in Japan by accepting foreign qualifications, certificates and licences.

■ Pensions

Yearly status report: limited progress. Social security agreements are being negotiated or have been concluded with Belgium, France, the UK and Germany, as well as the US and South Korea, but refunds of mandatory contributions to Japanese pension plans remain capped at a maximum of three years, approximately 1.5 million yen in the case of departing expatriates.

Recommendation:

- Japan’s Defined Contribution Pension Law of 2001 should be improved by increasing tax-exempt contribution levels, allowing matching contributions and permitting plan-holders to borrow against their pension reserves.
- Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers. As an interim measure, the raising of the cap on maximum remittances, from three to five years’ worth of contributions, currently being contemplated, should be implemented without delay.
- Contributions made to foreign-based pension plans should be subject to the same tax relief as contributions made to pension plans in Japan.
- The Government of Japan should conclude social security agreements with all European governments under a comprehensive economic integration agreement.

■ Dismissals of employees

Yearly status report: limited progress. Although the revision to the Labour Law permitted employee dismissals, it did not address the issue of severance payments, an area where standard practice urgently needs to be codified in law in order to avoid uncertainties and the risk of unnecessarily costly settlements. For operational efficiency and to maintain high standard working conditions for employees, companies need a clear mandate on the hiring and dismissing of employees.

Recommendation:

- Regulations governing employee dismissals should be further clarified to enhance management flexibility and operational efficiency. Specific rules defining acceptable grounds for dismissal based on economic reasons should be introduced, along with clear guidance on what would constitute an appropriate severance payment.

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INTELLECTUAL PROPERTY

Regulatory Developments

In recent years, the Government of Japan has taken significant steps towards protecting intellectual property rights. Since the inception of the 10-year action plan under the 2002 Intellectual Property Strategy Council and adoption of the basic law on IP, the legislature has passed a total of 40 laws and revisions aimed at enhancing intellectual property protection. From 2003, revisions to the Customs and Tariff Law made it easier for companies to apply to customs authorities to seize suspected counterfeit products at the Japanese border. In 2004, rights holders were given the right to obtain information about the importers of suspected counterfeit goods. In April 2005, Japan established the first High Court of Intellectual Property. Since April 2006, the Unfair Competition Prevention Law prohibits importation of goods similar to famous, widely known brands. Injunctions against counterfeit importers are now attainable within 6 months. The Trademark Law was revised to increase the fine applicable to importers of counterfeit goods from 150 million to 300 million Yen for legal entities and from 5 million to 10 million Yen for individuals. METI, under instruction from the Intellectual Property Policy Headquarters (IPPH), is considering further revisions to the Trademark Law to prohibit the import of counterfeit goods for personal use, but little has happened during 2007.

Progress can also be attributed to active engagement by the Japanese Customs authorities. They now proactively provide information on counterfeiters to rights holders and have stepped up efforts to enforce the ban on imports that violate patent rights as well as imports resembling brand name products. Customs authorities are now increasingly sharing information with rights holders by using image transmission via the Internet rather than requiring the company or rights holder representative to be present at the customs office to inspect the merchandise in person. Japan continues to collaborate with the EU and international trading partners under the auspices of the WTO TRIPS and WIPO. Despite these significant achievements, counterfeit goods in Japan continue to be a serious problem for businesses and a significant threat to consumer protection and government tax revenues. Trade on the Internet is a special source of concern as more than half the branded goods sold over the Internet are counterfeits. The EBC urges the Government of Japan to introduce concrete measures for more rigorous enforcement of trademark violations by focusing on border control, the sale of counterfeit goods on the Internet, and the import of counterfeit goods for personal use.

Prospects for EU-Japan Economic Integration

Protection of intellectual property rights is critical for Japan's knowledge-based economy. A strict intellectual rights regime brings an environment conducive to innovation, knowledge development, foreign investment, and economic growth. Counterfeit goods make up as much as 5-9% of total global trade and a considerable amount reaches Japan. The Japanese market for luxury goods is worth ¥1.17 trillion, representing 40% of worldwide consumption. The stakes are high for many European companies in the sector as they generate as much as a third of their global revenues in Japan. As a leading consumer and a benefactor of strict international intellectual property protection, Japan must take a more active role in curbing the flow of counterfeit goods. The progress achieved in the past few years through a series of revisions in trademark and patent law should be reinforced by further measures. The EBC proposes that further reforms aimed at intellectual property protection be addressed and conducted through a bilateral Economic Integration Agreement (EIA) between the EU and Japan. This EIA should comprise ambitious provisions on the protection of intellectual property, establishing identical protections for right-owners of both markets.

Priorities

- Establish identical protections for right-owners in both markets
- Establish mutual recognition of geographical indications, copyrights, and a patent protection and licensing system
- Establish common rules and principles of penalties for counterfeiting and patent infringements on the Internet

Key Issues and Recommendations

■ **Border control**

Yearly status report: some progress. Despite revisions of the Trademark Law and stepped up efforts by customs authorities, Japan has not been able to curb the imports of counterfeit goods. The legal acceptance of parallel imports and insufficient civil and criminal sanctions within the Customs Law contribute to the continued influx of counterfeits.

Recommendation:

- The Government of Japan should hold parallel importers accountable for the authenticity of goods being brought into the country. Rights holders should have the right to intervene through judicial means in procedures for seizing suspected counterfeit goods at the Japanese border and the burden of proof should be shared between the importer and the rights holder.
- The Customs Law should be revised to make it an offence for individuals or legal entities to attempt or act with intent to import counterfeit goods.

■ **Fake goods on the internet**

Yearly status report: progress. The Internet is now the principal mode of distributing fake and counterfeit goods in Japan. Changes in the application of the Specific Business Transaction Law requiring sellers to provide complete identification to the site vendor along with the introduction of identity and content control measures by the main Internet Service Providers (ISPs) have been instrumental in reducing the quantity of goods sold openly as counterfeits. However, the scope of the definition of counterfeiting is too narrow, making it inherently difficult to assert violations of property rights in cases other than obvious counterfeits. Furthermore current laws and monitoring practices do not cover the auction sites selling counterfeit goods on sites for mobile phones.

Recommendation:

- The Trademark Law should hold ISPs accountable for controlling the sale of counterfeit goods and force them to take more stringent measures against repeat offenders. The definition of counterfeiting should be widened in order to cover the counterfeits that cannot be appraised at first sight.

■ **Imports for personal use**

Yearly status report: no progress. Japanese law does not prohibit the importation of counterfeit goods into Japan that are for “personal use”. Commercial importers import fake products in small quantities to reduce the risk of detection and foreign exporters use the same method to sell counterfeit goods on the Japanese market. While the Intellectual Property Headquarters have expressed an intent to prohibit “personal” imports, this has yet to materialise. The Customs authorities issued an order requiring that upon the discovery of a suspicious item by a Customs officer, a letter be sent to the recipient asking for confirmation of the product’s authenticity or confirmation that the product is for personal use. If it is not for personal use, then the product is prohibited.

Recommendation:

- Although the confirmation system implemented by the Customs authorities has proven to be quite efficient, the Trademark law should be revised so as to prohibit the importation of counterfeit goods regardless of whether they are meant for personal or commercial use.

■ **Designs**

Yearly status report: no progress. The cost of design registration in Japan remains expensive, and the examination procedures are complex and cumbersome. Furthermore, Japanese courts take a narrow view in interpreting counterfeits under the Design Law. The designs are often judged to be different, which prevents counterfeit goods from being treated as infringements.

Recommendation:

- The Government of Japan should strengthen the protection of designs by reducing application costs. Japanese courts should take a more stringent approach to the interpretation of similarity of designs.

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RETAIL & WHOLESALE

Regulatory Developments

Little has changed for the better in past years for foreign retail and wholesale companies wishing to invest in the Japanese market. Although Japan is the second largest retail market in the world, very few non-Japanese retailers are active in the Japanese market. Despite a marked expansion of foreign retail activity in the specialty retail channel (albeit with many outlets operated via franchises or under licence to Japanese companies), it has proved extremely difficult for foreign retailers to take advantage of global scale logistics when entering the Japanese market. The process for developing and opening new retail outlets has remained fraught with restrictions, inefficiency and delay. Opportunities to streamline the new Large Store Location Law of 2000 - intended to improve efficiency by decentralizing control and decreasing administration - with the Building Permit and Environmental Impact Assessment procedures were not taken. Instead the new law led to individual local governments imposing their own procedures and in some cases new licence conditions, thus increasing costs and delays. The effect, combined with restrictions on opening retail stores above 10,000 m², has been to discourage foreign retailers further by making the costs to enter and establish operations in Japan even higher. The Government took note of EBC's concerns and introduced crucial exemptions to the new restrictions for large-scale retailing before the revisions to the City Planning Law were passed in the Diet in early 2006.

Prospects for EU-Japan Economic Integration

The Japanese retail market is one of the largest and most vibrant in the world. However, unlike many markets, non-franchised outlets of overseas retail chains are rare. Successful entries into Japan by European retailers have been few and the failures have been given considerable coverage by the local and international media. This has led to a perception, sometimes unfair, that Japan is simply 'too difficult': competition is intense, costs are high, the threat of a rise in consumption tax is real, and regulatory requirements and enforcement are opaque. Many retailers looking to expand internationally pass over Japan in favour of other markets that provide examples of non-local retail success. Nevertheless, a number of European retailers that have made careful studies of the Japanese market have elected to 'set up shop'. It is important that they be allowed the opportunity to succeed. Their success benefits the Japanese consumer by offering them greater choice. Success of European retailers in Japan also benefits Japanese retailers and wholesalers by providing new opportunities to compete and to further strengthen their global competitive edge. Importing, certifying and labelling various consumer products continue to be overly costly and complex, due to insisting on additional product testing against specifically Japanese standards, even where products are already covered by international and European standards. The EBC can see no reason why products already certified for the European market have to undergo testing and certification anew if to be sold on the Japanese market. As standards for most retail products are similar, the EU and Japan should swiftly move to establish mutual acceptance of standards and certification.

Priorities

- Mutual acceptance of standards and certification for retail and wholesale products

Key Issues and Recommendations

■ Large-scale retailing

Yearly status report: limited progress. While progress has been made in clarifying many of the provisions in the Large-scale Retail Location Law, lack of transparency and unequal regional implementation limit the entry of foreign retailers into the market. Local interpretation of construction, safety and environmental regulations is inconsistent. This adds to investment costs and increases uncertainty and risk, effectively undermining any learning curve benefits for retailers attempting to expand operations in Japan. The conspicuous rarity of foreign-owned and -operated large-scale retailers in Japan bears witness to the impact this has on investment. The discussion on new restrictions on large-scale retailing is, however, continuing. The EBC urges the Government of Japan to exercise caution and not introduce any further restrictions as it will only exacerbate the situation at the regional level, leaving the countryside with no global retailers, limited selection, reduced competition and, in the long-run, lowered economic activity.

Recommendation:

- Regulations governing applications for and implementation of business licenses for large-scale retail facilities should be made more transparent and consistent. The Government should ensure that the exemption of larger cities (more than one million inhabitants) from new restrictions on new large-scale retailing is continuously respected under the revised City Planning Law implemented in 2007.

■ Liquor

Yearly status report: some progress. Since 2001, deregulation has gradually liberalised liquor licensing in the retail sector in Japan. The withdrawal of the interim measure establishing “Urgent Adjustment Areas” in September 2006 was a significant step towards complete liberalisation. The EBC applauds the progress made and asks the Government to apply the same measures to the wholesale market, where the lack of liberalisation is becoming an issue of increasing concern.

Recommendation:

- Wholesale liquor licensing should be completely deregulated.

■ Prohibitive import, certification and labelling rules

Yearly status report: limited progress. Reluctance to accept EN and ISO standards or CE marking of products exported to Japan delays the introduction of new products to the market and increases import costs. While accepting the need to safeguard consumer health and safety, the EBC urges the Governments of Japan and Europe to mutually recognise standards and products.

Recommendation:

- Japan and the EU should mutually accept regulations governing the application process for importing and selling/using products with particular consideration for consumer safety and health so that products certified for one market are automatically accepted in the other market.

■ Labelling of household products

Yearly status report: new issue. 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. Local governments inspect retailers regularly, seemingly with no legal grounds and issue a warning when finding violations. The combination of legal uncertainty and detailed rules cause considerable problems for retailers sourcing on a global basis. If forced to comply with these rules, they would have to alter their global production system adding unacceptable costs for customers.

Recommendation:

- METI 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.

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LEGAL SERVICES

Regulatory Developments

The past few years have witnessed a number of positive changes in the regulation of the legal profession in Japan, particularly as a result of the 2005 Foreign Lawyers Law, which lifted some restrictions on the form of association through which Japanese lawyers and foreign lawyers may operate. However, significant regulatory impediments to competition still remain, preventing firms of *bengoshi* and *gaiben* already collaborating together from incorporating their firms; restricting the advice foreign lawyers can give on third-country law; and preventing a foreign firm operating in Japan from benefiting from limited liability status recognised in its home market. Discriminatory regulations impact individuals as well as firms, requiring foreign employees to gain experience in the country in which they qualified before they can be licensed as a *gaiben* in Japan, and restricting Japanese lawyers from giving advice in the name of a foreign employer unless one of the firm's partners is also a Japanese lawyer. So long as these regulatory impediments continue, Japanese consumers will be deprived of choice in the crucial field of legal advice, while foreign firms will be unfairly deprived of potential customers.

As lawyers, the EBC Legal Services Committee follows legal developments closely. A number of significant reforms have been introduced by the Government in past years that have affected the legal structure of businesses in Japan. Foremost is the new Company Law, which generally came into force in 2006, and the new provisions enabling triangular mergers, which came into force in 2007, enabling foreign companies to use their own stock as consideration when merging with Japanese companies. This is an important step, though the liberalisation of the tax rules needs to be reviewed, as the current rules make the structure impractical for foreign companies that do not have a pre-existing substantial presence in Japan.

In dealing with "poison pill" schemes, also made possible by the new Company Law, the EBC believes that excessive defensive measures should not be permitted, and priority should always be placed on the interests of existing shareholders. To avoid such defensive measures being used as tools merely to maintain the interests of existing directors, strict conditions for activating poison pills should be applied – ideally the obtaining of the approval or endorsement of outside directors (*shagai torishimariyaku*) for implementation of the relevant scheme. Efforts should be made to ensure that "poison pills" are not used to block constructive proposals from new bidders. In addition, consideration should be given to whether the categories of "abusive bidders", which have been identified by the METI and in the courts, are necessarily appropriate in the light of the need in Japan for an improvement in returns on assets.

Another issue of concern is the application of the new rules relating to pre-approval of acquisitions of substantial interests in Japanese companies under the Foreign Exchange Law. The EBC urges the Government of Japan to ensure that the scheme is not used to restrict legitimate foreign investments in Japanese industry.

Prospects for EU-Japan Economic Integration

Foreign lawyers in Japan have provided a valuable service in introducing new corporate and financing techniques in Japan. They have a crucial role in the integration of both economies by providing assistance in interfacing between European and Japanese firms on cross-border investment, financial institutions investing or lending abroad, and in assisting Japanese companies wishing to access the European capital markets. Lawyers are, however, restricted in exercising their profession as legal qualifications are currently not recognised across jurisdictions and/or their activities are circumscribed by local rules.

Priorities

- **Mutual acceptance of legal qualifications, and acceptance of engagement in wider scope of activities as permitted by home jurisdiction rules**

Key Issues and Recommendations

■ Limited liability

Yearly status report: new issue. Under the current rules, limited liability status is not available to lawyers in Japan. This is consistent with the traditional position of lawyers in Japan, as court lawyers, rather than as handlers of complicated international commercial transactions and conductors of due diligence activities involving potential liabilities in the trillions of yen. Limited liability status is available to European firms in European jurisdictions. In many fields, professionals in Europe and other countries have been able to operate under a regime of limited liability, subject to financial disclosures, particularly in regard to the enormous potential liabilities for firms engaged in the financial markets. In Europe it has been considered unfair to exclude lawyers from the ability to participate in the use of such structures. However in Japan, the firms have to operate through individuals and their representatives in Japan are not permitted to have the benefit of the limited liability, which exposes all law firms in Japan to an inequitable level of risk.

Recommendation:

- A limited liability structure should be made available in Japan for both foreign and domestic law firms.

■ Bengoshi Hojin

Yearly status report: new issue. Under the current rules, it is not possible for a *gaiben* law firm, or a joint enterprise between *gaiben* and *bengoshi*, to establish themselves as a *bengoshi* corporation or *hojin*, which means it is not permitted for such firms to open more than one office in Japan as under current legislation only a *bengoshi hojin* is permitted to have more than one office. As the *bengoshi hojin* structure was recently introduced for Japanese firms, the EBC can see no reason why restrictions should apply only to foreign law firms merely on the pretext that there does not seem to be much current interest among these firms to establish branches.

Recommendation:

- The current discriminatory *bengoshi hojin* restrictions should be removed by making it be possible for *gaiben* firms and joint enterprises to establish *bengoshi hojin*.

■ Article 821

Yearly status report: no progress. Article 821 of the Company Law provides that a foreign company cannot conduct continuous transactions through a branch in Japan if the branch constitutes the de facto principal office of the company or if the primary purpose of the foreign company is to conduct operations in Japan. The Minister of Justice has given repeated assurances, both in Parliament and through a notification, that no new regulatory restrictions should be imposed on foreign companies as a result of the new article. We remain, however, concerned that Article 821 may bring into question the legality of many branches of foreign companies in Japan that otherwise are fully recognised legal entities.

Recommendation:

- Japan should amend Article 821 of the new Company Law to ensure legal certainty for branch offices of foreign companies operating in Japan. This would bring the law into line with the intent of the legislators as expressed in the resolutions attached to the Article by the Judicial Affairs Committee of the House of Councillors at the time of passage of the law.

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TAX

Regulatory Developments

New concepts of fundamental importance have been introduced to the corporate tax regime in Japan. The most notable of these has been the introduction of tax qualified corporate reorganisations and preferential withholding tax rates on dividends and capital gains (to stimulate the financial markets), both cornerstones of the Koizumi reform policies. Equally important is the system of consolidated taxation introduced in 2001. These reforms and the extension of the tax loss carry-forward period by two years were a crucial part of the economic restructuring process.

The introduction of the Bunsho Kaito (written reply system) has somewhat enhanced transparency and accountability, especially after the system was improved in 2004, entitling tax payers to written clarification of specific individual transactions. Another area where progress can be seen is the protection of confidentiality. Press reports on tax audits and about disputes between tax payers and tax authorities are less common now than five years ago. Moreover, information regarding amended corporate tax returns, usually filed in the course of tax audits, is no longer made public.

It is difficult to claim, however, that the Government of Japan has done enough to create a tax environment supportive of businesses. Tax deferral rules for cross-border mergers through the so-called triangular merger scheme are unnecessarily complex. The “business continuity test” especially imposes an insurmountable burden to market entrants. While the introduction of consolidated taxes was crucial, the qualifying conditions need to be relaxed if the system is to fulfil its potential.

Prospects for EU-Japan Economic Integration

A vital and robust economy is impacted by rules and regulations in the tax regime. The Government of Japan deserves credit for undertaking far-reaching tax reforms in recent years, however further measures are needed to create a tax system compatible with the globalisation of corporations and increased capital mobility. European firms continue to encounter inconsistent and arbitrary treatment from tax authorities and regulations that impede market access and growth. Discrepancies in the interpretation of common tax concepts found in European and Japanese tax laws, a deviation in the progress of tax treaty re-negotiations between Japan and European countries, inconsistent interpretation of OECD based transfer pricing policies, and a lack in clarity on rules pertaining to capital gains from cross-border mergers must be addressed.

Priorities

- **Eliminate double taxation between the EU and Japan**
- **Eliminate the withholding tax on dividends, royalties and interest. These should be reduced to 0% for qualified entities, such as provided for in the treaties recently concluded between Japan and the UK, France and the US**
- **Enable employer’s and employee’s contributions to social security systems within the EU and Japan to be tax deductible on a mutual basis**
- **Establish EU-Japan joint guidelines on interpretation and harmonise documentary requirements between the EU and Japan for transfer pricing assessments**

EBC Tax Committee Member Companies

ARQIS Foreign Law Office	Loyens & Loeff/Loyens & Volkmaars
ASG Tax Corporation	Mazars Japon
BASF Japan	Nippon Boehringer Ingelheim
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Henkel Japan	Shin Nihon Ernst & Young
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Key Issues and Recommendations

■ **Accountability and confidentiality**

Yearly status report: some progress. Taxpayers may now seek written clarification of specific transactions as a result of changes to the Bunsho Kaito system enacted in March 2004. Despite this improvement, an overall lack of transparency and systematic accountability continues to impede the development of business in Japan. European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. The EBC views any "leaking" of information protected by Japanese taxpayer confidentiality laws with extreme concern. The EBC welcomes the termination of both the publication of the annual list of top income taxpayers and the names of corporate taxpayers who have filed amended tax returns.

Recommendation:

- The National Tax Agency (NTA) should provide public and private letter rulings as a matter of international standard practice, and not only in response to requests received under the formal Bunsho Kaito system. Public rulings should be made available in an anonymous format on a regular basis. There should also be an option for private letter rulings to ensure confidentiality where an anonymous format would not ensure confidentiality, e.g. where a matter is well known to the public. Existing legislation protecting taxpayer confidentiality should be strictly enforced.

