



Time for Change

The EBC Report on the Japanese Business Environment
2009

The European Business Council in Japan
The European (EU) Chamber of Commerce in Japan

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The European Business Council (EBC) is the trade policy arm of the 17 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 2,500 local European companies and individuals who are members of their national chambers of commerce. Around 300 company executives 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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Message from the Chairman

Japan wants change: after more than fifty years of near uninterrupted government by one party, culminating in the country's deepest recession of the post-war era, the Japanese people have clearly said enough is enough. They have turned to the Democratic Party of Japan (DPJ) to deliver a fresh approach and a more prosperous future. The country's new leadership enjoys a commanding majority in Parliament and a clear mandate for reform: what an outstanding opportunity to act!

There is much to do. Many of Japan's problems are both structural and chronic. The economy suffers from over-dependency on foreign markets for manufactured goods, combined with low levels of domestic demand and an inefficient services sector. Competition has been hampered by powerful vested interests and a bloated bureaucracy that frustrates innovation, regulatory reform and foreign investment. Meanwhile, the rising cost of caring for a shrinking and ageing population threatens to overwhelm public finances. Entrenched and persistent as they are, these problems must be urgently addressed if Japan is to create the basis for sustainable growth.

The European Business Council in Japan (EBC) recognises not only the immense challenge facing the new Government, but also the unprecedented opportunity to reform the underlying structure of the economy and so unleash new drivers for growth, benefiting consumers and the economy as a whole. The aim of this report, the EBC's 2009 overview of the Japanese business environment, is to pinpoint the areas where we believe change is most crucial, achievable and potentially fruitful, both for foreign and domestic companies.

Prime Minister Hatoyama's commitment to improve transparency and political control over the policy-making process is a promising start. Such measures could help to foster greater competition and efficiency in the market place, better serving the interests of consumers and so stimulating increased demand. This in turn could facilitate a healthier balance in the economy, making it less reliant on foreign markets. The EBC urges the Prime Minister to focus particularly on three critical barriers to reform, which have proven resistant to the efforts of previous leaderships:

- Government ministries that traditionally control the policy-making process, setting their own agenda and timetable, at arms-length from democratically elected politicians;
- Powerful vested interests, including existing suppliers and their allies in government ministries, that frustrate new competition, making markets inefficient and resistant to innovation and maintaining high price structures;
- Excessive bureaucracy that slows and, in some cases, thwarts innovation, new investment and greater competition.

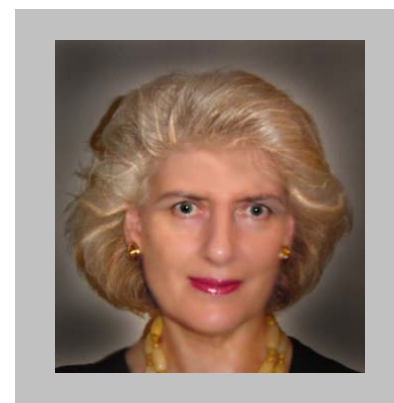
The work of the EBC, including this report, underlines the importance of Japan to European companies and our conviction that, if market access improves, the country can offer new and exciting business opportunities, bringing growth, jobs and increased prosperity. For this reason, we continue to urge the authorities in Japan and in the European Union to commit to an Economic Integration Agreement that would offer a lasting platform for boosting mutual trade and investment as well as learning and progress.

We trust that the recommendations in this report will serve as an inspiration to all those committed to building a brighter economic future for our countries: a win-win situation for all.

Honestly, what are we waiting for? It is time for change!

Tommy Kullberg
Chairman, European Business Council in Japan
(Chairman & Representative Director, Kullberg & Partners KK)

Message from the Executive Director



The European Business Council in Japan (EBC) is pleased to present its 2009 report on the Japanese business environment: *Time for Change*. The report represents the views of European business in Japan on developments over the past year and highlights areas where reform would most benefit the economy, consumers and companies alike.

The report appears at a time when world trade is still suffering the effects of prolonged financial turmoil and Japan languishes in its deepest recession of the post-war era. The full vulnerability of an economy reliant on exports has been exposed: Japan's output has fallen dramatically, leading to rising unemployment, falling wages and entrenched deflation. Stimulus packages have given some short-term relief, but it is clear that more permanent solutions are required, tackling the underlying structural problems in the economy and building sustainable growth. The strong mandate enjoyed by the new Government under the leadership of Prime Minister Hatoyama represents an unparalleled opportunity to address these challenges.

The EBC annual report aims to contribute to the Government's process of identifying key areas for action by highlighting issues that, in the view of European business in Japan, hold back prospects for economic revival. It underlines the crucial role of open markets and fair competition in promoting competitive firms and products that excite consumers and stimulate growth. Its recommendations are based on input from the EBC's 29 sector-based committees, some 2,500 companies and our key stakeholders, the European National Chambers of Commerce and other business organisations represented in Japan. Together they ensure the report is built on real professional experience and expert knowledge of where reform is most needed. The final document owes much to the EBC's Policy Director, Jakob Edberg, whose extensive knowledge of the issues is only matched by his unflagging enthusiasm for tackling them.

On behalf of the EBC, I would also like to acknowledge the valuable support and expertise offered to the EBC by the Delegation of the European Commission to Japan and the European national embassies in Tokyo. Finally, I would like to thank the many EBC Members whose financial support makes this publication possible and whose generosity is acknowledged in the sponsors and supporters sections at the end of the report.

The combined effort of so many individuals, companies and organisations in producing the EBC report demonstrates the commitment of European business to the Japanese market and their resolve to boost its prospects for growth. The report offers a valuable source of ideas and we believe can make a significant contribution to the new Government's search for solutions to Japan's economic challenges. Moreover, as the European Union itself wrestles with the aftermath of global financial turmoil and its own economic problems, we continue to underline the enormous potential benefit for both the EU and Japan in working together towards an EU-Japan Economic Integration Agreement (EIA) that would substantially improve mutual trade and investment.

We commend the EBC report to all our readers and trust that its recommendations will prove useful to all those committed to building a brighter economic future.

Alison Murray
Executive Director
European Business Council in Japan

Introduction

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INTRODUCTION

A new start for Japan?

The production of this report has coincided with the most dramatic event in modern Japanese political history: the landslide victory of the Democratic Party of Japan (DPJ) in the August 2009 general election. Having won a total of 308 seats in the lower house - the largest number ever held by a political party in Japan - the DPJ enjoys an overwhelming majority. The change could not be more dramatic: the Liberal Democratic Party (LDP) has gone from holding 303 seats to just 119, in what proved the biggest defeat in its history and the end to almost fifty straight years in power.

Such a defeat will inevitably be seen as a vote of no confidence in the old government's ability to solve the huge challenges facing Japan, many of which the EBC has been addressing for years. Since the bubble burst, now more than 15 years ago, Japan's domestic economy has proven stubbornly difficult to tease out of recession: attempts at monetary stimulus have led only to exceptionally low interests rates and in turn, to carry trade, thus lowering the value of the yen to levels many believed artificial. It was therefore no surprise to find that when the financial crisis hit last year, the unwinding of this carry trade caused the yen to surge rapidly. The effect has been to expose once again Japan's vulnerability in relying on its export industry to drive the economy forward.

The core of the problem is Japan's reluctance to completely abandon its post-war growth model, characterised by central government guiding industry in the search for global market share and then redistributing the resulting export profits, while protecting domestic industry from competition. Once effective, this model has proved to be a poor fit for the realities of global markets, a fact acknowledged four years ago, when finding a new model became the main theme of the 2005 elections.

At that time, the Japanese electorate handed LDP leader Junichiro Koizumi a landslide victory, on the promise that his policy of Postal Privatisation would be the key to changing the whole economic system, bringing an over-powerful bureaucracy under control and preventing special interests from undermining much needed reform. Hopes of "true change" ran high, despite the Koizumi regime's relatively poor record, reflected in the 2005 EBC report, which catalogued a long list of "reforms undermined in implementation" and urged the Koizumi cabinet to use its election victory to wrest control of the policy process from bureaucrats' hands. Yet four years on, the EBC's disappointment at the inability of successive LDP prime ministers to implement change seems to have spread to the Japanese public, becoming a major factor in the party's historic defeat.

The LDP legacy I: inheriting work in progress

Despite everything, Prime Minister Koizumi and his three successors did manage to implement a number of wide-ranging reforms of the Japanese business environment. Mr Koizumi took the lead in introducing a new Corporation Law, which modernised legal structures for firms in Japan, giving them greater flexibility and a wider choice of forms of legal presence. He also broke with the government's protectionist tradition by establishing a credible policy of non-intervention, which forced financial institutions to deal squarely with bad debts and non-performing loans. Streamlining of the multiple financial services regulators and the introduction of a no-action letter system also helped. Introduction of the new company law was praised by the EBC for providing much needed flexibility, by relaxing restrictions on using foreign stocks as consideration in a merger or acquisition. Perhaps most dramatically, the Koizumi Government implemented a drastic cut in public spending on

infrastructure projects - a clear change of direction from the practice of previous governments of throwing money at projects as a way to stimulate the economy out of recession. The governments under Prime Ministers Abe and Fukuda followed suit, though arguably with less enthusiasm. The launch of policy reviews aiming to boost Tokyo's position as a global financial centre, the liberalisation of airline pricing, and the ambitious but very slow moving programmes to reduce delays in introducing new drugs and medical devices to the market, were important steps which kept many of the EBC committees busy in monitoring and providing input.

However, with the notable exception of liberalised pricing for international airfares, the outcome of these efforts has been depressing. The Cabinet orders and guidelines which followed the revision of the Financial Instruments Exchange Law made it, in practice, difficult to integrate different financial services firms under one umbrella in Japan, even though this is common practice in most other jurisdictions. Announced measures to remedy the delay in introducing innovative drugs, medical equipment, and medical diagnostics products into Japan, though impressive, have yet to materialise. In fact the EBC Medical Equipment Committee points out that still only half of all products used in Europe and the USA are available to Japanese patients, held back mainly due to the time and resources needed to ensure market authorisation in Japan. In their view, so far little has changed for the better.

While the administrations of Prime Ministers Abe and Fukuda may have had good intentions to introduce reforms, they apparently lacked the necessary energy to follow through and so failed at implementation. The EBC had still less to celebrate during the year of Prime Minister Aso's administration. Structural reforms were understandably low on the agenda during the financial crisis, but at a time when Japan most needed a new vision and model for the future, the government "outsourced" key policy decisions to bureaucrats, thereby strengthening the hand of vested interests and disregarding the needs of consumers.

The LDP legacy II: learning from past mistakes

The repeated failure of the LDP administration to seize opportunities for more bold economic reform seems in part rooted in a fear of exposing domestic companies to open competition in Japanese markets. The risk of a backlash from some unhappy voters who might, as a result, lose their livelihood or shareholding was perhaps too great for the leadership to contemplate. Yet such inaction has contributed to an outcome even more painful for the party – a complete loss of power. Put simply, the chronic lack of a competitive domestic economy left demand amongst Japanese consumers too weak to compensate when global demand for Japanese products fell, and so pushed Japan even further into the crisis that cost the LDP the election. The new Government has inherited a country in which output is declining, unemployment rising, wages are lower and deflation entrenched.

It is clear that reforms are needed to put the Japanese economy on a more positive track, especially those that will create new drivers for sustainable growth, and amongst these, stimulating a long-term increase in private domestic demand will be crucial. The Government must seize the opportunity of a strong electoral mandate and crisis conditions to open up markets, so that greater competition, stimulating the design and supply of products more closely matched to consumer demand, can be allowed to reinvigorate the economy. Too often, the consumer interest in more innovative, efficient products and services comes second to the interests of existing suppliers and their allies in bureaucracy, who prefer to maintain the status quo. There will be no sustainable change for the better until the Government reverses this model so that the interests of the consumer come first. To do this, the Government must regain control of the policy-making process and deliver reforms that lower barriers to market entry and remove regulation and bureaucracy inhibiting competition.

The new Government: Welcome first initiatives...

The first month of the new DPJ administration has resulted in more initiatives than in the entire past three years. The EBC welcomes many of the new policies announced, including the Government's very ambitious target of reducing wasteful spending and providing "value for money". The EBC is dedicating much of this, its annual report on the Japanese business environment, to offering specific, practical recommendations on how this target can be met.

A central element in the DPJ plan is to review the special accounts held by Government ministries as a means of ensuring their own source of income outside the general budget held by the Ministry of Finance. In an effort to cut wasteful spending, the DPJ wants to eliminate all but the most necessary of these special accounts. The EBC strongly supports the new Government in this endeavour. Not only do such complex accounts frustrate attempts to get a clear overview of the state of public finances, but they are also a vehicle for inefficient allocation of resources in the economy, since they are used by ministries to entrench their own power and to protect special interest groups closely linked to them.

In particular, the DPJ's intention to eliminate the special account for airport development - whereby existing airports have to pay fixed fees for apparently never-ending construction of new airports throughout Japan - is in line with recommendations made by the EBC and is most welcome. Contributions to this special account have ensured that air transport costs in Japan have remained the highest in the world. The new Government should see that any future arrangements avoid compulsory support for the politically-driven development of new airports of little or no public value. The EBC also welcomes the Government's intention to re-consider the whole airport infrastructure plan and reiterates the need to make it practically feasible for all, including European, airlines to use Haneda when it opens up for intercontinental flights next year.

In its desire to reduce wasteful spending and provide value for money, the new DPJ Government has also promised to focus on procurement, an issue of great importance to European companies. A special entity will be set up to review all contracts and procurement policies of government agencies with a view to cutting costs. Notwithstanding the difficulty that can be expected in confronting the many interests opposing reforms, the review is most promising. The field of defence is a very good case in point. This report shows how aligning Japanese procurement practices with those in Europe would not only deliver a better product for a lower price but would also strengthen the Japanese defence industry. The same argument can be found also in the aeronautics, space and construction sections.

Healthcare is another area attracting attention: the DPJ has publicly pledged to prioritise and rationalise medical services. The discussion on appropriate reimbursement prices for pharmaceuticals and medical equipment has already started and the EBC again underlines the crucial importance of rewarding innovation as a way to both improve patient welfare and cut overall costs to society. Within this context, the Pharmaceuticals, Vaccines, Medical Equipment and Medical Diagnostics chapters of this EBC report all emphasise that streamlining Japan's certification process, by establishing mutual recognition of standards with Europe, is the single most important measure for cutting costs and improving patient welfare, without compromising safety concerns.

There are also several interesting DPJ proposals in the field of taxation. The plan to lower corporate tax to 11% for SMEs is welcome news. The same can be said for abolition of the vehicle acquisition tax. In addition, the EBC welcomes the DPJ call for increased transparency, not least because European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. This report shows how taking on issues such as secret comparables and introducing an unlimited tax loss carry forward period could provide an effective and immediate stimulus to companies, without undermining the tax base.

... and a few notes of caution

The EBC not only welcomes the new Government's plans where it sees these will benefit the business environment, but also highlights in this report those plans it believes risk taking Japan in the wrong direction.

The EBC supports the DPJ's stated intention of creating an independent government committee as an independent regulator for the telecommunications and broadcasting industries, and argues that the new committee should have a mandate of overseeing regulation and business practices within the communications sector from a consumer perspective. The focus on network competition rather than a mix of network- and service-based competition is, however, problematic as it may fail to deliver necessary improvements to the competitive environment in the telecommunications sector.

A second area where stated DPJ policies might have an adverse effect on consumers and industry alike is the call for a renewed food labelling system, which would make inclusion of the country-of-origin mandatory for all ingredients in food. This is an unrealistic approach given that a necessary condition for providing processed food on a global basis is a flexible procurement regime.

Finally, this report expresses reservations about DPJ language relating to a revision of the privatisation of Japan Post. Though the privatisation process has been far from ideal – the EBC has expressed deep concerns about the prospects of Japan Post launching new products before a level playing field has been established – returning to the situation prior to privatisation would raise serious questions about the role of the state in the economy. Japan Post funds played a crucial role in the stalled economic growth model, financing much of the wasteful spending that the DPJ has pledged to cut. Notwithstanding the crucial role of Japan Post in many local communities, merging the units (Bank, Kampo, Delivery and Offices) back into one unit on the pretext of improved service provision is not viable. The interest of Japan as a whole should be considered when embarking on such a journey and the risk of up-front state competition with private sector companies should be avoided at all costs.

Finding a vision and model for the future

Putting specific concerns aside, the big question is whether the new Government can actually deliver on the promises it has made to create a prosperous new Japan. The magnitude of the task can never be underestimated. Over the years so many good intentions have been undermined by vested interests working through ministries and political groups. The EBC has long recommended strengthened central control of the policy-making process both to protect sensible policies from being weakened by such interests and to improve transparency, and believes that this will be key to the new Government delivering the changes necessary for Japan.

Yet strong political control of the administration will not be enough. Japan needs a clear vision of what the alternative to stagnation and economic decay could be – a vision that could be shared by the public, the administration and the political parties, a vision that could be translated into a model for future prosperity. The new Government currently enjoys unprecedented public support and a strong mandate for change, but many pieces of the vision are missing, and to-date there is no model for growth articulated at all.

The EBC believes that an EU-Japan Economic Integration Agreement (EIA) could play a vital role not only in boosting reforms through the process of policy alignment, but also in providing inspiration and direction for a new economic model, built on openness to global trade and common values. The experience of EU Member States in establishing the Single Market testifies to the real benefits that can be gained from such a project - as well as the challenges involved. Yet realising what was at stake, the Member States invested in making the Single

Market a success, culminating in a body of singularly robust rules and regulations establishing the free movement of goods, people, services and capital. These rules and regulations have boosted trade within the EU and could easily serve as a model to inspire – and even give substance to – a body of rules and regulations that would boost trade between the EU and Japan. The EBC is encouraged to see that Japanese business groups are now looking at an EIA with the EU as a way to stimulate competition, growth and welfare and recommends that the Government of Japan look at the potential of relations with the EU from this same perspective.

The EU and Japan have much in common in terms of priorities and values, emphasising a co-operative, inclusive and sensitive approach to solving socio-economic issues. We share many of the same concerns and challenges at the global trade level, being strong believers in rules-based free trade. An ambitious EU-Japan Agreement should present no danger to the multilateral system, but complement it by addressing issues currently beyond the scope of WTO negotiations, and provide an example of a way forward for the benefit of all.

Seize the moment: it may not last

The new Government of Japan inherited an economic model that has long outlasted its usefulness. Although the barriers set up years ago to protect domestic industry from competition are now damaging the economy, it has proved enormously difficult to break with them. Blinded by memories of past success, Japan's political leaders have for years struggled to establish a vision for the future. While Prime Minister Koizumi managed to move the political consensus in a more reform-friendly direction, he was not able to secure implementation. All of his successors lost momentum soon after taking office, with Prime Minister Aso fully occupied in dealing with the immediate financial crisis during his short term. Thus ministries and other government agencies have remained largely unchallenged in their control over individual industry sectors, ensuring that policies do not diminish their own powers or the interests of their closest, often ailing, industry allies. Prime Minister Hatoyama has the opportunity to change all that. His Government enjoys a commanding majority in the lower house and a clear mandate from the electorate for reform. It is a golden opportunity – and it may not last.

