

A stylized yellow map of Japan, showing the four main islands: Hokkaido, Honshu, Shikoku, and Kyushu, with surrounding smaller islands. The map is positioned in the background of the title text.

Going for Growth

The EBC Report on the Japanese Business Environment 2010

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

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2010

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The European Business Council (EBC) is the trade policy arm of 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 400 company executives participate directly in the EBC's 28 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 Union to 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

It is now more than a year since the Japanese electorate turned to the Democratic Party of Japan (DPJ) to deliver a fresh approach to government and a much-needed lift to the economy. Locked into its deepest recession for many decades, Japan was languishing from the effects of the global financial crisis and deep structural problems at home. Low levels of domestic demand and an inefficient, under-performing service sector could not compensate for falling export demand, so the economy faltered, just as public finances risked becoming overwhelmed by the costs of caring for a shrinking and ageing population.

So what has happened since then? Certainly, there has been a great deal of activity, but sadly, not in the field of economic reform. Instead, at a time of entrenched deflation, with every day seeming to bring a further rise in the yen and fall in the stock market, the country has been subjected to the spectacle of a distracted political leadership endlessly consumed by its own internal struggles. Party politics has taken precedence over policy, the economy, and the interests of the people: surely this is the wrong priority?

Yet all is not lost. Prime Minister Naoto Kan and his Government enjoy a clear electoral mandate and an unmissable opportunity to set the agenda for the coming period. It is time for them to turn their attention to the pressing needs of the country, for while they have focused on party elections, China, India, South Korea and many others have been hard at work shoring up their finances, boosting their economies and going for growth. Japan must do the same.

Top priority must be given to policy directions that will put the economy back on track. Earlier initiatives to kick-start regulatory reform should be pursued more vigorously, focused on stimulating innovation, competition and foreign investment. Efforts to wrest power from vested interests that have stood too long in the way of change, must be brought to a successful conclusion. The target must be to re-establish Japan as a strong competitor in the global economy, firmly positioned for sustainable growth, benefiting not only business and public finances, but also every consumer and citizen.

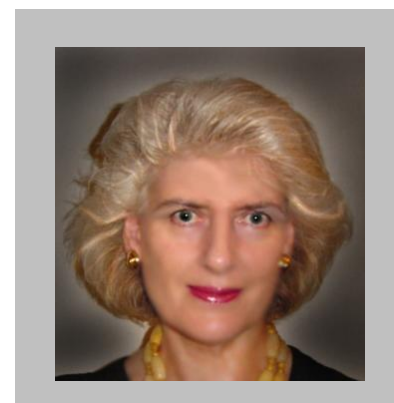
The European Business Council in Japan (EBC) recognises that this is easy to say and far more difficult to achieve. The aim of the EBC's 2010 report on the Japanese business environment is to pinpoint those areas where we believe change is most crucial and offer carefully considered suggestions on what should be done. We hope that Japan's politicians and government officials will regard it as a valuable resource and proactively seek dialogue with the EBC not only on the various recommendations listed in the chapters, but on other issues of mutual interest as well. Our recommendations are based on the experience and insight of the EBC's expert committees, who offer extensive knowledge of operating businesses both in Japan and other markets and a deep conviction that, if market access improves, Japan can offer enormous, exciting new opportunities for business growth, leading to increased employment and prosperity for all.

The EBC is deeply conscious that Japan is not alone in facing a challenging economic future: the European Union, too, is struggling to recover from the global financial crisis and remains beset with problems of sovereign debt, high public expenditure and fierce competition in its traditional markets. Yet this is not all the EU and Japan have in common: they also share the benefits of skilled and educated workforces, world-class R&D and manufacturing facilities, leading-edge businesses, significant home markets, similar profiles of economic development and strong commitments to public welfare and environmental sustainability. For these reasons, we believe that, by together building on these strengths, fostering mutual trade and cooperation, and working towards a truly free, shared market, the EU and Japan could offer each other lasting opportunities for growth and global competitiveness.

We trust that our recommendations will serve as an inspiration to all who share our concern to build a brighter economic future for our countries. The EBC is not asking for any privileges or benefits for European industry: we simply ask for a level playing field and competition on equal terms and conditions! It is not too late, but there is no time to waste. Japan must get to work and go for growth!

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 2010 report on the Japanese business environment: “Going for Growth”.

The timing of the report coincides with a new start for the Government of Japan. As we go to press, it seems that months of political turmoil may finally be ending and the spotlight turning towards the country’s economic plight. Japan’s recovery from recession continues to be undermined by, on the one hand, a strong yen curbing export demand and, on the other, weak business and consumer confidence curbing domestic demand. The country seems locked into deflation and relying on external factors to change its fortunes. Yet the truth is that, while the global financial crisis may have contributed to the current malaise, many of Japan’s underlying problems are self-inflicted. For years, the EBC and other organisations have been warning of the over-dependence on exports and urgent need for structural and economic reform. Successive governments have flinched and looked away. This Government must take a different approach, face up to the challenges and go for growth!

The EBC annual report aims to contribute to the Government’s process of identifying key areas for action by focusing on issues that, in the view of European business in Japan, hold back prospects for economic revival. The report’s recommendations are, unsurprisingly, business-like: practical and concise, with a clear emphasis on eliminating unnecessary costs and bureaucracy, improving openness and transparency, and promoting innovation and competition. They are drawn directly from the experience and expertise of the EBC’s 28 sector-based committees, some 2,500 companies and our key stakeholders: the European National Chambers of Commerce and other business organisations represented in Japan. The final document owes much to the tireless efforts of the EBC’s new Policy Director, Bjorn Kongstad, in capturing and coordinating the multitude of inputs, ideas and information that have come forward.

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

We believe the EBC report offers a treasure-trove of insights and ideas that could make a significant contribution to the Government’s search for solutions to Japan’s economic challenges. EBC members have Japan as the base of their business and are employing Japanese people. They make up a crucial part of the Japanese market and merely seek a level playing field. Moreover, they also work hard to encourage their respective headquarters to continuously engage and invest in Japan. Their personal commitment to Japan could not be stronger nor their recommendations more sincere!

Moreover, as the European Union itself struggles with many similar problems, and economic power moves inexorably towards China and India, we continue to urge the EU and Japan to work together with a strong commitment to achieving a significant and sustainable boost to mutual trade and investment in the changing global business environment.

We commend the EBC report to our readers and trust it will prove useful to all those committed to going for growth!

Alison Murray
Executive Director
European Business Council in Japan

Introduction



INTRODUCTION

It is more than a year now since the European Business Council in Japan (EBC) welcomed the election of a new Government promising a fresh approach to economic reform. The Prime Minister had just set to work, announcing a raft of new policies, including ambitious targets to increase transparency, reduce wasteful spending and provide “value for money”. No stone was to be left unturned: the “special accounts” of ministerial fiefdoms, uncompetitive public procurement contracts, inefficient health services and even the opaque tax system would all be exposed to scrutiny and, where necessary, reformed in the light of the new priorities. It seemed that, at last, Japan was going to become an open, fair and competitive economy.