■ **M&A and corporate restructuring**

Yearly status report: progress. The tax treatment of triangular mergers, made possible through changes to the Company Law in May 2007, is in practical terms a barrier to market entrants (with no established business in Japan) using their shares to acquire a Japanese company. Current rules do not, in principle, allow for a tax deferral if the transaction is carried out using a Japanese special purpose company, although the definition of the latter is subject to debate. If the Government is committed to promoting investment to Japan, non-discriminatory treatment of foreign shares as currency in mergers with Japanese companies is the most important policy step to take. The 2006 tax reform introduced limitations on the utilization of tax loss carry forwards after the acquisition of more than 50% of the shares of a company. The EBC recommends that the new rules be applied narrowly and further clarified.

Recommendation:

- Current rules should be revised so as to permit a deferral of capital gains for shareholders receiving shares from a foreign company with no previous operations in Japan under the triangular merger scheme and other reorganization schemes.
- Rules and regulations underpinning the corporate reorganisation laws should be further clarified to reduce the discretion that the tax authorities retain in defining key concepts. Key terms such as "business continuity test" should be defined precisely to make the rules more transparent.
- Taxpayers should be able to obtain public or private letter rulings on whether or not an intended reorganisation complies with the conditions for a tax-qualified reorganisation.

■ **Consolidated taxation**

Yearly status report: no progress. Current restrictions on tax consolidation limit the consolidated tax system from being fully or actively utilized among corporate taxpayers in Japan.

Recommendation:

- A 50% threshold should replace the requirement that only 100% subsidiaries may be consolidated. Furthermore, the obligatory integration of all 100% subsidiaries if a group wishes to consolidate should be eliminated.
- The expiry of companies' pre-consolidation period losses when they enter the consolidated group should be eliminated, as well as the obligatory taxable revaluation of certain assets of companies entering the consolidated group.
- Local taxes should be included in the consolidation.

■ **Transfer pricing**

Yearly status report: limited progress. The Japanese tax authorities continue to base transfer pricing assessments on secret comparables which makes it difficult for the taxpayer to confirm product and functional similarities. Moreover, the use of secret comparables for audit assessments is inconsistent with the transfer pricing methodology of Advanced Price Agreements (APA), in which company-level profitability of public companies is commonly used as reference point.

Recommendation:

- Establish EU- Japan joint guidelines on interpretation and harmonise documentary requirements between the EU and Japan for transfer pricing assessment.
- Transfer pricing assessments should not be based on the use of secret comparable information, nor on any information to which the taxpayer does not have access. Furthermore, there should be consistency between the transfer pricing methodology for audit assessments, and that used for APAs.

■ **Tax treaties**

Yearly status report: some progress. Japan is currently re-negotiating tax treaties with the Netherlands and Germany.

Recommendation:

- The EBC encourages the Government of Japan to review current tax treaties with European countries and particularly welcomes treaties that include the exemption of withholding tax on royalties, and qualified dividends and interest such as the revised Japan-UK and Japan-France tax treaties.

■ **Factor-based taxation**

Yearly status report: no progress. Criteria other than profits, such as capital, employee expenses, etc., are part of the Corporate Enterprise Tax applicable to firms with share capital over ¥100 million. Such a tax discourages foreign investment and defies global trends that are moving away from the use of criteria contravening the principle to tax in accordance with the ability to pay.

Recommendation:

- The current factor-based taxation system should be revised.

■ **Financial markets**

Yearly status report: no progress. At present, the issue of permanent establishment taxation of private equity and hedge funds is unclear and ambiguous. Dividends and capital gains from portfolio investments are temporarily taxed at preferential withholding tax rates of 10% only.

Recommendation:

- Foreign-based private equity funds should be able to clearly determine whether their presence in the Japanese market will result in a taxable permanent establishment. The EBC welcomes the current domestic discussion on tax measures to revive the financial markets and appreciates any measure enabling a more flexible flow of capital to the equity markets. In particular, making current temporary tax benefits to equity investments permanent from 2008 onwards, will promote cross-border investments and international financial institutions in Japan.

■ **Reduction of corporate tax rates**

Yearly status report: no progress. The effective corporate tax rate for companies based in Tokyo with a share capital of ¥100 million and less is 42% (40.7% where the factor based tax applies imposing additional 0.48% on salaries, rents, interests, etc and 0.2% on equity).

Recommendation:

- The Government of Japan should reduce the effective tax rate from the current top international bracket to an average international level.

Financial Services

**Asset management
Banking
Insurance**

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ASSET MANAGEMENT

Regulatory Developments

Despite considerable growth in the asset management industry in Japan over the past years, due mainly to the liberalisation of the sales channels for funds, the Japanese Government continues to unduly restrain the operation of asset management companies. Rules governing the types of securities that asset managers may deal in are much more restrictive than in other global markets. Moreover, the approach to licensing remains inconsistent, with a variety of bodies issuing regulations and thereby driving up compliance costs. The creation of a new Financial Instruments and Exchange Law (FIEL) did not result in the consolidation of the two separate Trust Management and Investment Advisory Laws, although it became easier to obtain a sub-license after the law was introduced. Obstacles remain to the sales and service of offshore funds, inhibiting firms from taking a proactive approach to marketing the offshore products of their affiliates. There have been some bright spots, such as changes in the corporate pension system in 2001 and legislation introduced in 2003 allowing Japan Post to delegate fund management, but more regulatory reform is needed before asset management companies can operate effectively and efficiently for the benefit of Japanese consumers.

The licensing system is in need of urgent reform to ensure more consistency and transparency in the application process. The Financial Services Agency (FSA) and the Ministry of Finance (MOF) Bureaus have been reluctant to define and disclose the types of side-business that applicants may conduct. Restrictions on side business licences have in general been relaxed since the introduction of the Financial Instrument and Exchange Law in 2007, but different firms have received different authorisations, depending on the scope of the application submitted, even though the underlying business objectives do not differ substantially between firms.

This lack of regulatory consistency calls into question the supposed neutrality of the regulatory environment and makes it difficult for firms to pursue new business opportunities for fear of non-compliance. The EBC is disappointed that the creation of the Financial Instruments and Exchange Law (FIEL) did not address the problems of multiple rules and regulators. Although it was supposed to become a comprehensive law for all financial services, the FIEL does not incorporate the Investment Advisory Service Law and the Investment Trust Law.

Prospects for EU-Japan Economic Integration

Professional management of pooled assets is becoming increasingly important in Japan, as the financial basis of the social security system steadily weakens. With the birth-rate at its lowest level ever and the post-war baby-boom generation starting to retire, even a sustained economic upturn with a potentially increased tax base would be unlikely to reverse the trend of decreasing revenues. This is happening at a time when interest rates have remained at historically low levels for a long period, causing a clear shift in the market from a strong preference for traditional savings in bank (or post) accounts to an increased appetite for products with the potential for higher returns. By providing professional advice and innovative services in an increasingly complex market, global professional asset management companies can contribute to the more effective allocation of resources in the economy at large. Currently, financial services companies cannot provide clients with the same trust management and investment advisory services in Japan as they do in Europe due to strict firewall and severe license restrictions. The result of regulatory barriers is inefficiencies in resource allocation in the economy as a whole and less than optimal return on capital. Without a joint framework extending to all financial services, European and Japanese financial services companies will never be able to fully integrate their European and Japan operations and will continuously be restrained in providing the same products on both markets.

Priorities

- **Mutual acceptance of principles governing the financial services industry under a principle-based regulatory system**
- **Establishment of common rules and principles for trust management and investor advisory services**

Key Issues and Recommendations

■ **Creation of a single regulator for asset management**

Yearly status report: limited progress. Although the businesses of investment trust management and investment advisory services do not differ in content, these businesses require separate licensing, filing and customer disclosure requirements. The EBC is disappointed that the new Financial Instruments and Exchange Law (FIEL), which passed the Diet in May 2006, fails to truly integrate the competing legal frameworks governing the asset management industry. A transfer of supervision authority from the Ministry of Finance (MOF) to the Financial Services Agency (FSA) is likely to lead to the merger of the Japan Investment Trust Association (JITA), and the Japan Securities Investment Advisers Association (JSIAA).

Recommendation:

- The Government of Japan should harmonise its rules and regulations governing the asset management industry. The licensing system should be revised to ensure more consistency and transparency in the application process. Regulations related to licensing, filing and customer disclosure should be put into one regulatory framework under the supervision of the FSA only.

■ **Reporting requirements for publicly traded funds**

Yearly status report: limited progress. A revision to the Securities Exchange Law in 2006 altered the reporting system for professional investors, requiring them to report within five working days if their own stake in a listed company exceeds 5% of total stock and every second week in regards to the consolidated holdings of the whole financial group. When applied to asset management companies, this imposes not only a significant new administrative burden, but also requires sharing of customer information with other companies in the same financial group, which is strictly forbidden under the very same law. The EBC believes that discretionary investment advisors and investment trust managers should be treated differently from activist professional investors, and allowed to continue to report their share holdings once every three months and within 15 days when acquiring a more than 5% stake in a listed company.

Recommendation:

- Changes to existing law that would make publicly traded funds report holdings of shares in listed companies in excess of 5% every second week on a consolidated basis should be reconsidered. Such a measure would potentially entail violation both of firewall restrictions and of fiduciary duties towards customers, as well as imposing undue administrative burdens on asset management companies.

■ **Improve transparency by revising inspection practices**

Yearly status report: new issues. Firms inspected by the FSA usually have very little leeway for discussions and explanations when under inspection. The regulated entities are generally advised to agree with the conclusions of the inspectors, since failure to agree is deemed by the FSA to demonstrate a "lack of compliance consciousness", warranting harsher sanctions against the regulated entity itself, in addition to the usual guidance to the entity on appropriately punishing any employee responsible for infractions. The inspectors revisit other observations and increase the severity of their conclusions until the regulated entity agrees with their findings. Generally, because of these practices, regulated entities agree even when the findings conflict with their own conclusions and those of their outside advisors. Such a situation does nothing to advance understanding and transparency in financial regulation. Moreover, since the regulated entity is then ordered by the FSA not to discuss the contents of its inspection with any third party, the only public record is an announcement of the sanction on the FSA's website, offering insufficient detail to allow other regulated entities to understand what has happened.

Recommendation:

- Transparency and inspections should be improved by allowing third party lawyers to take part in inspections and give advice on the interpretation of laws, and also make the findings handed down to one regulated entity generally available to the industry as a whole by issuing ex parte "interpretive statements".

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BANKING

Regulatory Developments

Reform of the Japanese financial sector has been high on the Government's agenda ever since the burst of the bubble in the early 1990s. The Hashimoto "Big Bang" reforms initiated in 1998, which allowed for the formation of financial holding companies, was followed by consolidation of the banking sector and efforts to clean up bad debts and non-performing loans under the Koizumi cabinet. Multiple financial services regulators were streamlined and a no-action letter process was introduced to enhance transparency, while limited structural reform was achieved by enabling Japanese city banks to engage concurrently in trust and banking businesses.

However, much remains to be done to bring current regulations and practices in line with international standards. Reforms of trust banking have not been extended to foreign bank branches. Although an integrated legal framework supposedly covering all financial products was introduced with the Financial Instrument and Exchange Law in 2007, Japan has persisted in trying to manage risk through firewall regulations. This means the costly separation of banking, securities and asset management operations, long after the recourse to such regulations was abandoned in other major financial jurisdictions. The focus of financial regulators across the world has indeed shifted from simply forbidding companies to engage concurrently in certain types of businesses, to enforcing internal control and corporate governance mechanisms, which ensure that potentially conflicting interests (such as underwriting and brokerage) are kept separate. The trend is for regulators to work together with industry participants to develop clear codes of conduct and rules of enforcement. This kind of cooperation is still rare in Japan, hindered by a lack of understanding of the business on the part of the regulator as few personnel and experience transfers occur between the private sector and government.

Prospects for EU-Japan Economic Integration

Japan's relative prosperity has decreased considerably in the past decade, apparent in the steady decline of Japan's GDP per capita ranking, from second highest in the world in 1995 to a ranking of twentieth in 2006. Japanese consumers have continued to save throughout this period, but while the rest of the industrialized world has enjoyed record capital growth, their own return on their capital has been extremely poor. Innovative financial products and instruments commonly used in Europe have not been available in Japan as the regulatory framework is not conducive to services and structures that do not fit into predetermined categories and prescriptions. Firewall regulations not only imply administrative inefficiencies and obstacles to integrate the Japan business with global operations but also are, at times, in conflict with European home regulator requirements. Discrepancy in views on basic principles relating to risk management and handling conflicts of interests between regulators, makes it inherently difficult for firms to integrate Japan and EU businesses. European and Japanese financial institutions active on both markets have a lot to gain if the EU and Japan could unite on the general principals for good governance in the financial sector, once established, under a principle-based system. Common or mutually accepted principles of good governance in the financial sector should also lead to mutual acceptance of the home country regulator as the core regulator for generic aspects such as capital adequacy and proper governance structure. Such an acceptance of the home regulator as the core regulator, as is practiced in the integrated European market, would eliminate redundant administrative burdens and open up for a true integration and seamless development of innovative products for both markets.

Priorities

- Mutual acceptance of principles governing the financial services industry under a principle-based regulatory system
- Mutual acceptance of the home regulator as the core regulator

ABN AMRO Bank	Dresdner Kleinwort (Japan)
ABN AMRO Securities	HSBC
Banca di Roma	ING Bank
Barclays Bank	Intesa Sanpaolo
BNP Paribas	Rabobank Nederland
BNP Paribas Securities	RBS Securities Japan
Calyon Capital Markets	Shinsei Bank
Commerzbank	Societe Generale Securities (North Pacific)
Deutsche Securities	Standard Chartered Bank
Dresdner Bank	Swedbank

Key Issues and Recommendations

■ Integrated financial services market

Yearly status report: limited progress. Measures taken to date to relax the firewall regulations applicable to banks and securities companies have had little practical impact. Foreign groups are not permitted to be represented by a single country manager in Japan. Each of the business entities needs to maintain certain separate functions and organisational structures, which could otherwise be shared on a group basis. Such duplication creates inefficiencies, extra costs and makes it very difficult to integrate the Japan operations into the global business. The Globalisation Subcommittee under the Council for Economic and Fiscal Policies as well as the Internationalisation of the Financial Market Subcommittee under the Financial Council have recommended a review of firewall regulations to be concluded within 2007. The issue of foreign bank branches not being allowed to concurrently engage in trust and banking business through Japanese city banks remains unresolved.

Recommendation:

- The Japanese Government should abolish article 33 of the Financial Instruments Exchange Law (FIEL), which prohibits financial firms from operating banking and securities concurrently
- The Government of Japan should revise Article 1 of the Law concerning Concurrent Management of Trust Business by Financial Institutions to allow for branches of foreign banks in Japan to engage in trust and banking businesses concurrently, just as for Japanese city banks.

■ Regulatory transparency

Yearly status report: progress. Duplicate inspections by the Financial Services Agency (FSA), Securities & Exchange Surveillance Commission (SESC), Tokyo Stock Exchange (TSE), Japan Securities Dealers Association (JSDA), Ministry of Finance (MOF) and Bank of Japan (BOJ) have long caused an excessive administrative burden on regulated firms. The EBC welcomes efforts to streamline processes and clarify purpose, processes and legal sanctions applicable to the respective inspections, and encourages the Government to further increase efficiency and transparency. One area of critical concern is the lack of clear, generally valid guidelines. The trend in the industry is to seek “informal” advice rather than go through the cumbersome no-action letter process. The fact that the regulators are willing to give such informal guidance is welcome, but this approach presents a serious drawback: the guidance given is known to only one regulated entity and does not benefit the industry as a whole.

Recommendation:

- FSA rules and regulations should be applied consistently and clarified in accordance with fair and current universal guidelines. Firms should not have to wait for clarification to emerge from precedents established through inspections or informal consultations with the regulators.

■ Promote financial innovation by moving towards principle-based regulation

Yearly status report: new issue. Despite gradual change, the rule-basis of the Japanese regulatory environment leaves little room for innovation by the regulated entity, without extensive prior consultation with the regulator. This prescriptive, yet unclear, regulatory framework cannot keep up with the pace at which financial products and markets are changing. Regulated firms must be allowed greater flexibility to decide by themselves what business controls and processes should be put in place to achieve regulatory outcomes decided by the regulator. Over time, this would lead to a more competitive and innovative market. Continuous innovation and improvement are to be encouraged, not stifled, as they benefit consumers and markets. Continuous dialogue, rather than one-way consultation, between regulators and regulated entities on principles and structures is a prerequisite for good governance.

Recommendation:

- The FSA and other regulators should encourage innovation and competitiveness of the financial services markets by establishing general principles of good governance and an open-ended dialogue with regulated entities on how to comply with these principles.

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INSURANCE

Regulatory Developments

Substantial progress has been made in the regulatory environment of the insurance sector in recent years. Sales of insurance products through the bank channel have been partially deregulated, privatisation of Japan Post has begun, and the Financial Services Agency (FSA) is taking action to improve consumer protection that should result in the customer having a better understanding of product features, risks and fees. New reserving regulations were introduced for separate account products in 2005, and the FSA has launched a review of solvency margin standards which should result in methodologies that better reflect the wide range of product designs and improve risk management.

The EBC welcomes FSA plans to allow banks to sell all life and non-life insurance products from December 2007, and looks forward to this distribution channel operating under the same rules as other channels without unnecessary anti-pressure sales measures. Despite these developments in the regulatory environment, further work is required to reflect modern risk management techniques and for this sector in Japan to come into line with international standards.

Enhancing the regulatory environment for the insurance industry is critical to future development, particularly ensuring a level playing field for all sellers of insurance. Issues such as the privatisation of Japan Post, bringing Kyosai into the insurance framework, addressing solvency calculations, streamlining the product approval process, and clear and consistent application of rules and regulations are beneficial for the domestic financial business industry, consumers and Japan's ability to retain foreign investment

Prospects for EU-Japan Economic Integration

An Economic Integration Agreement should create freedom of capital and service provision to the market. Unless common rules are created, companies operating in both Japan and the EU will not be able to operate effectively. In recent years, the life insurance industry has seen growth in the medical and variable annuity sectors, the latter following the initial stage of bank assurance deregulation. The market share of foreign affiliates in Japan is increasing, but they continue to encounter regulatory obstacles that can limit efficient development of their businesses. An example of this is the rigid reserving and solvency regulations on variable annuity and variable life insurance products. The harmonisation of Japanese solvency and accounting methods with international standards is a priority that would have a direct positive impact on the ability of European companies to do business in Japan.

Priorities

- **Common rules on competition and regulation to ensure transparent, fair and equal rules for all issuers of insurance**
- **Common rules for solvency calculations using market-based techniques, based on Solvency II**
- **Common rules to improve the transparency and predictability of regulations, using a risk-focused approach**

Key Issues and Recommendations

■ **Creating a level playing field by establishing common rules for all actors**

Yearly status report: some progress. Japan Post was officially privatised in October 2007, however the government is still the only stockholder. The Postal Privatisation Committee has focused on the need to make Japan Post profitable by allowing the expansion of product lines. The Committee has acknowledged the need to strengthen compliance and risk management functions within the Japan Post Life Insurance Company (Kampo), but has not made this a priority. The implementation plan for privatisation also leaves many questions unanswered. A special section has been created within the FSA to deal with privatised Japan Post insurance and bank companies, but these privatised entities are not regulated by the same divisions as industry competitors. Despite amendments to the Insurance Business Law (IBL) to bring FSA supervision to the insurance business of unregulated Kyosai, the system remains inconsistent with some Kyosai still regulated under tailor-made laws.

Recommendation:

- The privatisation of Japan Post should be implemented in a manner that ensures a level playing field. The Kampo insurance business should be subject to the same regulatory oversight as well as capital, solvency margin, tax and policyholder protection funding requirements as private sector insurers. Limits are needed on expansion of product lines until compliance and risk management requirements have been met. Competitive safeguards should be established to prevent cross-subsidies from its existing dominant position.
- The FSA should conduct an inspection of Japan Post to ensure it fulfils the same compliance requirements as the private sector. The insurance business of all cooperative societies (kyosai) should be subject to the same regulatory and legal requirements as private sector insurers, including the Insurance Business Law (IBL) and FSA supervision.

■ **Solvency calculations**

Yearly status report: limited progress. Japanese solvency calculation methodologies inhibit product innovation and are a misleading indicator of the relative financial health of the insurers. Harmonisation with global best practices would force insurers to use modern simulation techniques to model risks (including operational risks), make senior management more aware of the risks faced, and resolve the mismatch between assets (which are marked to market) and liabilities (which are not). The establishment of the FSA Working Party on Solvency was a welcome development, but has not led to firm recommendations. What is needed now is a roadmap to solvency reform, with a clear and transparent process and open dialogue with the industry. Adopting a principles-based scheme would increase management awareness of risk and freedom to innovate in relation to emerging trends.

Recommendation:

- The EBC urges Japan to adopt methods being developed in Europe (Solvency II) and ensure consistency with ongoing solvency discussions by the International Association of Insurance Supervisors (IAIS).

■ **Policyholder protection corporation (PPC) reform**

Yearly status report: no progress. Debate has not yet begun on how to reform the life PPC in 2009.

Recommendation:

- Japan must begin discussions on reforming the PPC and move from a pre-funded system to a post-funded system to ensure it is used only as a last resort.

■ **Product approval process**

Yearly status report: no progress. The FSA product approval process is overly lengthy, and FSA availability is limited. This results in product development delays and makes effective planning difficult.

Recommendation:

- The FSA should increase the efficiency and flexibility of the approval process, enabling faster, more frequent and innovative product development. In the long term, a “file and use” system should be introduced.