The glimmer of an export-driven recovery prior to the current economic crisis and the apparent durability of old structures suggested to some that there might yet be life in the old economic model, that maybe reform, though inevitable, could once more be postponed. The new Government has committed to making changes. It has promised to break the control of vested interests working through special ministries. That is a promising start. The EBC urges the Government not to delay: it must quickly use its mandate for reform to free the economy from structural barriers to enduring growth; it must welcome the invigorating force of free and open competition; and it must put consumer interests first. Previous governments may have intended much, but delivered too little. This Government should not make the same mistake. This is the time for change.

How this report is organised

This Report consists of 32 chapters, each addressing the concerns of a specific EBC sector committee and based on the collective first-hand experience of committee members doing business on the ground in Japan. Committees contribute their expertise and knowledge to the chapters, which consist of an overview, a series of recommendations for further regulatory reform, and comments on prospects for economic integration. This introduction is written by the Policy Director to address more general issues raised in all committees. We trust this Report will prove to be a positive contribution to the thinking of the Government and all other authorities in Japan and in the EU 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

Introduction

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 for the long-term vitality of the Japanese economy. Companies are being forced to streamline their management, improve working conditions, enhance operational efficiency and find new sources of labour from abroad. In the light of these challenges, it is critical that labour regulations and human resource management facilitate international commercial transactions and provide the best means of acquiring and retaining a highly 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.

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 (MOJ) has for many years administered 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. Ten years later, in 2009, a further revision of the Act has been passed by Parliament that will fundamentally change the system and eliminate the re-entry permit system – but not for another three years. Restrictions on work permits also pose a challenge for businesses wanting 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 can be demonstrated.

Revisions to labour laws over recent years have been successful in creating greater employment flexibility in terms of working hours, compensation, pension schemes and contracts, while nevertheless continuing to uphold the long-term employment system. The Labour Standard Law was amended in June 2003 to permit employee dismissals only if the employer meets stringent criteria for economic hardship. The amendment failed to set out specific criteria for determining 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, amendments are still required to enable the refunds of mandatory Japanese pension fund contributions to be expanded in the case of 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 could streamline the process of brokering multiple individual agreements on social security pension reimbursement. It would also provide an opportunity to revise all visa and work permit requirements between the EU and Japan with a view to creating a single labour market extending to both regions in the long-term.

Key Issues and Recommendations

■ Immigration and re- entry permits

Yearly status report: progress. The Council for Regulatory Reform of Japan recommended that the re-entry permit system be reformed before the end of fiscal year 2007. Though the system still remains unchanged, the Parliament has passed a revision, merging parts of the Immigration Control Act and the Alien Registration Law. The plan is to issue a resident card at the port of entry when a foreigner first arrives in Japan, instead of later, after he/she registers at a local municipal office, as is currently the case. The EBC applauds the Government for finally submitting and passing the necessary revisions of relevant laws but is disappointed that the implementation period has been set for as long as three years.

Recommendation:

- The Government of Japan should abolish the re-entry permit system by speedily implementing the Immigration Control Act revision, which has already passed Parliament.

■ Pensions

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

Recommendations:

- 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.
- 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 EU Member States under a comprehensive EU-Japan Economic Integration Agreement.

■ Work permits for spouses

Yearly status report: new issue. Working opportunities for family members (spouses) is an important issue for companies recruiting international talent and multinational companies wishing to send employees to overseas posts. It is becoming increasingly difficult to send families to locations where the prospect of spouses continuing and developing their careers is bleak. In Japan, spouses of expatriates are not allowed to work more than 28 hours a week without changing their visa status, which in turn requires employment and a sponsor company in Japan. This barrier makes it difficult to attract families with more than one professionally active member to postings in Japan.

Recommendation:

- The Government of Japan should grant a work permit automatically for spouse visa holders so that multinational companies can attract the best talent to postings in Japan.

Mr. Laurent Dubois

Chair, Patent/Trademarks/Licence Committee

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INTELLECTUAL PROPERTY

Introduction

Japan remains the world's most attractive market for luxury products as it still accounts for 29% of worldwide consumption of luxury goods and is worth around Euro 14.3 billion. Given the sheer size of the market, Japan is among the principal targets for trade in counterfeit goods. Most of the counterfeit goods entering and circulating in Japan are sold through Internet auction websites. More than 20% of well-known foreign brand goods sold on the Internet and mobile phone auction sites are fake. Yahoo!Japan, Rakuten and DeNA are the principal auction site operators in Japan and play a significant role in the fight against counterfeits. In the last few years, the Japanese authorities have also started to more pro-actively counteract violations of intellectual property rights. However, notwithstanding important legal improvements and encouraging results following intensified surveillance over the past few years, crucial issues remain unresolved. Though we have recently witnessed a somewhat lower frequency of interventions, the EBC believes that the Japanese authorities are seriously looking for solutions to deal with outstanding issues.

Since the launch of the Intellectual Property Strategy Council's 10-year action plan, adopted in 2002, Japanese authorities have shown a significant interest in intellectual property rights protection, issuing some 40 new initiatives, including new laws and revisions of existing laws. The 2003 reform of the Customs and Tariff Law was part of this reform policy, which has improved cooperation between the customs services and companies holding infringed intellectual property rights. In 2004, these companies were given the right to receive information concerning the importers of alleged counterfeit goods from the customs services. Moreover, in 2005, the first High Court of Intellectual Property was established as a specialised branch of the Tokyo Court of Appeal. In 2006, the prohibition of importation was extended to goods that are similar to famous-name brands. Reform of the Trademark Law increased the fine applicable to importers of counterfeit goods for commercial purposes to 300 million yen for legal entities and from 5 million to 10 million yen for individuals.

Reform of the rules for applying the Act on Specified Commercial Transactions also resulted in significant improvements. This measure strengthens control of the identity of vendors on Internet auction sites, compelling vendors to furnish their complete identity data when selling twenty or more luxury brand goods. In the event that they do not comply with this obligation, the Ministry of Economy, Trade and Industry (METI) may request the banning of the vendor from the auction website. As a consequence, auction site operators have strengthened their control of vendors to the extent that they are now able to provide intellectual property rights-holders with information collected on counterfeiters. The measures taken by the operators against repeat counterfeiters have also been strengthened considerably. Such regulatory revision represents an important achievement in the fight against counterfeits and gives substance to the authorities' guidelines for stopping the spread of counterfeit product sales in the Japanese market.

Despite significant improvements, however, crucial issues remain unresolved, as Japanese regulations prove still inefficient in the enforcement of trademark violations. This is demonstrated by the persistent acceptance of parallel imports, which implies inadequate border control of importation and facilitates the entrance of fake goods into Japanese territory. The Japanese police and prosecutors face, moreover, tremendous difficulties in proving that a counterfeiter is aware of distributing goods that are fake, which currently is a prerequisite for taking action. This difficulty in proving awareness allows some importers to continue importing counterfeits unpunished.

Key Issues and Recommendations

■ Fake Goods on the Internet

Yearly status report: progress. The Internet remains the principal instrument for purchasing fake goods in Japan, as more than 20% of well-known foreign brand goods being sold on the Internet and mobile auction sites are counterfeit products. Auction site operators have taken action to counter this new type of sale by strengthening measures against repeat counterfeiters. However, enforcement of the Act on Specified Commercial Transactions is not sufficiently systematic as it is not really applicable to goods sold on mobile auction sites and does not include restrictions on clothing, which represents a significant proportion of the counterfeit goods distributed in Japan.

Recommendations:

- Auction operators and vendors on the Internet should be rigorously checked and punished if found guilty of not fulfilling their obligations.
- The Act on Specified Commercial Transactions should be more systematically enforced, and extended to cover goods sold through auctions on mobile websites.

■ Border Control

Yearly status report: some progress. Despite revisions of the Trademark Law and stepped-up efforts by customs authorities to improve the appraisal process, Japan has not yet been able to curb imports of counterfeit goods. Customs services still invite intellectual property rights-holders to visit their offices to see suspicious goods rather than send pictures to rights-holders by e-mail, thereby delaying procedures. Parallel importation remains legal and civil and criminal sanctions under the Customs Law are insufficient.

Recommendations:

- Cooperation between customs services and rights-holders should be simplified by sending pictures of goods by e-mail whenever possible, and rights-holders should have the right to intervene through judicial means in procedures for seizing suspected counterfeit goods at the Japanese border.
- The Customs Law should be revised to make it an offence for individuals or legal entities to attempt or act with the intent to import counterfeit goods; moreover, applicable sanctions should be strengthened.

■ Imports for Personal Use

Yearly status report: no progress. The import of counterfeit goods for “personal use” is still legal in Japan, a loop-hole used by persons wishing to import fake products in small quantities for commercial purposes without legal risk. In the past couple of years, upon discovering a suspicious product, the Customs authorities have adopted the practice of sending a letter to the recipient of the package requiring confirmation of authenticity and purpose. Some 90% of recipients decide to abandon the counterfeit goods ordered upon receiving such a letter, but the efficiency of the system is gradually being eroded as importers are becoming increasingly aware of the non-binding nature of these letters.

Recommendation:

- 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, as this is the only way to ensure that no such products are imported.

■ Designs

Yearly status report: no progress. Procedures for applying for protection of intellectual property rights in respect of designs remain too complex and expensive, effectively denying foreign companies the benefit of protection enjoyed in Europe and most other markets.

Recommendations:

- Application fees should be reduced and examination procedures eliminated or substantially alleviated.
- A more stringent approach should be taken by Japanese courts when interpreting the similarity of design.

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RETAIL & WHOLESALE

Introduction

The Japanese retail market is one of the largest and most vibrant in the world. However, unlike in 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 in the local and international media. This has led to a sometimes unfair perception that Japan is simply 'too difficult'; competition is intense, costs are high, 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' and been very successful, including many of the EBC members. Their success clearly benefits Japanese consumers by offering them greater choice, often better prices and, many times, completely new products previously not available on the market. The success of European retailers in Japan also benefits the Japanese economy at large – it creates considerable employment and revitalises many cities which were previously in a dire condition. Japanese retailers and wholesalers also gain from the presence of European competition as it provides plenty of incentives to further strengthen their global competitive edge.

Despite these obvious benefits for Japan, the Government has not succeeded in providing a more welcoming environment. Little has changed for the better in recent years for foreign retail and wholesale companies wishing to invest in the Japanese market. Despite a marked expansion of foreign retail activity in the specialty retail channel (albeit with many outlets operating via franchises or under licence to Japanese companies), it has proved 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 remains fraught with restrictions, inefficiencies, and delays. Opportunities to streamline the new Large-scale Retail Location Law of 2000 - intended to improve efficiency by decentralising 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 of this situation, combined with restrictions on opening retail stores over 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 the 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. However, arguably even more important than restrictions on large-scale retailing per se is the local interpretation of construction, safety and environmental regulations. This adds to investment costs and increases uncertainty and risk, effectively undermining any learning curve benefits for retailers attempting to expand their operations in Japan. Moreover, predefined usage of most land through zoning and rigid zoning regimes in many cities make it extremely difficult to find new land for large-scale retailing.

Importing, certifying and labelling various consumer products continue to be overly costly and complex, due to the Japanese authorities 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 they are to be sold on the Japanese market. As standards for most retail products are similar, the EU and Japan should swiftly move through an Economic Integration Agreement to establish mutual acceptance of standards and certification.

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, a lack of transparency and uneven regional implementation limit the entry of foreign retailers into the market. Regional interpretations of construction, safety and environmental regulations are inconsistent. Strict zoning regimes make it close to impossible to establish new large-scale shops in many localities. This adds considerably to investment costs and increases uncertainty and risk. 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 licences 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 respected under the revised City Planning Law.

■ Prohibitive import, certification and labelling rules

Yearly status report: no 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 Government of Japan and the European Union 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: some progress. 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 and issue warnings when finding violations. The legal backing of the guidelines is weak and the legality of issuing public warnings therefore questionable. The combination of legal uncertainty and detailed rules causes considerable problems for retailers sourcing on a global basis. A particular problem is the rule stating that all measurements have to be stated in millimetres and not centimetres, in contrast to general practice in the industry. If forced to comply with all rules, manufacturers would have to alter their global production systems, adding unacceptable costs for customers. METI is adopting a flexible interpretation currently, but to solve the problem, clarifying guidelines should be issued.

Recommendation:

- METI should issue clarifying orders to provide retailers with alternatives for providing Japanese consumers with globally sourced household products while taking full responsibility for the quality and safety of the products.

■ Liquor

Yearly status report: no 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 deregulated.

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LEGAL SERVICES

Introduction

Foreign lawyers have been present in Japan for more than 20 years, since changes in the law made that possible in 1987. The law changed further in 1996, and again in 2004, permitting foreign lawyers to have combined practices with Japanese lawyers (*bengoshi*), something that had originally been prohibited.

Over the years, foreign lawyers have greatly contributed to the introduction of financing and corporate techniques to the Japanese market. Combined firms of *bengoshi* and foreign lawyers have trained young *bengoshi* and enabled them to play valuable roles in international transactions and cross-cultural exchanges. The presence of foreign lawyers has unquestionably helped to boost Japan's legal profession and contributed to the development of financial services in Japan. Within this context, the EBC believes it is crucial for the Government of Japan to realise the potential of further opening up for foreign lawyers and law firms to practice in Japan, and to acknowledge their key role in achieving the policy goal of establishing Tokyo as a global financial centre.

The EBC believes that, eventually, Japan will also have to address the issue of limited liability, currently not available to lawyers in Japan. The status quo reflects the traditional position of lawyers in Japan as court lawyers, ignoring their modern role as handlers of complicated international commercial transactions and conductors of due diligence activities involving potential liabilities in the trillions of yen. Professionals in many fields in Europe and elsewhere are able to operate under a regime of limited liability, subject to financial disclosure, which has proved both sensible and essential with 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, firms have to operate through individuals, and their representatives in Japan are not permitted to have the benefit of limited liability, which exposes all law firms in Japan to an inequitable level of risk.

Despite the obvious advantages arising from the presence of active foreign lawyers, very little progress has been made in recent years towards liberalising the legal services market in Japan. The EBC is particularly concerned about the prospect of the Japan Federation of Bar Associations (*Nichibenren*) looking into the possibility of regulating combined foreign lawyer-*bengoshi* firms even more severely, following these firms' success, particularly with foreign clients. A letter from the *Nichibenren* dated January 27, 2009 relating to their requirements for associates to be registered, and some of the comments in the interim report of the Foreign Lawyers System Study Group relating to corporations show that the issue of foreign lawyers active in Japan continues to be controversial.

EBC Legal Services Committee Member Companies

Allen & Overy	Herbert Smith
ARQIS Foreign Law Office	Linklaters
Ashurst	Lovells
Baker & McKenzie GJB (Tokyo Aoyama Aoki Koma Law Office)	Loyens & Loeff GJB Office
Clifford Chance Law Office	Morrison & Foerster LLP
Cotty Vivant Marchisio & Lauzeral	Sonderhoff & Einsel Law and Patent Office
Freshfields Bruckhaus Deringer	Squire, Sanders & Dempsey L.L.P.
Hayabusa Asuka Law Offices	White & Case LLP

Key Issues and Recommendations

■ Recognition and approval as a foreign lawyer in Japan

Yearly status report: questionable progress. In order to become registered as a foreign lawyer (*gaiben*) in Japan, three years of professional experience in the foreign lawyer's home jurisdiction is required, out of which two have to be obtained outside Japan. This rule is in stark contrast to the rules governing Japanese lawyers (*bengoshi*) who are not required to have any post-qualification experience before being recognised. The EBC believes that this practice is not only discriminatory, but also makes little sense as foreign lawyers are already acknowledged by the qualification of their jurisdiction. If there should be such a rule, what is important is the experience in home jurisdiction law, not where it is practiced. The procedure for admitting foreign lawyers as *gaiben* also still imposes undue costs on foreign firms and individuals. In May of this year a "guide" was published by the Ministry of Justice (MOJ) inviting comment, which on the face of it appeared to liberalise the application rules to some extent. It remains to be seen if the procedure will become any quicker in practice.

Recommendations:

- The rule requiring a specific number of post qualification years of experience should be abolished. At the very least, experience in home jurisdiction law should be recognised regardless of where it has been practiced.
- The rules for registration as *gaiben* should be simplified by allowing firms to be registered, rather than the individual lawyers who are members of the firms. Once a firm has been approved, there should be an accelerated procedure for registering new lawyers coming to Japan. More should be done to accelerate the application procedure for *gaiben* registration.

■ Branches

Yearly status report: questionable progress. Under the current rules, it is not possible for a *gaiben* law firm or a joint enterprise between *gaiben* and *bengoshi* to open more than one office in Japan. This possibility is open to *bengoshi*, who may do so through a *bengoshi* corporation or *hojin*. Currently, such a structure is not available to *gaiben*.

In August this year an interim report was published by the Foreign Lawyers System Study Group. The majority view of this committee recommended that *gaiben* should be able to establish corporations with other *gaiben*, and also with *bengoshi*, while minority views set out in the report contained restrictions on the proposal, which would make it unworkable

Recommendation:

- A system for *gaiben* to establish *hojin* in conjunction with other *gaiben* and with *bengoshi* should be created. The majority view of the reporting committee should be followed for this purpose.

■ Limited liability

Yearly status report: no progress. Under current rules, limited liability status is not available to lawyers in Japan.

Recommendation:

- A limited liability structure should be made available in Japan for both foreign and domestic law firms, and foreign firms should be able to practice in Japan through branches of their international firms.

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TAX

Introduction

The EBC applauds the new Japanese Government's announcement that it intends to create a more balanced economy by encouraging domestic demand, and no longer relying heavily on export markets. The magnitude of the challenges ahead for the Government, however, cannot be exaggerated. The Japanese economy has been heavily affected by the global economic and financial crisis that hit last year. Small, medium and large-sized corporations across all industries have incurred substantial losses and capital investments are being reduced as a result. It is becoming increasingly difficult to maintain high employment, as Japanese labour remains expensive by international comparison. The uncertain outlook for employment, in combination with the Japanese people's lack of confidence in the social welfare system, is suppressing consumption below already low levels.

With the public debt ratio rapidly approaching 200% of GDP, increasing public spending as a way out of recession is not a viable option. What Japan needs is a private-sector-led recovery, but the environment needed to support domestic companies and foreign investors in taking risks is simply not in place. The best starting point is to address the question of how to create an environment in which companies, both domestic and foreign, are able to generate sufficient cash flows, maintain healthy equity ratios, and make investments. The EBC believes that tax policies will be the key to solving that equation, and a transparent tax regime promoting business expansion will be crucial to success. However, this cannot be achieved by eroding the tax base.

Aware of the severe fiscal constraints the new Government is facing, the EBC is recommending a range of measures. Two of the three main recommendations will not have any direct negative impact on tax revenue whatsoever, while the third is likely simply to defer revenues to a later stage. The EBC's first recommendation addresses the fact that insufficient transparency and predictability in tax rules creates uncertainty and, as a consequence, lower investments and economic activity. The Government of Japan has tried to address the problem but the situation has not substantially changed. Improvements made to the formal tax ruling system *Bunsho Kaito* have unfortunately not led to a significantly higher number of tax rulings. The EBC is also disappointed to note that the tax administration continues to use secret comparables in transfer pricing disputes and continues to leak confidential taxpayer's information to the press. The second recommendation points out that addressing the transparency issues as a matter of urgency would be the most efficient way to promote business without having to spend extra money or undermine the tax base. The EBC's third recommendation argues that the introduction of an unlimited tax loss carry forward period would provide an effective and immediate stimulus to companies, regardless of industry or size. Such a measure would benefit all types of companies and ventures, Japanese and foreign-owned alike. Under the scheme, some tax income may be deferred to a later stage, but this would not have an immediate impact on tax revenues as firms suffering tax losses are not in a tax-paying position anyway. To secure tax revenues, a minimum taxation rule, such as the one introduced by Germany, would allow minimum taxation of companies that carry forward significant losses, while in the long-term incentivising them to revive their operations.