What has happened since? Sadly, the dynamism of the first few months was quick to fade, eclipsed by policy arguments and political wrangling from within the leadership’s own party. Yet, just as it seemed the Government was about to implode, the situation re-stabilised: it appears there is to be a second chance.

So once again, the EBC is in a position to welcome a new Government determined to give Japan a fresh economic start. The situation is now even more urgent than a year ago, for while Japan was distracted by bickering politicians, countries like China, India and Brazil were busy consolidating their finances and searching for new markets, at home and abroad, as platforms for future growth. Small wonder, then, that 2010 will go down in history as the year China replaced Japan as the second biggest economy in the world.

One of the first tasks of the Government should be to set about reversing the current disturbing trend of increasing insularity and start the country looking outwards again if it is to remain a global force. The EBC feels strongly that there are still excellent prospects for sustainable prosperity and growth, so long as the Government acts quickly and makes the right choices.

Let’s look first at what some of the wrong choices might be. For years, Japan has relied on its export industry to drive the economy, leaving it vulnerable when, as in 2008, overseas demand plummets or, as in 2010, the yen surges. At the same time, strength in export markets has been used to shield domestic companies from the forces of competition and change. Their resulting lack of competitiveness has been bad for industry and consumers alike and ultimately bad for Japan because, unlike China, India or even the US, the country has proved unable to stimulate demand at home to compensate for falling demand from abroad. Japan can no longer export its way out of trouble. The flaws of former policy choices have been exposed: this Government should not repeat them.

Yet the Government will be unable to chart a different course unless it succeeds in bringing Japan’s over-staffed and over-powerful bureaucracy under its control. Previous regimes effectively allowed unelected bureaucrats to determine policy, strengthening the hand of vested interests and ignoring the need for reform. Japan must aggressively tackle its regulatory framework to welcome goods, services, capital, technical knowhow and experts from abroad. This will bring much needed investment to Japan and make domestic companies more competitive. Competition benefits consumers, encouraging them to spend, which drives development and leads to growth.

Putting growth first means opening markets to allow more competition and so pushes a number of issues to the top of the Government’s priority list, including from the EBC’s perspective, the need to:

- Work with the EU Authorities towards mutual recognition of standards, product certifications and marketing authorisations, and adopt international standards where applicable;
- Overhaul competition rules to guarantee fair and equal treatment of all companies, domestic and foreign;
- Ensure fair and open competition in services and in the tendering of public procurement contracts;
- Improve conditions for foreign direct investment, including infrastructure and incentives, bearing in mind that Japan’s neighbours are competing fiercely in this arena;

- Lift barriers such as high costs, unnecessary bureaucracy and long approval times that prevent or delay innovative products from reaching the market;
- Ensure that company law and the tax and regulatory regimes contribute positively towards a business environment that encourages foreign direct investment.
- Enhance incentives for investment in R&D, such as reimbursement schemes in the healthcare sector, to recognise and reward innovation that improves human welfare and cuts overall costs to society.

The EBC believes that these and many other reforms are what is needed to make Japanese industry more competitive, boost consumer confidence and thereby stimulate a long-term increase in private domestic demand, counter the country's inward-looking inertia, and put the Japanese economy on a more positive track. The individual sections of this report offer sector-specific details and more precise recommendations for action that could help to achieve these goals. Yet we are far from arguing that Japan is alone in needing to find new paths to growth: the European Union shares many of the same challenges and it, too, is searching for solutions.

Indeed, for the past ten years, the EU and Japan have been engaged in a number of dialogues intended to boost their economies by facilitating mutual trade. These dialogues may have proved valuable tools for diplomacy but, critically, they lack the negotiating apparatus to deliver more concrete results. Consequently, the EU-Japan relationship is still far from achieving its full potential, yet neither side can afford to forego the opportunity it offers for greater prosperity and economic stability. So the EBC was pleased that the EU and Japanese authorities established a High Level Group in mid-2010 to look into the feasibility of a bilateral agreement that would abolish obstacles to mutual trade, integrate rules and regulations, harmonise certification and regulatory processes and provide for free competition, fair investment, enhanced intellectual property protection and transparent public procurement practices. The EBC calls for commitments on both sides to succeed in this endeavour as it would provide the EU and Japan with a unique opportunity to properly address longstanding trade issues and foster strong competitive businesses, serving the best interest of their consumers, and thereby contributing to growth.

The EBC believes that by focusing on their similarities, not their differences, the EU and Japan can together have the economic strength and dynamism not only to deliver sustained prosperity to their domestic populations, but also to set the standard for trade and investment on the global stage. We should not forget that Europe is still the biggest consumer market in the world, boasting leading-edge businesses in goods and services and more than 500 million wealthy citizens, while Japan offers unrivalled technological creativity and expertise, plus a commitment to quality and delivery second to none. By together building on these strengths, the EU and Japan could provide the impetus for a dramatic change in EU-Japan relations and significantly strengthen the position of both the EU and Japan in the global economy.

We trust all the information, ideas and recommendations in this report will prove to be a positive contribution to the thinking of the Government of Japan and all other authorities, including in the European Union, who genuinely wish to improve the environment for business and investment. We especially urge the Government of Japan to use the coming year to free the economy from structural barriers, foster free and open competition and put consumer interests first: in short, to go for growth!

How this report is organised

This report consists of 31 chapters, each addressing the concerns of a specific EBC sector committee and based on the collective first-hand experience of committee members operating businesses in Japan. Chapters are written by the committees and consist of an overview of the business environment for their sector and developments over the past year, followed by a series of recommendations for further regulatory reform. This introduction, prepared by the EBC's Policy Director, aims to address some of the over-arching issues raised by the committees and the potential benefits of closer EU-Japan trade and economic cooperation.

Business

Fundamentals

Human resources
Intellectual property
Retail & wholesale
Legal services
Sustainable development
Tax

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HUMAN RESOURCES

Introduction

Japan's economic and demographic outlook is bleak on many fronts. A future 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 human resources in the current recession, but as the working population decreases, there will be increasing pressure to find new sources of labour both domestically and from abroad. In the light of these challenges, it is critical that labour regulations and human resource management facilitate and provide the best means of acquiring and retaining a highly skilled, competitive workforce. To meet the evolving demands of today's fast-paced global economy, the Government must remove obstructive regulations on immigration and employment tenure, and must encourage further participation of women in the workforce through flexible new labour laws in line with international standards and practices.

In July 2012, a fundamental change will be seen in the current "Alien Registration System", with the abolition of the "Alien Registration Act" and the amendment of the "Immigration Act" bringing all immigration information control together under the Immigration Bureau of the Ministry of Justice (MoJ). The new system and "Resident Card" cast the changes to immigration policy in Japan in a fairly positive light and, for most of the foreign population there will be significant improvements over the current system. However, the new system fails to reflect the vision required to bring more foreigners to Japan and really only represents an improvement for those already here. For example, dependent spouses, who are often, like their working foreign partners, highly qualified, are still not eligible to work unless they go through the entire immigration process again, including finding a company willing to sponsor their application. This provides little motivation for career-minded foreign couples to consider relocating to Japan to take up work.