Transportation & Communications

**Airlines
Business aviation
Logistics & Freight
Media & communications
Shipping
Telecommunications
Telecommunications equipment**

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AIRLINES

Regulatory Developments

Increased security concerns and sky-rocketing fuel cost have severely affected the global airline industry in the past few years, leading to higher costs and a substantial negative impact on route profitability. For European airlines operating in Japan, this situation has been exacerbated by the extreme weakening of the Japanese Yen against the Euro, the underdeveloped air transport infrastructure, restrictive pricing and high operating costs.

Airlines have limited means to sell products and services directly and transparently to consumers in Japan. Furthermore, airlines are only allowed to advertise and sell fares for international travel to and from Japan at rates officially approved by the International Air Transport Association (IATA), or in the case of Internet bookings, at rates within limits defined by the Ministry of Land Infrastructure and Transportation (MLIT). As the rates set by the IATA do not accurately reflect current market conditions, most individual fares are repackaged group discount tickets that can be sold only through licensed travel agents. Although restrictions on pricing and distribution have been relaxed for certain ticket types in the past two years, the permitted price range for certain IATA categories remains minimal.

The cost structure makes Japan the most expensive place in the world to operate airlines. Airlines have long been required to pay prohibitive landing fees, navigation charges, airport terminal rent, airport terminal common user charges, and cargo handling fees. While the EBC welcomes the drive to lower costs initiated by the management of the newly privatised Narita Airport, the EBC urges the Japanese government to continually work towards reducing charges overall. To date, the scope and pace of change has been disappointing.

Another area, which needs acute attention, is the lack of landing and take-off slots in Tokyo for routes to and from Europe. European carriers are lining up to increase frequencies and to add on new destinations, but only a few new slots have been allocated. The US-Japan Aviation Treaty has resulted in preferential treatment of trans-Pacific routes often connected with major Asian destinations. It is crucial that the Government of Japan does not introduce new discrimination between carriers, types of operations, and destinations when new slots become available at Haneda Airport.

Prospects for EU-Japan Economic Integration

The global economy depends on networks, be it telecommunication or transport on the ground or in the air. The services provided by the airlines are indispensable for the efficient functioning of the global economy. By the same token, the success of the Japanese economy is to a large extent dependent on a well-functioning link between Japan and other countries. European airlines are willing and ready to increase capacity to and from Japan, but the infrastructural constraints and regulatory environment do not permit the expansion of services. Improved access to the Kanto-market, more freedom in setting prices, and lower charges will enable international airlines to contribute to the economic development of Japan and support the Japanese Government in its ambitious plans to double foreign direct investment by 2011 and increase the number of visiting foreign tourists by 2010 to ten million per year. The EU and Japan should address issues with free pricing and access between Tokyo and Europe as an essential part of a EU-Japan Economic Integration Agreement.

Priorities

- Establish free pricing for routes between the EU and Japan
- Improve access between Europe and Japan with new slots at international airports in the Kanto region

Key Issues and Recommendations

■ Pricing and distribution

Yearly status report: progress. The pricing and distribution mechanism for air travel in Japan is still not efficient nor consumer friendly. Some restrictions continue to inhibit the development of direct sales to consumers, more so for international air travel than for domestic routes. The EBC welcomes the new pragmatic principle assuming the “automatic concurrence” of Japanese carriers with any price filed by European carriers at MLIT in 2006 and the new scheme for “promotion campaigns” introduced in May 2007. The abolishment of the de facto lower limit on economy class fares is expected in 2008. However restrictions remain on certain IATA ticket categories which results in a substantial administrative cost burden for both the airlines and the distribution sector.

Recommendation:

- The Government of Japan should fully deregulate the distribution, pricing and settlement of airfares in Japan so that carriers can publish competitive net fares in a transparent fashion directly to the consumer, including over the Internet. Foremost, the EBC recommends the gradual introduction of a wider range of advanced-purchase fares into the system and the abolition of the consideration of outdated IATA full economy fares as a minimum requirement to set business class fares. Ultimately a simple “file-and-use” system for pricing approval should be introduced to speed up all processes and reduce administrative costs. Restrictions on the direct transfer of net-remittances on market fares sold through IATA travel agents should be eliminated as soon as possible.

■ Airport infrastructure

Yearly status report: limited progress. In 2006 some slots at Narita were reallocated and offered to European countries for operations on the second runway, however this second runway does not allow take off of fully loaded long-distance aircrafts and only a few additional operations were thus possible. The extension of the second runway at Narita (which will not be implemented before 2010) must include an adequate taxiway system. The construction of a fourth runway at Haneda will be finalized by 2010. An expert group under the Council on Economic and Fiscal Policy of the Cabinet Office has recommended the unconditional opening up of Haneda for international traffic and MLIT has announced its intent to allow for regular international night flights after 2010. In the meantime, a special “scheduled charter flights” scheme has been introduced for point-to-point traffic in Asia and seasonal operations by Japanese carriers.

Recommendation:

- Haneda Airport should be opened up to regular international traffic, including flights to/from Europe, on a non-discriminatory basis.
- The flight movements per hour at Narita should be increased, and slots from the two runways at Narita pooled in order to generate higher productivity and subsequently lower unit costs for users.
- The second runway at Narita Airport should be extended to 2,500 meters and connected with adequate taxiways.

■ High costs

Yearly status report: limited progress. For Narita Airport an average net cost reduction effect of approximately 10% was negotiated. The EBC expects a further decrease following privatisation. In the long term, the Government of Japan needs to reduce the costs associated with the provision of air transport in Japan by as much as 50% in order to remain competitive with other hubs in Asia.

Recommendation:

- Prohibitive landing, navigation, and common user fees charged by airport authorities in Japan should be substantially reduced.

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BUSINESS AVIATION

Regulatory Developments

A range of issues and factors accounts for the slow development of business aviation in Japan. These include restrictive Extended-range Twin-engine Operational Performance Standards (ETOPS) requirements, a lack of suitable airports and infrastructure, difficulties in obtaining slots for landing at Haneda and Narita (Narita has just 5 slots a day allocated for business aviation), high landing fees and navigation costs, the lack of FBOs (Fixed Base Operators), and a lack of understanding within businesses and the government about the efficiency gains that can be achieved by using private aviation.

Nevertheless, general interest in business aviation is gradually increasing in Japan. Discussions on deregulation with the Japan Civil Aviation Bureau (JCAB) of MLIT are ongoing in the areas of operating certificates, continued airworthiness certificates, airport slot allocations, and landing and navigation fees. Although the problems faced by the industry are generally understood, progress is very slow and in some cases the business environment is deteriorating.

The lack of a prosperous business aviation industry puts Japan at a relative disadvantage in relation to other global financial centres. A more prominent business aviation industry would not only generate considerable revenue opportunities within Japan, but also make Japan much more accessible to foreign businesses and governments. Given the nature of the firms using corporate jets, Japan could be losing a major business opportunity every time a decision is made not to fly to Japan because of Japanese flight restrictions. More importantly, the relatively small business aviation industry also translates into a disadvantage for any global business based in Japan. Furthermore, Japanese corporations cannot use private jets for their operations to the same degree as their overseas competitors.

Prospects for EU-Japan Economic Integration

The business aviation industry is experiencing growth worldwide and forecasts indicate that the demand for business aircrafts will continue to rise. With new airline safety and security requirements in place at all international airports, many business people and governments are chartering aircrafts or considering buying a corporate jet to increase the efficiency of their respective operations. Nevertheless, there are relatively few business aircrafts in Japan considering Japan's position in the global economy. In 2005, close to 1000 flights were registered in Japan, 30% of which came from the USA, 30% from China, 10% from Europe, and the rest from other countries in Asia, while only 38 flights were operated by Japanese registered aircraft.

Priorities:

- **The EU and Japan should discuss and develop common business aviation rules according to best global practices**

Key Issues and Recommendations

■ Creation of a regulatory framework for business aviation

Yearly status report: limited progress. Japan does not have a regulatory framework specific to business aviation and on-demand charter flights. Instead, rules and standards for scheduled airlines are applied, without consideration of the special nature of the business. The application of complicated and strict rules created for operations involving several hundred passengers to operations requiring high flexibility is excessive and effectively hinders the development of business aviation in Japan. Japanese operational requirements for charter operators follow Federal Aviation Regulations (FAR) Part 121, rather than FAR Part 135, even though the latter standard was developed and is used for chartered and private flights globally. The Japanese situation is unique in that Extended-range Twin-engine Operational Performance Standards (ETOPS) requirements are applied to privately owned jets. This results in Japan-registered airplanes having to make detours while others can fly direct. Such excessive regulations force Japan-based operators to fly their aircraft under foreign registrations.

Recommendation:

- The Government of Japan must acknowledge the lack of services and infrastructure for business aviation in Japan.
- The EBC urges the Government to establish a regulatory regime enabling greater use of business aviation and on-demand charter flights in Japan.

■ Infrastructure for business aviation

Yearly status report: no progress. The requirements of business aviation are different from those of other airlines. VIP clearance, direct access to the aircraft, separate customs and immigration counters, fixed-base operators, and the availability of hangars are just a few of the factors that contribute to the efficiency of business aviation. These requirements are commonly met around the globe, but are not available in Japan.

Recommendation:

- A Government committee should be put in place to assess the need for business aviation infrastructure in Japan and issue recommendations for the next steps.
- The Government should establish the proper infrastructure to deal with the increased demand for business aviation. VIP treatment for users requiring smooth entry in and out of the country and direct access to aircraft must be improved.
- Foreign investors and companies should be encouraged to participate in the build-up of infrastructure for business aviation in Japan.

■ Maintenance and airworthiness

Yearly status report: limited progress. Certificates of airworthiness need to be renewed every year in Japan, irrespective of the number of hours flown, requiring a plane to be on the ground for about a month every year at high cost. Other countries have established programmes with aircraft manufacturers and are using progressive inspection schedules, which guarantee that the aircraft is always airworthy and not grounded for a “one-month” inspection. Such progressive inspections are tied to hours flown and ensure that aircrafts are repaired when necessary. Furthermore, Japanese maintenance requirements are out of line with international practice, exemplified in the type-certified mechanics system. Moreover, replacement parts have to be pre-certified making maintenance very slow, especially overseas, where Japanese certified parts are not accessible. Unnecessarily rigorous and Japan-specific regulations increase costs to such an extent that it makes little economic sense to own a business aircraft in Japan.

Recommendation:

- Regulations covering airworthiness and maintenance requirements should be brought in line with global best practice.
- Foreign maintenance companies should be encouraged to build facilities on Japanese airports.

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LOGISTICS & FREIGHT

Regulatory Developments

European carriers and forwarding companies in Japan struggle with high costs and insufficient infrastructure at international airports, rigid custom clearance procedures and outdated restrictions on foreign-owned companies engaging in domestic freight forwarding business in Japan. The newly privatised Japan Post aims to aggressively expand while still enjoying preferential regulatory treatment, thereby posing a serious threat to the functioning of the market and the ability of competitors to provide services to the Japanese public.

Japan Post is already competing with private-sector express carriers with the Express Mail Service (EMS), a special value-added international express package that today comprises around 18% of the outbound express market. EMS is increasingly popular among businesses, as well as with individual consumers. Japan Post is working hard to improve the quality of service in terms of speed, trace ability, reliability and increased weight range. It has further made EMS a key part of its business expansion plans, and focused on its expansion by collaborating with China Post and launching an advertisement campaign in leading business newspapers. As EMS is not subject to the same strict regulations that apply to other express services, the expansion is highly questionable from a competition point of view.

The Ministry of Internal Affairs and Communications (MIC) defends this regulatory discrepancy by arguing that EMS is part of basic universal service and, hence, should be regulated like regular letter mail. However, this argument disregards the fact that with EMS, Japan Post is directly competing with private-sector operators. Therefore EMS should be removed from the universal postal service, just as Japan Post's domestic parcel service ("Yu-Pack") was removed in 2005.

The privatisation implementation plan submitted by Japan Post has been accepted by the Postal Privatisation Committee to "be in line with the general guidelines" and hence consistent with equal footing requirements. However details of the plan are not publicly disclosed, disallowing any opportunity for questions or debate. The Government of Japan should make the complete privatisation plan public and address the issues and concerns raised by express delivery industry.

Prospects for EU-Japan Economic Integration

A well-functioning freight forwarding and logistics services market is crucial for global integration and competitiveness of the Japanese industry. All companies active in Japan, whether foreign or Japanese owned, with customers and/or operations outside of the country depend on efficient freight services both domestically and across borders. European companies offering Japanese consumers access to their worldwide logistic operations have largely been successful, but still face serious regulatory challenges. Distorted competition caused by a discrepancy in rules and regulations for carriers providing the same services, prohibitive costs, insufficient infrastructure at airports, and restrictions on foreign-owned carriers ultimately results in inefficiencies and higher prices for users. The recent privatisation will allow Japan Post to expand its business area to logistics services. If Japan Post continues to enjoy regulatory and financial benefits unavailable to private international express carriers and freight forwarders, it will not only have an adverse effect on the economic vitality of the logistics, express delivery and postal sector, but also the Japanese economy as a whole. Freight forwarders play a crucial role as facilitators in the economic integration of the EU and Japan. Facilitating logistics capability through a unified regulatory structure should, therefore, be at the core of an EU-Japan Economic Integration Agreement.

Priorities

- **Establish common competition rules ensuring the elimination of any regulations that cause discrepancies between companies and distort free and open competition with the view of granting the complete freedom in the provision of services between the EU and Japan**
- **Abolish any restriction on foreign ownership in freight businesses**

Key Issues and Recommendations

■ Customs clearance

Yearly status report: new issue. Freight forwarders and express carriers employ hundreds of people to clear cargo through customs for both imports and exports and pay several hundred million yen for overtime work of the Customs offices and the use of the online clearance system (NACCS) to ensure that high-quality service is provided to customers. Freight forwarder and express carrier companies are required to declare details of the shipments and to pay customs duty on behalf of their customers. The newly privatised Japan Post is not required to undertake any of these costly measures as Custom officers themselves perform the inspections and hence the costs are a public expense covered by tax revenue. Acknowledging this discrepancy, the Ministry of Finance (MOF) revised the Customs Law so as to require that all postal cargo from Japan Post valued above 200,000 Yen is subject to the same customs clearance procedures as applied to international express carriers. However, cargo from other international express carriers must undergo customs clearance procedures when cargo is valued above 10,000 Yen. A timetable has not yet been set for Japan Post to comply with the same 10,000-Yen limit imposed on the other international carriers.

Recommendation:

- The Government of Japan should revise the postal service law so that all EMS cargo, regardless of value, is subject to same custom clearance procedure.

■ Security

Yearly status report: new issue. Private freight and express carriers are subject to security regulations implemented by the Ministry of Land, Infrastructure and Transport (MLIT) and the MOF but these regulations do not apply to Japan Post. Security is an issue of increasing importance in the world today and for Japan Post to be exempt from complying with the standards expected by the rest of the industry in Japan seems an anomaly and constitutes not only an unfair competitive advantage, but also a potential security threat.

Recommendation:

- The Government of Japan should ensure that Japan Post is subject to the same regulations and supervised by the same regulatory agencies as all other private carriers.

■ Exemption from parking laws

Yearly status report: new issue. Local police agencies have exempted postal vehicles from the parking law. While private express carriers' vehicles are prohibited from and ticketed for parking, postal vehicles carrying EMS are parking in the same locations without a similar penalty. In busy commercial areas this is a significant advantage. Recently, the police agency declared that they will remove EMS pick-up from the exemption of parking law restrictions and apply the same approach as for "Yu-pack" pick-up. However, it is unclear how the police can distinguish between pick-up of EMS and other mail services as the same vans are used for these services.

Recommendation:

- The Government of Japan should enforce the same parking law restrictions on all express carriers.

■ Ban on foreign operations

Yearly status report: new issue. The Freight Forwarding Business Law was introduced in Japan to support the creation of an integrated freight forwarding industry utilising all different freight modalities (sea, land, railway and air). However, the law forbids foreigners (a person who does not have Japanese citizenship or a corporation based in foreign country, or a foreign-controlled local company) to engage in domestic air freight forwarding business. The restriction applies only to air freight. This implies that a European freight forwarder is allowed to transport shipments from customers' sites to the gateways on road and/or rail, but may not use air within Japan.

Recommendation:

- The Government of Japan should revise the Freight Forwarding Law so as to allow foreign companies to engage in domestic air freight.

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MEDIA & COMMUNICATIONS

Regulatory Developments

The Japanese media market is massive. No country in the world prints more newspapers per day, and few countries have such a high rate of television penetration and viewing. Some 3,600 separate magazine titles publish over 4 billion copies per year, while the advertising market is the second largest in the world. Although these figures suggest a thoroughly modern industry, it is difficult to maintain that the Japanese media is functioning in a similar way as in other leading markets in the world. The Japanese media industry continuously places emphasis on traditional face-to-face meetings and harmonious relations, resulting in a rather closed market, difficult for outsiders to penetrate.

Closed and exclusive business practices pervade most sectors of the media industry. In journalism for example, the prevalence of the *kisha* clubs effectively controls the flow of information from official sources to consumers. Although membership at *kisha* clubs was extended to include properly accredited European journalists in 2002 following criticism from the Delegation of the European Commission to Japan, the nature of these clubs makes them structurally inclined to favour the source rather than the public's right to information. Moreover, the fact that freelance and magazine journalists – including Japanese nationals – are still barred from joining the *kisha* clubs constitutes a de facto restriction on press freedom.

Currently dominated by a handful of firms, the advertising industry employs methods that are not in line with international standards. The cost of media buying, for example, is often not disclosed by agencies to advertisers, a practice that clearly benefits the agency. The largest agencies have a near total monopoly of the market and maintain a status quo by agreeing not to interfere in each other's business. The dominant agency is directly involved in monitoring both print and television, casting further doubt on the impartiality and fairness of the industry. In comparison, the media market in countries such as the UK or France are much more competition driven. In the case of the UK, auditing of circulation numbers is thorough and provides transparency for advertisers, whereas in France, legislation makes the disclosure of fees and rewards mandatory. As a result, advertisers are properly protected in both markets.

The Japanese government has been slow in taking on the issue of media convergence. Piecemeal legislation has delayed the transformation to a consumer-driven media market and prolonged the dominance of the quasi-monopolistic traditional broadcasting firms. Rather than enabling the access of smaller players to the growing content-provision area of the Internet, the status quo has been protected, limiting user access to new content via new technologies. An effective flow of information and a transparent communications structure are of crucial importance to allow for deeper economic integration across borders.

Prospects for EU-Japan Economic Integration

Japan is one of the most media-intensive societies and holds the second largest advertising market in the world worth nearly 6 trillion yen (37 billion euros) in 2006. After the economic hardship of the past decade, demand for advertising has started to grow again and overall expenditures have increased for the past three years. The media and advertising industry in Japan remains relatively closed and highly influenced by the government, public organisations and mega corporations. European companies and foreign journalists have specifically highlighted the limited flow of information to foreign press, the restrictive *kisha* club system and the lack of transparency and competition in the advertising industry. Recent attempts by new IT companies to buy into or merge with 'old' media organisations have so far failed. As a competitive global economy that aims to attract foreign investment and become an international financial centre, Japan should take measures to promote the free flow of information and foster market competition in the communications sector.

Priorities

- EU-Japan common competition rules should include mandatory pricing disclosure for advertisement positions in media

Key Issues and Recommendations

■ Competition and transparency in advertising

Yearly status report: no progress. The advertising market in Japan lacks fair competition. Publishing companies are not required to transfer advertising positions to the paying advertiser and sell positions to the middlemen – the advertising agencies - without knowledge to the end user - the advertiser. Advertisers are normally not informed about the net fares, information made available only to the publisher and advertising agencies. This practice leads to monopolisation and a structural bias for established interests. The industry also lacks reliable and meaningful circulation figures putting buyers and newcomers to the industry at a further disadvantage. The Fair Trade Commission has been looking into these problems, but corrective measures have not yet been undertaken in the sector.

Recommendation:

- The Government of Japan should enforce accurate circulation reporting by establishing meaningful benchmarks for auditing. It should also ensure that such third party auditing firms are impartial and free from undue influence.
- The Government of Japan should foster an open market among publishers by making mandatory, the disclosure of advertisement positions in media.

■ Broadcasting and telecommunications convergence

Yearly status report: new issue. The broadcasting and telecommunications industries have long been highly regulated areas, due to the high impact they have on the public. However, the current structure of the sector, with dominant vertical players along with the lack of a comprehensive legal framework, is inhibiting the development of a converged market, where consumers can choose how and when to view contents. While convergence of media and IT is progressing in Europe and North America, Japan has been slow to provide the necessary direction to the market actors and is only now trying to catch up.

Recommendation:

- The Government of Japan should focus on access standards, and let the free market determine which media shall prevail. Consumers should be given the choice as to which contents they wish to view, as well as how they view these contents.
- The Government should put in place a legal infrastructure to enable Internet transmissions of copyright-protected broadcasts.

■ Reporting of financial information

Yearly status report: some progress. Financial news regarding listed companies is often leaked in advance to the largest business-daily newspaper ahead of the scheduled release date, placing foreign media at a major disadvantage. The Japanese government has openly claimed an interest in boosting foreign investment, therefore the needs of these investors – and the media who serve them – should be met in a fair and equal manner.

Recommendation:

- The Government should monitor and punish companies that do not control leaks of sensitive financial information ahead of established reporting time.