Swiftly implementing these three measures alone would contribute to sustainable growth of businesses and the overall economy and, therefore, also prove instrumental in combating the most serious threat to tax revenues, erosion of earnings.

Tax-reforms undertaken so far have been largely piecemeal and, moving forward, it is clear that a new approach is needed. The EBC encourages the new Government of Japan to take on the tax policy challenges upfront and address the issues on the following pages as a matter of priority.

Key Issues and Recommendations

■ **Accountability and confidentiality**

Yearly status report: progress. Taxpayers may now seek written clarification of specific transactions as a result of changes made to the *Bunsho Kaito* system under the 2008 tax reforms. Despite this improvement, an overall lack of transparency and systematic accountability continues to impede the development of business in Japan. The 2008 tax reform has led to an increase from formerly 31 rulings per year to 34 rulings per year, which is insufficient. 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.

Recommendations:

- The tax authorities should be obliged to accept and process applications for tax rulings and the tax law should provide for a right to request and obtain tax rulings.
- The Government should stop intentional leakage of confidential taxpayers' data to the press and the tax administration should be held accountable for secrecy duty violations.

■ **Transfer pricing**

Yearly status report: limited progress. The Japanese tax authorities continue to reserve the right to base their transfer pricing assessments on secret comparables, which make 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 the company-level profitability of public companies is commonly used as a reference point. The National Tax Agency should ensure a nationwide uniform application of transfer pricing rules.

Recommendations:

- The EBC recommends that the use of secret comparable information be disallowed. There should be consistency between the transfer pricing methodology for audit assessments and that used for APAs.
- Joint EU-Japan guidelines on interpretation should be established and documentary requirements between the EU and Japan harmonised for transfer pricing assessment.

■ **Introduction of an unlimited period to carry forward tax losses**

Yearly status report: new recommendation. The current tax loss carry forward period in Japan is seven years, whereas in the UK, France, Belgium, The Netherlands and Germany, losses can be carried forward indefinitely. Limiting the carry-forward period creates a competitive disadvantage for Japan and holds back economic activity. The introduction of an unlimited tax loss carry forward period would provide an effective and immediate stimulus to companies, regardless of industry or size. In jurisdictions where tax losses can be carried forward indefinitely, so called deferred tax assets can improve balance sheets and the credit rating of companies. However, due to the seven-year tax loss limitation, the deferred tax assets of Japanese companies are subject to impairment at an earlier stage. In order to secure tax revenues, the German minimum taxation rule could be considered. Under this rule, only 60% of tax losses exceeding Euro 1 million (130 million yen) qualify in a given business year. The remainder can be used in future business years, subject to the same restriction. This enables both a minimum level of taxation and a deferred, but ultimately unlimited carry forward of tax losses.

Recommendation:

- The EBC strongly recommends the introduction of an unlimited tax loss carry forward period.

■ Corporate Restructuring

Yearly status report: progress. The current tax treatment of cross border and triangular mergers, made possible through changes to Japan's Company Law in May 2007, are in practical terms a barrier to those market entrants who have no established business in Japan but aim to use their own shares to acquire a Japanese company. Current rules do not permit tax deferral in respect of stock swaps between foreign and domestic companies even if the transaction is carried out using a Japanese special purpose company. Eliminating discriminatory treatment of foreign shares used as consideration in mergers with Japanese companies is the most important policy step to facilitating Foreign Direct Investments into Japan. The triangular mergers scheme was introduced for this purpose, but has proved to be impractical as the conditions for tax deferral remain non-transparent, making use of the scheme inherently risky. Elimination of the tax deductibility of impairment losses incurred by certain intra group asset disposals is currently under discussion within the framework of the 2010 tax reform.

Recommendations:

- Current rules should be revised so as to permit a deferral of capital gains tax for shareholders receiving shares from a foreign company with no previous operations in Japan under both the triangular merger scheme and other cross border reorganisation 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.
- The 2010 tax reform should allow continued tax deductibility of impairment losses incurred through internal group restructuring.

■ Consolidated taxation

Yearly status report: no progress. Current restrictions on tax consolidation limit the consolidated tax system from being fully or actively utilised among corporate taxpayers in Japan. The EBC welcomes the fact that consideration is being given to repealing the taxable revaluation of certain assets of companies entering a consolidated group and to allowing the inclusion of pre-consolidation subsidiary losses.

Recommendation:

- A 50% threshold should replace the requirement that only 100% subsidiaries may be consolidated. The obligatory integration of 100% of all subsidiaries if a group wishes to consolidate should be eliminated.

■ Tax treaties

Yearly status report: some progress. Japan is currently re-negotiating tax treaties with The Netherlands, Switzerland and Germany. The EBC 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. !

Recommendation:

- The EBC encourages the Government of Japan to review current tax treaties with EU Member States

Financial Services

**Asset management
Banking
Insurance**

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ASSET MANAGEMENT

Introduction

Professional management of investment portfolios 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 combined with a potentially increased tax base is unlikely to generate sufficient tax revenue to support the financial and social needs of the ageing population. According to the Bank of Japan, Japan's combined household and pension financial assets amount to approximately 1,790 trillion yen. Of this total amount, household assets account for 1,490 trillion yen, and pension funds for the rest. The proportion of Japan's financial assets managed by investment management firms is relatively low compared to other major economies, at 8.4% of the total (151 trillion yen), while another 12% is managed by life insurance companies (209 trillion yen). By providing professional advice in an increasingly complex market, global professional asset management firms help companies raise the capital they need and help the public to save for retirement.

The size of the market for asset management services in Japan, compared to the EU or the USA, is small. The relative cost of excessive or unique regulation in Japan is therefore higher given that business opportunities are so limited. The reason for the relatively low level of penetration by investment management firms is plain. Active asset management in Japan only really took off when pension reforms were introduced in 2004, spurring a rise in the number of investment management firms and new contracts. Since then, assets under discretionary management have more than doubled, with Japanese pension funds accounting for a significant part of this growth. By providing professional advice and innovative services in an increasingly complex market, global professional asset management companies are proving they can contribute to more effective allocation of resources in the economy at large.

Nevertheless, regulation in Japan imposes unnecessary burdens, both in terms of the basic cost of compliance and in the additional cost arising from "regulatory disparity", where regulation and enforcement practices in Japan are unnecessarily different from those in other jurisdictions. Moreover, the rules and enforcement practices in Japan governing the industry are in many areas excessive, which results ultimately in depressed competition. Asset management regulations often appear to reflect historical circumstances, rather than current conditions; and to result from the automatic application of brokerage regulations to asset management business, despite important differences between the two areas.

We encourage the Government of Japan and the Financial Services Agency (FSA) to consider reform, with a view to stimulating more vigorous competition, both on its own initiative and in the context of an Economic Integration Agreement between the EU and Japan.

Key Issues and Recommendations

■ Institutional Offshore Funds

Yearly status report: new issue. Before investing in a European managed fund, Japanese financial institutions and other qualified investors will often seek advice from the Japanese affiliate of the European fund manager. Soliciting and explaining foreign investment funds to financial institutions and other qualified investors requires a Type 1 financial instruments exchange (FIE) business registration. Many Japanese affiliates of European managers elect, however, not to apply for such registration because of the substantial costs involved in maintaining the registration over time. The result is a narrower range of product choices, less competition in fees, and reduced understanding of the various investment products for such investors.

Recommendation:

- The Financial Services Agency should not require the Japanese affiliate of a foreign fund manager to acquire and maintain a Type 1 FIE business registration in order to solicit and explain to financial institutions and other qualified investors a fund managed by its foreign affiliate. A less stringent regulatory framework should be adopted for this situation.

■ Reports of Large Shareholdings

Yearly status report: 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 with regard to the consolidated holdings of the whole financial group. The EBC appreciates that the system for reporting of large shareholdings (FIEL Chapter II-3) is helpful in promoting fairness and transparency in boardroom battles between shareholders and managers. However, it is not necessary to impose the most stringent requirements on investors who are not actively contesting for corporate control, which is normally the case for asset management companies. If an investment management company that is subject to regulatory supervision files a statement affirming no intention to actively contest for management control of the issuer, it should be subject to a less stringent reporting regime in terms of the required speed and frequency of reports.

Recommendation:

- The requirement for investors to disclose holdings of shares in listed companies in excess of 5% every second week on a consolidated basis should not be applied to asset management companies that are not actively contesting for management control of the companies in which they invest.

■ Improved inspection regime

Yearly status report: progress. The EBC acknowledges that there have been substantial improvements in regulatory supervision and inspections since 2005. However, the EBC is very concerned about duplicate inspections and the apparent requirement to obtain prior approval from the inspection supervisor before consulting a lawyer.

Recommendations:

- The inspection units of the Securities Exchange and Surveillance Commission (SESC), Kanto Local Financial Bureau (KLFB), and the JITA should be merged to avoid unnecessary duplication of inspections.
- The SESC should not supervise communications with lawyers and Head Office representatives. Such a claim of power by government officers is inconsistent with fundamental principles of democracy and the freedom of speech and expression.

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BANKING

Introduction

Japan's relative prosperity has decreased considerably in recent years, as is apparent from the steady decline in Japan's GDP per capita ranking, from second highest in the world in 1995 to twentieth in 2006. Japanese consumers have continued to save throughout this period, but their return on capital has been the lowest in the industrial world. 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. This has not gone unnoticed.

Reform of the Japanese financial sector has been high on the government agenda ever since the bursting of the bubble in the early 1990s. The Hashimoto "Big Bang" reforms initiated in 1998, which enabled the formation of financial holding companies, were 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.

Although an integrated legal framework supposedly covering all financial products was introduced with the Financial Instrument and Exchange Law (FIEL) 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 recourse to such regulations was abandoned in other major financial jurisdictions. The EBC was, therefore, extremely pleased to see the inclusion of firewall reforms at the core of the Financial Services Agency's (FSA) plan to revitalise Tokyo as a financial centre.

The EBC also welcomed the revision of the Financial Instruments and Exchange Law that took effect in 2008, as it reflected the fact that financial regulators across the globe have shifted their focus 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. However, the FSA guidelines issued after the FIEL revision continue to contain stringent restrictions on the sharing of undisclosed customer operations and double-hatting, which, along with an impractical mandatory opt-out system, unfortunately undermine the original intent of the revision. As a result, it remains very difficult to integrate operations in Japan into the global financial group.

The EBC has welcomed the "better regulation" initiatives taken by the FSA over the past few years. With a good regulatory regime and principles in place, the EBC believes that the EU and Japan should be able to mutually accept the home country regulator of a European or Japanese institution as the core regulator for such generic aspects as capital adequacy and proper governance structure. This would mean that the local regulator would focus on licences and the business carried out in its own jurisdiction.

The EBC also believes that when applying for new licences, it should be possible to assess capital adequacy on the basis of the global group. Currently, this is not the case in Japan, where capital adequacy is calculated on the basis of the Japanese entity in isolation, which can be a substantial barrier for newcomers. Finally, working within an Economic Integration Agreement and with a view to making universal banking the norm in both regions, the EBC believes the EU and Japan should embrace the principle that a single branch in the other territory can be granted licences covering Banking, Securities, Trust Banking, Asset Management, and Insurance, without having to establish separate structures.

Key Issues and Recommendations

■ Integrated financial services market

Yearly status report: some progress. Foreign financial groups are now formally permitted to be represented by a single country manager in Japan and to exchange a larger amount of client information between group entities than previously possible, but guidelines for the implementation of this reform have made it difficult in practice to take advantage of these new opportunities. Moreover, each business entity still needs to maintain certain separate functions and organisational structures, which could otherwise be shared on a group basis. Such duplication creates inefficiencies and extra costs and makes it very difficult to integrate operations in Japan into the global business.

Recommendation:

- The Government of Japan should abolish Article 33 of the Financial Instruments and Exchange Law, which prohibits financial firms from operating banking and securities concurrently. At the very least, the FSA should alter guidelines to allow the same level of information sharing as in Europe, a simplified opt-out system, and reasonable double-hatting.

■ Transparency and regulatory efficiency

Yearly status report: progress. Duplicated inspections by the Financial Services Agency, Securities Exchange and Surveillance Commission (SESC), Tokyo Stock Exchange (TSE), Japan Securities Dealers Association (JSDA), Ministry of Finance (MOF), and the Bank of Japan (BOJ) have long imposed an excessive administrative burden on regulated firms. The EBC encourages the Government to further increase efficiency and transparency and applauds the FSA for releasing an annual inspection programme, which clarifies the focus issues for the year, and for providing pre-notification of inspections in certain cases. Despite this improvement, the overly rule-bound regulatory environment in Japan leaves little room for innovation by the regulated entity, unless there is extensive prior consultation with the regulator on precisely how the rules are to be interpreted and applied. Such a prescriptive, yet unclear, regulatory framework cannot keep up with the pace at which financial products and markets are changing.

Recommendations:

- FSA rules and regulations should be applied consistently and clarified in accordance with fair and current universal guidelines.
- The FSA and other regulators should encourage innovation and competitiveness in the financial services markets by operating on the basis of published general principles for good governance and an open-ended dialogue with regulated entities on how to comply with these principles.

■ Disclosure rules for secondary offerings

Yearly status report: new issue. The FIEL was revised in 2009 to extend the requirements for primary disclosure to secondary offerings as well as to abolish the exception that had been made under the previous system for secondary offerings of up to 50 securities of “equal economic terms”. An indemnity clause has also been added to the disclosure requirements. We support the move to clarify the public offering system and disclosure requirements. However, if this new system is implemented without new exceptions, the risk of breaching the disclosure requirement by merely getting involved in the sale of foreign government bonds may be so high that financial firms will suspend or substantially reduce their trading of foreign securities and foreign government bonds on the Japanese market.

Recommendation:

- The FSA should exempt securities issued by governments and government agencies of major countries, including European governments, as well as securities listed on the exchanges of European markets, with appropriate disclosure requirements, from the proposed amendment of rules for secondary offerings.

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INSURANCE

Introduction

The Japanese insurance market is the second largest in the world, and is of key importance to global insurance groups. European insurers bring their expertise to the market and provide proven insurance products to Japanese consumers to meet their insurance needs. 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. Examples of this are the rigid reserving and solvency regulations and the lengthy product approval process. Future growth in Japan will come from the ageing of the population, driving a need for products dealing with extended retirement, changes to family structures and rising demand for medical products. With a principles-based regulatory regime, under which the regulator focuses on risk management and allows innovation and flexibility, striking a careful balance between innovativeness and regulation, the insurance market can adapt appropriately to deal with changes in policyholder needs and changing financial conditions. The EBC welcomes the Financial Services Agency's (FSA) initiatives towards better regulation and hopes that they will move Japanese regulation forward on this basis.

The Summit on Financial Markets and the World Economy (G20 Summit) upheld that once the economy recovers, more stringent regulations should be introduced. We caution that governments should be prudent in determining whether the economy is truly on a recovery track, and make sure the regulations themselves, as well as the timing of their implementation, are considered with flexibility. The stability of financial markets and their proper regulation are important for market users, including companies that raise capital. While we currently see government intervention in markets in order to stabilise the financial system and support institutions, such intervention must not distort the market and so must be removed as soon as practicable. We also believe that the level playing field between financial institutions with public money infusion and those without such arrangements should be secured.

As regards the Japan Post privatisation, we welcome the clear statements from the regulator confirming the consistent implementation of regulations across the private sector and new companies. The EBC welcomes the FSA's regulation of Japan Post Insurance (*Kampo*) to ensure that *Kampo* achieves the standards required for adequate consumer protection as well as a level playing field. The EBC welcomes the use of third company products by Japan Post as a way to expand the product range, as this will provide both good distribution opportunities to current players and know-how in terms of risk management and product structure to Japan Post. There is still work to be done, however, on bringing risk management and compliance practices up to the standards set in the private sector. More generally, in the bancassurance field, the EBC welcomes the last stage of bancassurance deregulation and the fact that an ever-broader range of products is available through bank channel distribution, but regrets the continuation of unduly restrictive sales controls. The EBC hopes that these will be removed by the end of 2010 after the FSA's three-year monitoring period.

Japanese regulations need to converge with global methodologies in terms of market-based solvency (Solvency II) and International Financial Accounting Standards (IFRS) to improve risk management and understanding among insurers, provide confidence to the market, and reduce the costs of operating across different territories. Such convergence would have a direct positive impact on the ability of European companies to do business in Japan, and the EBC hopes and expects that the FSA will continue to move towards harmonisation as it develops its new solvency regulations. A permanent and post-funded scheme needs to be put in place for the Policyholder Protection Corporation (PPC). Enhancing the regulatory environment for the insurance industry is critical to future development, particularly for ensuring a level playing field for all sellers of insurance. Appropriate handling of issues such as the way Japan Post is privatised, bringing *Kyosai* into the insurance framework, streamlining the product approval process, and clear and consistent application of rules and regulations, will contribute to recovery from the financial crisis and prove beneficial to the domestic financial services industry, consumers and Japan's ability to retain foreign investment. An EU-Japan Economic Integration Agreement (EIA) should contain common rules on competition and regulation to ensure transparent, fair and equal rules for all issuers of insurance. Furthermore, it should have common rules for solvency calculations using market-based techniques based on Solvency II, and common rules for improving the transparency and predictability of regulations using a risk-focused approach.

Key Issues and Recommendations

■ Harmonisation with global standards for Accounting and Solvency Margins

Yearly status report: some progress. The EBC welcomes the update of the Solvency Margin factor and positive statements made by the FSA on establishment over the medium-term of a market-based methodology, consistent with the principles of Solvency II. Further alignment of the FSA's proposed Solvency Margin requirements with the approach of Solvency II is crucial for European insurers in Japan as it would enable them to use the same methodologies in all territories and better develop group-wide risk management strategies. Such a move will both encourage and reward improved risk management within insurance companies – a goal shared between the regulator and insurers.

Recommendations:

- The Government of Japan should accelerate reforms aiming at attaining convergence between Japanese and global standards by establishing a roadmap for convergence with IFRS and Solvency II.
- The market based Solvency Margin calculation methodology should be further aligned with Solvency II.

■ Policyholder Protection Corporation (PPC)

Yearly status report: little progress. The current framework for the PPC expired in March 2009, but open discussions with industry on how to move forward have not yet started. There is a need for a permanent scheme with Government backing, to provide the required level of reinsurance to the public and maintain confidence. A move to a post-funded scheme would be optimal as it would remove the unnecessary burden of providing early funding to the PPC. An already available PPC fund is a potential moral hazard as it reduces the onus to find a market-based solution, and raises costs for well-managed healthy insurers.

Recommendation:

- The Government of Japan should introduce a permanent PPC with the backing of a Government guarantee and post-funded contributions. Wider industry discussion is needed before decisions are made on the new set-up, building on the expertise and requirements of all PPC members.

■ Product Approval

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. Further, approvals, when granted, are not flexible enough for the development of new products and features that are sensitive to volatile capital markets, in particular in response to the financial crisis.

Recommendation:

- The FSA should increase the efficiency and flexibility of the approval process, enabling faster, more frequent and innovative development sensitive to changing markets. The FSA should allow sufficient flexibility to enable adaptation to changing markets. In the long-term, a “file and use” system should be introduced.