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. Further amendments were made in 2010 to the "overtime laws" for larger companies resulting in a higher rate of compensation for overtime once a certain threshold of overtime hours is reached. It is now also possible for companies to have their employees take leave in 1-hour units, instead of the previous half day or 4-hour units. The EBC takes a positive view of these developments.

Coupled with the need for further drastic changes to immigration policy, Japan is in desperate need of motivating its female population to return to the workforce. Initiatives such as the system for "Short-Time Regular Employees" (*tanjikan-kinmu-seishain*) have been introduced, but are generally not well known or utilised, so many of Japan's housewives still feel unable to commit to becoming a regular employee (*seishain*) and therefore unwilling to enter the workforce. This can only be described as a waste of available resources. Moreover, the Worker Dispatching Act is earmarked for change to protect workers dispatched by temporary worker agencies from expulsion during the economic downturn, which may de-motivate companies from taking on such workers, of whom a large percentage is women.

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 refund of mandatory Japanese pension fund contributions to be expanded to expatriate workers leaving Japan. Refunds of pension payments are covered by social security agreements concluded or in the process of being negotiated with Belgium, France, the UK, Germany, the Netherlands, the Czech Republic, Ireland, Spain, Italy, Switzerland, Luxembourg and Hungary. The Government of Japan should act quickly to conclude social security agreements with all remaining EU Member States as well as Norway and Iceland. A comprehensive Economic Integration Agreement (EIA) between the EU and Japan could streamline the process of brokering multiple bilateral 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, re-entry permits and the new “Resident Card”

Yearly status report: good progress. The proposed merging of the Immigration Control Act and the Alien Registration Law and the introduction of the proposed “Resident Card” were passed by Parliament on July 15th 2009. The target for launching the new system is set for July 2012. The Human Resources Committee has reviewed the current framework extensively, and applauds the Government for keeping the process transparent.

Recommendations:

- The Immigration Bureau should acknowledge the inconvenience of regular trips to Immigration Bureau Offices due to their limited locations and implement on-line and postal application systems that allow changes to “Resident Card” details to be made without visiting the Immigration Bureau.
- The Japanese Government should eliminate the re-entry permit system entirely. The exemption of resident card holders who come back to Japan within 12-months is a move in the right direction, but the EBC sees no logical reason for continuing the re-entry permit system under the new Immigration Act.
- The EBC encourages the Immigration Bureau to be diligent in ensuring information protection, and in seeking privacy equality between both Japanese citizens and Foreigners. The MoJ should cautiously consider the security of IC Chip technology to be used in the new Resident Card, the use of IC Chip readers and the personal information to be displayed on the Resident Card.

■ Work place diversity

Yearly status report: no progress. Much of the future of Japan depends on maintaining a workforce sufficient to support the ageing population and drive Japan’s economy. By far the easiest way to increase the working population would be to increase female participation in the workforce. The EBC strongly urges the Japanese Government to place more focus on workplace diversity and to support and encourage more female participation in the workforce and more male participation in households and child rearing.

Recommendations:

- Remove the “spouse special income tax credit (*haigusha-tokubetsu-kojo*)” that discourages “dependent spouses” from earning more than 1.4 million yen annually.
- Raise awareness of the “Short-Time Regular Employee System (*tanjikan-kinmu-no-seishain seido*)” within corporate Japan, and incentivise companies to use the system through tax breaks, benefits or other means.
- Vastly increase and improve the infrastructure necessary for sufficient child care facilities, systems and staffing to support female participation in the workforce and male participation in the home.
- Automatically grant work permits to spouse visa holders so that multinational companies can attract the best talent to postings in Japan.

■ Pensions

Yearly status report: gradual progress. Social security agreements have been concluded or are being negotiated with Belgium, France, the UK, Germany, the Netherlands, the Czech Republic, Ireland, Spain, Italy, Switzerland, Luxembourg and Hungary, 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:

- Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers, and payments should be made without the requirement for 25 years of contributions into the system.
- 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.

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INTELLECTUAL PROPERTY

Introduction

Japan remains one of the world's most attractive markets for luxury products and is therefore among the principal targets for the trade in counterfeit goods. Nowadays, most fake products entering and circulating in Japan are bought through Internet websites. The problem stems from Japan's legal system, which notably allows the import of fake goods as long as they are for personal use. Accordingly, there is an inflow of counterfeit goods bought through mid-sized auction websites based overseas, which are outside Japan's jurisdiction yet targeted at Japanese people. Moreover, even though major auction websites or shopping malls can easily remove obvious counterfeit products, removal is more difficult when there is no prima facie evidence of infringement available from the information on the screen. It is thought that such counterfeit goods exceed 10% of all articles sold as well-known foreign brands. In the last few years, the Japanese authorities have started to more pro-actively counteract violations of intellectual property rights. However, notwithstanding important legal improvements and encouraging results following intensified surveillance, crucial issues remain unresolved. Although the intellectual property programme of the Koizumi Cabinet aimed at more action, the EBC has subsequently witnessed a somewhat lower frequency of interventions and believes that the Japanese authorities should seriously look for solutions to deal with outstanding issues.

Since the enforcement of the Intellectual Property Basic Act in 2002, Japanese authorities have shown a significant interest in intellectual property rights protection, notably formalised through new laws and revisions of existing laws. In particular, the 2003 reform of the Customs Tariff Law has improved cooperation between the customs services and companies holding infringed intellectual property rights. In 2005, the Unfair Competition Prevention Act extended the import prohibition to goods that are similar to famous brands. In 2006, reform of the Trademark Law increased the fine applicable to importers of counterfeit goods for commercial purposes. In 2007, the Unfair Competition Prevention Act banned the export of such look-alike products. The same year, custom offices permitted right-holders to request a photo transfer from custom services by email in order to submit a written argument.

Reform of the rules for applying the Act on Specified Commercial Transactions also resulted in significant improvements. This measure strengthens checks on 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) can request the banning of the vendors from access to the auction website.

Major auction websites such as Yahoo! Japan, Rakuten and DeNa play an important role through their management in the fight against counterfeits. Yahoo! Japan has, for example, built a system involving more than 200 people to monitor its own auction website and to exchange information on counterfeit goods and counterfeiters with famous brand companies through the right-holders' associations. Rakuten and DeNa are also making great efforts to meet such standards. On the issue of removing counterfeit goods from the Internet, Japan has implemented measures that are as advanced as those set up by the USA and European countries. Despite significant improvements, however, crucial issues remain unresolved, as the Japanese regulations remain ineffective in the prevention of trademark violations. This is demonstrated by the fact that the import of counterfeits for "personal use" is permitted and parallel imports are persistently accepted, 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 is currently a prerequisite for taking action. This difficulty in proving awareness allows some importers to continue importing counterfeits unpunished.

The EBC hopes that any future negotiations on an EU-Japan Economic Integration Agreement (EIA) will include discussions on IPR to further improve the situation and to establish common rules and principles.