■ Kisha Clubs

Yearly status report: no progress. The *kisha* club system still nurtures an environment where public organisations and semi-private companies control the flow of information, to the detriment of fair and unbiased reporting. Loyalty is rewarded by “leaks” of sensitive information, further perpetuating inherent bias in the media.

Recommendation:

- The Japanese Government should continue to monitor the practices of *kisha* clubs and ensure that the needs of the public are met by the *kisha* club system and the way it functions.

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SHIPPING

Regulatory Developments

The international supply chain provides the vehicle for globalisation and thus facilitates the development of vast new opportunities for countries, companies and consumers. To maintain its position as one of the largest economies in the world, Japan needs to remain part of this supply chain by offering competitive and efficient port and harbour facilities. Costs associated with the provision of shipping services and port operations in Japan are amongst the highest in the world. Foreign shipping companies account for 70-75% of all containerised traffic in and out of Japan. Its European members offer considerable experience of operating in Japan and internationally, including in the global containerisation business. They would be pleased to share their experience and insights in a regular dialogue with the Ministry of Land, Infrastructure and Transport (MLIT), aiming to identify opportunities where mutual efforts could lead to increased productivity and efficiency gains at Japanese ports.

Reforms aimed at improving Japan's overall business infrastructure have not done more to remedy the challenges to shipping services. The Super Core Port initiative, announced by the MLIT in November 2002, has yet to yield tangible improvements to the high cost structure of Japan ports. The development of Japanese container ports and terminals is being initiated by local authorities rather than by the central government so that the anticipated economies of scale and efficiencies will remain difficult to achieve.

Recently the Japanese Government has begun promoting local Japan ports as part of the 'Asia Gateway' program striving to enhance shipments to and from Japan to other Asian countries. Usually smaller sized vessels are being employed on these routes and such smaller vessels have more port and terminal alternatives in Japan. These alternatives also create competition and thus terminal costs for the 'Asia gateway' are much more competitive than costs for major trunk line shipping operators.

Initiatives such as the 'Asia gateway' could be the first genuine step towards creating competition if it were extended to larger terminals. Offering a wide array of ports for shipping lines to foster competition is almost critical at this point, because cargo will continue to shift away from direct Japan services to transshipment services through other Asian countries if low cost and efficient alternatives are not provided. Therefore, Japan risks becoming more dependent on services and reliability in other countries for the handling of its own exports and imports rather than direct connections from its own ports. Such a situation would significantly undermine the international trading interests in Japan and the economy of Japan as a whole.

Competition on the Japanese waterfront is stalled by the current system of "prior consultation". Under this system, all changes to shipping line operations that might possibly reduce employment or adversely affect working conditions require prior approval from the Japan Harbour Transportation Association (JHTA), an organisation comprised of all major waterfront businesses except shipping lines. The JHTA reviews applications for changes (from the extremely minor to the potentially significant) and, after consulting with labour unions and other relevant parties, hands down a decision that shipping lines are effectively bound to accept. The system lacks transparency and effectively gives the JHTA and its members the means to inhibit shipping lines from seeking competitive bids for waterfront services.

Key Issues and Recommendations

■ Port costs and development

Yearly status report: limited progress. Port costs in Japan are exceptionally high in comparison to other advanced economic nations. High costs not only hinder European companies from operating to their maximum potential in Japan, but also drive many Japanese companies to switch production overseas and ship lower volumes through Japanese ports. High port costs also undermine the competitive position of Japanese ports in Asia, for example in the provision of trans-shipping services, as Korea and China offer far more competitive services. Furthermore foreign shipping lines are still not allowed to trans-ship their own overseas cargo on their own vessels in Japan, thus encouraging them to trans-ship such cargo in other countries, further reducing business at Japanese ports. Whilst this applies to shipments within a European country as well, it is possible for a Japanese carrier to transport cargo within the EU e.g. from Germany to France, which meets geographical and environmental requirements.

Recommendation:

- The Government of Japan should address the high cost of the port operations structure within the Asia Gateway Strategy Council.

■ Transparency in supervision of port operations

Yearly status report: limited progress. The Japan Harbour Transport Association (JHTA) still wields enormous discretionary power on the waterfront. Shipping lines wishing to make changes to their operations require prior approval from the JHTA. The process lacks transparency and effectively prevents shipping lines from seeking alternative, competitive services on the waterfront.

Recommendation:

- The Government of Japan should allow shipping companies to freely change their operations without seeking prior approval from the JHTA for routine business matters.

■ Terminal operations

Yearly status report: limited progress. Shipping lines still have to apply for a license to operate a terminal and whilst MLIT has committed to processing applications within two months of receipt, requirements such as minimum employment levels prevent the development of a competitive market for port services in Japan. It is not yet possible for a foreign company to set up its own terminal handling operations in Japan.

Recommendation:

- The Japanese Government should enable companies to establish new terminal operations, including those operated by shipping lines by providing concrete guidance on how to establish operations in practice, now that the legal framework is in place.

■ Competitive bidding for stevedore services

Yearly status report: no progress. While changes to the Harbour Transport Law implemented in November 2000 enables shipping lines to subcontract with multiple stevedore firms at confidential rates, in reality the concept of independent and systematic competitive bidding has yet to be implemented.

Recommendation:

- Competitive bidding for stevedore services through open tenders should be promoted and regulated.

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TELECOMMUNICATIONS

Regulatory Developments

The past years have seen great change in the Japanese telecommunications market with rapid technological and market development, including the explosion of broadband services and IP-based telephony, and successive regulatory reforms. The EBC had high hopes that liberalisation would lead to greater transparency and fairer competition.

In 2001, the Diet passed legislation reforming the Telecommunications Business Law (TBL). This introduced the dominant carrier concept and addressed anti-competitive conduct, structural and accounting separation, and the establishment of a dispute resolution commission. In 2002, further revisions were announced, including the elimination of licensing categories based on the ownership of facilities and the elimination of the requirement for carriers to file tariffs. However, while welcoming the reduction in the regulatory burden, the EBC raised concerns that the new laws and their implementing ordinances would not sufficiently regulate the market power enjoyed by the NTT Group companies and could actually facilitate NTT leveraging its dominant position into new business areas. The EBC therefore found it necessary to press for the strengthening of competitive safeguards against the abuse of dominance.

Despite these changes in the Japanese market over the past five years, interconnection fees have remained stubbornly high compared to other OECD countries and were the subject of an unprecedented court case brought against the regulator by a group of Japanese and foreign carriers when further fee increases were announced. Benefits of the decision to exclude Non Traffic Sensitive (NTS) costs from the fixed interconnection charge were undermined by the very long phase-out period (five years) granted to NTT and the creation of a Universal Service Fund, which will simply allow NTT to recover NTS costs by another route.

Meanwhile, the Government's spectrum allocation policy for the 1.7 GHz and 2.0 GHz spectra bears the potential for further concentration of the 3G spectrum in the hands of the dominant mobile operator, although limited spectrum was allocated to new entry carriers in 2006. The use of current subscriber numbers as the main factor by which growth needs are determined risks causing considerable damage to the competitive environment in Japan. The allocation policy has been a major factor in the EBC's continuing call for fundamental reform of the institutional structure of Japan's telecommunications regulatory environment, including full privatisation of NTT and the establishment of a regulator independent of the Government and commercial interests.

Prospects for EU-Japan Economic Integration

The global economy is increasingly dependent on access to well functioning networks. The fee structure for connectivity is a crucial element for the success of many businesses. Whilst Japan developed one of the most sophisticated information infrastructures in the world, it remains one of the most regulated telecommunications markets. In most markets, operators in Japan can do very little without first consulting and obtaining the formal or informal approval of the regulator. Regulatory supervision and control extends to almost every aspect of business. This restrictive business environment has been a major factor in the decisions of European carriers to withdraw from Japan. In order to recreate confidence in the market, the EBC urges the Government of Japan to implement measures that guarantee transparent costs, ensure that charges to competitors are cost-based, and monitor anti-competitive behaviour in relation to the price and non-price terms of supply.

Priorities

- **EU-Japan common competition rules should include guidelines on funding Universal Services and calculating connection fees**

Key Issues and Recommendations

■ Strengthening the competitive safeguard

Yearly status report: limited progress. The existing regulatory framework is not sufficiently effective in preventing anti-competitive behaviour by the dominant carrier. In many ways, revisions to the Telecommunication Business Law in 2003 have made the situation even worse. The EBC urges the Ministry of Internal Affairs and Communications (MIC) to strengthen the establishment of effective process and procedure to ensure effective competition. This is particularly important in new market segments. Current developments suggest that voice, data and video applications will merge together into multiple applications within the same IP network in the near future. In such an environment, with both vertical and horizontal service providers on the market, it is crucial that policies are put in place to ensure fair and transparent access to IP networks. Such a policy prescribes that current competitive imbalances will not be carried over to the next generation telecom service market.

Recommendation:

- The Ministry of Internal Affairs and Communications (MIC) should put emphasis on effective process and procedure to ensure the equality of access to the bottleneck facility, including in many cases the last mile offered by the dominant local access provider, NTT. The Government should ensure that all operators receive services from the dominant provider on the same terms and conditions as NTT offers to the companies of its retail arm. The dominant carrier should be obliged to work with other carriers to ensure interconnectability on IP networks as well.

■ Interconnection charge and Universal Service

Yearly status report: limited progress. A new formula in which all subscribers to telecom services contribute a set monthly amount to establish a Universal Service Fund has been implemented without the dominant carrier being forced to establish costs imposed on them for maintaining the network. The EBC welcomes plans to suspend the universal fund freeing NTT from its universal service obligation by establishing a tax-financed scheme providing IP telephony and other voice services also to rural areas. The interconnection charge will remain a key area, especially for the IP network, known as NGN. Interconnection charges remain unreasonably high.

Recommendation:

- The Government should ensure that any Universal Fund or any other future universal services scheme recovers only the actual costs for maintaining a common infrastructure. The Government should also ensure fair competition between the dominant and competitive operators by revising the calculation of interconnection charges and Universal Service charges for IP-IP, IP-Legacy, and the Legacy-Legacy network.

■ Institutional reform

Yearly status report: limited progress. It is inappropriate for the Government to act as both regulator and shareholder. The MIC has wide-ranging statutory powers of intervention and control in the Japanese telecommunications sector. The absence of a clear separation between the Government as both owner and regulator introduces a high degree of uncertainty and unpredictability into the regulatory process. Most other countries have independent regulators who are obliged to promote only the long-term interest of consumers and a competitive market environment. Accountability could also be improved by strengthening the public consultation process. At present, important policy decisions are usually made before the public is given a fair chance to comment.

Recommendation:

- The Government of Japan should reform the institutional structure of its telecommunications regulatory environment. NTT should be fully privatised and a regulator independent from commercial interests and the Government should be installed.

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TELECOMMUNICATIONS EQUIPMENT

Regulatory Developments

The Japanese Government was largely successful in implementing the national “IT Strategy” goal of making Japan a leader in IT by the year 2005. Internet access costs have decreased dramatically and access to broadband infrastructure is now amongst the most developed in the world. Following this success, in 2006, the e-Japan Strategy devised by the IT Strategic Headquarters set out to improve the hyper-speed network infrastructure, competition policy, e-commerce, and e-government. The agenda also includes a new competition framework underway in a special committee on the “Optimum Competition Policies for the Telecommunications Industry to Promote the IT Revolution”. The Japanese government is also considering strategic measures to further strengthen their competitive edge in the global telecommunications market, in terms of research, development, standardization and structure of the domestic market.

The EBC appreciates the opportunity to contribute to Ministry of Internal Affairs and Communications (MIC) policy committees as an official participant and respects the Government’s overall commitment to an industry-led, global approach to standards and platform development. Important steps have been taken to facilitate the product approval process firstly, by signing an EU-Japan Mutual Recognition Agreement (MRA) for telecommunications terminal equipment in 2001 and, secondly, by introducing a Supplier’s Self Verification of Conformity in 2004.

Despite these significant achievements, however, implementation to date has been disappointing. The number of accredited testing bodies designated under the Mutual Recognition Agreement (MRA) remains low and the self verification of conformity still applies only to wired telecommunications terminals, with limited application to wireless/radio equipment. Shortcomings in public sector procurement practices must also be addressed, if the public sector is to benefit from genuinely competitive product offerings. Fragmented qualifying procedures, sole sourcing, and selectively disclosed specifications for certain projects continue to inhibit foreign firms from supplying Japanese government entities with telecommunications equipment. The EBC urges the Japanese government to make further improvements to areas such as disclosure, bid criteria/performance specifications, qualification procedures, and open bidding procedures to ensure that public sector procurement of foreign telecommunications equipment keeps pace with the private sector.

Prospects for EU-Japan Economic Integration

Japan is the second largest telecommunications equipment market in the world. Telecommunications equipment accounts for 12.5% of Japan’s total industrial output worth an estimated 108 billion euros. Structural reforms under the Government of Japan’s IT Strategy have supported the introduction of a high-speed, large-capacity IT infrastructure, lowering of communications rates, and the development of e-commerce and e-government. The EBC urges the Government of Japan to further strengthen international competitiveness, innovation and productivity in the sector by stimulating competition, opening up public procurement, and adopting global product standards. With the view of deepening the economic integration between the EU and Japan, duplication of telecom equipment products certification for the European and Japanese markets should be eliminated. An economic integration agreement between the EU and Japan should establish true mutual acceptance in which telecommunications equipment products certified for either the European or Japanese markets would automatically be approved in the other. The current framework provides only for recognised certification organisations to test for both markets.

Priorities

- **Mutual acceptance of technical standards and certifications for all telecommunications equipment**
- **Inclusion of telecom equipment in discussions on public procurement in an economic integration agreement**

Key Issues and Recommendations

■ **Establishing common technical standards and certification procedures**

Yearly status report: some progress. Although the details are not substantially different, the EU and Japan maintain different technical standards for the same products, which means double testing and certification for manufacturers. The current EU- Japan Mutual Recognition Agreement provides only for recognised certification organisations to test for both markets. The certification process in Japan is also different from Europe. The EBC welcomed the introduction of Self Verification of Conformity by the Japanese Government at the beginning of 2004, which is similar to the Suppliers Declaration of Conformity (SDoC) introduced in Europe. However, the EBC is disappointed that this system is limited to wired telecommunications terminals with limited application to wireless/radio equipment, and that the application has not been expanded to other telecommunication equipment.

Recommendation:

- The EU and Japan should establish mutual acceptance of technical standards and certifications for all telecommunications equipment.
- SDoCs issued by European producers should be accepted in Japan without any additional testing or administrative requirements, not only for wired terminals, but also for specified radio equipment.

■ **Harmonization in spectrum for IMT-Advanced (systems beyond IMT-2000)**

Yearly status report: no progress. The International Telecom Union plans to identify spectrum for IMT-Advanced and IMT-2000 according to the Agenda Item 1.4 of the World Radio Communication Conference in 2007. The EBC acknowledges that the Japanese Government has been active in trying to identify a globally harmonized spectrum identification system for IMT-Advanced. This system would bring enormous benefits to the industry and consumers by eliminating the need to develop local variations of new telecommunication equipment while the economy of scale would lower prices on products and facilitate international roaming.

Recommendation:

- The Japanese government should, jointly with other governments, work to realise globally harmonised spectrum identification for the IMT-Advanced system in the World Radio Communication Conference in 2007.

■ **Network neutrality**

Yearly status report: new issue. The Japanese Government is discussing a new framework of rules to ensure network neutrality in the Internet and Next Generation Networking (NGN). It is widely argued that such a framework would grant users (consumers) so-called “net freedoms” such as access to all lawful Internet content, freedom to run applications/services of their choice, freedom to connect the equipment of their choice to the network, and freedom to take advantage of competitive offers, as long as these actions do not disturb the network or degrade its performance.

Recommendation:

- While fully supporting the network neutrality concept as an appropriate guideline for all actors on the market and respecting the existing obligations on dominant service providers, the EBC urges the government to refrain from introducing any new rules or obligations that are not harmonised

Health Science

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Medical diagnostics
Medical equipment
Pharmaceuticals
Vaccines**

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ANIMAL HEALTH

Regulatory Developments

In recent years, the business climate for European companies operating in Japan has been difficult. The Government has been trying to reinforce consumer protection, which should have been consistent with the promotion of consumer welfare and better access to beneficial new products. Instead, the effort has merely increased bureaucracy. Thus the Government commitment, made in 1995 and reconfirmed every year since, to approve new products within 12 months of the initial application is still rarely achieved. The creation of the Food Safety Commission (FSC) in July 2003 has added further regulation resulting in a growing backlog of products awaiting approval. Equally, revisions to the Pharmaceutical Affairs Law (PAL) introduced in April 2005 have imposed additional certification and compliance requirements, when faster and less costly approaches would have achieved the same results.

A benchmark study conducted by the International Federation of Animal Health suggests that the application process for product approvals in Japan lacks speed, predictability and quality. Moreover, in spite of global trends to streamline approval processes, Japan-specific data still have to be added to dossiers for new product applications, at times without any obvious scientific justification. If these conditions persist, international animal health companies will be increasingly likely to stop developing products for the Japanese market.

Reduced requirements in the area of batch-release toxicity testing for feed-grade antibiotic products have shown how administrative burdens can be reduced without compromising animal or consumer welfare. The same is true for the elimination of the national assay for most in-vitro diagnostics in August 2006. Further government action is now urgently needed to develop a more appropriate risk-based approach that will eliminate unnecessary steps throughout the product approval and post-approval processes.

Given the expected implementation of a seed-lot system and an accelerating global trend towards self-regulation to ensure product conformance under the Good Manufacturing Practice (GMP) regime, the EBC encourages the Japanese government to continue shifting from the use of the national assay to in-house testing for veterinary biological products.

Prospects for EU-Japan Economic Integration

Introduction of innovative European animal health products into Japan such as veterinary pharmaceutical products, veterinary vaccines and feed additives is essential to enhancing animal health and public health for companion animals and food animals. Japan is one of the largest animal health products markets and therefore of crucial importance to European manufacturers. However, the current regulatory regime lacks transparency, and arduous administrative processes obstruct the introduction of products that have already been accepted in the EU, into the Japanese market.

Priorities

- **Mutual recognition of European and Japanese marketing authorisation for veterinary products. In the meantime, mutual recognition of GMP certification of veterinary medicines**
- **Harmonised regulations on animal vaccines by abandoning National Assays and ensuring product conformance under a unified GMP regime**

Key Issues and Recommendations

■ Product approvals

Yearly status report: regress. Products already approved in the EU have to undergo further rigorous controls and tests before being accepted in Japan although reasons related to safety remain obscure. The Ministry of Agriculture, Forestry and Fisheries (MAFF) has set a standard administrative review process of 12 months, but this target is rarely met. Delays derive from the long time allowed to elapse between the submission of a dossier and the so-called “hearing” at MAFF; the slowness of the review process carried out by the Food Safety Commission; and finally from excessive time in issuing notification after the Executive Committee (Yakuji-Bunkakai) has approved the product. The review of registration dossiers has been transferred from MAFF headquarters to the National Veterinary Assay Laboratory with the aim of speeding up and improving efficiency of the process. The result has been an increased regulatory burden and even longer review periods. The administrative procedures need to be streamlined and accelerated. Moreover, unnecessary and scientifically unjustified requirements should be eliminated. MAFF should use all possible means to accelerate administrative processes so that reviews are completed within 12 months, especially for products that do not need a review by the FSC.

Recommendation:

- The Government of Japan should take all measures available to speed up product approvals and completely harmonise domestic regulations with international practices, including recognition of European certification schemes.
- Additional local clinical trials should not be required for human-use drugs already in wide use by veterinarians and for which effectiveness is well documented.
- Guidelines for in-vivo bio-equivalence studies in animals should be swiftly introduced to enable MAFF to accept data from international trials and make local trials obsolete.
- Teratogenicity tests for companion animal products not intended for use in breeding animals should be eliminated.
- MAFF should accept technical English language documents submitted with new animal drug applications written in English, with only a summary provided in Japanese. As a precedent, the Ministry of Health, Labour and Welfare (MHLW) accepts this procedure for human drugs.

■ National assay of vaccines

Yearly status report: some progress. The EBC commends the MAFF initiative to introduce the seed-lot system and eliminate the current batch release requirement based on national assays for animal vaccines. The EBC, however, is concerned about the new and unique requirements for a vaccine to be eligible for the seed-lot system, - such as the requirement for an immunogenicity test - which are not in line with the international practice of the seed-lot system. These unique requirements are expected to increase the burden of European vaccine manufacturers and reduce the value and usefulness of the new seed-lot system. Given the expected implementation of a seed-lot system and an accelerating global trend towards self-regulation to ensure product conformance under the GMP regime, the EBC encourages the Japanese government to continue shifting from the use of the national assay to in-house testing for veterinary biological products.

Recommendation:

- The national assay for vaccines should be abolished as early as possible, once it is rendered unnecessary by implementation of the seed-lot system. The requirements for the seed-lot system should be aligned with international standards, eliminating those requirements that are unique to Japan.

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MEDICAL DIAGNOSTICS

Regulatory Developments

Medical diagnostic reagents and equipment are used to perform diagnostic tests in hospitals, commercial laboratories, physicians' offices and blood banks. Reagents are an essential component of any healthcare regime, indispensable in preventing sickness, detecting and diagnosing diseases, ascertaining the side effects of drug therapy, monitoring treatment, improving patient quality of life and decreasing total healthcare costs. Repeated cuts to reimbursement prices have reduced pricing levels below that of comparable overseas markets. This has reduced the incentive to invest in the development of new products for the benefit of Japanese patients. Reimbursement prices for medical diagnostic procedures and facilities were cut by 10% in the latest round of price revisions in April 2006. Reimbursement prices have now been cut by about 50% on a cumulative basis since 1998, with double-digit reductions in 2002, 2004 and 2006. Furthermore, the fact that reimbursement prices are the same for the same type of assay, even when the respective speed, quality, and contribution to patient care are totally different, acts as a disincentive for conducting better IVD tests.