■ Encourage long term savings

Yearly status report: no progress. In Japan there are insufficient incentives to encourage long-term savings.

Recommendation:

- Tax advantageous schemes to encourage saving for retirement or medical needs, such as long-term care, should be introduced, drawing on successes in other countries.

Transportation & Communications

Airlines
Business aviation
Logistics & freight
Media & communications
Shipping
Telecommunications
Telecommunications equipment
Railways

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AIRLINES

Introduction

The global economy depends on networks, be they for telecommunications or transport on the ground or in the air. The services provided by airlines are indispensable to the efficient functioning of the global economy. By the same token, the success of the Japanese economy is to a large extent dependent on well-functioning links between Japan and other countries. The global financial crisis and outbreak of swine flu have led to a severe drop in business and leisure travel in and out of Japan. This, in combination with the high cost of airport infrastructure, has had a substantial negative impact on route profitability for European airlines operating in Japan.

The Government of Japan has in recent years made substantial and commendable efforts to facilitate business for foreign carriers, much in line with the EBC's recommendations. Restrictions on pricing and distribution have been relaxed. Approval times for new fares have been shortened, but a simple notification procedure should be introduced to further expedite the process. With pricing largely liberalised and the fare filing system modernised, it is high time to address the restrictions on direct sales by airlines.

Japan must also face the cost issue squarely. While welcoming the drive to lower costs initiated by the management of the privatised Narita Airport, the EBC urges the Government of Japan to continually work towards reducing charges overall. To date, the scope and pace of change have been disappointing. Airlines have long been required to pay prohibitive landing fees, navigation charges, airport terminal rent, airport terminal common user charges, and cargo handling fees. Heavy political involvement in the air transport sector has resulted in the over-establishment of airports, often in areas where there is little or no demand. The so-called Airport Development Special Account has exacerbated the situation further, since losses at local airports and the development of new airports are covered by collective funds in this account, drawn from the user fees collected at all airports. The existence of this account results in Japanese airports being uncompetitive, as costs are fixed due to the set fees that must be paid and the same applies to the normally high interest on the public loan provided. Over-establishment of airports in Japan has, ironically, led to a serious loss of competitiveness between airports, since local airports closer to city centres, such as Itami, divert traffic to Narita at the cost of international airports (e.g. Kansai International Airport). The EBC is encouraged by comments from the Minister of Land Infrastructure, Transport and Tourism (MLIT), suggesting that the new Government appears to be considering establishing a fundamentally different system in which all airports can compete on cost, being relieved of the burden of financing new airports.

Healthy competition is a pre-requisite for establishing a vibrant market driven by an economic rather than political rationale. While welcoming the opening up of Haneda Airport for intercontinental flights upon completion of the new runway next year, the EBC urges the Government to ensure that this is done on equal terms for all carriers. The former cabinet suggested a window of operations (22.00 hrs - 07.00 hrs) for intercontinental traffic to and from Haneda. If landing is not possible before 22.00 hrs, European carriers will be denied the possibility of connecting with the domestic network of their Japanese competitors. While European carriers would be limited to serving the Tokyo metropolitan area at very inconvenient times, Japanese carriers would be able to leave Japan around midnight and return early morning, feeding to and from connections to practically every Japanese domestic airport.

The Government should also carefully consider the competition implications of any further re-capitalisation of Japan Airlines. The necessary restructuring process of the company must be carefully implemented and monitored in order to avoid market distortion.

Key Issues and Recommendations

■ High costs

Yearly status report: no progress. For Narita Airport, an average net cost reduction of approximately 10% was negotiated in 2007, and a further small decrease in 2009, but this was only accepted with the caveat that a “passenger fee” equivalent to the same amount should be introduced. The root of the problem is the Airport Development Special Account to which airports have to pay fixed fees for the apparent never-ending construction of new airports throughout Japan. The result is that the cost of air transport in Japan remains the highest in the world. The EBC urges the new Government to consider a new set-up, which does not force airports to contribute to politically driven development of new airports that are of no or little public value. 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. In this context, the EBC has taken positive note of the recent initiative by Kansai International Airport to offer additional discounts not only for new entrants, but also carriers that have already been serving the market for a long time. Kansai International Airport, despite already shouldering a heavy financial burden, is investing in its future, helping struggling airlines to cope with high landing fees

Recommendation:

- The Airport Development Special Account should be abolished to pave the way for lowering the prohibitively high landing, navigation, and common user and security fees charged by the airport authorities in Japan. The cost of security measures at airports should not be levied on airlines, but be absorbed by the balance sheets of the respective airports.

■ Airport infrastructure

Yearly status report: limited progress. Japan lacks a coherent plan for optimum utilisation of existing infrastructure. Over-establishment of domestic airports has created an unhealthy situation in which local airports divert the traffic away from the local international hubs, such as Kansai or Nagoya, to Narita and, in the near future, to Haneda. The result is further demand for slots out of Narita and substantially lower usage of local airports with international traffic, such that higher costs must be shared among the remaining few operators at these airports. This is happening at a time when the Kanto region is boosting capacity. The construction of a fourth runway at Haneda will be finalised by 2010. The MLIT has stated its intention to allocate some 60,000 new slots to international routes and permit flights to and from non-Asian destinations during the night-time (22.00 hrs -07.00 hrs), following a cabinet decision in 2008. The new Government should consider the implications for competition between local airports and also between airlines. It is essential that when Haneda opens up for intercontinental flights, all airlines should be able to use the airport on a practical basis. The time-frame under current consideration is practicable for flights taking off to Europe, but the time difference does not allow landings at commercially reasonable times for inbound flights.

Recommendation:

- Japan should establish a plan for the efficient use of all available airport infrastructure. Haneda Airport should be opened up to regular international traffic, including flights to/from Europe, on a non-discriminatory basis. Time restrictions, if introduced, should be limited to take-off times and not applied to landing times after 17:00 hrs.

■ Direct Sales

Yearly status report: substantial progress. The EBC welcomes the price liberalisation implemented in 2008. Airlines are now fundamentally free to set and market fares. However, basically they are not allowed to introduce any fare that is not connected to a published fare, thus cannot freely compete with other distribution channels. The fare approval process should be replaced by a simple notification procedure.

Recommendation:

- The Government of Japan should introduce free pricing for all ticket categories and permit unrestricted direct sales for the benefit of consumers.

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BUSINESS AVIATION

Introduction

The business aviation industry is experiencing growth worldwide and forecasts indicate that the demand for business aircraft will continue to rise. With new airline safety and security requirements in place at all international airports, many business people and governments are chartering aircraft or considering buying a corporate jet to increase the efficiency of their respective operations. Nevertheless, there are relatively few business aircraft 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 Japan-registered aircraft.

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 five slots a day allocated for business aviation), high landing fees and navigation costs, a 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 the Ministry of Land, Infrastructure, Transport and Tourism (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.

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 involving just a few individuals 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.

Recommendations:

- 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.

Recommendations:

- The Government of Japan should establish a committee to assess the need for business aviation infrastructure in Japan and issue recommendations for next steps.
- The Government of Japan should establish the proper infrastructure to deal with 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 aircraft are repaired when necessary. Furthermore, Japanese maintenance requirements are out of line with international practice, exemplified by 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.

Recommendations:

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

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LOGISTICS & FREIGHT

Introduction

A well-functioning freight forwarding and logistics services market is crucial to the global integration and competitiveness of 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 logistics operations have largely been successful, but still face serious regulatory challenges. Distorted competition caused by differences in the rules and regulations applied to carriers providing the same services, prohibitive costs, insufficient infrastructure at airports, and restrictions on foreign-owned carriers ultimately result in inefficiencies and higher prices for users. European carriers and forwarding companies in Japan struggle with high costs and inadequate 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 its Express Mail Service (EMS), a special value-added international express package that today accounts for 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 its EMS service in terms of speed, traceability, 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 advertising 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 the basic universal postal 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 new cabinet under Prime Minister Hatoyama is currently reviewing postal privatisation and is likely to recommend a new target structure for Japan Post. The need to establish a level playing field with private operators will, however, remain crucial regardless of the future structure of Japan Post and the Government should therefore treat the EMS issue as a matter of urgency.

Key Issues and Recommendations

■ Customs clearance and declaration

Yearly status report: no progress. Currently the minimum threshold value for import shipments to attract duty is 10,000 yen. Compared with other major developed countries, there is room to increase this value; for example, in EU Member States the minimum is Euro 150. By increasing the minimum value, the burden on customs offices and brokers would decrease and importers would have the benefit of reduced duty payments. For consumption tax purposes, however, the threshold could remain at 10,000 yen. Customs declaration procedures should also be improved. Currently, declarations are submitted from a customs clearance operation, which is physically located within the territory of the responsible customs office. However, if for example, the customs declarations for shipments warehoused in Kansai Airport could be made from Tokyo, this would increase flexibility and improve capacity planning for operators.

Recommendations:

- The Government of Japan should increase the minimum threshold value for import shipments to attract duty to at least 20,000 yen.
- The Government of Japan should introduce freedom in terms of the declaration location, independent of the territory of the responsible customs office.

■ Level playing field with EMS of Japan Post

Yearly status report: no progress. Currently, EMS packages are subject to customs declaration only on goods exceeding 200,000 yen in value, substantially above the level applied to private sector operators. The Parking Law is in practice not applied to EMS-carrying vehicles, although the National Police Agency has declared that EMS is subject to its provisions. EMS shipments containing quarantine-related goods are not checked by quarantine offices at the airports, in stark contrast to the thorough check performed on packages arriving with private operators.

Recommendations:

- The Government of Japan should announce a date by which the customs threshold for EMS will be lowered and instruct local police offices to apply the Parking Law strictly to EMS vehicles.
- The Government of Japan should change the import process for EMS so that no EMS quarantine shipments can be transported out of international airport facilities without inspections and approvals by the Ministry of Agriculture, Forestry and Fisheries (MAFF) and the Ministry of Health, Labour and Welfare (MHLW).

■ Competition safeguards

Yearly status report: limited progress. Accounting procedures related to the co-use of universal service operations processes and assets by any new competitive services of Japan Post are not transparent. MIC has established a study group to assess the appropriateness of the accounting system of Japan Post in this regard. However, the assessment process is largely being kept confidential so that third parties do not know the details.

Recommendation:

- The Government of Japan should establish a third party organisation to supervise and assure the arm's length nature of transactions between the universal services and competitive services of Japan Post. The methodology and the process followed by the investigation into the accounting system should be made transparent.

■ Ban on foreign operations

Yearly status report: no progress. The Freight Forwarding Business Law defines “foreigners” and forbids them to engage in domestic air freight forwarding business. From July 2008, foreign freight forwarders have been allowed to contract air freight services through Japanese freight forwarders. This is a welcome step, but the discriminatory practice of not allowing foreign freight forwarding companies to contract air freight services directly still exists in law.

Recommendation:

- The Government should revise the Freight Forwarding Business Law so that the definition of “foreigners” is completely removed, thereby creating equal conditions for domestic and foreign freight forwarding companies.

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MEDIA & COMMUNICATIONS

Introduction

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 4,500 separate magazine titles publish over 4 billion copies per year, while the advertising market remains the second largest in the world. Although these figures suggest a thoroughly modern industry, it is difficult to maintain that the Japanese media functions similarly to the media in other leading markets in the world. The Japanese media industry places great emphasis on traditional face-to-face meetings and harmonious relations, resulting in a rather closed market that is difficult for outsiders to penetrate. After a decade of economic hardship, demand for advertising grew for several years, only to face a sharp contraction in 2008. But despite this reduction, the Japanese advertising market still accounted for over 5 billion Euros of sales last year.

The media and advertising industry in Japan remains relatively closed and highly influenced by the Government, public organisations and mega-corporations. Closed and exclusive business practices pervade most sectors of the media industry. In journalism for example, the prevalent *kisha* clubs continue to control a major part of 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. There are signs that the new Government under the Democratic Party of Japan may be softening its stance on this issue, as shown from the very first press conference given by Prime Minister Yukio Hatoyama, where Internet and other non-traditional media were invited to participate.

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 benefits the agency. The largest agencies have a near total monopoly of the market and maintain the 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 markets 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, while in France, legislation makes the disclosure of fees and rewards mandatory. As a result, advertisers are properly protected in both markets.

The Government of Japan 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. The EBC welcomes therefore the establishment of a group within the Ministry of Internal Affairs and Communications (MIC) to consider a unified Telecom and Broadcasting law. An effective flow of information and a transparent communications structure are of crucial importance to allow for deeper economic integration across borders. 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 economy on the global stage 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. An EU-Japan Economic Integration Agreement should develop common competition rules including mandatory pricing disclosure for advertisement positions in the 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 instead sell these positions to middlemen – the advertising agencies – without the knowledge of advertisers. In addition, advertisers are normally not informed about net prices as this information is often kept between publishers and advertising agencies. This practice leads to monopolisation and a structural bias towards established interests. The industry also lacks reliable and meaningful circulation figures, which puts 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.

Recommendations:

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

■ 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 (and their readers) at a major disadvantage. This practice seems to be much more widespread among Japanese companies than foreign companies operating in Japan. The Government of Japan has openly claimed an interest in boosting foreign investment, therefore the needs of foreign 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 the established reporting time.

■ Kisha Clubs

Yearly status report: some 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 Government of Japan should continue to extend invitations to news events to all accredited media and not just press club members, as a means of setting a precedent to other organisations that have been closed to the media.

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SHIPPING

Introduction

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. Amongst them, European companies offer considerable experience in 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, Transport and Tourism (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 much 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's ports. The development of Japanese container ports and terminals is being initiated by local authorities rather than by the central Government, such that the anticipated economies of scale and efficiencies will remain difficult to achieve.

The Government of Japan has begun promoting local Japanese ports as part of the 'Asia Gateway' programme, striving to enhance shipments between Japan and other Asian countries. Usually smaller sized vessels are 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 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. Japan risks becoming more dependent on the services and reliability of other countries for the handling of its own exports and imports rather than on direct connections provided by its own ports. Such a situation, if allowed to develop, would significantly undermine Japan's international trading interests and its economy as a whole.

Competition on the Japanese waterfront is stifled by the current system of "prior consultation". Under this system, all changes to shipping line operations that might 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 for the 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 economies. 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, since South 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 between member states.

Recommendation:

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

■ Promote competition in port operations

Yearly status report: limited progress. The Japan Harbour Transportation 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. If shipping lines want to operate a terminal independently, they may apply for a licence. Whilst the MLIT has committed to process applications within two months of receipt, requirements such as minimum employment levels still prevent firms from developing true competition for port services in Japan. It is not yet possible for a foreign company to set up its own terminal handling operations in Japan.

Recommendations:

- The Government of Japan should promote competition by establishing a system through which shipping companies could change their operations without seeking prior approval from the JHTA for routine business matters.
- The Government of Japan should allow foreign shipping companies to own their own handling facilities or, at the very least, be allowed to run port operations in a competitive manner

■ Competitive bidding for stevedore services

Yearly status report: no progress. While changes to the Harbour Transport Law implemented in November 2000 have enabled 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

Introduction

The global economy is increasingly dependent on access to well functioning networks. Whilst Japan has developed one of the most sophisticated information infrastructures in the world, it remains one of the most regulated telecommunications markets. Operators in Japan can do very little without first consulting and obtaining formal or informal approval from the regulator.

The fee structure for connectivity is a crucial element for the success of many businesses. Despite changes in the Japanese market over the past few 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. The 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.

In 2006, the Ministry of Internal Affairs and Communications (MIC) initiated a new programme to promote competition - "New Competition Promotion Program 2010". The main objective of the Program is to set out fair competition rules by the early 2010's in order to further promote competition in telecommunications markets and to secure user benefits. The MIC has identified 10 specific measures in the Program and plans to commence discussions on the restructuring of NTT in 2010 to enhance fair competition in the telecommunications industry in Japan.

However, the new Government headed by the Democratic Party of Japan (DPJ) has made public some of their policies about telecom-related issues, including fair competition policies. The first is to establish an independent regulator. The EBC believes that to be independent, members of the regulatory body should be selected from outside government and the committee should report directly to the Diet, and not to the MIC. Another DPJ policy intention is to reconsider NTT regulation from an international competition perspective.

The EBC welcomes the DPJ's proactive approach to the study of these issues, but maintains that any measure taken should fully reflect global best practice and not be used as a way to unfairly promote the competitiveness of domestic operators. Regulation is a key consideration in any company's investment decisions. To invest in a country, a company needs to know that that country's regulatory system is predictable, fair and not shaped to help domestic operators.

Key Issues and Recommendations

■ Institutional reform

Yearly status report: no 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 DPJ recommends creating an independent government committee as an independent organisation. The EBC welcomes this proposal and suggests that the new committee should have a mandate of monitoring regulation and business practices within the communications sector from a consumer perspective.

Recommendation:

- An independent, well-resourced and empowered telecommunications regulatory authority should be established with a pro-competitive mandate that measures its success in terms of a market that provides choice and rapid new services innovation as well as reliable and cost effective basic telecom/other services. To be independent, members should be selected from outside government and the committee should report directly to the Diet, not to the MIC.

■ NTT re-organisation

Yearly status report: new issue. In 2006, the Koizumi cabinet and then the LDP agreed to re-open the discussion on the organisation of NTT in 2010. The new Government led by the DPJ has announced its intention to re-consider this decision from the perspective of global competitiveness, taking into account competition from players such as Google and Yahoo. The DPJ seems to consider that fair competition should be achieved through focusing on network competition rather than through a mix of service- and network-based competition. Most industrialised countries seek to promote competition in both dimensions. Network-based competition requires huge investment and tends to suppress competition when there is a strong incumbent with a vast network as in Japan. The EBC feels, therefore, that service-based competition is a more appropriate target for Japan.

In particular, NTT should be obliged to provide equality of access between its own business and those of competitors and to provide suitably separated published accounts. Transparent account separation should also be established and NTT obliged to provide services to competitors at the same rate and under the same conditions as the services available to its own retail operation. Customer information must be kept confidential and not, for example, passed from the “wholesale/infrastructure” to the “retail” divisions of the incumbent.

Recommendation:

- The new Government of Japan should start an in-depth discussion on a new NTT organisation, which could guarantee fair competition, transparency, and non-discrimination. Different types of competition should be taken into consideration, without simply relying on network-based competition.

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TELECOM EQUIPMENT

Introduction

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 Euro 108 billion. Structural reforms under the Government of Japan's ICT Strategy have supported the introduction of high-speed, large-capacity ICT infrastructure, lowering of communications costs, and the development of e-commerce and e-government. The Government was largely successful in implementing the national "ICT Strategy" goal of making Japan a leader in ICT by 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 ICT Strategic Headquarters set out to improve the country's hyper-speed network infrastructure, competition policy, e-commerce, and e-government. The agenda also includes a new competition framework under discussion in a special committee on the "Optimum Competition Policies for the Telecommunications Industry to Promote the ICT Revolution". The Government of Japan is also considering strategic measures to further strengthen Japan's competitive edge in the global telecommunications market, in terms of research, development, standardisation, and the structure of the domestic market.

The EBC appreciates the opportunity to contribute to the 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 (SVC) 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 remains low and the Self Verification of Conformity still applies only to wired telecommunications terminals, with limited application to wireless/radio equipment.