Key Issues and Recommendations

■ Fake goods on the Internet

Yearly status report: some progress. The Internet remains the principal instrument for purchasing fake goods in Japan. Auction site operators have taken action to counter this new type of sale by strengthening measures against repeat counterfeiters, such as improving surveillance and removing fake items by exchanging information with the right-holders. 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:

- The Act on Specified Commercial Transactions should be more systematically enforced and the corporate guidance and coordination system between auction websites should be strengthened.
- The Japanese Government is encouraged to seek closer cooperation with overseas authorities for the closure of websites offering counterfeit goods aimed at the Japanese market.

■ Border control

Yearly status report: some progress. The Customs Act has been revised and the notification procedure used by the customs authorities improved. Where the importer does not object to the qualification procedures, there is no longer a need for the right-holder to submit comments before the import can be suspended. Moreover, in 2007 it became possible for right-holders to receive an image of a suspended product by e-mail rather than having to check the item physically at the custom offices as was previously the rule. However, the rule applies only up to a maximum number of ten suspended products.

Recommendations:

- The maximum limit of ten products for sending information by e-mail is not realistic and should be extended without limitation or on a case-by-case basis. In many cases, there are 10,000 pieces of the same product and yet, in reality, a single picture would suffice.
- 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. At least 90% of recipients receiving such a letter used to abandon the counterfeit goods they had ordered. However, the effectiveness of the system is gradually being eroded as people become increasingly aware that the letters are not binding and import is possible under the guise of the products being “for personal use”.

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 the protection of intellectual property rights in respect of designs remain too complex and expensive, effectively denying foreign companies the benefit of the 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 the Japanese courts when interpreting design similarity.

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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 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 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 a marked expansion of foreign retail activity in the speciality 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 of 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 with an area of over 10,000 m², has discouraged foreign retailers further by making the costs of entering and establishing 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 of the City Planning Law were passed in the Diet in early 2006. However, arguably even more troublesome 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.

Procedures for 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. This comprises several areas as described in the recommendations. 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, and vice-versa. As standards for most retail products are similar, the EBC's Retail and Wholesale Committee believes that the EU and Japan should swiftly move to establish, through an Economic Integration Agreement (EIA), mutual acceptance of standards and certification, which will benefit companies in both markets.

Key Issues and Recommendations

■ Large-scale retailing

Yearly status report: limited progress. While many of the provisions in the Large-scale Retail Location Law have been clarified, a lack of transparency and uneven regional implementation limit the entry of foreign retailers into the market. In 2007, the City Planning Law, Large-scale Retail Location Law, and the City Centre Revitalisation Act were revised with a view to improving control over large-scale retailing expansion. Construction of new large-scale stores (larger than 10,000m²) was banned except for cases in pre-zoned areas, but all attractive retailing sites in these zones had already been taken. Although the rules were amended, in principle, to allow for more flexibility in re-zoning land, the revised rules have been ineffective as only local governments and not private enterprises are eligible to apply.

Recommendation:

- The Large-scale Retail Location Law should be revised to facilitate much needed investments in the retail sector. This could be done by exempting areas around larger cities.

■ Prohibitive import, certification and labelling rules

Yearly status report: no progress. Reluctance to accept EN (European standards) and ISO standards or CE (conformité européenne) 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. Furthermore the EBC, while understanding the need for ensuring the safety of the consumer, requests the Government to revise the legislation applying to products with food contact and the related import system to facilitate smoother trade.

Recommendations:

- 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.
- Internationally harmonised and compatible food manufacturing hygiene standards should be established and enforced in Japan.

■ 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.

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. This is of increasing concern especially as regards the right to sell *nihon-shu* and *shochu*.

Recommendation:

- Wholesale liquor licensing should be deregulated.

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LEGAL SERVICES

Introduction

The reader of successive White Papers over the years may be forgiven for thinking that not much has changed during that time. On the big structural issues that is correct. However, in the last year there have been welcome efforts by the Ministry of Justice (MoJ) to attempt to streamline the application process for admitting foreign lawyers (*gaiben*), including the introduction of a new application form. We will need to wait and see if this results in a faster application time in practice. In addition, in its final report at the end of 2009, the committee on the legal system reporting on the ability of foreign lawyers to establish *bengoshi hojin* (corporations) recommended the more liberal of the two regimes that had previously been under discussion. We understand that related legislation is under preparation within the MoJ, which will lead to a change in the law in 2011 or 2012. While this point has been on our list for a number of years as involving clearly discriminatory treatment for foreign lawyers, it is not among the main issues that trouble foreign lawyers, which continue to be the time required for registration and the 3-year experience rule.

When attempting to review the regime involving foreign lawyers in Japan from a broader perspective, the EBC notes that the legislation and system were introduced in the 1980s, at a time of much greater international trade tension and when legal services were still primarily domestic. The EBC believes that, almost 25 years since the inception of the *gaiben* law, it is time for a major overhaul of the legislation, to make it fit the types of law firms that are establishing themselves in Japan and to take account of the way the *gaiben* registration system has developed to date. This would resolve most of the issues on which it seems that otherwise no progress will be made in the short term.

At present, lawyers in Japan have no possibility of operating through an entity that can provide them with limited liability. With the involvement of lawyers in increasingly larger transactions in the financial markets, and the accompanying potentially enormous financial liabilities, it seems discriminatory to exclude lawyers from the benefits of limited liability structures, while it is possible for professionals in so many other fields to operate through them. The EBC believes that it would be beneficial to the whole legal services sector if Japan modernised its legal system to take into account the expansion of the “non-court” legal services sector in Japan.

In this context, mutual acceptance of legal qualifications, acceptance of vehicles through which lawyers can operate, and acceptance of engagement in a wider scope of activities as permitted by home jurisdiction rules could usefully be included in an EU-Japan Economic Integration Agreement (EIA), which would also address a number of the concerns set out on the following page.

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 in Japan, three years of professional experience in the foreign lawyer's home law 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 the lawyers are already acknowledged by their jurisdiction of qualification. If there should be such a rule, what is important is the experience in their home jurisdiction law, and not where it is practised.

The procedure for admitting foreign lawyers as *gaiben* also still imposes undue costs on foreign firms and individuals. In July 2010, a revised and shortened application form was introduced by the MoJ, which on the face of it, seemed to reduce the information required.

Recommendations:

- The rule requiring a specific number of post-qualification years of experience should be abolished. At least, experience in home jurisdiction law should be recognised regardless of where it has been practised.
- Continuing focus needs to be put on accelerating the application procedure for *gaiben* registration to the greatest extent possible.
- An overhaul of the existing system should be undertaken. This would enable changes such as the registration of firms rather than individuals, which would do much to eliminate frustrations with the existing system.

■ Branches

Yearly status report: significant 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. Such a possibility is open to *bengoshi*, who may do so through a *bengoshi* corporation or *hojin*. Currently such a structure is not available to *gaiben*. However the Foreign Lawyers System Study Group has recommended that *gaiben* should be able to establish corporations with other *gaiben*, and also with *bengoshi*, and work within the MoJ is currently being done to introduce legislation to implement the recommendations of the report.