The past years have witnessed a number of improvements in the regulatory environment for medical diagnostics. Efforts to reduce bureaucratic delays in approving new products were boosted by the revision of the Pharmaceutical Affairs Law, implemented in 2005, introducing a third party/self-certification process based on risk classifications. More substantial progress was, however, impeded by the absence of practical guidelines for companies wishing to initiate applications under the new regime, as well as by the retention of risk classification methodologies and data requirements, which are unique to Japan. Meanwhile, biennial revisions of reimbursement prices have led to continuous erosion in prices for medical diagnostics, with little information made public about the decision process and little heed taken of the relative economic or clinical benefits or the innovative nature of individual products. All together, these factors raise significant concerns not only for European manufacturers, who find Japan an increasingly unattractive market for their products, but also for the country's healthcare system, which, in a mistaken short-term attempt to save money, may miss out on the longer-term economic benefits of deploying modern medical diagnostics. The current approach of treating medical diagnostics only as another expense, with a re-imbursement price that does not respect the added-value of each product, leads to incorrect diagnosis and unnecessary or wrong treatment and, in the end, excessive healthcare. The EBC is encouraged to see that IVD has now been introduced as a topic under the new Medical Industrial Vision study in which not only MHLW, but also METI and MOF are participating. The EBC is actively joining in the dialogue and sincerely hopes that the new tone of the debate will also bring a shift in focus areas, such as product approval and reimbursement.

Prospects for EU-Japan Economic Integration

Japan must change its medical diagnostic regime drastically if it is to create a competitive market for medical diagnostics that are of interest to European and Japanese manufacturers alike. The EBC can see no reason for why products that have undergone thorough tests in Europe and are certified with CE marking for the European market have to go through additional tests for Japan. Mutual acceptance of standards and certification between the EU and Japan would not only deliver products to Japanese consumers, but also provide a great business opportunity for Japanese manufacturers.

Priorities

- **Mutual acceptance of standards and certification for medical diagnostics products**

Key Issues and Recommendations

■ Product approval and smooth introduction

Yearly status report: some progress. The new product approval systems have been implemented in accordance with the revised Japan Pharmaceutical Affairs Law. The introduction of a Ministry approved system, third-party certification and self-certification system based on risk classifications and strengthened safety measures, is an important step in the right direction, but still falls short of what is needed. In addition to these regulatory aspects, risk classification methodologies and data requirements, which are unique to Japan, technically make the application and review process discouragingly slow and/or redundant. This makes it impossible to initiate application procedures for many products - a situation that should be remedied immediately. At the same time, in Europe, an in-vitro diagnostic Directive (IVDD) came into effect on June 2000, from which time products bearing the CE marking have been granted free movement within the European Economic Area. IVDD should be considered as a positive example of an integrated cross-border standard.

Recommendation:

- The EU and Japan should accept products certified for either market as equivalent to the products certified for their home market.
- The product approval process should be made more efficient. Application data requirements unique to Japan should be eliminated. A fast-track review system should be introduced to expedite the approval process for new and innovative products, and requirements for the new product categories (D1/D2) should be clarified.

■ Reimbursement

Yearly status report: no progress. No information has been made public regarding the decision-making process for biennial revisions to reimbursement prices, on either how decisions are made or what the basis is for price cuts. It is said that the IVD reimbursement points are benchmarked against the price for hospitals to send work out to commercial laboratories. If true, this is an unfair comparison, since outsourcing prices do not include such costs as pre-treatment of patient samples (i.e. blood) and management of the patient test result history. Medical diagnostics expenses are thus seen as just another medical materials cost that can be cut, without due consideration to the unique role of properly conducted diagnostic testing in lowering total medical costs.

Recommendation:

- The EBC urges the Japanese Government to establish a more rational, transparent review process for reimbursement pricing. Prices for medical diagnostics (In-Vitro Diagnostics) should better reflect their clinical value, based on differences in quality (accuracy, specificity, laboratory certification), speed (emergency response, urgent test for out-patients), and contribution to comprehensive patient care (infection control, risk management, qualitative indications).

■ Diagnosis Procedure Combination (DPC)

Yearly status report: no progress. DPC was introduced in selected Special Function Hospitals in 2003. The introduction of this system has led to a reduction in the number of diagnostic tests performed, as hospitals focus on reducing costs and outsourcing procedures. The underlying infrastructure for diagnostic testing is likely to erode if this situation persists.

Recommendation:

- The Japanese government should establish guidelines, in consultation with the medical community, to promote the effective use of medical diagnostics, with the aim of improving the quality of care, reducing the risk of misdiagnosis, and reducing total healthcare cost.

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MEDICAL EQUIPMENT

Regulatory Developments

Some 45 years after its introduction, the Public Health Insurance Scheme is coming under extreme pressure from demographic changes and a resulting 3-4% increase every year in healthcare costs (equivalent to approximately one trillion yen). The unstable performance of the overall economy does not provide for a similar sustained increase in contributions to the scheme. The growing gap between contributions and costs led the Government to cut total healthcare reimbursements by 2.7% in 2002 and by a further 3.16% in 2006. These cuts were justified by referring to lower prices in foreign markets, even though these markets are structurally different from Japan: the retail structure in Japan and the way the Japanese Government determines medical-related reimbursements through the public insurance scheme are unique and render any straight comparison between prices here and in other countries meaningless.

The EBC has long called for a reduction in the time and costs associated with introducing innovative new treatments to the Japanese healthcare system. Despite the original intent of using the revision to facilitate procedures and bring Japanese rules in line with global standards, the revised Pharmaceutical Affairs Law (PAL) resulted in the introduction of unique Japanese requirements, longer approval times, and less consistency with international practices. Much hope was pinned on new opportunities for third party testing of low-risk products and for sub-contracted manufacturing, introduced under the revised Pharmaceutical Affairs Law in 2005. However, expectations that this Law might shorten product approval times and streamline application processes have been dashed – the level of bureaucracy and cost has in fact risen.

Meanwhile, efforts by the Japanese Government to improve efficiency have been solely focused on reducing prices paid out under the insurance reimbursement system. Cuts have been made across the board, ignoring the long-term economic and clinical benefit of individual treatments, equipment running costs and the need to recover initial investments in research and development. The EBC believes that a fundamental overhaul of the Government's healthcare strategy and regulatory approach is needed to ensure that Japanese healthcare provision can, in the future, keep pace with technical innovation, public expectation and demand.

Prospects for EU-Japan Economic Integration

Healthcare in Japan is in general of high standard as suggested by the average life expectancy and lowest infant mortality rates in the world. However, inefficiencies in the system, such as the structural over-consumption of certain services and unparalleled long stays in hospital, need to be addressed urgently. The financing of the healthcare system will continue through the Public Health Insurance Scheme and demographic changes are leading to lower contributions and higher consumption. Consumers expect higher quality medical services, which will come under increasing strain in the years ahead. Efficient medical equipment should in this context be seen as an investment that not only offers the individual patient a substantially higher quality of life, but also can offer reductions in total expenditure on medical care over time. However, the current regulatory structure and reimbursement regime constitute an obstacle to introducing such equipment to the Japanese market and deprive Japanese consumers of access to products available in other industrialised countries, including China and South Korea. An Economic Integration Agreement between the EU and Japan should ensure that products certified in one market be automatically accepted in the other market. Such a measure would lower costs and in the long-term, eliminate the device-gap between Japan and other industrialised countries as virtually all devices on the world market today are certified according to EN standards.

Priorities

- Establish mutual acceptance of standards and certifications for medical equipment
- Establish common Good Clinical Practice (GCP) and Quality Management System (QMS) regulations

Key Issues and Recommendations

■ Mutual recognition and acceptance of EN standards

Yearly status report: no progress. One major reason for revising PAL in 2005 was to facilitate the entry of medical equipment onto the Japanese market by aligning domestic rules to international standards, as recommended by the “Global Harmonisation Task Force.” However, the addition of Japan-specific requirements on top of international standards, together with the lack of clarity about how these requirements are applied, has resulted in even greater differences than before. One example is the mandatory, product-category-based pre-examination of manufacturing facilities, introduced into PAL as part of the QMS - an evaluation which is in direct contradiction to ISO 13485. The Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) is again considering new measures to counter the “device-lag”, this time together with the medical device industrial associations.

Recommendation:

- The Japanese government should shorten the medical equipment certification process by accepting clinical trial data generated overseas, and by 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.

■ Reimbursement prices

Yearly status report: no progress. The 2006 revision of prices paid out under the reimbursement scheme resulted in price reductions for medical material equivalent to 60 billion yen in total. Reimbursement prices were reduced by more than 25% in the case of more than 34 product categories. The purported reason for this largest ever cut was to correct price differences between Japan and foreign markets, although the merits of directly comparing final price levels are clearly limited. The government is considering introducing regular price revisions every year and using prices in other Asian markets as points of reference in its blind pursuit of further reductions. In the long run, this will only undermine the interest of foreign manufacturers in the Japanese market. Reimbursement setting is now decided after the safety and review process prescribed within PAL which exacerbates the “device-lag” between Japan and other industrialised countries.

Recommendation:

- The reimbursement price set by the government for medical equipment should more accurately reflect the technical sophistication of the product and its associated research and development costs. It should also reflect costs unique to introducing the product to the Japanese market, such as cumbersome certification processes, and maintaining old production lines for equipment used only in Japan. The Government of Japan should allow applications for reimbursement pricing earlier in, rather than at the conclusion of, the safety review process for categories C1 and C2 devices.

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PHARMACEUTICALS

Regulatory Developments

The pharmaceutical industry in Japan is undergoing structural change with a critical evaluation of the development, review and registration, and the funding system. The general drive for lowered costs in public health insurance seems to have reached an end with the realisation that cuts over the line cannot ensure sustainable healthcare. Drugs are not simply an expense, but a way of reducing social costs and boosting economic performance as the population is allowed to benefit from improved therapeutic and preventative healthcare. Cost-cutting and life-saving innovations should be treated as investments and rewarded accordingly. The price revisions in 2006 took the first cautious steps in that direction, but nothing less than a complete overhaul of the current system will be sufficient considering the strains that demographical changes will place on it in coming years. Due protection of intellectual property rights is also crucial if pharmaceutical companies are to be confident in continuously developing new products for the market. With Japan approaching European protection rules for data, progress is gradually being achieved. Japan is also addressing the development of new drugs and the long lead times in introducing new drugs to the Japanese public. Although there has not been any obvious improvement in the clinical trial environment, the government seems to realise that Japan can no longer afford to refrain from participating in international cooperation on the development of drugs and has announced an intention to improve the environment for clinical trials. The EBC takes an active part in the dialogue on improving clinical trials environment and hopes that this time, good intentions will be translated into real policy change. The government has also decided to boost the review and regulatory capacity of the PMDA with the goal of eliminating the drug-lag between Japan and other advanced countries.

Prospects for EU Japan Economic Integration

While the global pharmaceutical industry has consolidated and put most of its efforts into developing drugs on a global scale, the pharmaceutical industry in Japan has remained largely isolated. Good Clinical Practice (GCP) rules remain different from global standards, which makes clinical trials more expensive in Japan and participation by multinational companies troublesome. By having common GCP rules, the EU and Japan could boost cooperation in the development of drugs, cut introduction costs, and, by doing so, substantially strengthen the competitive strength of the domestic industry. Registration and review remain problematic. The Pharmaceuticals and Medical Devices Agency (PMDA) has been struggling with capacity problems since its inception in 2004. The EBC welcomes new plans to expand capacity but invites the Government of Japan to consider taking advantage of the data and evaluations already undertaken by European Medicines Agency (EMA) for drugs circulated on the European markets. Mutual acceptance of marketing authorisation for medicinal products between the EU and Japan would substantially cut costs, reduce introduction times and eliminate the drug-lag between the economies, to the benefit of everybody - patients, society and the industry. Finally, the EU and Japan should also work together to ensure that registration data and brand names are protected with the view of stimulating further innovation. Japan must create an environment in which innovation can thrive. Innovation leads to a better quality of life for patients, decreased social costs, and a strong industry. Working with Europe would be a very cost-efficient way to achieve all this.

Priorities

- Harmonised Good Clinical Practice (GCP) rules
- Mutual acceptance of marketing authorisation for medicinal products
- Ambitious agreement on protection of intellectual property covering data protection and rules for brand names for new drugs

Key Issues and Recommendations

■ Pharmaceutical pricing reform

Yearly status report: limited progress. The 2006 revision of pricing rules improved the premium rate for new drugs and relaxed the requirements for usefulness price premiums. In pricing for new paediatric drugs, however, the requirement for price premiums remains extremely strict and the premium rate limited. For new products as a whole, discussions on relaxing varieties of scientific data or other evidence to be used for price premium claims have been inconclusive. Japan needs a new NHI drug pricing system taking into account the need to properly value each drug, reward innovation and respect intellectual property.

Recommendation:

- The Government of Japan should revise the NHI drug price system so that it rewards innovation and more properly reflects the value of drugs.

■ Improved environment for clinical studies

Yearly status report: limited progress. Differences between Japanese Good Clinical Practice (GCP) and GCP established by the International Conference on Harmonisation (ICH-GCP) continue to make clinical trial costs more expensive and unnecessarily complicate participation in multinational clinical trials. The EBC is pleased to see that the Government of Japan during the past year has taken up this problem as a generic issue, beyond the borders of MHLW alone and EBC welcomes the conclusion made in the “New Pharmaceutical Industry Vision”.

Recommendation:

- The Japanese GCP should be harmonised with ICH-GCP.

■ Regulatory review of pharmaceutical products

Yearly status report: limited progress. PMDA has taken important steps to increase its capacity, and also proposed a number of measures to solve the drug-lag between Japan and other markets by 2011 (currently a 2.5-year delay compared with the USA). The number of consultations with PMDA is expected to increase further and the development of biotechnology-related drugs, cell therapies, vaccines, and international clinical trials are on the rise. It is, therefore, essential for the PMDA to increase the number of staff members and further develop their capacity.

Recommendation:

- The EBC urges the Government of Japan to increase the review and regulatory capacity of PMDA in accordance with the report issued by the Council for Science and Technology Policy of the Cabinet Office. In particular, it is crucial that the introduction of a pre-application consultation system scheduled for 2009 is implemented in accordance with the plan.

■ Intellectual property protection

Yearly status report: significant progress. MHLW issued a notification in April 2007 to the effect that the re-examination period for new drugs will be extended from six to eight years. The EBC welcomes this change as it is in line with EBC’s request that the data protection period for new drugs be eight years, but regrets that the notification only applies to drugs containing a new chemical entity and not new combination drugs, drugs with a new indication, and drugs with a new administration route. The EBC is also concerned that the MHLW is changing its views on selection of the brand names for new drugs. Global companies have invested heavily in a given brand name and will be severely damaged if that brand name is not acknowledged in Japan as well.

Recommendation:

- The EBC requests that new combination drugs, drugs with a new indication and drugs with a new administration route also be eligible for an eight-year extension.
- With the objective of securing intellectual property protection and preventing medication errors, the GOJ should take measures to ensure that globally used brand names of drugs are recognised in Japan as well.

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VACCINES

Regulatory Developments

Under pressure from severe funding restrictions caused by an aging population and a declining birth rate, the Government of Japan must establish a sustainable new healthcare system. In such difficult circumstances, preventive medical care takes on increasing importance, since it can substantially reduce medical costs and offer the Japanese population the benefits of a life free from vaccine-preventable diseases. Clearly, vaccines can be a major evidence-based and proven medical tool in Japan's future preventive medical care. Recent outbreaks in Japan of measles, Japanese encephalitis and other infectious diseases have made the public aware of the need for modern vaccines and supportive vaccine policies.

The Japanese vaccine market is dominated by domestic products, representing more than 99% of the market and internationally available, cutting-edge vaccines are not in use. Japan has continuously and with increasing speed fallen behind other developed countries in terms of the vaccines available to protect the population. Vaccines widely available in the EU and US, such as MMR (Measles-Mumps-Rubella), Rotavirus, Human Papilloma Virus, IPV (Inactivated Polio Vaccine), DTPa (Diphtheria-Tetanus-Pertussis) combination vaccines that reduce needle sticks and increase compliance, pneumococcal 7v, overseas travellers' vaccines and others are still not available to Japanese risk group populations. From a public health perspective, the vaccine gap poses the risk of high outbreaks of diseases that could have been prevented by new vaccines that are not yet available in Japan.

Japan's domestic-led vaccine supply policies have been based on the belief that domestic supply is the only way to secure stable and prompt supplies of vaccines essential to the protection of public health. However, domestic manufacturing capacity is not necessarily a prerequisite for securing a stable supply. Multiple suppliers, in-country stockpiles, and a strong communication network with other countries are the building blocks of a stable vaccine supply in Europe and the US. This can be achieved by a combination of domestic production and import of vaccines from abroad. Furthermore, a more attractive Japanese vaccines market would give the Japanese population access to existing and innovative new vaccines to protect their health. It would also provide an attractive climate for foreign investment in innovative biotechnology research and development.

European manufacturers have seen no signs of change in the vaccine policy nor improvement of the market in the past five years. However, the MHLW has published a paper setting out a 'Vaccine Industry Vision'. The paper is the first sign that the Government is planning to make changes to improve the environment for the vaccine industry in Japan. This effort is very welcome, as the current vaccine industry should be a primary focus for reform and foreign vaccines manufacturers can contribute greatly to the improvement of healthcare for the Japanese population.

Prospects for EU-Japan Economic Integration

Vaccines are not included in the scope of the International Conference on Harmonisation (ICH). As a result, global harmonisation and an appropriate legal and regulatory framework for vaccines and biological products has not been achieved to bring alignment between bodies like the WHO, the EU, the US and Japan so that the quality, efficacy and safety of vaccines can be ensured in the most efficient way. The Japanese Government should be actively involved in these initiatives and the exchange of experience with other developed countries. Harmonisation with the European Medicines Agency (EMA) could eliminate unnecessary duplication of resources. Furthermore, Japanese manufacturers and the Government should consider harmonising release specifications and quality requirements, so that foreign as well as Japanese companies can supply vaccines manufactured in Japan to worldwide markets. This would facilitate the introduction of high quality vaccines to Japan.

Priorities

- **Harmonise EU-Japan licensure and regulatory standards for vaccine approval**

Key Issues and Recommendations

■ Improve availability of new vaccines

Yearly status report: limited progress. Vaccines, including those from foreign manufacturers, have the potential to make a significant, positive contribution to improving the health of people living in Japan. They play a major role in public health, especially for children and the elderly - two important population groups in Japan. Yet Japanese citizens are not currently offered the same level of vaccine protection as is available to people in the US or the EU.

Recommendation:

- The Government of Japan should improve the availability of new vaccines to the Japanese population.

■ Harmonise vaccine standards and requirements with the EU

Yearly status report: limited progress. Currently, vaccines are not included in the scope of the ICH. Since Japan has adopted independent quality requirements and specifications for vaccines, manufacturers need to undertake complicated processes to introduce Japanese vaccines to foreign markets and to bring foreign vaccines into the Japanese market. Harmonising the Japanese requirements with those of the EU and EMEA would address these issues and facilitate the development and introduction of new vaccines to Japan.

Recommendation:

- A taskforce similar to that of the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) should be established and dedicated to biological products, in order to work towards the harmonisation of licensure and regulatory standards for vaccine approval in Japan.
- The vaccine specifications currently used in Japan for quality control and release – the Japanese Minimum Requirements for Biological Products (MRBP) – should be harmonised with EU and US specifications so that foreign vaccines can be imported into Japan, and Japanese vaccines can be exported from Japan.

■ Establish national funding for new vaccines

Yearly status report: limited progress. A significant increase in new vaccines for Japanese citizens will require a new system of financing. If not, there is a risk that Japan's current system of central recommendation and local funding will face difficulties in financing this new area of protective healthcare. The Government should ensure that vaccines are positioned as a cost-effective tool for reducing overall healthcare costs and serve as a good example of investing in health to achieve economic productivity.

Recommendation:

- The Government of Japan should immediately start considering how to establish new funding for vaccines in the national health budget.

Consumer Goods

Cosmetics
Cut flowers
Liquor
Food

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COSMETICS

Regulatory Developments

In Europe, there is only one product category for cosmetics, while in Japan the very same products are classified as either cosmetics or quasi-drugs. There is a significant difference between permitted efficacy claims in Europe and Japan, and ingredients on the positive list are different. In Europe, emphasis is put on post-marketing control instead of entry control. To promote the international distribution of products, the EBC urges the Japanese government to proactively work towards harmonisation of standards with Europe.

Revision of the Pharmaceutical Affairs Law (PAL) represents the single most important regulatory development in this sector in Japan in recent years. The marketing approval holder license was created with a view to adopting best global practices. The Good Vigilance Practices (GVP) and Good Quality Practices (GQP) were introduced as requirements, emphasising post-marketing controls. For quasi-drugs, however, the entry control (i.e. marketing approval) and the discouragingly long lead time for approval remains. The EBC urges the Government of Japan to disclose information about substances already approved and shorten the application times for new approvals and partial changes in approved items. The requirement to undergo screening anew when introducing to quasi-drug products ingredients already used in cosmetics should be abolished.