The EBC urges the Government of Japan to further strengthen international competitiveness, innovation and productivity in the sector. The blanket-licensing system of mobile phone handsets has resulted in an operator-centred market for mobile handsets and restricted competition. This is becoming more obvious as the Government is also considering extending the blanket licensing to units entering the market outside of traditional operator sales channels (e.g. laptops with WiMAX access). The EBC is concerned that a blanket licence would also extend the barrier to market access to handsets operated by a Mobile Virtual Network Operator (MVNO) on a Mobile Network Operator's (MNO) network.

With a view to deepening economic integration between the EU and Japan, duplication of telecommunications equipment product 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. Mutual acceptance of technical standards and certifications for all telecommunications equipment would be a natural part of an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Establishing Common Technical Standards and Certification Procedures

Yearly status report: some progress. The EU and Japan maintain different technical standards for the same products, which, although not substantially different in their detail, leads to 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 Japanese certification process is also different from that of Europe. The EBC welcomed the introduction of Self Verification of Conformity (SVC) by the Government of Japan 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 telecommunications equipment.

Recommendations:

- The EU and Japan should mutually accept each other's technical standards and certifications for 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.
- The application of SVC should be expanded to all equipment in the category of "Specified Radio Equipment".
- Measurement methods for the Specific Absorption Rate (SAR) of terminal equipment in Japan should follow international standards, and results measured by European bodies according to the international standards should be accepted in Japan.

■ Harmonisation in Spectrum for IMT (IMT-2000 and IMT-Advanced)

Yearly status report: some progress. The International Telecom Union identified spectrum for IMT (IMT-2000 and IMT-Advanced) according to Agenda Item 1.4 of the World Radio Communication Conference in 2007. The EBC acknowledges that the Government of Japan has been active in trying to identify a globally harmonised spectrum for IMT systems. This would bring enormous benefits to the industry and consumers by eliminating the need to develop local variations of new telecommunications equipment, while creating economies of scale that would bring down the prices of products and facilitate international roaming.

Recommendation:

- The Government of Japan should work jointly with other Governments to achieve a globally harmonised spectrum allocation for IMT systems in accordance with the findings of the World Radio Communication Conference in 2007.

■ Blanket Licensing

Yearly status report: new issue. Mobile handsets need to be covered by a radio licence to be used lawfully in Japan. For this purpose, mobile operators are granted a so-called blanket licence, which automatically covers the radio licence for each mobile handset within their networks. In Europe, only the base stations of the cellular network require a radio licence, and handsets do not. Unlike in Europe, Japanese mobile operators also maintain operator-specific technical protocols for services (e.g. connection to the web), which further strengthen their ties to individual clients. As a result, manufacturers of mobile phone devices cannot sell to consumers directly in Japan, but have to go through mobile operators, which limits competition and prevents manufacturers from introducing their own technical solutions to the market. The EBC believes that the best way to foster competition is to abolish the current system of extending radio licensing to handsets and, instead, introduce a self declaration of conformity to regulatory requirements for manufacturers. This would bring benefits through lower research and development expenditure by the operators, and cost savings for manufacturers.

Recommendation:

- The Government of Japan should introduce a Supplier Self Declaration of Conformity regime in line with the EU's R&TTE Directive to enable manufacturers to sell directly to the market, without having to go through operators.

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RAILWAYS

Introduction

About 70% of Japan's railway network is operated by Japan Railways (JR Group), while the remaining 30% is operated by some 85 private railway companies, especially in and around the metropolitan areas. Japan Railways is the successor to the Japanese National Railways (JNR), which was privatised in 1987. The JR Group comprises six regional passenger railway companies - JR Hokkaido, JR East, JR Central, JR West, JR Shikoku, and JR Kyushu - and one freight railway company, JR Freight. Together they operate a nationwide network of urban, regional, and interregional train lines.

All in all, there are approximately 68,000 cars running on the 32,000kilometre-long Japanese railway network, 75% being Electric Multiple Units (EMU) and high-speed Shinkansen trains. Approximately 2,500 new cars are built yearly, out of which about 500 are exported. Some 80% of all new cars are EMUs or Shinkansens. Japan has 2,459 kilometres of high-speed rail tracks and the Tokaido Shinkansen line, which started operating as early as 1964, is the most heavily travelled high-speed line in the world, transporting more passengers than all other high-speed rail lines in the world combined. The market is huge by any standard, yet foreign penetration is negligible.

Part of the reason is the strong position held by the operators, the JR companies in particular, which only purchase products and solutions from manufacturers who develop them exclusively for JR usage. This not only means that it is extremely difficult for foreign suppliers to break into the Japanese market but also that products developed in Japan can only be exported as parts of a total system. All major and economically sound railway projects outside of Japan draw the best products and solutions from many countries and many different suppliers, based on the suppliers' own developments and harmonised international standards. Japan-specific standards deny Japanese manufacturers interoperability and opportunities to export.

The global transport sector is a major producer of CO₂ emissions, already accounting for over one-fifth of CO₂ emissions worldwide. These emissions are projected to double within just 40 years. By virtue of their providing better energy efficiency in terms of consumption per passenger kilometre and having relatively low carbon emissions, railways are crucial to reducing greenhouse gas emissions and developing sustainable transport systems. With growing awareness of the damage caused by global warming and the related introduction of ambitious CO₂ reduction targets, governments all over the world will have to invest in new railways.

As pioneers with a long history of building and maintaining railways, Europe and Japan are in an excellent position to take advantage of this increased emphasis on railway transportation, a trend which is quickly picking up momentum. The European and Japanese industries possess excellent and, in many ways complementary, expertise. They each have a long history of railway development and are, therefore, at a great advantage in spreading this technology to the rest of the world where a modern railway network has not yet been developed. However, to achieve this requires international harmonisation of railway standards and application of the harmonised system in the home market. The EU is realising this and has an ambitious programme to have harmonised standards, the European Rail Traffic Management System (ERTMS), in place across the continent by 2020. By working jointly with Europe through open integrated systems built on harmonised standards, Japan would be able to benefit from the best technologies available in Europe, and export its own products to the rest of the world.

Key Issues and Recommendations

■ Introduction of an open integrated railway system

Yearly status report: new issue. Although European manufacturers of railway equipment, components, measuring signalling systems and railway track solutions offer state-of-the-art technology, the European share of the Japanese market is considerably lower than its average worldwide share. Product development in Japan is dominated by operators who appoint manufacturers to develop new products according to pre-set specifications within a closed system, instead of allowing manufacturers the freedom to find the most appropriate solution. This results in Japan-specific solutions that make little or no sense for global suppliers to produce for and deprives Japanese manufacturers of the possibility of competing with their product in international projects, which are almost exclusively open integrated solutions.

Recommendation:

- The Government of Japan should promote open-ended integrated railway systems, in which the operators only set the performance criteria and the manufacturers develop and provide the solutions, as a way to boost competition on the domestic market and boost export prospects for Japanese manufacturers.

■ Harmonisation of standards and mutual recognition of certification

Yearly status report: new issue. The combined JR companies run on more than two-thirds of the railways, whereas the remaining one-third is controlled by more than 80 private carriers. This means that JR testing and acceptance standards serve as de-facto requirements for railway equipment to be exported to Japan. Though standards are not so different and data generated at European research facilities are relevant for Japan, duplicate testing in Japan is required for the Japanese market. No European testing institute is recognised to test for sales in Japan. Duplicate testing raises the costs of imports, making them less competitive than domestic products.

Recommendation:

- The Government of Japan and the EU authorities should work toward establishing a mechanism through which test data and certification of railway equipment provided by European organisations is accepted in Japan, and vice versa.

■ Open procurement in line with GPA

Yearly status report: new issue. Japan and the EU are both signatories of the Plurilateral Agreement on Government Procurement (GPA). The Agreement stipulates which actors have to follow the agreed rules when procuring new equipment and JR is listed as one such actor. An exception can be made, for safety reasons, which in practice means that the prescribed procedures are rarely, if ever, followed. The EBC regrets this situation as JR, 22 years after privatisation, still holds a semi-monopolistic position in the sense that any manufacturer needs de-facto approval by JR in order to enter the market.

Recommendation:

- Japanese major operators should follow the GPA when undertaking procurement and use the safety escape clause only for actual safety requirements.

■ Investment in railways and enforcement of environmental standards

Yearly status report: new issue. For environmental reasons, the increase in transport by train is widely welcomed. Both passenger and freight trains reduce the number of cars and lorries significantly and CO₂ emissions from trains are much lower. The Government of Japan must invest further in the railway system, especially for cargo, if it is to fulfil its ambitious CO₂ reduction target. Japan is also in acute need of enforcing stricter environmental standards on existing railways. Noise emissions and vibrations from rolling stock and tracks plague some estimated 120,000 households along the Shinkansen lines alone, negatively affecting quality of life as well as causing annoyance and health problems. Japan has sensible environmental guidelines in place, but these are voluntary and, unfortunately, not enforced.

Recommendations:

- The Government of Japan should promote investment in existing and new railways as a major contribution to fulfilling its CO₂ emissions target.
- Existing environmental guidelines relating to noise and vibration should be made mandatory.

Health Science

**Animal health
Medical diagnostics
Medical equipment
Pharmaceuticals
Vaccines**

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ANIMAL HEALTH

Introduction

Japan, being the second largest market for animal health products in the world with annual sales of approximately 83 billion yen, is an important market for European animal health companies. Stringent requirements in respect of the safety, efficacy and quality of any new veterinary medicinal product mean that the cost of development and registration is high. Most innovative veterinary medicinal products are now developed on a global basis by a few global companies. While these new veterinary medicinal products go through a rigorous review process in Europe and the USA prior to registration, substantial additional testing is required in Japan under the Pharmaceutical Affairs Law before approval is granted. Regulatory requirements for an innovative veterinary medicinal product based on biotechnology are especially stringent in Japan, and therefore, products readily available to veterinarians and animal owners in Europe are often not available in Japan. Increased harmonisation of regulatory requirements would certainly improve access to innovative animal health products. More rapid access to new animal vaccines and medicines is also necessary for the Japanese livestock industry to remain competitive with foreign producers. If producers in Japan cannot maintain competitiveness, Japan will continue to become more and more dependent on imported animal products or may have to expand its agriculture subsidies.

Marketing authorisation of a veterinary medicinal product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal drug intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labour and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process is complex and inefficient, requiring a similar dossier to be submitted to each of the three different authorities; moreover, the review takes an extremely long time.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), in which Japan, Europe and the USA participate, has significantly accelerated the harmonisation process by generating harmonised study guidelines to avoid the repetition of similar studies. However, the VICH guidelines are sometimes interpreted in different ways in different countries. While the VICH is tackling several new topics, it still far from covers all elements of the registration dossier, and a substantial number of additional new studies have to be conducted in order to meet Japan's unique regulatory requirements. For example, since the pharmacopoeia has not yet been fully harmonised, product specifications have to be re-written in some cases based on the Japanese pharmacopoeia. For biological products, most of the specification items are unique to Japan, including the requirement for a serological potency test on live vaccines, and product specifications have to be newly established purely for the Japanese market.

While studies conducted under Good Laboratory Practice or Good Clinical Practice are usually accepted by the Government of Japan for inclusion in the dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. This means that any overseas production facilities that are involved in the manufacture of veterinary medicinal products imported into Japan have to be accredited by MAFF, even though their GMP status is authorised by European authorities. This process involves a large amount of redundant administrative work.

MAFF has been somewhat successful in implementing measures to improve the predictability, quality, and speed of the registration process in Japan, following the release of benchmark surveys conducted by the International Federation of Animal Health in 2007. However, there are still delays in the review process for some product segments. An EU-Japan Economic Integration Agreement should aim for mutual recognition of European and Japanese marketing authorisations for veterinary products, by starting off with the mutual recognition of GMP certification for veterinary medicines. Harmonisation of regulations on animal vaccines, abandoning National Assays at the earliest opportunity and ensuring product conformance under a unified GMP regime should also be addressed under such an Agreement.

Key Issues and Recommendations

■ Product approvals

Yearly status report: progress. Products already approved in the EU have to undergo further rigorous controls and tests before being approved in Japan. Requirements for additional animal testing without obvious scientific rationale create serious animal welfare concerns. The procedure involving the “hearing” at MAFF and subsequent Committee review, which had been a major cause of delays, has been improved. However, the applicant is still required to answer questions of little relevance to the safety and efficacy of the product. It seems some Committee reviewers still lack a proper understanding of the internationally harmonised (VICH) guidelines. Since three different regulatory authorities (MAFF, FSC and MHLW) are involved, the registration of food-producing animal products can take an extremely long time, despite the standard administrative review process of 12 months set by MAFF. While MAFF is positively considering reduced requirements for translation of English reports, concrete implementation remains unclear.

Recommendations:

- The Government of Japan should take all measures available to speed up product approvals and fully harmonise domestic regulations with international practices, including mutual recognition of product registration schemes.
- In view of animal welfare concerns, requirements for additional animal studies should be minimised where similar studies are already available in other countries.
- MAFF should take the initiative to coordinate with MHLW and FSC to further reduce the registration timeline for veterinary medicinal products for food-producing animals.
- MAFF should implement acceptance of technical reports written in English as soon as possible.

■ Seed-lot system and national assay of vaccines

Yearly status report: progress. The seed-lot system enables the production of vaccines using a working seed virus/bacteria derived from an established master seed virus/bacteria. The EBC commends the MAFF initiative to introduce the seed-lot system and reduce or eliminate the current batch release requirement based on national assays for animal vaccines. However, the EBC is concerned about some additional testing requirements for eligibility for the seed-lot system. Requirements for the master seed safety study also go beyond the framework of the VICH guidelines for reversion to a virulence study. According to recent MAFF requirements, an inactivation test on the finished product is required only for imported inactivated vaccines and not for similar domestically produced inactivated vaccines. Despite the fact that the safety of vaccines for dogs and cats is tested in the target animals, an abnormal toxicity test using laboratory animals is required, which raises animal welfare concerns.

Recommendations:

- Requirements for eligibility for the seed-lot system should be aligned to the internationally recognised requirements, and no new unique-to-Japan requirements should be added.
- The requirement for an inactivation test on the finished product for inactivated vaccines should be eliminated.
- The requirement for an abnormal toxicity test on vaccines for dogs and cats should be eliminated.

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MEDICAL DIAGNOSTICS

Introduction

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 in Japan below those of comparable overseas markets.

The EBC welcomed the national health insurance review in 2008 through which reimbursement of In Vitro Diagnostics (IVD) was improved significantly, and encourages the Government to also address structural issues. The current overall approach of treating medical diagnostics only as another expense, with a reimbursement price that ignores the added-value of the product, may ultimately lead to medical practitioners failing to use the most advanced technology due to inadequate reimbursement, and so risk incorrect diagnoses and unnecessary or inappropriate treatment, and in the end, excessive healthcare. The EBC is encouraged to see that the topic of IVD has now been introduced into the Medical Industrial Vision study in which not only the Ministry of Health, Labour and Welfare (MHLW), but also the Ministry of Economy, Trade and Industry (METI) and the Ministry of Finance (MOF) are participating. The EBC is actively joining in the dialogue and sincerely hopes that the new tone of the debate will bring a shift in focus to areas such as product approval and reimbursement.

Reimbursement prices for medical diagnostic procedures and facilities were cut by 10% in the 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, although the revision in 2008 was not quite so drastic, especially for IVD products.

Recent 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 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, and by the retention of risk classification methodologies and data requirements that are unique to Japan.

Meanwhile, biennial revisions of reimbursement prices have led to continuous erosion of prices for medical diagnostics, with little information made public about the formula for price-setting 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 EBC can see no reason 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 a wider range of products in a more timely way to Japanese consumers, but also provide a significant business opportunity in Europe for Japanese manufacturers. Mutual acceptance of standards and certification for medical diagnostics products should be part of an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Product approval and smooth introduction

Yearly status report: no progress. New product approval systems have been implemented in accordance with Japan's revised Pharmaceutical Affairs Law. The introduction of a Ministry-approved system, third-party certification and a 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 that are unique to Japan make the application and review process technically slow and/or redundant. This makes it impossible to initiate application procedures for many products - a situation that should be remedied immediately. A new In-Vitro Diagnostic Directive (IVDD) came into effect in the European Union in 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 good 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 and make the product approval process more efficient. Application data requirements unique to Japan should be eliminated.

■ Reimbursement

Yearly status report: progress. The EBC welcomed the national health insurance review in 2008 through which reimbursement of IVD was improved significantly following greater recognition by the Government of their value. The Government also needs to tackle structural issues within its reimbursement regime for medical diagnostics if it is to create a competitive market of interest to European and Japanese manufacturers alike. The fact that reimbursement prices remain the same for the same type of assay, even when the speed, quality, and contribution to patient care provided by different products are totally different, acts as a disincentive to conducting better IVD tests.

Recommendations:

- The reimbursement price of IVD should better reflect 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).
- The Government of Japan should establish a periodic performance assessment system to evaluate the performance of products already on the market.

■ 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 Government of Japan 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 costs.

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MEDICAL EQUIPMENT

Introduction

Healthcare in Japan is generally of a high standard, as suggested by the country enjoying the highest average life expectancy and lowest infant mortality rates in the world. However, inefficiencies in the system, such as structural over-consumption of certain services and unparalleled long stays in hospital, need to be addressed urgently. The method of financing the healthcare system 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 be seen as an investment not only offering the individual patient a substantially higher quality of life, but also offering 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. Only 50% of the medical devices marketed and sold in the EU and the US are available in Japan.

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 Government's original intent of using the revision of the Pharmaceutical Affairs Law (PAL) to facilitate procedures and bring Japanese rules in line with global standards, the revised Law unfortunately resulted in longer approval times. A major factor explaining this outcome is the discrepancy between international standards and Japanese guidance in respect of Good Clinical Practices (GCP) and international Quality Management Systems (QMS).

As a condition of marketing authorisation both in Europe and Japan, satisfactory evidence of the clinical safety and performance of a medical device is required. Information from the Japanese Ministry of Health, Labour and Welfare (MHLW) indicates that, in the case of a large majority (about 70%) of medical devices subject to pre-market authorisation and for which clinical investigation data are required, data gathered outside Japan are accepted as the sole or primary clinical data. However, in those cases where such data are not accepted, significant additional delays and expense are incurred by having to conduct a new clinical investigation in Japan.

One of the more significant reasons for the Japan's refusal to accept foreign clinical investigation data is where such data are non-compliant with MHLW's own GCP requirements. Whereas the international standard ISO14155 is generally accepted in Europe and elsewhere as GCP for medical device clinical investigations, MHLW requires conformity with Japan-specific guidance. There are no scientifically important differences between the two regimes, but several non-substantive differences lead to significant administrative costs and requests for new data. In Europe, manufacturers are obliged to ensure conformity with Quality Management System requirements and International standard ISO13485 is generally applied as the basis for demonstrating conformity with the QMS requirements of European medical device directives. Similarly, in Japan, MHLW has issued medical device QMS guidance substantially based on, and compatible with, ISO13485. The systems are, however, completely separate and manufacturers are therefore plagued with duplicate fees and inspections. In Japan, because marketing authorisation of a medical device is tied to, and dependent on (amongst other conditions) the timing of QMS audits by the Pharmaceuticals and Medical Devices Agency (PMDA), this often leads to delays in authorisation and considerable loss for both the manufacturer and patients who may be denied access to current technologies.

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. Special focus should be placed on the mutual acceptance of certifications for medical equipment by establishing common Good Clinical Practice and Quality Management System regulations.