Recommendation:

- The proposed legislation enacting the recommendations of the reporting committee is welcome and should be enacted as soon as possible. However, the EBC wonders whether, in practice, the *hojin* form will be widely used by major international firms. A better and simpler solution would simply be to abolish the restriction on branching, which is archaic and does not suit the needs of either domestic or international law firms.

■ Limited liability

Yearly status report: no progress. Under current rules, limited liability status is not available to lawyers in Japan. This is consistent with the traditional position of lawyers in Japan as court lawyers, rather than as handlers of complicated international commercial transactions and conductors of due diligence activities involving very significant potential liabilities. In many fields, professionals in Europe and other countries (including Japan) have been able to operate under a regime of limited liability, subject to financial disclosure, particularly 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 participating in the use of such structures. However in Japan, law 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.

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. This could be achieved by an overhaul of the existing *gaiben* system to permit foreign lawyers to operate in Japan through branches of their home entity.

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SUSTAINABLE DEVELOPMENT

Introduction

Sustainable development is arguably the defining issue of our time; it refers to development that "meets the needs of the present without compromising the ability of future generations to meet their own needs" (*The Brundtland Report, 1987*). Unless we find the means to achieve this within the necessary time frame, not only the environment and society, but also business, trade and investment, will suffer serious consequences.

The EBC Sustainable Development Committee aims to ensure that all European companies supporting sustainable development have ready access to the Japanese market, and are not hindered by trade or investment barriers of any kind. Although both the EU and Japan place great emphasis on sustainable development and have similar goals, fundamental differences remain in philosophy, approach, and policies. Consequently, progress remains far short of what is required.

While Japan has tended to focus on environmental technology and innovation, business practices and consumer behaviour have not followed with the same sense of urgency. The continued use of excessive packaging, which in the rest of the world is proactively discouraged, is perhaps the most visible example. As far as construction is concerned, it seems that Japan's environmental requirements are far less demanding than those of the EU or US, resulting in disappointing progress in reducing energy consumption in buildings. In Japan as in other advanced countries, buildings are the foremost producers of greenhouse gases. Studies have shown that up to 40% of greenhouse-gas emissions come from buildings, a much higher proportion than from the transport and industrial sectors. In light of this statistic, improving building performance will play a crucial role in creating a sustainable future and government legislation will be vital to ensuring that the necessary energy-saving technology and materials are adopted.

Japan is lagging in this respect. For example, single glazing is still a common feature in Japanese buildings, whereas Europe moved to triple glazing long ago. In Japan, to date, the focus has been on "appliances". For example, Japanese manufacturers are leaders in producing low energy consuming air-conditioning equipment. What is missing is the focus on the actual building. Buildings should be constructed in such a way that they do not require the addition of elaborate energy-consuming equipment in the first place. In terms of energy use, the exterior envelope is the most important system. It should be well-insulated and use components that transfer as little thermal energy as possible - heat from outside to inside in summer, and from inside to outside in winter. European manufacturers have some of the solutions on the market already, and increased efforts should be made to reduce any regulatory hurdles to their adoption and to promote their acceptance by the Japanese construction industry.

The EBC encourages the Government of Japan to take a much stronger stand on, and implement measures to improve, sustainable development in all key areas, including infrastructure, business, and consumer behaviour. The EU strategy, for example, has the following targets: put an end to the destructive link between economic growth and damage to the environment; encourage businesses and the general public to use objects that have been produced responsibly; aim to have public authorities across Europe buying products and services that do not damage the environment; increase the market in technologies and innovations that are environmentally-friendly; and improve the welfare of animals both within the EU and beyond.

The EBC Sustainable Development Committee believes that a dramatic acceleration of progress in all the areas indicated above is required and that an EU-Japan Economic Integration Agreement (EIA) would be a key vehicle for further cooperation and coordination in the area of sustainable development.

Key Issues and Recommendations

■ Improved sustainable development awareness & behaviour

Yearly status report: new issue. Japan, while at the forefront of environmental technology, is lagging when it comes to behaviour. There are very few incentives to encourage consumers to change their behaviour. The Government should implement measures that better guide behaviour towards sustainability.

Recommendations:

- The Government should raise awareness regarding sustainable development. The EBC believes that this will also help Japan reach its environmental targets.
- Better collaboration between Japan and the EU in setting environmental targets and agreeing on the actions required to achieve these, should be a key part of an EU-Japan EIA.

■ Organic food

Yearly status report: no progress. Organic food represents only about 0.2% of all food sold in Japan. This is about 10 times lower than in Europe and possibly the lowest level amongst developed countries. Japanese agriculture still relies heavily on chemical inputs in the form of pesticides, fertilisers and hormones. Japan should take the necessary measures to rapidly increase the growth of the organic food sector, including the development of local organic and sustainable agriculture.

Presently, food which is certified as organic in Europe and meets organic Japanese Agricultural Standards (Organic-JAS) regulations and which is labelled in Japan, must obtain a supplementary organic certificate from the Embassy of the country from which it is being imported every time it is imported. This is a meaningless process that adds unnecessary cost and complexity.

Recommendations:

- The Government of Japan should abolish the need for the issuing of supplementary organic certificates as part of an EIA between the EU and Japan. It should be sufficient that the producer be EU-organic-certified and that the importer be Organic-JAS-certified.
- The Government of Japan should abolish tariffs on organic food as part of a future EIA (since organic food already carries a price premium, tariffs only serve to make such food exorbitantly expensive).
- The Government of Japan should encourage more sustainable farming through the use of fewer pesticides and antibiotics.

■ Framework for sustainable construction

Yearly status report: new issue. Buildings, in Japan as in other advanced countries, are the foremost producers of greenhouse gases. Studies have shown that up to 40% of greenhouse-gas emissions come from buildings, a much higher proportion than from the transport and industrial sectors. The average lifespan of a building in Japan is 30 years, suggesting a lower level of building sustainability in Japan compared to the United Kingdom, where it is 90 years. Moreover, insufficient insulation, which is common in Japan, leads to a large transfer of thermal energy. To catch up, Japan needs to implement technology from abroad and provide an incentive to use foreign materials.

Recommendations:

- The EBC recommends that Japan introduces a system to make sustainable and green buildings more attractive.
- The Government of Japan should take advantage of European technology in the construction sector to reach its goals for greenhouse gas emissions.

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TAX

Introduction

The EBC welcomes the discussion by the Japanese Government on stimulating the Japanese economy by bringing corporate tax rates closer to international levels, to improve the competitiveness of Japan for the benefit of both Japanese and foreign companies. Encouraging domestic demand is imperative in the light of the recent appreciation of the Japanese yen and will help Japan decrease its dependency on exports. The magnitude of the challenges ahead for the Government, however, cannot be exaggerated. 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 lack of confidence of the Japanese people in the social welfare system, is suppressing consumption below already low levels.