The list of 55 allowable cosmetics efficacy claims was announced in 2001. No new efficacy claim has been added since, and marketing advertisements are still tightly regulated. This restriction not only deprives consumers of important information when choosing a product, but also constitutes a disincentive for marketing approval holders to develop new products. False marketing claims could be more effectively restrained by applying the Act against Unjustifiable Premiums and Misleading Representations.

The difference between the positive list of ingredients between the EU and Japan remains a critical issue. At the time of introducing the positive list in 2001, the Ministry of Health, Labour and Welfare (MHLW) issued a notification on the process for adding new ingredients, but this has proved to take too long a time. The EBC urges the European and Japanese Governments to establish procedures enabling swift and continuous addition to the Japanese positive list of new ingredients recognised in Europe.

Prospects for EU-Japan Economic Integration

Japan is the second largest market for cosmetics in the world worth about 1.4 trillion yen per year. The share of imports compared to domestic production continues to increase, with European companies accounting for a large proportion of imports. European firms, however, find it continuously difficult to expand their business due to the difference in standards for ingredients and permitted efficacy claims between Japan and the EU and the Japan-specific product certification procedures for so-called quasi drugs.

Priorities

- Common regulations on certification of medicated cosmetics, so-called quasi drugs (disclosure of approved ingredients, standard application times)
- Common regulations on efficacy claims and advertisements
- A common positive list of allowable ingredients in cosmetics
- Establishment of joint standards for alternatives to animal testing

Key Issues and Recommendations

■ Reform of quasi-drugs approval system

Yearly status report: no progress. The past twenty years have seen no shortening of standard application times for medicated cosmetics, the so-called quasi-drugs. The Ministry of Health Labour and Welfare (MHLW) does not provide sufficient information to the market on the substances it has already approved, which often results in a long lead time for product approval from the stage of dossier preparation. The Government needs to disclose this information to the market while giving due consideration to the protection of intellectual properties of individual companies. In particular, this may contribute to making the lead time shorter for the approval of products that fall within the scope of already approved products (Category 2).

Recommendation:

- MHLW should disclose information about substances already approved for quasi-drugs.
- The product approval process, including that for partial changes in approved items, should be simplified with the view to substantially reduce standard application times.

■ Reform of cosmetics regulatory system

Yearly status report: no progress. Compared to the EU, where manufacturers may make efficacy claims according to scientific data, the general nature of permitted claims in Japan makes it extremely difficult to differentiate and market new products. The list of permitted efficacy claims has not been changed since 2001 when it was expanded to cover 55 claims, leaving a difference in the scope of cosmetics between Japan and the EU. The positive list of ingredients in Japan and the EU is different, repeatedly hindering the introduction of European products into Japan. The cosmetics importation scheme introduced in the revised PAL 2005 has made the importation of cosmetics cumbersome and directly contradicts the supposed guiding principle for all regulatory reforms - "efficient e-government". Despite the strengthened regime, many products imported and sold under false representations by companies that clearly do not meet GVP and GQP standards are still circulating on the Japanese market. This situation should be improved to ensure the quality, efficacy and safety of all products in market circulation for the sake of consumers.

Recommendation:

- Expand the current scope of efficacies and allow marketing approval holders to run advertisements of their own products based on scientific and objective data.
- Harmonise the positive list of ingredients with that of the EU and establish a mechanism enabling swift acceptance of ingredients widely used or recently recognised in Europe.
- Streamline the importation system, enabling an online subscription system for importation dossiers.

■ Establishing alternatives to animal testing

Yearly status report: some progress. The cosmetics industry worldwide is currently working towards developing alternative methods to animal tests following the EU Cosmetic Directive. The EBC appreciates the stance on alternative testing expressed by the MHLW in July 2006, and asks the Ministry to ensure that the capability to review data generated by alternative methods in an appropriate and swift manner is set up.

Recommendation:

- In light of the ban on animal tests in the EU, the EBC requests the Government of Japan to ensure that using data generated by internationally-recognized alternative methods will not result in delays of approvals for quasi-drugs nor for revisions of cosmetic standards.

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CUT FLOWERS

Regulatory Developments

Foreign companies interested in importing cut flowers into Japan have seen very slow improvement in the business. The Government of Japan has gradually addressed some of the barriers to trade in cut flowers: airport procedures have been slightly improved through extended inspection schedules, inspection fees have been reduced, the number of plant quarantine inspectors has increased, and a number of pests have been added to the non-quarantine list.

Nevertheless, the lack of adequate temperature-controlled warehouse facilities and fumigation capacity is a recurring problem. Equally, while the list of non-quarantine organisms was expanded in 2005, many non-harmful organisms that are widespread in Japan remain subject to costly fumigation requirements. Restrictive Japanese plant quarantine regulations are by far the largest barrier to trade in cut flowers. In theory, zero-tolerance is applied only to organisms that are considered to be harmful on the basis of the Sanitary and Phytosanitary chapter of the GATT Uruguay Round Agreement. In 1996, the risk assessment chapter was added to Japan's Plant Quarantine Law, but this revision has not had any beneficial effect on cut flower imports, as the Japanese Government has not made a practical distinction between harmful and non-harmful organisms. In April 2005, in response to demands from the EBC and the EU, the Japanese Government increased the number of organisms on the non-quarantine list. However only 3 organisms - thrips tabaci, tetranuchus urticae and Panonychus ulmi - out of the 9 requested have been added to the list. Insects such as mites and aphids have not been included, even though they are widespread in Japan. Moreover, it still takes much too long for shipments to be made available for inspection, for customs procedures after arrival, and for the shipment to be distributed after clearance.

In 2003, the Japan Fair Trade Commission called for the elimination of price fixing and other collusive practices between the only two companies providing fumigation services at Narita Airport, but the announcement was not followed by any concrete measure let alone a fall in prices. The EBC continues to request that a system of ad random inspection replace the current re-inspection of pre-inspected flowers at ports of entry, but no action has yet been taken. Trends in the cut flower industry are quasi-irreversible and imports will increase in light of natural market forces and demographics. The aging population of Japanese growers, the small scale of the average nursery and the high costs of operating in Japan, make it extremely difficult for Japanese growers to compete on a global scale. While fully respecting the need to guarantee safe imports, the interest of Japanese consumers in having a larger and better-priced selection of quality flowers on the market must also be considered. The Japanese government should provide a proper infrastructure to facilitate the import of quality flowers. This should be done by upgrading the capacity of plant quarantine inspection offices, increasing cooling capacity, improving handling of the products at port of entries, and bringing the list of non-quarantine pests in line with international standards. An imported flower that has not been fumigated and kept at cool temperatures during the clearance process is a better flower for all consumers in Japan to enjoy.

Prospects for EU-Japan Economic Integration

Alongside Europe and the United States, Japan is one of the leading consumers of flowers, yet domestic growers control an exceptionally high market share of nearly 90%. In most other industrialised countries, over 85% of the flowers consumed are imported. In Japan, excessively strict plant quarantine regulations, a lack of cargo handling capacity at Narita Airport and a lack of competition between fumigation companies, make the importing of perishable goods costly, risky and difficult. Swift and decisive Government action is urgently needed to ensure a fair and efficient market that would lower prices and bring a wider selection of high-quality flowers to Japanese consumers.

Priorities

- **Establish joint plant quarantine standards**
- **Competition rules should include a provision on undue pricing by firms**

Key Issues and Recommendations

■ Plant quarantine regulations

Yearly status report: some progress. In March 2006, the non-quarantine list was expanded to include thrips. Further steps should be taken to ensure impartiality and thoroughness in quarantine inspections. The process lacks transparency as importers are often ordered to fumigate without being systematically and thoroughly advised about which pests have been found in their shipments.

Recommendation:

- The Japanese authorities should extend the list of non-quarantine organisms to include all non-harmful organisms found in cut flowers until plant quarantine regulations are in line with the Sanitary and Phytosanitary chapter of the General Agreement on Tariffs and Trade (GATT). The focus should be on the main insects (mites, aphids and thrips) and the goal should be to abolish the zero tolerance principle for insects common in Japan. In addition, quarantine inspectors should be required to compile a quarantine report specifying the precise names of pest species found in order to avoid arbitrary judgments and unnecessary fumigation.

■ Capacity problems at Narita

Yearly status report: no progress. Inspection capacity has improved somewhat in recent years, and processing fees charged for holidays and overtime have been lowered. While there are cooler temperature-controlled warehouses available from May through October, capacity is limited and prices remain high. The facilities are not able to deal with the current volumes of cut flowers and other perishables coming into the airport.

Recommendation:

- The EBC recommends further improvements at bonded warehouses and dispatch areas, especially at Narita Airport, where the largest volumes of imports are handled. Cold storage capacity must be improved substantially, inspections should be made in the cooled storage space, and fumigation facilities should be installed next to storage, all to avoid exposure to highly damaging heat. Inspection capacity must be increased substantially by adding more inspectors and increasing facility size to truly speed up the inspection process.

■ Fumigation costs

Yearly status report: no progress. Prices for fumigation have not been reduced and remain approximately five times higher than at airports in countries with similar restrictions, such as New Zealand.

Recommendation:

- The EBC encourages further competition in the provision of fumigation services to help reduce fumigation costs at Japanese airports. If high costs persist, the EBC recommends proactive intervention by the Japanese Government.

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LIQUOR

Regulatory Developments

In the past five years, market conditions for the sale of European liquor have been substantially improved through a series of reforms and deregulation. In compliance with WTO rulings, the Government of Japan reduced the gap in liquor tax rates between domestically produced distilled liquor or shochu and imported liquors. By 2002, Japan had eliminated tariffs on whisky, brandy, vodka, rum, liqueurs and gin. This progress was followed in 2003 with an attempt to deregulate retail channels by eliminating requirements for minimum distance requirements between retail licensees. The deregulation was temporarily undermined by the designation of large numbers of “Urgent Adjustment Areas” to which the deregulation did not apply. Fortunately, by September 2006, such exceptional procedures were discontinued and the deregulation of retail channels was uniformly applied. In 2006, the Ministry of Finance launched a program aimed at long-term reform of the liquor tax regime that entails streamlining of tax categories and an adjustment of the tax rates.

The goals envisioned by the reform program are positive, but certain provisions of the program, including the current system of product categorization do not comply with WTO rulings and international standards. The Ministry of Finance has made clear its long-term goal of putting wine and Japanese sake in the same category, ignoring fundamental differences between the two products. The EBC fears that this intention is in contradiction to the 1998 WTO ruling, which prescribes that the level of substitutability in terms of production and consumption should be the overriding determinant when setting tax categories for alcoholic beverages. In contrast, the EU, US and Australia have implemented the WTO provision so that spirits, beer, wines and intermediate products are placed in separate general categories complemented by specific categories for country-typical products. The lack of accurate product definitions and categorization for taxing purposes indirectly protects domestic producers and in the long term, will limit competition from European businesses.

Prospects for EU-Japan Economic Integration

Europe is the leading exporter of liquor and wine worldwide. The Japanese liquor market is one of the largest in the world with estimated annual liquor sales of 6 trillion yen and a growing wine consumption. Despite such figures, in terms of volume, foreign imports account for only 3.7% of the total Japanese liquor market (including beer and beer like products) while Japanese producers account for almost 96.3% of the total market share. The Government has implemented a notable reduction in taxes. However, Japan lags behind in the application of international standards of product definition and elimination of non-tariff barriers to market access.

Priorities

- Eliminate tariffs on alcoholic beverages
- Adopt definitions and categories for liquor in line with international standards and specifications

Key Issues and Recommendations

■ Product definition

Yearly status report: no progress. Product definitions for alcoholic beverages are broad and do not comply with internationally accepted product specifications that are based on production methods and geographical indications. Many brands of Japanese liquor marketed under the name of "whisky" and "liqueur" would not qualify as such products in Europe. Domestic products like Sochu and Sake products are not subject to the same rate of liquor taxes as authentic whisky, liqueur and cognac imported from Europe. This provides domestic producers with a competitive advantage in terms of lower costs. Such inaccurate use of definitions gives domestic producers an unfair competitive advantage, misleads Japanese consumers and undermines the quality and brand integrity of the genuine European liquor.

Recommendation:

- Product definitions for alcoholic beverages in Japan should conform to international specifications as defined in the EU and the US and endorsed by the International Federation of Wines and Spirits.

■ Licensing

Yearly status report: progress. In 2006, licensing requirements for retail channels such as minimum distance and population quotas were abolished. However license applications for wholesale and retail continue to be complex and are not processed in a clear, transparent and consistent manner.

Recommendation:

- The EBC endorses deregulation of liquor retailing in Japan and requests the Japanese Government to further simplify the liquor licensing process for both retail and wholesale channels.

■ Liquor tax

Yearly status report: no progress. The current liquor tax regime is complex with 10 different tax rates applied to beers, wines and spirits. The Ministry has announced an intention to apply the tax rate on sake to wine, a change that may increase the current tax from 80 yen to 120 yen per litre.

Recommendation:

- Categorization of alcoholic beverages for tax purposes should use the same categories as in the EU and the US, which distinguish between spirits, beer, wines and intermediate products.

■ Tariffs

Yearly status report: no progress. The Japanese Government has drastically reduced the tax rate on non-shochu liquor over the past five years in compliance with a WTO ruling issued in 1996. However, certain tariffs are still applied to Sparkling Wine, Still Wine, Sherry, Port and Fortified Wine.

Recommendation:

- The EBC urges the Japanese Government to continue working towards the eventual elimination of tariffs on imported liquor products.

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FOOD

Regulatory Developments

Japan seriously lags behind its main trading partners in the development of its food market. People in Japan have less choice and must pay considerably higher prices for European food than possibly in any other developed economy in the world. This is due to overly restrictive and cumbersome regulations as well as punitive duty rates. With its rich traditions and well-developed food market, Europe has much to offer curious and quality-conscious Japanese consumers. More choice through access to the world's leading products and ingredients would benefit not only consumers, but also the food industry since Japanese food manufacturers rely on both locally sourced and imported ingredients to realise their maximum creative potential.

A major factor preventing access of high-quality food to the Japanese market is Japan's approved food additives list, which remains out of step with the rest of the industrialised world. Of the 786 food additives authorised in Japan, only 294 are accepted by the Food & Agriculture Organisation of the United Nations and the World Health Organisation (FAO/WHO). In contrast, over 600 substances accepted as safe by FAO/WHO and widely used worldwide are not allowed in Japan. In recognition of this problem, on December 19, 2002, the Ministry of Health, Labour and Welfare (MHLW) submitted a list of 46 priority substances for review. Initial optimism rapidly faded as it became evident that progress remained slow and the system was non-transparent. MHLW took steps in 2005 to improve transparency and speed. The former has improved with the publishing of regular updates. However, only 7 out of 46 substances have been approved, 5 years after launching this initiative. Several reasons are given for this slow rate of progress, including lack of resources in the Food Safety Council (FSC) and outdated data. Understandably, the EBC remains disappointed.

Moreover, the EBC is concerned that standards and restrictions applied to European food products are not always consistent with standards applied to domestic products and imports from other trading partners. Whilst outbreaks of BSE and classical Swine Fever in Europe triggered immediate strict restrictions on imports, domestic outbreaks of BSE and influenza A (H5N1), also known as "avian flu" or "bird flu", along with a number of domestic scandals involving improper labelling of products, the use of illegal food additives and poor quality control, have not resulted in correspondingly strict measures. Moreover, whilst the ban on American beef imports was lifted in 2003, discussions on lifting the ban on European beef did not begin until 2006. An EU-Japan Economic Integration Agreement should abolish all tariffs, quotas, minimum prices and state trade in food products, and enable mutual acceptance of standards on safety of food and food ingredients, and regulations including testing procedures for food imports. Such an agreement would serve as an example of promoting free trade of quality food as well as assuring consumer safety.

Prospects for EU-Japan Economic Integration

More than 60% of Japan's food supply is dependent on imports. In 2006, this equated to about 35 billion Euros in value. Considering the limited capacity for domestic food production, further undermined by the ageing and declining population, a reduction in trade restrictions on trade in food is long overdue. Tariffs, quotas, minimum prices and state-supported trade disrupt the free market mechanism and result in less choice and higher prices for consumers. The difficulty in importing perfectly safe high-quality food into Japan is further exacerbated by differences in food safety standards between Japan and Europe. Unconditionally opening up the markets and establishing mutual acceptance of food-related regulations through an EU-Japan Economic Integration Agreement, would bring more affordable high-quality food to both regions, without compromising consumer protection. As a result, Japan and Europe would strengthen their global positions as leading food and culinary markets.

Priorities

- Abolishment of all tariffs, quotas, minimum prices and state trade in food products
- Mutual acceptance of standards on the safety of food and food ingredients, and regulations

Key Issues and Recommendations

■ Tariffs

Yearly status report: no progress. The import duty rates on many foods and food ingredients remain far too high; for example, chocolate for professional use (29.8%), confectionery (25%), and dairy products (over 30%). Tariffs make European packed foods and semi-finished food products unnecessarily expensive for Japanese consumers.

Recommendation:

- The Governments of Japan and the EU should abolish tariffs on all food products as part of an EU-Japan Economic Integration Agreement.

■ Food additives

Yearly status report: limited progress. Since December 2002, only 7 out of the 46 additives on the Government's own "priority list" have been approved. Another 19 additives have been evaluated by the Food Service Commission (FSC), of which 6 have been notified to the MHLW and have been discussed by the subcommittee (Polysorbates 20, 60, 65, 80, Calcium Silicate, Calcium L-Ascorbate). An additional 6 are under consideration, whilst 4 have been requested for evaluation. This leaves 10 as having had no progress at all. Also, current standards restrict the usage of already accepted commonly used preservatives such as Sorbic Acid, Potassium Sorbate and Sulphur Dioxide to certain pre-defined food categories which works especially against imported foods that tend not to fit these categories.

Recommendation:

- The Japanese Government should set a deadline of December 31 2008 to approve all remaining additives on the priority list adopted by the Government in 2002 (i.e. 6 years allowed in total). Standards of use should also be reviewed so as not to penalise imported food.

■ Testing of food in the market place

Yearly status report: no progress. Under the current system, local authorities inspect food in market circulation. When products not fulfilling prescribed standards are found, the retailer, rather than the manufacturers and importers, are notified. This notification practice often causes the retailer to overreact and withdraw the tested product and related products even if the deviation from the standard is minor and does not pose a health risk.

Recommendation:

- The Government of Japan should oblige local food inspectors at public health centres to communicate a violation to the manufacturer or importer before notifying the retailer. A demand for an immediate recall should only be made where a health risk is involved.

■ European beef

Yearly status report: no progress. In May 2005, the Food Safety Commission recommended that meat from animals younger than 20 months should be considered safe for import, a recommendation that was also endorsed by the Ministry of Agriculture, Forestry and Fisheries (MAFF). The European beef industry is capable of tracing and guaranteeing the age of individual animals, but Japanese authorities have only recently started to discuss the terms and conditions for lifting the ban on European beef. In addition, the World Organization for Animal Health (OIE) has set internationally accepted scientific standards as to what can be considered safe beef. Japan however, though member of the organization, disregards the findings of the international scientific community in its own domestic safety assessments.

Recommendation:

- The Government of Japan should consider internationally accepted scientific standards on beef safety and consequently review restrictions on European beef imports and be consistent and uniform in its application of conditions and standards on all beef importing countries. Conditions on resuming U.S. beef exports should also apply to beef exports from Europe.

■ Organic Products

Yearly status report: no progress. The organic market in Japan remains one of the smallest in the world despite increased consumer interest. The revision of Organic Japan Agricultural Standards (JAS) in 2006 made market entry even more difficult for European organic food producers. Third party certifying organisations are now empowered to apply various inconsistent and non-transparent rules and charging systems that create unnecessary complexities and costs for importers. The current system also involves wasteful bureaucracy where, for example, organically certified products in Europe require supplementary organic certificates to be issued by the respective embassies in Japan every time the products are imported. Furthermore, minor differences in organic standards between Europe and Japan mean that many important European organic products cannot be called organic in Japan. The present system results in limited choice and higher prices for organic products, which are desired by Japanese consumers. Europe is a leader in the organic market and is well-placed to help meet demand for such products in Japan, demand which cannot be met by locally sourced products alone.

Recommendation:

- The Government of Japan should seek with urgency, mutual acceptance of organic products standards with the EU. In the meantime, it should simplify the process for having European organic products marketed in Japan.

■ **Maximum residue levels**

Yearly status report: limited progress. The Positive List System introduced in 2006 sets strict standards for agriculture chemical residues in food. Foods imported from China have, on several occasions, been withdrawn from the market after extremely high levels of residues have been traced. The EBC endorses such action where a clear health risk exists, but fears overreaction if a certain chemical amongst the potential 1,000 or so chemicals is found to be just over the specified limit. Most importers and manufacturers are struggling to comply with the regulations and will need more time and resources to ensure full compliance as the whole production chain must be controlled.

Recommendation:

- While supporting the punishment of clear violations of the Positive List System for Agricultural Chemical Residues implemented from May 26, 2006, the EBC requests the Government of Japan to take steps to avoid overreaction to minor infringements during an appropriate interim period as certain ambiguities still prevail.

■ **Listeria**

Yearly status report: new issue. The difference between EU and Japanese regulations on *Listeria monocytogenes* curbs the exports of many products from EU to Japan such as charcuterie. EU regulations prescribe that up to 100 cfu/g of *L. monocytogenes* may be present during the whole consumption period as such a minimal level is perfectly safe for human consumption. Japan, however, bans all products containing *L. monocytogenes*, though tests are presently not undertaken.