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Philips Electronics Japan
Radiometer
Sata
Senko Medical Trading
Siemens-Asahi Medical Technologies
Smith & Nephew Wound Management
Sorin Biomedica Japan

Key Issues and Recommendations

■ Mutual recognition and alignment of GCP and QMS

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, GCP and QMS were not implemented in a manner consistent with international standards. Japanese GCP guidance applies to clinical investigations of medicinal products, medical devices, and biological products, whereas the ISO standard is specific to medical device trials. This creates slightly different requirements and means foreign manufacturers must adapt the internationally recognised GCP and skip general guidelines that apply to a larger range of medical products. The QMS of the medical device manufacturer is analogous to Good Manufacturing Practices (GMP) for medicinal product manufacturers. In Europe, Japan, and elsewhere, QMS forms the basis for ensuring the quality, safety, and performance of medical devices, from early design through marketing and obsolescence. Ensuring conformity with QMS requirements is an obligation for the manufacturer under both regulatory systems, but the systems are separate, leading to duplicate inspections and significant delays in market introduction.

Recommendations:

- The Government of Japan should shorten the medical equipment certification process by accepting clinical trial data generated overseas, and by harmonising its GCP guidance with international standards. In the meantime, the Government should work towards regarding clinical data generated according to European standards as sufficient for Japan.
- The Government of Japan should acknowledge that, for the purposes of issuing market authorisations, QMS audits conducted by responsible Notified Bodies in the EU are generally sufficient as evidence of compliance with quality management system requirements.

■ 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 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 following the safety and review process prescribed within PAL, which exacerbates the “device-lag” between Japan and other industrialised countries.

Recommendations:

- 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 maintenance of old production lines for equipment used only in Japan because of the time lag.
- The Government of Japan should allow applications for reimbursement pricing earlier in, rather than at the conclusion of, the safety review process for category C1 and C2 devices.

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PHARMACEUTICALS

Introduction

At 34 trillion yen, Japan's national expenditure on medical care in FY2007 was some 19% higher than it had been a decade earlier, driven up by the ageing of the population and more sophisticated medical care. However, expenditure on drugs had increased by just 3%, to 7.2 trillion yen over the same period. There are two main reasons for this. First, the Government of Japan had been actively promoting generic drugs as a way to save costs, with the goal of generics accounting for 30% of the market by 2012. The second reason is that, because of the Government's pricing policies, manufacturers were taking a long time to recover the research and development costs of existing products, meanwhile delaying the introduction of innovative drugs available in other countries and postponing work on new drugs that could meet as yet unfulfilled medical needs, thereby creating Japan's "drug lag".

Japan's current National Health Insurance (NHI) drug system, designed so that the prices of most drugs are continually reduced even if they are innovative and new, is problematic. In 2008, the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) proposed Exceptional Treatment for Maintenance of NHI Drug Prices at the Chuikyo Special Committee on Drug Prices, seeking to maintain NHI prices for new drugs throughout both the patent and re-examination periods and to reinvigorate investment in new drug development. These measures should help promote innovation and eliminate Japan's drug lag. The EBC therefore supports the proposal. Moreover, in 2007, the Pharmaceuticals and Medical Devices Agency (PMDA) raised examination fees, increased the number of examiners and engaged in human resources development in a bid to reduce the time taken to examine applications for new drug approval and improve the quality of the process. The PMDA has also recently become more actively involved in guaranteeing drug safety. The Government is encouraging improvement of the clinical trial environment in Japan as well as active participation in international cooperation on drug development. The EBC supports these efforts by the Government of Japan and regulatory authorities and will be maintaining a continuous dialogue with them and carefully monitoring progress to see goals are met.

The process of integration and consolidation across the global pharmaceutical industry has increased focus on global research and development of drugs. Many Japanese pharmaceutical companies are now recognising the merits of this approach, helped by the fact that Japanese Good Clinical Practice (GCP), which used to differ significantly from the global standard, has steadily come more into line through promotion of the International Conference on Harmonisation (ICH). However, there has been no progress in extending the scope of the Mutual Recognition Agreement (MRA) for EU and Japanese Good Manufacturing Practices (GMPs); the MRA remains limited to oral solid preparations, so inspections of manufacturing facilities for all other types of product are still essentially redundant. The absence of an MRA means that the process of launching any new product is more labour-intensive and potentially takes longer. By establishing common rules, the EU and Japan would be able to expand cooperation in the development of drugs and reduce launch costs, thereby dramatically strengthening the competitiveness of their pharmaceutical industries.

While welcoming the PMDA's new plan to address its shortfalls in processing capacity, the EBC also asks the Government to actively use data and evaluations already guaranteed by the European Medicines Agency (EMA) concerning drugs distributed in the European market. It also suggests that many of the EU guidelines covering the development of drugs could prove useful for drug development in Japan. Consulting the EU guidelines more extensively and increasing the use of overseas data would drastically reduce costs, shorten the time required for market launch, eliminate the drug lag between the EU and Japan and benefit patients, industry, and society as a whole. Ultimately, the EU and Japan should also cooperate in efforts to ensure protection of data for applications and brand names, in order to further promote innovation. Much work still needs to be done to develop and upgrade Japan's innovation environment. Innovation can contribute to improved patient quality of life, reduction of social costs and robust industrial growth. Active collaboration with Europe is an extremely cost-effective way of attaining all these goals. An EU-Japan Economic Integration Agreement should therefore seek to expand the scope of the MRA to include guidelines on the quality of drugs, non-clinical areas, clinical development, and data protection, as well as rules concerning the brand names of new drugs.

Key Issues and Recommendations

■ NHI Drug Pricing Reform

Yearly status report: some progress. The EBC welcomes the relaxation of the criteria for innovative new drugs and the applicable premium rate introduced in the 2008 price revisions. None of the revisions undertaken so far has, however, stopped the eroding of prices for drugs still subject to intellectual property protection, nor gone far enough to reward innovation. The Pharmaceutical industry has been calling for a freeze on drug price reductions during the patent period. Fundamental changes to the way innovation in new drugs is evaluated requires rapid introduction of the new industry-proposed NHI drug price system in which NHI drug prices would not be reduced during either the patent or the re-examination periods. Japan needs a new NHI drug price system in which individual drugs are appropriately evaluated, innovation is rewarded and intellectual property rights are respected.

Recommendation:

- The Government of Japan should make fundamental changes to the drug price standard system so that innovation is properly rewarded and the value of drugs more appropriately evaluated.

■ Development and Upgrading of the Clinical Research Environment

Yearly status report: limited progress. Widespread understanding and implementation of the “5-Year Plan for Invigoration of Clinical Trials”, jointly published by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) and the Ministry of Health, Labour and Welfare (MHLW) in 2007, is important for improving the clinical trial implementation environment. Two years after its publication, positive changes, though limited, can be seen in the simplification of the clinical trial procedure, development and upgrading of the infrastructure of medical institutions carrying out international joint clinical trials and the speed of case registration. Currently, the 5-year plan is in the review phase.

Recommendation:

- Clinical research should be simplified by unifying the format of clinical trial-related documents and processes, and an efficient way of carrying out SDV should be discussed. Greater effort is needed to increase and upgrade the convenience of the clinical trial network currently under development. In the mean time, discussion is needed on reasonable levels of clinical trial cost.

■ Market Launch of New Drugs

Yearly status report: limited progress. The EBC welcomes the fact that information on an applicant’s place on the waiting list is now available, both in terms of deliberation and reduction in the number of CTD revisions, achieved as a result of the “Information Sharing by Applicant and PMDA in Approval Examination of New Drugs”. The EBC also recognises that the PMDA’s Office of New Drugs has been reorganised (and an Office of New Drugs V established) and preliminary evaluation interviews introduced, to increase the speed of examination. However, it is still too early to tell whether these new measures will lead to more efficient examination.

With regard to post-marketing safety measures, the number of PMDA personnel in charge of safety measures has been sharply increased. Moreover, a government-private sector joint task force has started reviewing safety measures.

Less positively, the scope of the EU-Japan MRA concerning GMP is still limited, leading to potential delays caused by redundant inspection and testing of non-solid preparations.

Recommendations:

- Safety measures should be harmonised with international standards (from surveillance to vigilance) and active use made of overseas information regarding the risk evaluation of drugs. At the same time, efficient collection and communication of safety information is needed, through use of IT, as well as increased transparency of the safety evaluation made by the PMDA. Equally, it is important to clarify the roles of the national Government, medical institutions and corporations in relation to drug safety.
- The scope of the EU-Japan MRA concerning GMP should be expanded to include non-solid preparations.

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VACCINES

Introduction

The Japanese vaccine market is currently worth Euro 570 million, representing just 5% of the total market worldwide. In contrast, pharmaceutical sales in Japan account for 10% of their respective world market. The reason for this discrepancy lies in the fact that most new vaccines available in industrialised countries are not available in Japan. In fact, the Japanese market has lagged behind overseas markets for a long time and the trend is becoming more and more pronounced. MMR (measles, mumps and rubella) vaccine, rotavirus vaccine, HPV (human papillomavirus) vaccine, IPV (inactivated poliovirus vaccine), and combination vaccines which increase vaccination coverage by reducing the number of administrations, and pneumococcal 7v vaccine, which are all widely used in the EU and the USA, are not available in Japan (although the HPV vaccine and the pneumococcal 7v vaccine are expected to be approved in October 2009).

Yet this is not to say Japan has no interest in vaccines; like many countries, it has responded to the World Health Organisation's (WHO) Phase 6 (highest) pandemic alert in respect of A/H1N1 influenza, and its manufacturers have, like others, now started to produce vaccines. The role of preventative medicine is becoming increasingly important to Japan: fiscal constraints caused by an ageing and shrinking population are putting pressure on the entire healthcare system, while vaccines offer the prospect of protecting people from developing preventable diseases that would otherwise represent a major cost burden. Clearly vaccines could play a valuable role in the future of preventive medical care in Japan.

No new vaccine has been researched and developed in Japan for a decade, and only a few novel vaccines developed by foreign-owned companies have been launched. Compared with other countries, Japan makes very little effort to develop new vaccines. The reasons for this may be historical, including supply policies tailored towards vaccines made in Japan. The absence of clinical development guidelines and standards for certification of foreign products for biological preparations certainly make vaccine development in Japan more difficult and time-consuming.

From the public health perspective, this situation is not without risk; Japan is vulnerable to outbreaks of disease that could be prevented by using new vaccines easily accessible in other countries. The recent outbreak of measles in Japan demonstrated this and heightened public awareness of the latest vaccines and the need for a vaccination policy. The Government is now starting to act, but despite signs of a change in policy, there are as yet no specific measures.

The "Vaccine Industry Vision" published by the Ministry of Health, Labour and Welfare (MHLW) in 2007 served to provide some directionality and an opportunity for dialogue between MHLW, the medical community, and the vaccine industry. The EBC calls on the Government to promote further such dialogue. It should also implement reforms that will encourage Japanese and foreign vaccine manufacturers to invest in the development and production of innovative vaccines to improve preventive medicine for the Japanese people.

While there are no specific clinical development guidelines in Japan, the European Medicines Agency's (EMA) clinical development guidelines should serve as a good reference point. The EBC believes that vaccines approved by the EU should be accessible in Japan. Harmonisation of clinical development guidelines and the biological preparation standard should be incorporated into the proposed EU-Japan Economic Integration Agreement. Meanwhile, work towards such harmonisation is in progress in the form of a MHLW research project, and there are expectations of a fruitful outcome.

Key Issues and Recommendations

■ Vaccine Gap

Yearly status report: some progress. Many of the vaccines widely used and easily obtained in other countries are yet to be available in Japan. The resulting “vaccine gap” increases indirect costs in the form of inefficient preventative medicine and treatment of preventable infection, and has an adverse effect on public health both in Japan and abroad.

Recommendation:

- The Government of Japan should eliminate the vaccine gap between Japan and other industrialised countries by making international-standard vaccines available in Japan.

■ Harmonisation of Clinical Development Guidelines and Biological Preparation Standards with the EU

Yearly status report: progress. The absence of clear guidelines for clinical development and pharmaceutical affairs in respect of vaccines, alongside uniquely Japanese Minimum Requirements for Biological Products (MRBP), hinder the development of a sound and competitive vaccine industry in Japan. Differences in approach to pharmaceutical regulation mean that the Japanese people are far less protected than their counterparts in the EU against the threat of infectious diseases, preventable through use of existing foreign-made vaccines. The EBC welcomes the MHLW’s recent initiative in setting up a working group to establish vaccine guidelines in respect of non-clinical, clinical, and adjuvant applications. Furthermore, Japanese and foreign vaccine manufacturers have recently been added to the existing members of the group looking at revision of the MRBP.

Recommendation:

- The EU and Japan should immediately join forces to address harmonisation of vaccine and engineering standards and ensure that the expert group has a clear mission, deadline and milestones. Guidelines for clinical development of vaccines should be created, based on the best of the examples provided by the EMEA and other regulatory authorities. Clear policy on approval conditions should be given to vaccine manufacturers as soon as possible and certainly before any investment is made in vaccine development. To increase the speed of clinical development, the Government of Japan should accept overseas clinical data and avoid unnecessary repetition of clinical trials.

■ Securing Public Funds for New Vaccines

Yearly status report: no progress. The National Health Insurance system is long established and widely recognised in Japan as the vehicle for channelling contributions towards the cost of standard medical expenditure on drugs. It is designed to provide medical care without regard to social status. Yet the National Health Insurance system in Japan does not cover vaccines. Only 40% of vaccines available in Japan are covered by public funds and these funds come from the coffers of local rather than central Government. The inevitable consequences include regional disparities and lower immunisation coverage in areas hard pressed financially. As a result, vaccines often fail to reach the people who need them most.

Recommendation:

- Vaccines should be incorporated into the National Health Insurance system, which offers a more consistent approach than the current system for vaccines funded by local government.

Consumer Goods

**Cosmetics
Liquor
Food**

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COSMETICS

Introduction

European firms produce a wide variety of innovative and safe cosmetic and quasi-drug products that provide value for consumers. Our products help consumers improve their daily lives in many ways, including helping to keep their bodies clean and healthy, protecting them from the damaging effects of extreme weather, preventing decay and the spread of germs, and improving the way they look. Our companies work to ensure the quality, efficacy, safety, and environmental sustainability of cosmetics in many ways, such as by investing in research and development of new ingredients and technology, by conducting clinical studies on efficacy and safety, by monitoring global developments in scientific knowledge, by providing information to consumers and by meeting or exceeding strict post-marketing surveillance and control requirements to follow Good Vigilance Practice and Good Quality Practice.

Japan is the second largest market for cosmetics in the world with 2008 sales of 1.5 trillion yen. Japan imported 171 billion and exported 111 billion yens' worth of cosmetics in 2008, including 90 billion yen of imports from Europe and 12 billion yen of exports to Europe. European cosmetic and quasi-drug products comprise a large share of imports because Japanese consumers recognise their value. However, European firms face challenges in bringing cosmetic and quasi-drug products to Japanese consumers in an efficient manner due to the insufficient regulatory transparency, low degree of harmonisation with standards used in other parts of the world, and unnecessarily complex approval and manufacturing requirements that characterise the Japanese market. As a result, some of our global products do not enter the Japanese market in a timely manner despite having clinically proven efficacy. Some quasi-drugs need to be reformulated because their global version uses new active or inactive ingredients for which approval is too time consuming or difficult to obtain in Japan.

For example, information on which active and inactive ingredients have already been approved in Japan is very limited. The EU and Japan maintain different rules governing what ingredients are allowed in cosmetics through negative and positive lists. Even when an ingredient does not require regulatory approval when used in a cosmetic, the use of the same active ingredient in a quasi-drug often requires a lengthy approval process. Approval for products covered by existing approval standards is delegated to prefectural authorities, but different prefectural offices often have inconsistent interpretations of how the approval standards must be met. In some cases, efficacy claims that are allowed in advertising for cosmetics are not allowed in advertising for quasi-drugs that use the same active ingredient, even when these claims can be supported by clinical data. The fact that previous versions of a quasi drug cannot go through the quality check process after a partial change request has been approved creates difficulties in predicting approval timing and means sea freight importers must hold large amounts of excess stock in Japan to ensure a stable supply. This results in unnecessary costs.

Globalisation has brought unprecedented benefits to consumers world-wide, in terms of products offering new benefits, greater variety, higher quality, and lower prices. However, European companies are still required to develop, manufacture and market products based on the wide variety of quality, efficacy, and safety standards used in different countries around the world. This leads to a significant increase in complexity and cost. Increasing transparency, streamlining the approval process, and promoting greater regulatory harmonisation between Japan and the EU would make it easier to bring more highvalue-added products to Japanese consumers in a timely manner.

The EU and Japan should show leadership by bilaterally negotiating harmonised regulations for quasi-drugs, the expansion of efficacy claims, and aligned positive and negative lists. The EBC also strongly supports greater leadership by the EU and Japan in the International Cooperation on Cosmetic Regulation (ICCR), an international group of cosmetic regulatory authorities from the USA, Japan, the EU, and Canada that gathers to discuss how to promote multilateral regulatory coordination and harmonisation in order to minimise barriers to trade while maintaining the highest level of global consumer protection.

Key issues and recommendations

■ Reform the quasi-drug approval system

Yearly status report: limited progress. The Ministry of Health, Labour and Welfare (MHLW) cooperated with industry requests by disclosing a list of approved ingredients for medicated cosmetic-type quasi-drugs in December 2008.

Recommendation

- The time required for standard product applications and simple changes in excipients should be reduced. Precedents in terms of previously approved ingredients should be disclosed. After partial change approvals, there should be a grace period during which the previous version can undergo quality checks and be sold.

■ Expand efficacy claims for cosmetics

Yearly status report: no progress. The scope of Japan's 55 pre-defined efficacy claims for cosmetics does not take into account advances in research and technology or improved products that better meet consumer needs.

Recommendation:

- Japan should approve new efficacy claims for products that "make wrinkles due to dryness less noticeable" and "prevent photo-ageing caused by exposure to ultra violet light."

■ Increase transparency for cosmetic ingredients

Yearly status report: some progress. The MHLW has issued notices to increase transparency regarding which medical ingredients fall into the category prohibited for use in cosmetics. However, the inconsistency between Japan and the EU in the maintenance of positive and negative lists remains unaddressed.

Recommendation:

- The EU and Japan should work towards the harmonisation of regulations on ingredients.

■ Apply same standards to all market participants

Yearly status report: no progress. Manufacturers and importers of cosmetics and quasi-drugs are legally required to spend considerable resources implementing post-marketing surveillance and control schemes to monitor safety and quality. However, parallel importers do not comply with these requirements, sometimes illegally using registered trademarks, importing versions of products that use ingredients not approved in Japan, and selling products with damaged or missing labels or that are past the expiration dates.

Recommendation:

- Japan should ensure everyone complies with the same legal requirements related to safety and quality.

■ Establish alternatives to animal testing

Yearly status report: no progress. The global cosmetics industry is developing and validating alternatives to animal testing to confirm safety but the MHLW still requires animal testing and has not validated alternatives.

Recommendation:

- Japan should develop a system for accepting products developed under an animal test ban regime that is in line with JaCVAM and should establish animal protection environments based on the 3R concept.