Aware of the severe fiscal constraints the 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 the consequences are 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 pleased to see that some progress has been made regarding secret comparables in transfer pricing, but disappointed to note that confidential taxpayer information is still leaked to the press. The second recommendation points out that addressing 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 Government should review recent changes in the way in which the relationship between taxpayer and tax inspector in European jurisdictions like The Netherlands and the UK is organised and how these changes have improved transparency, reliability and predictability for the taxpayer and the tax administration alike. The third EBC 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. Swiftly implementing these three measures alone would contribute to the sustainable growth of businesses and the overall economy and, therefore, also prove instrumental in combating the most serious threat to tax revenues, the 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 Government of Japan to take on the tax policy challenges upfront and address the issues detailed on the following pages as a matter of priority.

The EU and Japan should, within an Economic Integration Agreement (EIA), strive to mutually eliminate double taxation, and withholding tax on dividends, royalties and interest, as provided for in the treaties concluded between Japan and the UK, France, The Netherlands, Switzerland and the US. An EU-Japan EIA should, furthermore, enable employers' and employees' contributions to social security systems within the EU and Japan to be tax deductible on a mutual basis. The EIA should provide for a mandatory arbitration clause to ensure that double taxation will effectively be solved between Japan and the other treaty partner if the tax treaty text itself does not avoid double taxation in effect.

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. 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.

An open relationship based on mutual trust providing for transparency and certainty is vital for investors to be willing to invest and for the Government to collect the applicable revenues and maintain the tax base in the most efficient way possible. The Dutch and British governments have recently introduced systems in their tax collection process called Horizontal Monitoring, Risk Rating and Senior Accounting Officers, which in essence shift the tax compliance and monitoring burden from the tax authorities to the taxpayer. This provides certainty to the taxpayer while maintaining the same amount of tax revenue for the government. In return, the tax authorities provide timely advice and clearance regarding their position on such disclosures, as well as responding faster to any other questions, and taking clear positions. Tax audits take place on a less frequent basis and are less detailed. Horizontal Monitoring, Risk Rating, and Senior Accounting Officers constitute a way of working together between the taxpayer and tax authorities. They do not impact the amount of tax payable collected, but they do make the work of the tax authorities more efficient.

Recommendations:

- The tax authorities should be obliged to accept and process applications for tax rulings, and tax law should provide for the right to request and obtain tax rulings.
- The Government should stop intentional leakage of confidential data to the press and the tax administration should be held accountable for secrecy duty violations.
- The Government should study the system of Horizontal Monitoring, Risk Rating, and Senior Accounting Officers.

■ **Transfer pricing**

Yearly status report: limited progress. The Japanese tax authorities have clarified some of the requirements of transfer pricing documentation and the consequences for failure to comply with these requirements. As a result, it appears that the right to base a transfer pricing assessment on secret comparables has in theory been somewhat restricted. However, at the same time there has been an alarming increase in the use of domestic corporate tax rules relating to donations to make assessments in relation to transfer pricing. This has been done ostensibly to avoid the mutual agreement procedures arising under Japan's tax treaty network. In addition, there continues to be inconsistency between the basis for assessment of transfer pricing during an audit and the basis for assessment under the APA (Advanced Pricing Agreement) system.

Recommendations:

- The EBC recommends that all cross border transactions should be dealt with under transfer pricing legislation and not under domestic corporate tax rules relating to donations.
- There should be consistency between the transfer pricing methodology for audit assessments and that used for APAs.

■ Introduction of an unlimited period to carry forward tax losses

Yearly status report: no progress. The current tax loss carry forward period in Japan is seven years, whereas in the UK, France, Belgium 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.

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 is, 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.

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.
- 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.

■ Tax treaties

Yearly status report: progress. Japan concluded new tax treaties earlier this year with Switzerland and The Netherlands and is currently re-negotiating its tax treaty with Germany. The EBC welcomes treaties that include the exemption of withholding tax on royalties and qualified dividends and interest.

The treaty between Japan and The Netherlands contains a mandatory arbitration clause to ensure that double taxation will effectively be solved between Japan and the other treaty partner if the treaty text itself does not avoid double taxation in effect. In practice this is an important improvement and the EBC would welcome its inclusion in all future treaties.

Recommendations:

- The EBC encourages the Government of Japan to review current tax treaties with EU Member States.
- The EBC requests that any new or revised treaty addresses the problems with withholding tax on royalties and qualified dividends and interest.

Financial Services

**Asset management
Banking
Insurance**

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ASSET MANAGEMENT

Introduction

Professional investment management in Japan continues to increase as the burden on social security and pension systems swells due to the ageing of the population and stubbornly low birth rates. Both public and private investment pools seek higher returns but with effective risk controls, which fuels demand for increasingly sophisticated investment expertise. Moreover, the prolonged period of low interest rates has resulted in certain pooled funds seeking to diversify even their conservative portfolios. To meet the critical needs of the users of investment management services, it is imperative that the Government of Japan continues with reform measures designed to provide the investing public with appropriate products, whether new or innovative, in a flexible, user-friendly investment management framework that promotes growth and does not hamper expansion by rigid and inflexible regulation.

Nevertheless, regulation in Japan imposes unnecessary burdens, both in terms of the basic cost of compliance and in the additional cost arising from “regulation disparity”, where regulation and enforcement practice 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.

The EBC believes that continued development of a free and fair regulatory framework aligned to global norms is the only way forward for Japan to become an international financial centre. Moreover, recent developments in other areas are seen as a step backward. Examples include: (1) transfer pricing policy, which is less defined than in other jurisdictions, leading to a lack of consistency and transparency in the interpretation of existing rules; (2) the tax rate for gains on listed equity securities, which was temporarily lowered by law and may be increased again in 2012; and (3) the recently proposed creation of yet another industry association, this one for companies licensed as Tier 2 entities under the Financial Instruments and Exchange Law (FIEL) - this proposal flies in the face of demands to merge the Investment Trust Association, Japan (JITA) and the Japan Securities Investment Advisers Association (JSIAA), a merger that was thwarted at a late stage by the industry associations themselves.

Currently, financial service companies cannot provide clients with the same trust management and investment advisory services in Japan as they do in Europe due to firewall and licence restrictions. The result of such regulatory barriers is inefficiencies in resource allocation within the economy as a whole and less than optimal return on capital. Without a joint framework extending to all financial services, European and Japanese financial services companies cannot fully integrate their respective operations and will continuously be restrained from providing the same products on both markets. The EU and Japan should therefore include these issues in an Economic Integration Agreement (EIA).

Key Issues and Recommendations

■ Standardisation of performance reporting for investment trusts

Yearly status report: new issue. An important reform priority in recent years has focused on converting individuals from savers to investors. This effort has been effective, as evidenced by the expansion of investment trusts. However, despite the ever-growing number of investment products, a standard for performance reporting by product providers has not developed. Similar funds report performance in different ways, making even simple comparisons difficult. To ensure that individual investors can make intelligent investment decisions based on reliable information, the EBC recommends the development of investment reporting guidelines, standards and/or best practices that will assist the consumer of investment management services in comparing multiple products. Such development should be done by market participants in association with distributors and relevant industry associations and does not require new regulation. Government support will ensure that such measures are formulated and introduced in a timely manner. They need not be onerous but should comply with acknowledged performance reporting standards used for similar products in other recognised international financial centres.