Recommendation:

- Japanese regulations should be brought in line with European regulations on *Listeria*. Products that may have trace amounts of *L. monocytogenes* of up to 100 cfu/g, such as charcuterie or other products, should be allowed on the Japanese market.

Industry

Automotive components
Aeronautics
Space
Defence
Construction
Materials
Environmental technology
Automobiles

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AUTOMOTIVE COMPONENTS

Regulatory Developments

More and more European automotive components firms are dedicating resources to attracting business in Japan by investing in local infrastructure and improving technical competence, with the goal of promoting more direct contact and closer relationships with Japanese clients. European firms are looking to take advantage of the opportunities in Japan that have surfaced as a result of the recent transformation of the Japanese automobile manufacturing sector. Globalisation and intense competitive pressures at home and abroad have forced Japanese manufacturers to reassess procurement strategies, placing more emphasis on global procurement and cost-effective product development.

Unfortunately, European automotive component and systems manufacturers continue to face difficulties in promoting European technical expertise to the Japanese automobile industry, mainly due to continued reluctance in the industry to outsource product development on a global basis. Japanese firms are still uneasy about divulging proprietary information to outsiders, continuing to favour traditional suppliers for product design and production. It is also still often necessary to provide “Japanese solutions” to customers in order to adhere to company-specific requirements, which defies the global trend towards single platform development and volume production.

The process of globalisation and intense competitive pressures has meant that outsourcing of automobile component development and supply has emerged as a clear trend in the European automobile industry. The European system offers low risks, reasonable price and flexibility. However, for European component manufacturers these advantages have yet to translate into significant new opportunities to supply the Japanese automobile industry. Those that have enjoyed success with Japanese transplants in Europe have seldom been able to build on this to become suppliers of the parent company in Japan. Against this background, the EBC greatly values the ongoing, regular dialogue between European component manufacturers and Japanese carmakers as a vital mechanism for sharing information and promoting understanding. It is hoped that this will, over time, foster increased opportunities for mutually beneficial business development.

Prospects for EU-Japan Economic Integration

Japan is the second largest market in the world, yet European automotive manufacturing companies hold only a small share of the market. As Japanese automakers business is steadily growing overseas, this should provide an opportunity for growth for European automotive component manufacturers. The process of globalisation and intense competitive pressures has meant that outsourcing of automobile component development and supply has emerged as a clear trend in the European automobile industry. The European system offers competitive price, reliability and flexibility. However, for European component manufacturers these advantages have yet to translate into significant new opportunities to supply the Japanese automobile industry.

Key Issues and Recommendations

■ Globalisation of the automobile industry

Yearly status report: limited progress. The EBC welcomes the opportunity that internationalisation presents for innovative European firms to strengthen their relationship with Japanese automobile manufacturers in developing new products and sharing technical expertise. European firms are not tied to specific European automobile manufacturers, and have products proven to the rest of the auto industry. Japanese automobile manufacturers are increasingly making use of foreign tie-ups to develop their business and respond to competitive pressures both at home and abroad. Many firms are also reassessing their procurement strategies. Nevertheless, European automotive component and system manufacturers continue to face numerous challenges in promoting European technical expertise to automobile manufacturers in Japan. In general, Japanese manufacturers are still reluctant to outsource product development on a global basis and procure from non-traditional sources. Japan-specific requirements are common, and it is not unusual for specifications to differ between domestic and overseas production, even within the same company. Hence, even European component manufacturers successfully supplying to Japanese transplants in Europe are seldom able to build on this to become a supplier of the parent company in Japan.

Recommendation:

- The EBC urges the Japanese automobile industry to focus more on the technical, commercial and logistical aspects of automobile production in the procurement of components and systems. Increased purchasing on a global basis and more emphasis on single platform development would further benefit the cost-effectiveness of the Japanese industry.

■ Promoting information exchange

Yearly status report: limited progress. Face-to-face meetings between the European Association of Automotive Suppliers and Japanese car manufacturers were established in 1995 to promote information exchange between European and Japanese companies. These meetings have proven to be an extremely effective venue to discuss issues of mutual concern relating to products, platforms, global strategies and other important matters affecting the industry. The next meeting is scheduled for autumn 2008 in Turkey, and the EBC encourages top-level Japanese industry participation. The EBC also sees much potential in the Japan Society of Automotive Engineers' (JSAE) Automotive Engineering Exhibition and the annual congress/paper presentation scheduled for 21-23 May 2008 in Yokohama.

Recommendation:

- The EBC strongly supports the continuation of face-to-face meetings with leading representatives from the Japanese automobile industry. Such meetings have led to a greater understanding between European component manufacturers and Japanese carmakers, and hopes that the scope of these meetings will be expanded in the future to include Japanese venues as well.

■ Green procurement

Yearly status report: new issue. A significant number of Japanese companies purchasing departments are introducing "green procurement" (green chotatsu) requirements. Suppliers are required to document, specifically for Japan, a list of substances used in their manufacturing process, instead of accepting conformity to an RoHS-type "negative" list.

Recommendation:

- The EBC urges the Japanese automobile industry to adhere to accepted international practices when setting procurement requirements.

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AERONAUTICS

Regulatory Developments

Regulatory reforms by the Government of Japan have not reached the field of aeronautics where no improvements have been observed over recent years. Rather than facilitating foreign investments into the country, Japanese authorities seem to be preparing a set of stricter rules that risk hampering the potential for cooperation between Japan and the rest of the world. Already the legal limitation of foreign participation in the capital of Japanese aeronautical firms constitutes a significant hindrance to European investments and presence in Japan (see: Aeronautical Law article 4). Recent cases of Ministry of Economy, Trade and Industry (METI) suspensions or re-assessment of export authorisation for equipment that has for many years been supplied by Japanese companies on commercial aircraft programmes seem to go against the interests of all Japanese companies, and may undermine confidence in the reliability of Japanese suppliers. It would also be inconsistent with METI's efforts to promote industrial cooperation. Since the end of World War II, the Japanese aeronautics industry has been trying to rebuild domestic capability with strong financial support from the Japanese government. Attempts by METI to promote Japanese independence in the field of aeronautics through national projects have not achieved the level of success expected. Japanese companies still rely heavily on defence contracts, which account for over 50% of their total aerospace turnover, and on partnerships with Boeing for commercial contracts.

The Japanese market for large commercial aircraft and helicopters is one of the largest in the world, and has historically been dominated by the United States. The EBC would like Japanese companies to recognise the benefits of competition, the risk of depending on a single source, and the benefits of diversifying their suppliers. European companies provide state-of-the-art technology, high-quality final products and goods, as well as after-sales customer support.

Prospects for EU-Japan Economic Integration

The cooperation between Kawasaki Heavy Industries (KHI) and Eurocopter on the BK117 helicopter, and also between KHI/Mitsubishi Heavy Industries (MHI) and Rolls-Royce on Trent 1000, are encouraging examples of successful cooperation between the European and Japanese aeronautics industries. However, due to the long-standing relationship with North American companies, and limited information about the European aerospace sector, the Japanese industry is at times reluctant to work with European businesses. Proactive collaboration with successful European companies would enable Japanese companies to strengthen their position in commercial aeronautics. By participating in a wider range of projects, Japanese firms would be able to expand their international business opportunities and further develop their technological base. The EBC feels that there is much room for large-scale joint development programs between the Japanese and European industries, especially in the field of transport aircraft, and urges the Japanese Government and aerospace industry to give serious consideration to such an initiative.

An Economic Integration Agreement (EIA) could efficiently solve the issues confronted by the field of aeronautics and facilitate constructive commercial and industrial cooperation. Mutual recognition of aeronautics standards implies that trading partners accept each other's rules and administrative procedures. The differences between European and Japanese rules and regulations are not substantial, therefore comprehensive case-by-case discussions and mutual recognition are feasible.

Priorities

- Establish mutual recognition of aeronautics standards, specifically on airworthiness certification and export control

Key Issues and Recommendations

■ Promoting competition

Yearly status report: limited progress. Although European manufacturers of commercial aircraft, engines, components, and navigational equipment offer state-of-the-art technology at internationally competitive prices, the European share of the Japanese market for commercial aircraft and related equipment is still considerably less than the worldwide average. The Japanese aeronautical sector suffers from a general lack of transparency in equipment procurement as exemplified by the modernization of air traffic management. Although European companies are recognized worldwide as setting state-of-the-art standards, they have the greatest difficulties with new equipment procurement in Japan. The EBC strongly deplores this situation which may keep Japan behind the latest progress in safety standards.

Recommendation:

- Procurement decisions should be made on a competitive basis, free from political influence. The EBC encourages Japanese firms to diversify their sources of supply and consider the advantages of European products in the aeronautics field for the benefit of their customers, shareholders, and the general public. The Japanese authorities should facilitate the use of foreign companies' equipment since foreign companies can help address the need for improvements in air transport safety.

■ Promoting industrial co-operation

Yearly status report: limited progress. Cooperation in commercial aircraft development is still heavily biased in favour of North America. METI's support for the Boeing 787 programme should not limit the potential of future collaboration with Europe. The EBC is still convinced that there are mutually beneficial opportunities for cooperation between European and Japanese firms. METI's support on the Trent 1000 engine and the agreement on supersonic technologies should pave the way for more aeronautic cooperation. Although this may have symbolic significance, the scale of Japanese financial support for such activities with European companies remains significantly below that of activities with US companies.

Recommendation:

- The EBC is looking to increase industrial cooperation between Japan and Europe particularly in the field of commercial aircraft, engines, components and navigation systems. New challenges lie ahead in the development of innovative solutions designed to meet future needs in civil aviation. The EBC considers these challenges as a great opportunity to enlarge the scope of cooperation between Japan and Europe and encourages METI and other government-affiliated institutions to openly promote and fund collaboration with European companies in a similar manner as with North American firms.

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SPACE

Regulatory Developments

Japan is a leading space-faring nation with independent access to space. State of the art programs include launchers, satellites and ground equipment. Despite such advances, commercial success of the space industry in Japan is limited to a few fields because of low domestic volumes and political pressure from the US. Only recently has Mitsubishi Electric Corporation been able to sell a communications satellite to a Japanese commercial satellite operator. Government budget decreases have only recently been balanced by a move into earthquake and disaster prevention areas as well as the security area.

Ariane launchers have been successful in Japan. Japan's space industry maintains productive relations with authorities and cooperation between the Ariane 5 and H-IIA launchers is progressing. On the commercial side, Arianespace and Mitsubishi Heavy Industries (MHI) are cooperating to make it easier for customers to shift satellites from Ariane to H-IIA and vice-versa, in cases of technical problems with the originally contracted launcher. European and Japanese space authorities are discussing the implementation of a similar inter-government scheme for the mutual backup of Japanese and European government missions.

Ground equipment is a new field being spurred by the recent thrust of Japan's space activities into security and defence applications. Japan's space activities increasingly involve space imaging and the use of associated ground equipment for image processing and interpretation, for applications in agriculture, fisheries and geophysics (such as tsunami warning). In addition, several homeland security type applications naturally enhance a nation's defence capability. Non-transparent procurement methods are still being used in this sector to the disadvantage of foreign suppliers.

Japan has designated space as one of the National 'Frontiers' of Science and Technology. The Prime Minister will officially head Japan's top official space strategy group. The new Space Law is close to completion and will lay the foundation for limited national security applications of space and for more industrial and organizational efficiency. In 2007, the Japan Defense Agency was upgraded to the status of a Ministry and national security and human flight have recently been designated as priority areas alongside telecommunications.

Prospects for EU-Japan Economic Integration

Japan's commercial satellite market is relatively open. European satellite manufacturers could soon make their first sale in Japan of a complete satellite. Their high reliability is a key factor, as well as their transparency policy towards Japan, compared with US control policies, which are opaque and unreliable. Japan's cooperation in satellite development is biased towards the US, whose political influence has had an adverse effect on the development of the Japanese and European space industries in Japan. Japan Aerospace Exploration Agency (JAXA) is now closer to Europe in the area of space electronic components. This is due to the disappearance of local production sources because of profitability problems, and by lead-time problems with US components. JAXA is now a member of Europe's Space Components Steering Board.

Priorities

- Establish mutual recognition of export control procedures

Key Issues and Recommendations

■ General environment

Yearly status report: limited progress. Relations between the space agencies of Japan and Europe exist and both sides have expressed an interest in expanding cooperation, however this has been limited. Japan's usual practice of giving token responses to the best European cooperation initiatives has taken its toll on the Europe's intention to cooperate. Since other countries have been more responsive, it is surprising that Japanese officials cannot understand why Europe concentrates more of its cooperation efforts where they are more likely to be rewarded. The EBC is concerned by export license delays encountered in 2007 by European companies procuring Japanese parts and components that have never given rise to problems.

Recommendation:

- The EBC urges closer cooperation between the space agencies of Japan and Europe. This will require a conscious effort by the Japanese Government, which does not realise the extent of European frustration. Agencies should compare plans in new application areas at an earlier stage in order to take better advantage of cooperation opportunities.
- The EBC places high expectations on Japan's new Space Law and its potential to increase Japan-Europe cooperation, allowing both sides to make better use of limited space budgets. The EBC hopes that export licensing delays affecting European customers will be resolved.

■ Satellites

Yearly status report: limited progress. In 2007, JAXA and the Italian Space Agency held the first co-hosted event in Tokyo aimed at official exchanges to find future cooperation opportunities in the field of disaster contingency planning.

Recommendation:

- The EBC hopes for closer cooperation between the space agencies in satellite technology development and applications, and strongly requests pro-active promotion and actual execution of cooperation projects. As soon as Japan's new Space Law is promulgated, the Japanese government should encourage international cooperation with Europe through satellite or satellite equipment procurement in fields related to national security.

■ Launchers

Yearly status report: limited progress. The Japanese and European space authorities are studying the possibility of backing up each other's government launch missions. This will solve the problem of government mission delays in cases of technical trouble with a launcher, and prevent a one-sided flow of government missions away from the delayed launcher. This idea is not new. Although the space industry on both sides is working towards commercial and industrial cooperation, more government leadership is needed.

Recommendation:

- The EBC hopes that government and agency-level talks will bring about vigorous cooperation between our respective heavy-lift launchers. For technical reasons, this cooperation must be comprehensive and systematic for it to succeed. The EBC hopes that new launcher projects will help to consolidate existing cooperation initiatives.

■ Ground equipment

Yearly status report: no progress. Japan's international procurement activities in this area typically exclude entire systems and remain limited to small subsystems and components. Non-transparent procurement methods are still being used in this sector to the disadvantage of foreign suppliers.

Recommendation:

- The EBC hopes that Japan's international procurement activities in ground equipment will soon include whole systems. We also hope that full transparency can be granted in respect to procurement for standard ground processing products.

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DEFENCE

Regulatory Developments

The reforms of the Government have not reached the field of defence where no improvements have been observed over the period. On the contrary, the new regulations governing investments in 137 key technologies sectors threaten to stifle European investments and technology transfer efforts.

Japan's current 5-year defence plan includes an arms procurement budget of around 4 trillion Yen, of which an estimated 85% will be spent on weapon systems developed and built locally. Products built under licence from US manufacturers or directly imported from the US make up most of the remaining 15% of Japan's defence hardware market. With a few exceptions, European defence sales to Japan have consisted mainly of minor equipment or components for Japanese-made weapon systems, a situation that has yet to improve.

As with many other sectors of the Japanese economy, the European defence industry faces a number of non-tariff barriers to trade that limit European involvement in the Japanese market. The Japanese defence procurement process lacks transparency, creating difficulties for foreign companies to understand the timing, parties involved, and requirements of new programmes. This is compounded by a lack of fair competition, and often a reluctance of the Japanese defence establishment to receive product information. The defence establishment remains relatively uninformed about European products, and this lack of exposure leads to narrow views on defence and procurement policy. As a result, European defence firms face an uphill battle in their efforts to increase cooperation in product development with Japanese companies. US political pressure surrounding the trade imbalance, financial incentives to buy US products through the Foreign Military Sales programme, and unfounded Japanese fears of non-interoperability of EU products with US products have further restricted European access to the Japanese defence market.

Prospects for EU-Japan Economic Integration

For the time being, Japan prohibits co-development involving the exchange of defence-related information, including specifications for military equipment, with all countries except the US. Modifications to the three principles of Japanese defence (no technology exports, no product exports, no exchange of information related to armaments) are now being considered, but no conclusion has yet been reached. However the unstable global situation is pushing Japan in the direction of a greater interaction with other countries in defence-related matters.

The United Nations' peace keeping operations (PKO), the coalition's "war on terror", and international actions for humanitarian operations in hostile territories have created a new environment, which cannot leave Japan indifferent. Collective responses by the UN and other groups of nations call for interoperability and battle-proven equipment. In this respect, Europe has much to offer to Japan, not only on equipment, but also on expertise and design cooperative capacities.

The EBC would like to recommend that as an important step to leave the "insular" approach, the Ministry of Defence (MOD) should call on the Japanese industry to develop in depth cooperation with mature European defence industries. Exchange of information should be encouraged as well as security agreements with European governments and bodies. This is a conceivable approach in many sectors like mission airplanes, ground specialized vehicles, UAV technologies, C4ISR systems, and naval systems, just to give some examples.

Priorities

- **The Government of Japan should engage in discussions with its European counterparts to define a general framework for an agreement for exchange of defence-related information necessary to actually cooperate in both operational and industrial fields**

Key Issues and Recommendations

■ Promoting competition

Japan's current economic climate, combined with increasing tensions in the region, the expanding international role for Japan's defence forces, and major projects such as the Missile Defence programme, are placing tremendous pressure on defence procurement budgets, even though these have been modestly increased. The large number of key projects to be implemented in the near term cannot be accommodated within the present fiscal budget without significant re-evaluation of procurement policy and a much greater focus on cost-effectiveness.

Notwithstanding the success of Rolls-Royce with the Ministry of Defence (MOD) over the years, and also of AgustaWestland with the JMSDF (Navy), there have been few encouraging signs recently that Japan is prepared to select a European solution, even when such a solution meets a unique requirement or provides best value for taxpayers' money. The EBC would like to increase the European presence in the Japanese defence sector. However, the procurement process still lacks a true level 'playing field' and the assessment of European equipment remains deficient, as many recent examples have shown. Further improvement is still necessary before European firms can truly compete on an equal basis with Japanese and US firms.

While recognising the important role the US plays in the Japanese security structure, the EBC feels that the Japanese attitude towards interoperability is often exaggerated. Limiting foreign procurement to American products has not guaranteed interoperability with the US. Instead, this policy has restricted Japanese access to innovative European solutions to inter-operational problems. As a counterexample, the closest ally of US, the UK, has fully interoperable forces equipped almost entirely with European-designed systems.

Recommendation:

- The EBC encourages Japan to take advantage of this opportunity for change. A more transparent and competitive procurement process would increase Japan's access to off-the-shelf, cutting-edge-technology defence equipment, enabling the Japanese government to obtain higher value within the actual defence budget. European companies offer worldwide competitive pricing and combat-proven equipment. Moreover, since there is no security alliance between Japan and Europe complicating political relations, Europe can offer full technology transfer with no "political strings" attached. This would be of great benefit in ensuring military readiness in an era of fiscal constraint.

■ Promoting industrial cooperation

World use of new partnership approaches to procurement, like PFI (Private Finance Initiative) or LCS (Life Cycle Support) contracts have yet to be considered by the MOD. The EBC recommends that the Japanese procurement authorities consider these opportunities in the interest of more flexible and cost-efficient use of the defence budget. For the time being, Japan prohibits co-development involving the exchange of defence-related information, including specifications for military equipment, with all countries except the US. Modifications to the three principles of Japanese defence are now being considered.

Recommendation:

- The EBC urges the Japanese government to take this opportunity to start meaningful discussions with its European counterparts and support the development of mutually beneficial partnerships between Japanese and European companies. This will give Japanese industry and governmental agencies access to new technologies and processes developed to meet the requirements of real-world operational experience.

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CONSTRUCTION

Regulatory Developments

In past years, the construction sector in Japan has undergone change, largely because of drastic cuts in public spending that brought construction costs closer to international levels. Yet relatively little has changed to increase competition in the industry. European firms still find that project bidding is often more trouble than it is worth, given the complexity of the bidding process, lack of transparency and lack of clear bidding criteria on performance requirements and quality control. Foreign involvement is relatively low with only a few European firms operating in niche areas of the market.

According to Japanese regulations, a company must hold a permit (kensetsu gyo kyokasho) to be a contractor or a direct subcontractor of a general contractor for projects that are worth over 5 million yen (roughly 30,000 euros) in value. To obtain this permit, the company must have a resident management staff member with more than five years of relevant experience in the same company or in another company in the same field. Small foreign firms that cannot find an appropriate person are forced to make “go-between” side-deals with a permit-holding subcontractor, which increases the cost of doing business in the Japanese market. Although the Building Standard Law is now essentially performance-based, detailed specifications formulated under previous regulations are still widely valid, thereby obstructing the proliferation of high-quality alternative (foreign) materials on the market. The lack of consistent performance criteria has caused Japan to lag behind in the development of safer and more energy-efficient buildings. For example, several accidents, including fatal accidents involving children, have occurred in Japan as a result of using annealed float glass, which is accepted almost everywhere in Japan both on and inside buildings. In Europe, in unprotected areas and in ceilings, it is compulsory to use safer materials - such as tempered glass or laminated glass - that do not easily shatter into large pieces when subjected to external shocks.