■ Avoid confusing carbon footprint labels

Yearly status report: new issue. Japan has begun certifying methodologies to calculate and display numerical carbon footprints on product labels. However, insufficient validated datasets make it difficult to generate accurate numerical labels. Methodologies that are inconsistent with other countries could become a trade barrier, and the labels risk shifting attention away from other ways of promoting environmental sustainability.

Recommendation:

- Rather than numerical carbon footprint labels, Japan should promote a broader framework of sustainability, such as Life Cycle Analysis, based on technically valid and globally harmonised standards.

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LIQUOR

Introduction

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 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%. The main reasons for this are clear. While the Government of Japan has implemented a notable reduction in taxes on liquor, the country still lags behind the rest of the world in the application of international standards for product definition and in the elimination of non-tariff barriers to market access.

In recent years, market conditions for the sale of European liquor in Japan have been substantially improved through a series of reforms and deregulation. In compliance with World Trade Organisation (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 distances between retail licensees. The deregulation was temporarily undermined by the designation of large numbers of “Urgent Adjustment Areas” to which it did not apply. Fortunately, by September 2006, such exceptional measures had been discontinued and the deregulation of retail channels was uniformly applied. Also in 2006, the Ministry of Finance (MOF) launched a programme aimed at long-term reform of the liquor tax regime that entails streamlining tax categories and adjusting tax rates.

The goals of the reform programme are positive, but certain provisions, including the current system of product categorisation, 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 is concerned that this would be in contradiction of 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 to Japan, the EU, USA, and Australia have all implemented the WTO ruling 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 categorisation for tax purposes in Japan indirectly protects domestic producers and, in the long term, will limit competition from European businesses. The EU and Japan should eliminate tariffs on alcoholic beverages and adopt common definitions and categories for liquor within the context of an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Product definition

Yearly status report: no progress. Product definitions for alcoholic beverages in Japan are broad and do not comply with internationally accepted product specifications 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 in Europe. Domestic products like shochu and sake are not subject to the same rate of liquor tax as authentic whisky, liqueurs and cognac imported from Europe. This provides domestic producers with a competitive advantage in terms of lower costs. Such inaccurate use of definitions also misleads Japanese consumers and undermines the perceived quality and brand integrity of the genuine European product.

Recommendation:

- Product definitions for alcoholic beverages in Japan should conform to international specifications as defined in the EU and the USA 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 licence applications for both wholesale and retail channels 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 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 ten different tax rates applied to beers, wines and spirits. The Ministry of Finance has announced its 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:

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

■ Tariffs

Yearly status report: no progress. The Government of Japan 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 Government of Japan to continue working towards the eventual elimination of tariffs on imported liquor products.

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FOOD

Introduction

Japan's economy and food market both rank second in the world. Japan's food retail market is worth about 38 trillion yen, equivalent to about Euro 240 billion. Japan's packaged food market is worth about Euro 140 billion, which is about 11% of the world total of Euro 1.2 trillion. The food processing industry is estimated to have a value of about Euro 150 billion, making it the third largest sector in Japan, after electronics and car manufacturing.

Ten countries account for some 72% of Japan's total food imports: the USA (22% of total), China (17%), Australia (8.5%), Canada (5.6%), Thailand (5.3%), France (3.3%), Chile (2.9%), Brazil (2.7%), Korea (2.5%), and New Zealand (2.1%). It is worth noting that only one European country appears on this list.

The Ministry of Agriculture, Forestry and Fisheries (MAFF) consistently highlights the fact that Japan relies on imports for over 60% of the calories it consumes. However when looking at the value of imports in relation to consumption, as is done internationally, Japan's sufficiency rate is 66%, which is lower than Italy (89%) and Germany (73%) but higher than, for instance, the UK (49%). When looking at the value of food imports on a per capita basis, the figure for Japan (\$330/year) is considerably lower than that for France (\$607), Germany (\$698) and the UK (\$756), to mention just a few.

Generally speaking, Japan's regulatory environment favours the import of raw materials to be used by its own food processing industry and penalises processed food imports. The relative scarcity of imported packaged food in Japanese supermarkets compared to other developed countries bears witness to this. Indeed imported packaged food can generally only be found in the relatively small number of gourmet and upscale supermarkets that recognise differentiation as their only hope for survival in an increasingly price-driven market.

The EBC is very keen to work closely with all related parties in the Government of Japan and the European Commission to help bring about effective, positive change to support the goal of providing consumers with safe, high-quality food. We believe that our closely shared principles strongly support the establishment of an EU-Japan Economic Integration Agreement. Under such an Agreement, all tariffs, quotas, minimum prices and state trade in food products would be abolished.

With this goal in mind, and working systematically to improve Japan's food supply, existing ineffective practices should be identified and abolished, and new opportunities to improve choice, safety, and the affordability of food - three fundamental requirements of any supply system - identified and implemented. Within such a framework, this Annual Report highlights some areas that it considers should be addressed. These include tariffs, food safety, and logistics.

Key Issues and Recommendations

■ Tariffs

Yearly status report: no progress. Import duty rates for many foods and food ingredients remain far too high. Severe inflation in the cost of ingredients and transport, coupled with high import duties, make some imported foods prohibitively expensive - for example, butter (with an import duty rate of 35% +1,159 yen/kg), cheese (26–40%), chocolate for professional use (29.8%), confectionery (25%), fruit juice and fruit puree for babies (21.3%), and herbal tea (15%).

Recommendation:

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

■ Food additives

Yearly status report: some progress. In December 2002, the Ministry of Health, Labour and Welfare (MHLW) prepared a list of 46 food additives which, in their own words, “have been proven safe and are widely used in the world”. At the time of writing, only 27 of these 46 additives have been approved for use in Japan, with an additional one additive about to be approved. This is only two more than last year. The EBC’s understanding is that once all 46 additives have been approved an event apparently still many years away - the MHLW will abandon any further action to approve additives. In the meantime, the EU is preparing a new list of priority additives. For many years the EBC has also pointed out that some widely used additives (especially preservatives), such as sulphur dioxide and sorbic acid/potassium sorbate, have significantly different allowed usage levels in Japan, according to the food category. For sulphur dioxide, the allowed usage level can be as high as 5g/kg for certain foods, or as low as 0.3g/kg for “other foods”. Many European foods with reasonable levels of sulphur dioxide cannot be imported into Japan simply because they do not fit into any existing category. The situation is worse for potassium sorbate/sorbic acid as no “other foods” category exists, meaning that even a trace (possibly carryover) of sorbic acid found in such a food would result in the total recall of that food, despite there being absolutely no health risk whatsoever.

Recommendations:

- The Government of Japan should approve all remaining additives on its priority list without delay. Standards of use should be reviewed so as not to penalise imported food.
- Beyond this list, the EBC recommends a review of all additives; other widely used additives, recognised as safe in the EU and US, should be considered for early approval in Japan.
- The regulations covering commonly used preservatives such as sulphur dioxide and sorbic acid should be modified to allow more practical (higher) usage levels in “other foods”.

■ Meat / Beef

Yearly status report: some 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 perfectly capable of tracing and guaranteeing the age of individual animals, yet the ban on imports of European beef remains in place. Several interested Member States are currently working on technical questionnaires submitted by MAFF and MHLW and have already submitted data. The process is extremely slow and still only at the discussion level.

Recommendation

- The first step for the Government of Japan should be to speed up the process of examining the data submitted by the Member States, and to limit its questions to what is necessary for risk assessment. The aim must be to authorise imports again in the short term, considering the high level of safety of beef in the EU, and also considering the fact that the ban on US beef was lifted more than 2 years ago.

■ **Listeria Monocytogenes in Ready To Eat (RTE) Food Products**

Yearly status report: no progress. *Listeria monocytogenes* is a pathogenic bacterium widespread in the environment. It can contaminate foods causing a mild illness, called Listerial Gastroenteritis, or in certain cases, a potentially lethal disease called Invasive Listeriosis. The EU standard, fully taking into account consumer safety, stipulates zero tolerance for RTE foods that support the growth of the bacteria, whilst accepting minute levels of *L. monocytogenes* (less than or equal to 100 cfu/g) in RTE foods that are scientifically proven to not support the growth of the bacteria due to particular characteristics (e.g. pH, water activity, certain processes or treatment).

Recommendation:

- Japan should review its position regarding *L. monocytogenes*, and consider aligning its regulations with the “double approach” adopted by the EU, Canada and other countries, and also supported by the principles of Codex Alimentarius and USDA’s Food & Drug Administration (FDA). This would improve food safety by focusing attention and action only on those products that pose a health risk.

■ **Labelling & Food Sanitation Laws**

New Recommendation. A number of incidents in the Japanese food industry involving negligence and fraud have led to calls for improved labelling. The Democratic Party of Japan (DPJ) has proposed making indication of the country-of-origin mandatory for all ingredients and introducing a traceability system, which would allow each product sold on the market to be traced back to the producer. Whilst the EBC shares the concerns of consumers and the Government of Japan regarding food sanitation and proper labelling, it urges a more realistic response. The Government should consider the difficulty in stating the origin of each ingredient, both in terms of finding the space to put all this information on labels, especially for smaller products, and in terms of often multiple and varying sourcing.

Recommendation:

- The Government should carefully consider the most effective actions to ensure consumer safety and reduce the incidence of accidents and fraud; this can best be done by following the guidelines from CODEX, ISO, and HACCP.

■ **Supplementary Organic Certificates**

New Recommendation. Organic JAS regulations specify that organic products can only be marketed as such in Japan if: 1) they are organically certified in their own country, 2) the importer is organic JAS-certified, and 3) the products meet organic JAS regulations (minimum 95% of ingredients must be of organic agricultural origin, excluding water and salt). Products that have a Japanese legally compliant label affixed at the production site in Europe can then be organic JAS-certified only if the European supplier itself is organic JAS-certified. Products that have the Japanese label affixed in Japan (which is often the case where smaller quantities are involved) are subject to a time-consuming, costly, wasteful bureaucratic process, which seemingly fulfils no function whatsoever. Every single shipment has to be accompanied by a specific organic certificate from the supplier’s certifying body, containing details of the order (products, quantities and best before date). The supplier must pay for this certificate to be issued each time, and the importer must send the certificate to the relevant embassy of the country from which the products were imported, together with the invoice, packing list and waybill. The embassy can then issue a “supplementary organic certificate” to the importer, as required for the products to be labelled as “organic” in Japan.

Recommendations:

- The Government of Japan should abolish the need for issuing supplementary organic certificates. It should be sufficient that the importer be required to be organic JAS-certified, as well as to keep a file copy of the organic certificate for each product that it imports and sells.

Industry

Automobiles
Automotive components
Aeronautics
Space
Defence
Construction
Materials
Environmental technology

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AUTOMOBILES

Introduction

Under the impact of the global financial crisis, EU/Japan trade in automobiles has shrunk dramatically. Japanese exports to the EU have declined sharply, but sales of European cars in Japan have plummeted at an even faster rate. The luxury segments of the Japanese market, where European car sales are concentrated, have been hit particularly hard.

In the EU, emergency measures taken by Member States to revive the car market have had some success in stimulating sales of both domestic brands and imports. Indeed, Japanese brands have benefited disproportionately from the scrappage incentive schemes adopted by some Member States. The Japanese Government has moved more slowly. By contrast with the EU, the sales incentive schemes it has introduced have benefited domestic car producers largely to the exclusion of imports. While the schemes are nominally open to all, differences between the Japanese and EU fuel efficiency and emissions testing cycles used to assess a car's eligibility for subsidies and incentives for environmentally-friendly vehicles, largely disqualify European imports.

This calls for drastic action. Even before the financial crisis, the Japanese market was contracting. Japan is a mature market. As a result of the declining birth-rate and an ageing population, the overall market is unlikely to expand in the long-term. Against this background, the Japanese automobile industry has become increasingly dependent on exports, underlined by the impact of the global financial crisis. The EBC Automobile Committee hopes that, in accordance with the commitment in the Leaders' Statement adopted at the Pittsburgh G20 Summit, participants will pursue a "more balanced pattern of global growth"; the Japanese Government will take additional measures to stimulate the domestic car market so that European car importers can enjoy market opportunities in Japan comparable to those enjoyed by Japanese exporters in the EU; and more of the Japanese automobile industry's productive capacity can be absorbed at home. Such policies would be consistent with the pledge of the new Japanese Government to make future economic growth dependent less on exports than on domestic demand.

The EBC Automobile Committee welcomes the commitment of the new Japanese Government to review the system of taxation of automobiles. The Committee hopes the Japanese Government will stimulate the market by adopting the tax reform proposals set out below, resulting in equal market access for both domestic and imported passenger cars. The Japanese Government can also help boost sales, and facilitate the more rapid introduction to Japan of advanced European safety devices, by speeding up international harmonisation of technical standards and certification procedures within the framework of United Nations ECE Working Party 29, and by adopting transparent and flexible procedures for the approval of new safety technologies. So long as the domestic market contracts, and in the absence of harmonisation of standards, European manufacturers have a diminishing incentive to bring a full range of products to Japan. The Japanese consumer, deprived of choice, is the ultimate loser.

Member Companies

ACEA	Porsche Japan
Audi Japan	Volkswagen Group Japan
BMW Japan	Volvo Cars Japan
Fiat Group Automobiles Japan	Volvo Nippon
Jaguar Land Rover Japan	
Mercedes-Benz Japan	
Nicole Automobiles	
Peugeot Citroen Japon	

Key Issues and Recommendations

■ Tax Reform

Yearly status report: some progress. Compared with other countries, Japan imposes an excessively heavy tax on the purchase and ownership of motor vehicles.

Recommendations:

The Japanese Government should:

- Abolish the Automobile Acquisition Tax and Tonnage Tax.
- Simplify the structure of the tax on automobiles and reduce the overall tax burden on motorists in line with international best practice.
- Adopt internationally harmonised standards for measuring fuel efficiency and exhaust emissions to assess environmentally friendly vehicles.

■ Harmonisation of Technical Standards and Certification Procedures

Yearly status report: some progress. Japan plans to propose in WP29 in Geneva the adoption by 2015 of an International Whole Vehicle Type Approval (IWVTA) system. This would make mutual recognition of vehicle certification possible between Japan and the EU.

Recommendations:

The Japanese Government should:

- Accelerate its adoption of UN-ECE Regulations.
- Work closely with EU Member States and the European Commission to implement the proposal for an International Whole Vehicle Type Approval system.

■ Kei Cars

Yearly status report: no progress. The continued existence of regulatory and fiscal privileges for kei cars distorts competition.

Recommendation:

- The Japanese Government should put kei cars and other motor vehicles on the same footing.

■ Technical Guidelines for New Safety Technologies

Yearly status report: some progress. The procedure for obtaining approval for use in Japan of advanced safety devices which do not comply with technical guidelines set by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) lacks transparency. Amending existing guidelines to accommodate proven European technologies has proven difficult and time-consuming.

Recommendation:

- The Japanese Government should establish a transparent procedure and a prescribed timetable for establishing new Technical Guidelines for advanced safety devices and amending, or demonstrating compliance with, existing Technical Guidelines.

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AUTOMOTIVE COMPONENTS

Introduction

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 their 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 as well as intense competitive pressures have meant that outsourcing automobile component development and supply has emerged as a clear trend in the European automobile industry. The European system offers low risks, reasonable prices and flexibility. However, European component manufacturers that have enjoyed success with Japanese transplants in Europe have seldom been able to build on this base 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.

Japan is the second largest market in the world, yet European automotive manufacturing companies hold only a small share of the market. Presence of the overseas businesses of Japanese automakers should continue to provide an opportunity for growth for European automotive component manufacturers. The European system offers competitive prices, 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 to 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 base 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 logistics 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 for discussing issues of mutual concern relating to products, platforms, global strategies and other important matters affecting the industry. The next meeting schedule is currently under negotiation between the European Association of Automotive Suppliers and the Japan Automobile Manufacturers Association. 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 19-21 May 2010 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. The EBC also hopes that the scope of these meetings will be expanded in future to include Japanese venues.

■ 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, the list of substances used in their manufacturing process, instead of simply being able to establish conformity with 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

Introduction

The Japanese market for commercial aircraft and helicopters is one of the largest in the world, and has historically been dominated by the USA. The EBC suggests Japanese airlines and other aircraft operators should 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 second-to-none customer support services. For instance, the availability on the market of the unique A380 commercial aircraft offers unprecedented possibilities to airlines in Japan in terms of providing innovative services for their customers, whilst reducing congestion at the country's major international airports.

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 the Trent 1000, are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. As regards commercial aircraft, Airbus has been trying to forge ties with the Japanese aerospace industry since the 1980's. Though there are currently 21 suppliers in Japan to the A380 programme, the Japanese aerospace industry has recently been offloading manufacturing work for the Airbus A320/A321, Bombardier, and Embraer programmes to free capacity to support other ongoing developments with US firms. Due to its long-standing relationship with North American companies, and limited understanding of the European aerospace sector, the Japanese aerospace industry is at times reluctant to work with European companies, thus depriving itself of participating in many successful European programmes.

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 programmes between the Japanese and European industries, especially in the field of transport aircraft, and urges the Government of Japan and the aerospace industry to give serious consideration to such initiatives.

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 its average share worldwide. The Japanese aeronautical sector suffers from a general lack of transparency in the way it undertakes equipment procurement, as exemplified by the modernisation of air traffic management. Although European companies are recognised worldwide as setting state-of-the-art standards, they face great difficulty in even being considered in the process for new equipment procurement in Japan. The EBC deplors this situation, which may be keeping Japan from benefiting from the latest advances 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 in Japan is still heavily biased in favour of North America. So far, the Ministry of Economy, Trade and Industry (METI) has not supported any single aircraft development with Europe. METI's support for the Boeing 787 program should not limit the potential for future collaboration with European companies. The EBC is still convinced that there are mutually beneficial opportunities for cooperation between European and Japanese firms. METI's support for the Trent 1000 engine, the agreement on supersonic technologies, and the development of Structural Health Monitoring (SHM) 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 for activities with US companies.

The EBC sees the EU-Japan R&T Cooperation Agreement, to be signed before the end of 2009, as a positive step to further enable the participation of European and Japanese stakeholders in programmes of mutual interest. The EBC also welcomes initiatives at company level, such as the cooperation agreement on composite material technologies, signed in June 2009 between Airbus and JAXA.

Recommendations:

- The EBC strongly believes in the mutual benefits of increased 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.
- Europe is supporting ambitious research programmes to tackle environmental issues, from noise to emissions. The EBC believes the environment to be one of the fields where further links between European and Japanese academia, technology clusters, and industry at large could yield significant cooperation and business opportunities.
- The EBC would also welcome invitations from the Japanese aerospace industry for European companies to participate in domestic programmes or technology developments.

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SPACE

Introduction

Japan has a new political leadership, which is expected to bring policy changes. To-date Japan's space policies have largely ignored Europe. Since other countries have been more responsive, Europe in turn now concentrates its cooperation overtures where they are more likely to have an effect. Japan's new Basic Space Law offers a unique opportunity to reverse this trend, allowing both sides to make better use of their limited space budgets, but a concrete outcome has not yet been achieved. Japan is nevertheless a leading space-faring nation with major programmes in all sectors and significant achievements in international cooperation. The commercial success of Japan's space industry is limited only because of low domestic volumes and US political pressure. Only recently has Mitsubishi Electric Corporation been able to sell communications satellites to Japanese and Singaporean commercial operators. What will happen next is even more unclear than usual as Japan's new political leadership assesses priorities, but the tendency has been to seek domestic industrial growth without taking advantage of international cooperation.