Recommendation:

- The Government should encourage the development of investment reporting guidelines, standards and/or best practices by market participants, together with distributors and relevant industry associations, complying with acknowledged performance reporting standards used in other recognised international financial centres.

■ 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, as is normally the case with asset management companies. If a 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.

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.

■ Promotion of Japan as an international financial centre

Yearly status report: progress. The EBC applauds steps already taken by Japan to reach its stated goal of securing its place as an international financial centre, including measures to accommodate transferees to Japan from foreign countries, to reconcile certain differences in taxation schemes applicable to investment products, and to unify financial services regulation through introduction of the FIEL. However, many impediments remain, and the pace of change has been too slow to attract positive attention from the international community. The Financial Services Agency's effort to push reform measures within its control is highly commendable, but without a holistic approach encompassing all key functions, including tax and industry associations, continuing to push forward on certain fronts while retreating on others will fail to garner the respect and trust of the international community.

Recommendations:

- To further promote Japan as an international financial centre, the Government should develop a more holistic plan for reform, encompassing all relevant and key functions, including tax and industry associations, in order to strengthen the competitiveness of the local financial sector and earn the respect and trust of the international community. This should include reform of transfer pricing, stabilising of tax rates on listed equity securities and merging of industry associations.

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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 23rd in 2009 (International Monetary Fund). 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.

While remaining concerned about the issue of firewalls, the EBC would like to take this opportunity to commend the Japanese Government for introducing amendments that make life easier for financial conglomerates. The EBC welcomed the revision of the Financial Instruments and Exchange Law (FIEL) 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, guidelines issued by the Financial Services Agency (FSA) after the FIEL revision continue to contain stringent restrictions on the sharing of on-public customer information and double-hatting, which along with an impractical 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 applications are made 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 under the auspices of an Economic Integration Agreement (EIA) 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 where a bank is based in one territory with a single branch in the other territory, that branch can be granted licences covering Banking, Securities, Trust Banking, Asset Management, and Insurance, without having to establish separate structures.

EBC Banking Committee Member Companies

Barclays Bank	FXOnline Japan
BNP Paribas	ING Bank
BNP Paribas Securities	Intesa Sanpaolo
Commerzbank	Rabobank Nederland
Credit Agricole Corporate & Investment Bank	RBS
Deutsche Securities	Societe Generale Securities (North Pacific)
Ernst & Young ShinNihon	Standard Chartered Bank
Fortis Bank	

Key Issues and Recommendations

■ Integrated financial services market

Yearly status report: some progress. The EBC welcomes changes that have, in principle, enabled foreign financial groups in Japan to be represented by a single country manager and to exchange a larger amount of client information between group entities than previously possible. This has reduced the previous “double-hatting” problem. However, guidelines for the implementation of this reform have made it difficult in practice to take advantage of the 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. Changing this would be one step towards making Japan more attractive as a financial centre.

Recommendation:

- The Government of Japan should amend Article 33 of the FIEL, which prohibits financial firms from operating banking and securities concurrently. At the very least, the FSA should alter its guidelines to allow the same level of information sharing as in Europe and a simplified opt-out system.

■ Transparency and regulatory efficiency

Yearly status report: progress. Duplicated inspections by the FSA, Securities Exchange and Surveillance Commission (SESC), Tokyo Stock Exchange (TSE), Japan Securities Dealers Association (JSDA), Ministry of Finance (MOF), and 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. The FSA should in particular be complimented on improved communication, which has created a more stable environment. Despite these improvements, 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.

■ Banking agency system

Yearly status report: new issue. The banking agency system introduced in 2009 requires Japanese branches of European banks to apply for a special business licence each time they plan to introduce to their Japanese customers any new banking services provided by other banking entities, even if these are branches of the same financial group located outside Japan. This noticeably impacts cross-border services in which the Japanese arm of a global financial group supports its Japanese private or corporate clients in opening accounts abroad and introduces its Japanese clients to global cash management services or other services provided out of non-Japanese branches. While the EBC supports the Japanese authorities’ effort to provide an appropriate regulatory framework for cross-border transactions, the current system must be improved in order to clarify the criteria for applying for new banking agency licences and speed up the review and approval process at the administrative level.

Recommendation:

- The FSA should further clarify and streamline the application process for banking agency licences.

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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 reserving and solvency regulations that are inconsistent with European solvency requirements, and the lengthy product approval process. Future market growth in Japan will come from the ageing of the population driving a need for products dealing with extended retirement, changes to the family structure and rising demand for medical products. With a principles-based regulatory regime, where the regulator strikes a careful balance between innovation and regulation focusing on risk management, and allows innovation and flexibility, 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.

In December 2009, the new ruling coalition stopped the postal privatisation process. Subsequently, the Government of Japan unveiled a draft bill proposing realignment of the Japan Post group into three companies. On 31 May 2010, the bill cleared the House of Representatives amid protests from both foreign and domestic financial service companies. Due to the closing of the regular parliament session, the bill was not submitted to the House of Counsellors, but resubmission is expected during the autumn parliament session. The bill would give Japan Post Insurance (JPI) the right to introduce new products onto the market without any need to ensure equal competitive conditions between the Japan Post Group and private-sector companies. JPI will be exempted from a wide range of provisions under the Insurance Business Law and Banking Law, including licensing and inspection requirements, and will be given special tax treatment. Caps on insurance policies will be raised from 13 million yen to 25 million yen, bringing JPI into more direct competition with European and other foreign competitors. Moreover, JPI will be given near-exclusive access to most Japanese consumers through the post office network. As the EBC has consistently stated, we do not have an opinion on whether or not Japan Post should be privatised, but we do request that the Japanese Government facilitates a level playing field consistent with its obligations under the WTO General Agreement on Trade in Services (GATS), where all players on the market are given equal treatment. So long as JPI benefits from certain preferences, and a level playing field does not exist, it should also be subject to limitations to counterbalance its advantageous position.

Japanese regulations should converge with global methodologies in terms of market-based solvency (Solvency II) and International Financial Reporting Standards (IFRS) to improve risk management and understanding among insurers, provide confidence to the market, and reduce the costs of operating across different territories. Convergence would have a direct positive impact on the ability of European companies to do business in Japan, and the EBC hopes that the FSA will continue to move towards harmonisation as it develops its new solvency regulations. A permanent and post-funded scheme should be established for the Policyholder Protection Corporation (PPC). Enhancing the regulatory environment for the insurance industry is critical to future development, particularly in ensuring a level playing field for all sellers of insurance. Appropriate handling of issues such as the way Japan Post is privatised, bringing mutual aid cooperatives (*Kyosai*) into the insurance framework, streamlining the product approval process, and clear and consistent application of rules and regulations will contribute to Japan's recovery from the financial crisis. It will also prove beneficial to the domestic financial services industry, Japanese consumers and Japan's ability to retain foreign investment.