To achieve the desired increase in competition, the Government needs to implement new, firm measures to rationalise the construction industry. The ceiling price system (yotei kakaku) for public tenders should be abolished and requirements for bid participation relaxed. Rules peculiar to the construction of public works, such as the requirement for locally qualified and licensed engineers for all projects worth over 25 million Yen, and burdensome inspection requirements not found in private sector projects, should be eliminated. The widespread amakudari practice (private sector employment of retired ranking government officials) should be restricted. Finally, action should be taken to address the fact that current private financing initiative/public-private partnership (PFI/PPP) schemes provide little or no freedom in the means of delivery, do not reward innovation and are largely just a variant of contractor-financing (with deferred payments by the purchaser) rather than real PFI/PPP projects.

Prospects for EU-Japan Economic Integration

Although the relative share of the construction sector has decreased from 14.2% in 1998 to 10.2% of Japan's total GDP in 2006, the absolute size of the sector (363 billion Euro in 2006) makes it one of the largest in the world. The Government has made enormous efforts to increase the sector's efficiency by more than halving (54%) yearly public spending during the past 8 years, yet inefficiencies in the structure and management of the sector continue to prevent the creation of a market environment based solely on cost-effective merit. It remains almost impossible for foreign companies to sell and install building materials and equipment in Japan directly to end-users, especially for new building projects. Moreover, opportunities for European firms to use innovative designs, imported materials and modern construction methods – the key to their competitive advantage – are effectively eliminated in Japan by over-prescriptive regulation, resistance to change by local officials and complicated procedures to obtain the necessary approvals.

Priorities

- **Mutual acceptance of standards and certification for construction products convergence**
- **Improved transparency and strictly enforced common rules for government procurement**
- **Joint recognition of the role of construction in promoting a sustainable society**

Key Issues and Recommendations

■ Harmonisation of building materials standards

Yearly status report: limited progress. Building materials exported to Japan are tested according to both European and Japanese standards, although most of the tests are very similar. Few European testing institutes are accredited to test building materials for Japan. Inevitably, this raises the costs of imports to Japan and makes them less competitive than domestic supplies. In 2001, the Ministry of Construction (currently the Ministry of Land, Infrastructure and Transport - MLIT) issued a Cabinet Order to the effect that foreign standards and certification may be used as a way to prove structural strength for structural lumber and gluelam. Application for acceptance of CE Marking for these products is underway.

Recommendation:

- The Governments of Japan and the EU should work towards mutual recognition of JAS/JIS and EN standards for building materials. CE marking of construction products should suffice as a guarantor of high quality and safety.

■ Promotion of safe and environment friendly construction

Yearly status report: limited progress. Although a performance-based system was formally introduced in Japan through revision of the Building Standard Law in 1998, in practice, prescriptive product type specifications are still widely used. Such detailed product prescriptions are not only difficult for foreign manufacturers to fulfil, given the historical bias towards domestic standards, but have also failed to promote energy-efficient and safer buildings. Japan continues to use building materials that Europe classifies as dangerous and officials are not actively encouraging energy-efficient construction.

Recommendation:

- The Government should replace all remaining prescriptive product specifications and instead, use performance criteria. This is crucial in areas such as environment and safety where, in many respects, Japan lags behind other developed economies. Performance criteria based on best international practice (such as U-value) are needed to reduce energy consumption (and by extension CO2 emissions) and to increase earthquake/typhoon safety both for the occupants and passers-by of buildings with extensive glasswork.

■ Public procurement

Yearly status report: limited progress. The EBC appreciates strengthened enforcement of Japan's Anti-Monopoly Law and efforts of the Government to provide information on upcoming public works projects. However, the public works procurement situation remains far from ideal, and continues to limit opportunities for European firms to participate and increases the cost of public works to the Japanese taxpayer. The single-fiscal-year budgeting policy leads to large projects being broken up into arbitrary bid packages that are unrelated to the content of the work - this reduces efficiency and increases the price as future year packages are often awarded to the successful first-phase contractor with little or no real competition. This practice can also lead to individual awards falling below the WTO minimum threshold – a manipulation that contravenes the WTO Government Procurement Agreement (GPA). The application of PFI/PPP in Japan continues to be mediocre, merely implying deferred payment via contractor-financing. Procurement policies that would greatly improve the transparency and efficiency of public works procurement already exist in Japan, but are not widely applied. For example, the EBC would like to see greatly expanded application of the Comprehensive Evaluation Bidding System, which enables bidders to submit technical proposals that may give them a competitive advantage – and makes it much harder for contractors or commissioning entities to rig the bidding process.

Recommendation:

- The Japanese government should ensure that schemes such as the Comprehensive Evaluation Bidding System, which already exist in Japan, are more widely used. Similarly, the EBC believes much wider utilisation of third party CMr services would also improve the professionalism and accountability of the procurement process.

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MATERIALS

Regulatory Developments

Japan has developed a depth of knowledge and expertise in processing materials, and is at the forefront of many sensitive technologies, such as rechargeable batteries for hybrid vehicles, or nanotechnologies for manufacturing semiconductors and other various electronic components. These advanced technologies are largely based on the availability of key raw materials and Japan's ability to secure a stable supply of high quality materials. It is therefore of utmost importance that Japan secures its raw material supplies by adopting a strategy based on security, competitiveness, and access to its domestic market for overseas suppliers of raw materials.

Japan has been reluctant to reduce tariffs on industrial materials on a unilateral basis before formal negotiations on tariff reductions take place under the auspices of the WTO. With this as a pretext, the Government has more-or-less refused to take up the idea in discussions and no progress has been achieved. Japan, one of the main consumers of industrial materials in the world, would greatly benefit from unrestricted access to the reliable sources of high quality products at the market-based prices that European companies can offer. In this regard, the EBC welcomed the removal of duties on ferro-molybdenum imported from Chile. Moreover, following requests from the domestic stainless steel industry, the Government of Japan is now contemplating removing tariffs on chromium, a key ingredient in the manufacturing of all stainless steels. It is now understood that the Ministry of Economy, Trade and Industry (METI) supports the removal of the import duties on chromium products, while this request is being studied by the Ministry of Finance (MOF).

Prospects for EU-Japan Economic Integration

Tariffs damage competitiveness and threaten the future of the domestic Japanese industry. The tariffs on processed nickel significantly increase local procurement costs at a time when companies in sectors such as stainless steel production are facing stiff challenges from overseas competitors, particularly in Korea and China. The same situation applies to fused aluminium oxide (artificial corundum, tariff codes 281810010 sized grain and 281810090 not sized grain), and to silicon carbide (tariff codes 284920010 sized grain and 284920090 others), both widely used in the refractory and abrasive industry and in electric components. Silicon carbide in particular, is used in wire-sawing for electronics and photovoltaic use, a rapidly expanding application in Japan. Imported fused aluminium oxide and silicon carbide are both subject to a 3.3% tariff, even though domestic melting and base production can only fulfil at best 10% of the yearly requirements. While consumers can currently import much of their fused aluminium oxide requirements from tariff-exempt countries under the General System of Preference (GSP), this is becoming more difficult, given the global shift in production to non-GSP countries with larger-scale facilities. Moreover, some categories of products are neither produced domestically nor available from tariff-exempt sources. The result is that Japanese consumers are dependent on imported products subject to high tariffs, and the global competitiveness of the Japanese manufacturers suffers accordingly. In the case of silicon carbide, Japan is importing 97% of its requirements from only one source because it is a tariff-exempt country. A situation of dependency has been created, threatening the long-term stability of supplies to the Japanese industry.

Priorities

- Remove all import duties on industrial raw materials such as refined nickel products, fused aluminium oxide and silicon carbide

Key Issues and Recommendations

■ Nickel

Yearly status report: no progress. Approximately 60% of total stainless steel production contains nickel, corresponding to roughly 40% of total production costs. Therefore it is critical that Japanese manufacturers are able to procure their nickel requirements at competitive prices and are ensured easy and stable access to nickel products. However, Japan is the only developed country in the world to apply duties on processed nickel products, such as nickel metal (import code 750210000), ferro-nickel (import code 7202600100 / 7202600100) and nickel oxide sinters (import code 750120100 / 750120210). These products are subject to tariffs ranging between 3.0% and 3.3% or 44 yen/kg. The continuation of tariffs on imported processed nickel products and the impact this has on European producers can no longer be justified.

The impact of high tariff rates on refined nickel is a significant increase in costs for domestic users, particularly in the stainless steel industry. Japanese nickel producers have increased production to cover fixed costs, despite stagnant domestic demand, and so now export over 30% of their total output. They are competing with Korean and Chinese companies, who have to pay little or no import duties. The Japanese industry's global competitiveness is under threat from Korean and Chinese rivals, operating two to three times larger factories than any Japanese facility. European stainless steel rivals have also improved their competitive strength by concentrating production in a few giant mills. The EBC believes that eliminating tariffs on nickel would be an important step towards enhancing the competitive strength of Japan's stainless steel industry.

Recommendation:

- The Government of Japan should remove import tariffs on all industrial raw materials including nickel products.

■ Fused aluminium oxide and silicon carbide

Yearly status report: no progress. Fused aluminium oxide and silicon carbide are both subject to a 3.3% tariff, though most imports come from countries enjoying tariff exemption under the Generalised System of Preferences. For some categories, a duty is being applied to some products that are not even produced in Japan. This increases the price for imported fused aluminium oxide and effectively penalises the Japanese end-user, a situation exacerbated by a current shortage of supply. With regards to silicon carbide, almost all imports come from only one source. In this context, such dependency on only one source makes Japan vulnerable to supply shortages or market control attempts.

Recommendation:

- The Government of Japan should remove import duties on all raw industrial materials including aluminium oxide and silicon carbide.

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ENVIRONMENTAL TECHNOLOGY

Regulatory Developments

Although the Government of Japan is placing increasing importance on environmental protection, energy-saving, recycling, global warming and other environmental issues, there has been relatively little progress towards a comprehensive strategy to deal with the numerous environmental issues in the area of pollution, soil remediation, waste removal and water treatment.

The regulatory regime governing environmental protection and the environmental business is relatively weak in terms of consistent application and enforcement of rules, especially in regards to soil remediation. Legislation, such as the new dioxin emissions standards introduced in 2002, is enacted on a piecemeal basis, leaving many questions unanswered about how the Government intends to address its long-term environmental challenges. In the private sector, certain Japanese companies are world leaders in developing innovative environmental technologies to improve fuel efficiency and reduce pollution, yet public and private entities remain hesitant to divulge their challenges in terms of the environmental problems they face today and expect in the future. This weakens the interest of European companies, greatly experienced in this field, in investing in Japan and bringing the benefit of their expertise to the market.

The EBC is encouraged by a number of recent developments that bode well for the future of the soil remediation sector. The new Soil Contamination Measures Law, for example, creates a strict new environment for the remediation of contaminated soil sites, which will likely result in increased interest in soil remediation technologies in the immediate future. However, the long-term impact of this reform will depend to a large extent on the ability of the regulatory authorities to effectively implement these new guidelines. The EBC also remains concerned about the regulatory environment governing the soil remediation practices themselves. The Japanese Government has yet to develop clear guidelines regarding site characterisation standards, sampling and testing procedures, risk-based decision models for determining remediation urgency, and a comprehensive timeframe for cataloguing and cleaning up polluted sites. Many testing methodologies differ substantially from accepted international practice, and testing costs are much higher than in Europe. The EBC feels that increased competition in site assessment and testing services would benefit the environment and help society by reducing the costs associated with remediation.

The EBC believes that Private Finance Initiatives (PFI) and Public-Private Partnerships (PPP) represent a way forward for Japan to enhance the development and delivery of such services and attract European companies specialising in this field. Revision of the Water Law in 2002 enabled delegation of the management of drinking water and wastewater services to private professional operators through PFI/PPP schemes, but take up of this new provision has been limited. The EBC therefore urges the Japanese government and the EU to unite on principles and practices of PFI/PPP.

Prospects for EU-Japan Economic Integration

Japan's environmental technology market accounts for 16% of the global market, making it the second largest market in the world. The mere size of the market implies tremendous opportunities for foreign companies with innovative environmental technologies, machinery or services. However, foreign firms trying to enter the market are hampered by a closed government procurement system. The environmental industry and technology are to a large extent created and developed through environmental regulations and large-scale investment plans of governments. Government policies are therefore crucial for opening up the market to efficient and innovative services.

Priorities

- **Establish common principles and rules for fair public procurement and PFI/PPP**
- **Establish a common approach towards environmental regulation including urban pollution and emission standards**

Key Issues and Recommendations

■ Attitudes towards environmental remediation

Yearly status report: no progress. In Japan, environmental problems such as the illegal dumping of waste, high levels of soil contamination, low levels of plastic recycling, and an aging waste management infrastructure pose significant health and financial risks. Environmental remediation should not be regarded as an expense. The development of new technologies to combat environmental problems generates important economic benefits, and these should be emphasised.

Recommendation:

- The Government of Japan must improve education on environmental remediation and promote the development of new technologies that prevent, reduce, and manage environmental risks.

■ Regulatory structure

Yearly status report: no progress. While the regulatory regime governing environmental protection and environment-related businesses is highly developed in Japan, it is not always conducive to the introduction of innovative solutions to environmental problems.

Recommendation:

- Japan should further strengthen the regulatory regime governing environmental protection and environment-related businesses with special emphasis on consistent application and enforcement of the rules.

■ Government procurement

Yearly status report: no progress. Private Finance Initiatives (PFI) and Public-Private Partnerships (PPP) are gaining popularity in Japan. These means have long been applied in Europe for the funding of entities traditionally financed, managed, and operated by public authorities. European firms specialising in this field would like to enter the Japanese market, but conservative attitudes towards alternative service delivery continue to obstruct these initiatives. In the water sector, for example, public works development continues to be dominated by equipment manufacturers and construction firms. Private companies are not yet able to provide comprehensive operational management to help boost performance. This has resulted in high initial capital investment, high running costs, over-capacity, and a growing debt burden on municipalities.

Recommendation:

- The use of Private Finance Initiatives (PFI) and Public-Private Partnerships (PPP) as an efficient means of delivering public services should be further encouraged in Japan. The EBC urges more Japanese and European cooperation in the development of Japan's PFI/PPP strategy to draw on the wealth of European experience in this area.

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AUTOMOBILES

Regulatory Developments

The Japanese automobile industry is booming. Profits are at a record level. In 2006, production in Japan increased for the fifth consecutive year and exports soared by 21% in volume to 5.3 million units. The prosperity of the Japanese automobile industry is, however, disproportionately dependent on the growth of overseas markets. By contrast, the domestic market is in decline, except for Japan's unique mini-car ("kei" car) segment. Not surprisingly therefore, sales of imported vehicles are flat and have never recovered the peak of 311,000 units reached in 1996.

In 2006, imports – of which European brands have a share of more than 85% - took just over 5% of the total passenger car market, including mini-cars. However, import sales of 244,000 units were virtually unchanged from the previous year. The Japanese Government needs to take more vigorous action to stimulate the domestic market so that importers can enjoy similar opportunities in Japan to those which domestic manufacturers experience in overseas markets, including Europe, where Japanese exports grew by 11% in 2006 to 1.3 million units.

Prospects for EU-Japan Economic Integration

The automobile industry has been at the forefront of the globalisation of the world economy. The regulatory regime for automobiles is evolving to reflect the global operations of the industry. This gives European and Japanese automakers a common interest in the international harmonisation of technical standards. While competing fiercely in the market place, the two industries cooperate to ensure that the industry can meet the legitimate demands of consumers for safe and environmentally friendly products at the lowest regulatory cost.

In 1998, Japan became the first country in Asia to accede to the UN/ECE 1958 Agreement on the Mutual Recognition of Type Approval for Vehicles etc., which provides that vehicle devices that have received type approval according to ECE Regulations in one contracting party are exempt from testing in any other signatory country where those regulations have been adopted.

Since Japan became a signatory of the UN/ECE 1958 Agreement Japan has steadily brought domestic technical standards into line with UN-ECE regulations. But there are still areas where Japan has unique national technical requirements e.g. noise testing. More recently the pace of the adoption of UN-ECE regulations into Japanese law appears to have slackened. The number of regulations adopted by Japan is still well behind that of the EU. A faster rate of adoption would be to the mutual benefit of the Japanese automobile industry and to European exporters to Japan.

Japan is now considering proposing to other UN/ECE signatories the introduction by 2015 of a system of Mutual Recognition of Whole Vehicle Certification. The EBC Automobile Committee welcomes this initiative. If implemented, it would mean that once a vehicle had been certificated in either the EU or Japan, that vehicle would require no further testing to be sold in either region. This would go a long way towards the integration of the Europe and Japanese automobile markets. Even in advance of the realisation of this long-term goal, there are other steps set out below which the Japanese Government could take to facilitate the sales of imported vehicles in Japan.

Key Issues and Recommendations

■ Harmonisation of technical standards and certification procedures

Yearly status report: limited progress. So far, Japan has adopted a total of 32 out of some 120 UN-ECE Regulations. In FY 2006, Japan only adopted 3 additional UN-ECE Regulations. The schedule for FY 2007 is hardly more ambitious and does not include Regulation 51: Proximity Noise, an item of particular interest to importers of European rear-engine and high performance vehicles. MLIT has decided to incorporate the English text of ECE regulations directly into Japanese law. This will not affect Japan's long-term adoption schedule, but it should make it easier to incorporate amendments of ECE Regulations into Japanese law. Nonetheless, inconsistencies in the interpretation of UN-ECE Regulations continue to exist between Japan and Europe.

Recommendation:

- The Japanese government should speed up the adoption of UN-ECE Regulations and consult closely with other UN-ECE members before introducing new domestic requirements that either conflict with existing regulations or are outside their scope. The Japanese government should also work closely with EU Member States and the European Commission to realise as soon as possible a system of Mutual Recognition of Whole Vehicle Certification.

■ Tax reform

Yearly status report: limited progress. Compared with other major countries, Japan imposes an excessively heavy tax on the acquisition and ownership of motor vehicles. In addition to consumption tax, the purchaser of a vehicle must also pay an Automobile Acquisition Tax. To help stimulate the domestic automobile market, the EBC Automobile Committee strongly supports the call of the Japanese automobile industry for the elimination of this double taxation.

Recommendation:

- The Japanese government should abolish the Automobile Acquisition Tax.

■ Diesel promotion

Yearly status report: limited progress. The Japanese government increasingly recognises that diesel passenger cars have a role to play in enabling Japan to meet her CO₂ reduction targets under the Kyoto Protocol. However, even those diesel vehicles which comply with the most stringent emission requirements in the EU and the US cannot be sold in Japan without engineering modifications. To enable foreign manufacturers to recoup the development cost of this engineering, the Japanese government should accept for a fixed volume of imports whose compliance with the latest EU and US diesel emissions regulations meets the requirements of Japan's Post New Long Term Emission Standards.

Recommendation:

- The Japanese government should allow the certification under the Preferential Handling Procedure of diesel passenger cars which comply with the latest EU and US diesel emissions regulations.

■ Kei cars

Yearly status report: new issue. "Kei" or mini-cars are those vehicles legally restricted to a maximum length of 3.4m, a width of 1.48m, a height of 2m, and to an engine displacement of 660cc and below. Originally, conceived to provide affordable transport for low-income earners, kei cars now take more than 30% of the passenger car market. Kei cars benefit from lower automobile related taxes, automobile liability insurance and motorway tolls and are subject to less stringent overnight garaging requirements. The original justification for the kei car segment has meanwhile become questionable since more than 70% of kei cars are now operated as second cars. This segment is only supplied by Japanese OEMs since no similar segment, artificially created by regulation, exists in any other market of the world. The continued existence of the privileges enjoyed by kei cars is an anachronism which distorts the competition with imported compact and subcompact cars sold in other global

markets, which do not enjoy the same prerogatives as kei cars in Japan, even though their performance and specifications hardly differ.

Recommendation:

- The Japanese Government should abolish the fiscal and regulatory privileges accorded to kei cars.

■ **Treatment of modifications**

Yearly status report: new issue. A Completion Certificate must be issued in respect to each new vehicle registered in Japan verifying that the vehicle is identical in every respect with the model that has received type approval. Whenever a European manufacturer makes an improvement to the vehicle, the approval of the MLIT must be obtained before further Completion Certificates can be issued, even if the change in specifications does not affect the vehicle's compliance with safety and other regulations.

Recommendation:

- The Japanese Government should allow the applicant for type approval to continue to issue Completion Certificates, where a manufacturer has modified the specifications of a vehicle, provided that the device which has been modified has the relevant ECE certification, or the manufacturer guarantees that the modification does not affect the vehicle's compliance with safety and other regulations, and the importer retrospectively notifies the MLIT of the changes. In the unlikely event that the MLIT concludes that the vehicle no longer complies with the certification requirements, it would be subject to recall.

■ **Technical guidelines for new safety technologies**

Yearly status report: new issue. MLIT has set technical guidelines for new driving assistance systems on the verge of commercialisation. MLIT claims that, if a European automaker provides appropriate technical argumentation, the guidelines can be amended to accommodate safety devices installed in imported vehicles which achieve the same objectives but use different technology. In reality, amending the guidelines has proved difficult and time-consuming. The technical guidelines therefore act as a deterrent to the import of vehicles incorporating advanced safety features, which do not comply with the guidelines, to the detriment of the Japanese consumer.

Recommendation:

- The Japanese Government should discuss with the Japan Automobile Importers Association ways to facilitate the revision of the technical guidelines.

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