Japan's commercial satellite market is open, but the government satellite tender process is difficult for foreign companies due to contract language and currency problems. This and exchange rates prevent European manufacturers from selling their satellites in Japan, despite their high reliability and Europe's transparency policy towards Japan, which compares favourably with opaque and unreliable US control policies. Japan's cooperation in satellite development is inexplicably biased towards the US, whose political influence has had an adverse effect on the development of both the Japanese and European space industries in Japan. Japan's industry has been improving its satellite and component technologies, but has only a small domestic market. Ariane launchers are successful in Japan and play a role in cooperation: Ariespace and Mitsubishi Heavy Industries collaborate to make it easier for customers to shift satellites from Ariane 5 to H-IIA and vice-versa in the case of technical problems. However, talks between Japan and Europe's space authorities towards establishing mutual back-up of Japanese and European government launch missions have slowed, due to the lack of unified utilisation policies across the Japanese ministries, resulting in lower European interest. A Space Activities Act to be voted in mid-2010 will require Japanese commercial customers to seek government approval before they procure a foreign launch service. The need to wait for approval may become a hindrance to growth in this time-sensitive business.

Japan's investment in ground equipment has been spurred by the move into security and defence applications. Japan's space activities increasingly require ground equipment for image processing and interpretation, and for applications in agriculture, fisheries and geophysics (such as tsunami warnings). In addition, several homeland security-type applications serve to enhance defence capability. Non-transparent procurement methods are still being used in this sector to the disadvantage of foreign suppliers.

The main purpose of the 2008 Basic Space Law was to cancel a ban on space activities for defence purposes (e.g. allowing the Ministry of Defence (MOD) to own dedicated satellites) and to unify space-related jurisdictions. A Strategic Headquarters for Space Policy was established within the Cabinet Secretariat, headed by the Prime Minister as chairman. The Headquarters issued a Space Basic Plan, reviewed Japan's space organisations, and prepared legislation on space activities. The willingness of Japan's new Government to force Japan's administration to follow the Headquarters' policies and guidelines will now be put to the test. The EBC advocates an administrative structure where space-related matters can be discussed and central policies formulated, with the power to oversee and enforce implementation. The content of Japan's future space policies, however, is still unclear and should be clarified taking the real world, including Europe, into account. If care is not taken to rethink Japan's space policies on a wider scale, the new policies may only perpetuate the old ministry free-for-all and continue to render mutually valuable European-proposed cooperation opportunities mostly impractical or meaningless. The proposed mutual back-up of government launch missions mentioned above is one case in point. The unjustified bias of Japanese satellite development policies exclusively towards the US is another. The EBC is ready, willing, and eager to exchange views with Japan's new political leaders and the Strategic Headquarters.

Key Issues and Recommendations

■ General environment

Yearly status report: awaiting new government policies. Japan's new leaders will naturally make policy changes mainly for their own domestic reasons. To-date, Japan's space policies have largely ignored Europe. Other countries being more responsive, Europe now concentrates cooperation efforts where they are more likely to be rewarded. Yet openness and fairness towards European industry would be beneficial for the Japanese Government, industry and space effort as Europe provides better and cheaper technology in a cooperative way, excluding black-box policies. The new Basic Space Law offered a unique opportunity to reverse the trend, allowing both sides to make better use of their limited space budgets, but nothing has happened yet.

Recommendations:

- The EBC urges more Japanese cooperation with European space agencies and industry. Space agencies should compare plans at an earlier stage and take greater advantage of cooperation opportunities.
- The EBC also urges mutual recognition of Japanese and European export control procedures.
- Japan's new Government should increase cooperation with Europe. The EBC is ready to contribute ideas and help towards this goal, but Japan must be ready to act.

■ Satellites

Yearly status report: limited progress. European and Japanese space agencies continue meeting, but they do not achieve much progress in terms of meaningful cooperation.

Recommendations:

- The EBC recommends closer space agency cooperation in satellite technology development and applications, with pro-active promotion and execution of cooperation projects. The Government of Japan should encourage cooperation with Europe through satellite system or satellite equipment procurement in fields related to national security.
- METI and the MOD should not hesitate to procure high-quality European sensors or have Japanese industry produce them in Japan under a licensing arrangement.

■ Launchers

Yearly status report: no progress. The Japanese and European space authorities are capable of backing up each other's government launch missions. A back-up agreement would prevent technical delays to important missions and prevent the loss of government mission business. This idea is eight years old, but no agreement is in sight. For technical and cost reasons this cooperation must be comprehensive and systematic to succeed, but political leadership has been missing. The new Space Activities Act may make it more difficult for Japanese satellite communications companies to launch satellites urgently needed in a timely manner.

Recommendations:

- New government satellite programmes will require an additional number of timely launches. The EBC urges Japan's new Government to bring about effective, formal back-up cooperation between the Japanese and European heavy-lift launchers.
- The EBC stresses the importance for Japan's satellite telecommunications and broadcasting industry of not being subjected to administrative burdens, difficulties and delays when acquiring foreign launch services.

■ 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, and that full transparency can be granted in the procurement of standard ground processing products.

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DEFENCE

Introduction

Japan's current five-year defence plan includes a defence equipment procurement budget of around 4 trillion yen, of which 85% is supposedly to be spent on domestically built products, and the remaining 15% on purchases made either directly from the USA or through the Foreign Military Sales programme. In reality, however, much of the allocation for domestic spending is being used to acquire US equipment. Japan's long-term relationship with US manufacturers, politically sanctioned by the US-Japan security policy arrangement and economically driven by profits from Japanese trading houses, has resulted in little exposure to or knowledge of European technology at the Ministry of Defence (JMoD).

Though there are a few exceptions where equipment has been made under European license or even purchased direct – such as 120-mmRT mortars for the Army, and MCH101 and EC135 helicopters, 2,093 mine-hunting sonars, Ocean Master radars and marine turbine for the Japanese navy - the norm for Japan has always been to purchase US solutions at unreasonably high prices, often including technical solutions to which Japan has no access (so-called “black boxes”). JMoD still lacks the capacity to independently evaluate new projects and opportunities and, therefore, still depends on actors with vested interests for input on the new solutions available, drafting of specifications, and at times even financial arrangements, although the Ministry has made efforts to boost competence in recent years.

Fear of possible interoperability difficulties between US and European products also limits the access of European products to the market, despite the fact that NATO standards have worked excellently during more than 60 years of US-Europe cooperation. This combination of factors has led to a monopoly situation, which over time inevitably reduces value for money for the JMoD and the Japanese taxpayer, and reduces the quality of after-market support. The EBC applauds the efforts on the part of the previous Ministers of Defence to open up the procurement process, but is disappointed to see the slow pace of change and the resistance from within the administration.

The election of a new Government on a platform of cutting wasteful spending provides an excellent opportunity for Japan to address the acute need for reform. The lack of transparency in procurement processes is the core of the problem as it allows vested interests to resist new technology and cost reductions and to preserve the status quo. In Europe, open procurement regimes and joint developments have spurred technological innovation and cut costs.

The EBC welcomes the announced intention of the new Government to review suspicious relationships between industry, the administration and individual politicians to ensure that the performance and cost-efficiency of Japan's defence are not undermined. The EBC hopes that such a review will have bearing also on long-term defence programmes, which require bi-partisan political support over the years through shifting majorities in parliament.

The EBC encourages the new Government to consider closer co-operation with Europe as a viable way to re-balance Japan's foreign policy. Europe and Japan share the same security challenges and European industry is ready to share and jointly develop technology together with its Japanese counterparts. Working with Europe to provide defence solutions represents a unique opportunity for Japan to acquire technology and competitive strength, achieve a better balanced foreign policy without undermining the US-Japan alliance, and enhance defence at a lower price.

Key Issues and Recommendations

■ Increase competition

Yearly status report: some progress. The EBC welcomes the steps being taken by the Japanese Ministry of Defence to increase competition in the procurement process, opening it up to foreign suppliers. Publishing the Statement of Requirements (SOR) would increase transparency and increase the level of competition in any tendering process. It is also crucial that priorities be set by the Cabinet and Ministers for each important tender and that JMoD officials receive clear instructions about these priorities, to ensure that the small print does not derail the procurement process. The EBC strongly urges the Government to repeal the granting of unlimited liability in the terms and conditions of public tenders, since this automatically puts foreign bidders at a competitive disadvantage vis-à-vis Japanese contenders. A greater emphasis on Life Cycle Costs (LCCs) is also welcome. EU companies have considerable experience in modelling and predicting LCCs, and are confident about their ability to guarantee their predictions or enter into fixed price contracts. This can benefit JMoD budgeting by preventing price shocks and escalations. LCC models used in the EU can be shared with Japan, and are likely to be more relevant than those used by the USA, which have vastly higher manpower and equipment levels, requiring different maintenance and training policies.

Recommendation:

- The Government of Japan should improve transparency towards foreign suppliers by making the statement of requirements for each procurement process publicly available and by putting more emphasis on Life Cycle Costs. JMoD should adopt NATO standards from the initial R&D phase as a means of strengthening competition and reducing development risk, since this would encourage more diverse inputs and an increased number of partners.

■ Industrial Partnership

Yearly status report: some progress. EU Defence Companies look forward to assisting JMoD in meeting its cost reduction targets with such initiatives as Performance Based Logistics (PBL), Private Finance Initiatives (PFI), commercial off-the-shelf solutions, leasing schemes, and procurement techniques to minimise costs. Examples of the progress achieved by introducing LCC models, whether through an initial phase of performance-based logistic support or a fully integrated operational support programme, can be demonstrated by a number of European governments, which have already taken the initiative to partner with industry and are beginning to see the through-life cost benefits. This puts the European defence industry well ahead of its US competitors. Several decades of European experience in using an International Integrated Product Team (IIPT) would give an inestimable advantage to EU-Japan cooperation.

Recommendation:

- The Government of Japan should introduce innovative procurement approaches, such as partnerships with industry, in order to reduce procurement and Life Cycle Costs and promote the IIPT approach.

■ New security policy arrangement

Yearly status report: no progress. The European defence industry has established a reputation for international collaborative development of even the most complex defence systems (fighters, warships, missiles), not only between two countries, but also between several European partners and the US and other major defence markets. Unfortunately, Japan is left out of the richest pool of defence technology expertise available worldwide, because of its current security restrictions.

Recommendation:

- With a view to sharing costs and improving technological solutions, the Government of Japan should clarify that co-development projects between Europe and Japan do not violate the “three principles of weapons export”.

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CONSTRUCTION

Introduction

Although the construction sector's share of Japan's total GDP decreased from 14.2% in 1998 to 10.2% in 2006, the absolute size of the sector (Euro 363 billion in 2006) makes it one of the largest in the world. The Government of Japan has made enormous efforts to increase the sector's efficiency by more than halving (54%) yearly public spending over the past eight years, yet inefficiencies in terms of structure and management continue to prevent the creation of a market environment based solely on cost-effective merit. It remains almost impossible for foreign companies to sell 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 regulations, resistance to change by local officials and complicated procedures to obtain the necessary approvals.

In recent years, the construction sector in Japan has changed, largely because of drastic cuts in public spending that brought construction costs closer to international levels. Yet relatively little has been done 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 in respect of performance requirements and quality control. Foreign involvement is relatively low with only a few European firms operating in niche areas of the market.

A lack of consistent performance criteria has caused Japan to lag behind in the development of safer and more energy-efficient buildings. The EBC applauds Prime Minister Hatoyama's goal of reducing carbon emissions by 25% by 2020 compared to 1990 levels and would like to emphasise that this cannot be achieved without a major improvement in the performance of existing and new buildings. Over 30% of the energy in Japan is consumed by commercial and residential buildings, and consumption in buildings is growing faster than consumption in other sectors. Residential and commercial buildings continue to be constructed with low insulation performance compared to standard practice in many other OECD nations with similar climates. This is happening despite a decade of lip-service by the Government of Japan to the importance of promoting technological solutions to global climate change. Japan lacks policies to promote energy efficiency in the sector with the largest consumption and hence the largest potential for savings. The EBC believes that the best way to correct this problem is to introduce binding regulation, as experience in so many other markets has proven. Whilst regulations on energy efficiency and safety should be strengthened, the restrictions on contractors should be streamlined to allow for competition and innovation in the delivery of solutions. According to current 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 Euro 30,000) 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.

To promote competition, the Government also should abolish the ceiling price system (*yotei kakaku*) for public tenders and relax requirements for bid participation. 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 also be eliminated. 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. An EU-Japan Economic Integration Agreement should include mutual acceptance of standards and certification for construction product convergence, improved transparency and strictly enforced common rules for government procurement, and joint recognition of the role of construction in promoting a sustainable society.

Key Issues and Recommendations

■ Promotion of environmentally friendly and safe construction

Yearly status report: limited progress. We applaud the Government's ambitious CO₂ emissions reduction target. The Science Council of Japan along with other similar bodies from the G8 (Interacademy Council 2007) has indicated that the building sector offers a number of specific opportunities to reduce energy consumption and CO₂ emissions. Improved building insulation is one of the simplest and most effective ways to reduce energy use, and also generates a positive monetary return (McKinsey GHG curve). The Government of Japan should mandate the introduction of much stricter insulation standards for buildings, as current requirements lag alarmingly behind those of advanced European countries. Rating tools such as CASBEE, and schemes such as the Energy Efficiency Standard for houses and the PAL/CEC assessment for larger office buildings, are heading in the right direction but produce buildings that are quite simply not up to international standards. Moreover, Japan continues to use building materials that Europe classifies as dangerous.

Recommendation:

- The Government of Japan should strengthen regulation to promote energy efficiency in residential and commercial buildings as a way of fulfilling its international commitment to cut carbon emissions, and increase the earthquake/typhoon safety of buildings.

■ Public procurement

Yearly status report: limited progress. The EBC is encouraged to see a recent trend expanding 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. However, the public works procurement situation remains far from ideal. It 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. Review of this situation is in the interest of Japanese developers who would themselves benefit from new opportunities if an effective PFI/PPP mechanism stimulated an environment of greater investment potential. Adopting a broader composition of evaluation criteria and committee expertise, and embracing international best practice would serve to raise the standard of the public works procurement process. Similarly, the EBC believes much wider utilisation of third party CMR services would improve the professionalism in and accountability of the procurement process.

Recommendation:

- The Government of Japan should remain diligent in ensuring the proper application of the Comprehensive Evaluation Bidding System, thus fostering increased opportunities for European firms to deliver successful bids in fair and open, value-for-money based competition.

■ 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 cost of imports to Japan and makes them less competitive than domestic supplies. In 2001, the Ministry of Construction (now the Ministry of Land, Infrastructure, Transport and Tourism - 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 glulam.

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 when sold in Japan.

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MATERIALS

Introduction

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, nanotechnologies for manufacturing semiconductors, and various electronic components. These advanced technologies depend on the availability of key raw materials and Japan's ability to secure a stable high quality supply. It is therefore of utmost importance that Japan secures these raw materials by adopting a strategy based on the security of supply, competitiveness, and unrestricted access to its domestic market by overseas suppliers.

Japan, one of the main consumers of industrial materials in the world, would benefit greatly from better access to the reliable sources of high-quality products at market-based prices that European companies can offer. However, Japan has been reluctant to reduce tariffs on industrial materials on a unilateral basis before formal negotiations on tariff reductions are concluded under the auspices of the World Trade Organisation (WTO). Following a number of bilateral trade agreements and continued difficulties in reaching a breakthrough in the WTO's Doha round, Japan has started to reconsider this policy. The unilateral lifting of tariffs on high carbon ferro-chromium (tariff code 720241000), a key ingredient in the manufacturing of all stainless steels, is a welcome step of major importance.

Tariffs damage competitiveness and threaten the future of domestic Japanese industry. 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 those in South Korea and China. The same situation applies to fused aluminium oxide (artificial corundum, tariff codes: 281810010 sized grain and 281810090 non-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 photovoltaics, a rapidly expanding application in Japan. Imported fused aluminium oxide and silicon carbide are both subject to a 3.3% tariff, even though domestic production can only fulfil at best 10% of yearly requirements. While consumers can currently import much of their fused aluminium oxide requirements from tariff-exempt countries under the Generalised System of Preferences (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 Japanese manufacturers suffers accordingly. In the case of silicon carbide, Japan imports 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 Japanese industry. Another similar case in point is manganous manganic oxide or Mn_3O_4 , used in the manufacture of soft ferrites and rechargeable batteries, and therefore many electronic devices. Only four countries produce Mn_3O_4 , most notably China and Belgium. Belgian material is the only product facing a 3.3% import duty (tariff code: 282090000). However, Belgium is the sole producer in the world that does not use volatile Chinese manganese metal as an intermediate. Belgian Mn_3O_4 is made from in-house ore and in conformity with stringent environmental regulations. This is the required profile to guarantee a safe supply and stability on a long-term basis to Japanese industry. Import tariffs increase the dependency of Japan on Chinese suppliers and threaten the future of the domestic Japanese industry. An EU-Japan Economic Integration Agreement should include the removal of all import duties on industrial raw materials, such as refined nickel products, fused aluminium oxide, silicon carbide and manganous manganic oxide.

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 cost. Therefore, it is critical that Japanese manufacturers are able to procure their nickel requirements at competitive prices and are assured 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 South Korean and Chinese companies, who are required to pay only very low or no import duties. The Japanese industry's global competitiveness is under threat from South Korean and Chinese rivals, operating factories two to three times larger 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 following the well-received removal of tariffs from ferro-chromium, eliminating tariffs on nickel would be another 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, silicon carbide and manganous manganic oxide

Yearly status report: no progress. Fused aluminium oxide, silicon carbide, and manganous manganic oxide are all subject to a 3.3% tariff, though most imports come from countries enjoying tariff exemption under the Generalised System of Preferences. For some categories, duty is applied to products that are not even produced in Japan. This increases the price of imported fused aluminium oxide and effectively penalises the Japanese end-user, a situation exacerbated by a current shortage of supply. With regard to silicon carbide and manganous manganic oxide, 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 tariffs on all industrial raw materials including aluminium oxide, silicon carbide, and manganous manganic oxide.

■ Tariff classifications

Yearly status report: no progress. European supplies of industrial materials to Japan are occasionally subjected to arbitrary tariff classifications and revisions. Customs Offices do not apply classification rules on a consistent basis and there is no appeal mechanism available with which to challenge a classification ruling. This is a problem not only for products entering the market for the first time, but also for well-established products subject to sudden classification reviews.

Recommendation:

- The Government of Japan should rationalise its tariff classification regime and develop a comprehensive strategy to improve consistency between Customs Offices on classification rulings, and to strengthen dispute resolution mechanisms.

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ENVIRONMENTAL TECHNOLOGY

Introduction

Japan's environmental technology market accounts for 16% of the global market, making it the second largest market in the world. The sheer size of the market implies tremendous opportunities for foreign companies offering 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 the large-scale investment plans of governments. Government policies are therefore crucial for opening up the market to efficient and innovative services.

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 environmental business is relatively weak in terms of consistent application and enforcement of rules, especially with regard 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 the new guidelines.

The EBC also remains concerned about the regulatory environment governing soil remediation practices themselves. The Government of Japan 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 Japanese 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 Government of Japan and the EU to unite on principles and practices for PFI/PPP within an EU-Japan Economic Integration Agreement.

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 ageing 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 and Public-Private Partnerships are gaining popularity in Japan. These mechanisms 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 in Japan 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 for municipalities.

Recommendation:

- The use of PFI and PPP as 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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