The FSA product approval process is overly lengthy and FSA availability is limited. This results in product development delays and makes effective planning difficult. Approvals, when granted, are not flexible enough for the development of new products and features that are sensitive to volatile capital markets, particularly in response to the financial crisis. An EU-Japan Economic Integration Agreement (EIA) should eliminate all of these problems and 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

■ Japan Post reform

Yearly status report: new issue. With the introduction of the bill on postal reform, JPI will be given preferential treatment that is not extended to other market players. The EBC regrets this situation as it leads not only to distorted competition but also to a further expansion of what already is the world's largest financial institution. Once the current bill comes into force, not only will foreign insurance companies be affected, but also domestic insurance companies. The EBC would like to remind the Government of Japan about its obligations under the WTO General Agreement on Trade in Services (GATS).

Recommendations:

- The Government of Japan should put in place a level playing field before JPI can be allowed to introduce new products.
- The Government of Japan should ensure that JPI is not given preferential treatment if it is allowed to expand its current operations in any way.

■ Kyosai

Yearly status report: new issue. *Kyosai* are mutual aid cooperatives and they provide insurance products. Under commitments made by Japanese Government, they should be governed by the same rules and regulations as foreign insurance companies, which currently is not the case, as *kyosai* are not established under the Insurance Business Law. Instead different ministries regulate the various *kyosai* depending upon the sector in which the *kyosai* is active. For example, the Ministry of Agriculture, Forestry and Fisheries regulates the agricultural *kyosai*.

Recommendation:

- *Kyosai* should be brought under FSA supervision as well as being covered by the Insurance Business Law and should not be allowed to expand their business until such provisions are in place.

■ 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 by 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 reassurance 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. A pre-existing PPC fund is a potential moral hazard as it reduces the onus to find a market-based solution, and raises costs for well-managed 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.

Transportation & Communications

**Airlines
Business aviation
Logistics & freight
Railways
Telecommunications
Telecommunications equipment**

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AIRLINES

Introduction

In recent years, the global financial crisis and the outbreak of H1N1 flu both led to a severe drop in business and leisure travel in and out of Japan. In combination with high airport costs, this had a substantial negative impact on the financial results of airlines operating to and from Japan. Even now, in 2010, the numbers of incoming passengers and travellers departing from Japan for international destinations are still not back to their former levels.

The EBC urges the Government of Japan to continually work towards reducing charges at all Japanese airports, especially those that are supposed to offer vital links to and from international markets. To date, the scope and pace of change have been disappointing. Airlines have long been required to pay prohibitively high 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 must be covered by funds in this account - funds that are raised from the user fees collected at all airports. It is the existence of this account, and the normally high interest on any public loan provided, that serve to drive up fixed costs and explain why Japanese airports are so uncompetitive. The EBC is encouraged by comments from the Minister for Land, Infrastructure, Transport and Tourism (MLIT), suggesting that the Government is considering establishing a fundamentally different system in which all airports will compete on the basis of cost and be relieved of the burden of financing new airports. However, so far, the EBC has seen little in terms of actual implementation.

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 international flights when the new runway is completed next year, the EBC urges the Government to ensure that this is done on equal terms for all carriers. The former cabinet suggested a time window for operations of 22.00 - 07.00 for intercontinental traffic to and from Haneda. If landing is not possible before 22.00, European carriers will be denied the possibility of connecting with the domestic network of their Japanese and Asian competitors. Yet while European carriers would be limited to serving the Tokyo metropolitan area at very inconvenient times, Japanese and Asian carriers would be able to leave Japan around midnight and return early morning, feeding to and from connections to practically every Japanese domestic airport. Until a level playing field is established, Haneda will not serve as the hub envisaged by the Government and local cities will not benefit from the additional potential that a fully-fledged hub airport could provide.

In January 2010, Japan Airline (JAL) Corp. and its two major units filed for bankruptcy protection and applied for assistance from the government-backed Enterprise Turnaround Initiative Corporation (ETIC). ETIC has guaranteed various commercial transfers so that JAL can survive and be restructured in a controlled fashion. It is vital that the protection umbrella organised by ETIC and the use of tax-payers' money entail transparent processes with no distortion of competition. Focus should be placed on streamlining JAL's operations and cutting costs, and JAL should not be allowed to expand its operations or engage in price dumping while under rehabilitation. The EBC, therefore, welcomed the letter sent in February 2010 by MLIT to Mr Nakamura, Executive Director of ETIC, stating that JAL is not allowed to "...vainly lower fares..." (sic), while receiving public funds. The restructuring process must be carefully implemented and monitored in order to avoid market distortion by price dumping.

Key Issues and Recommendations

■ High costs

Yearly status report: no progress. A new round of negotiations is underway this year to determine user charges at Narita Airport. The small decrease in these charges seen in 2009 was only made possible by introducing a “passenger fee” equivalent to the same amount. The recent increase in the number of available slots should make further reductions possible, since the resulting lower airport unit cost should be reflected in lower charges for airlines. Moreover, inefficient processes should stop. If airports are not well used, they should be closed or consolidated, thereby contributing to resolving this issue. A new set-up aiming at reducing airport costs by as much as 50% is needed for Japan to remain competitive with other hubs in Asia. The plan to integrate Kansai International and Itami airports into one holding company is welcomed. However, a substantial reduction of fees at Kansai airport is still needed to stabilise the long-term presence of major airlines in this market.

Recommendation:

- The Airport Development Special Account should be abolished to pave the way for lowering the prohibitively high costs charged by airport authorities. The cost of security measures at airports should not be levied on airlines, but absorbed in the balance sheets of the respective airports. The availability of an increased number of slots at Tokyo airports should mean a reduction in costs for airlines, the main contributors to the Government’s growth strategy in the transportation sector.

■ Airport infrastructure

Yearly status report: limited progress. Japan lacks a coherent plan for optimal use of its existing airport infrastructure. A fourth runway at Haneda will be opened in October 2010. The MLIT has allocated some 60,000 new slots to international routes and will permit flights to and from non-Asian destinations during the night. However, these slots have not been evenly allocated and the Government should consider the implications for competition between local airports and between airlines. When Haneda opens up for intercontinental flights all airlines should have time slots allowing them to make practical use of the airport. Haneda airport cannot be regarded as a hub, if European airlines cannot use it to feed traffic into and from the domestic Japanese network.

Recommendation:

- Japan should establish a plan for the efficient use of all available airport infrastructure and open up Haneda Airport to all flights to and from Europe on a non-discriminatory basis. Time restrictions, if any, should be limited to take-off times (after 22.00) and not applied to landing times after 17:00. A reduction of night curfew hours at Narita Airport should be considered due to the much lower noise levels of modern airplanes.

■ Distribution sales

Yearly status report: progress. In September 2010, MLIT took steps to ease international air fare regulations. As a consequence, airlines should, in principle, be able to establish new tariffs or modify fare levels at any time in response to market demand fluctuations and to market net fares in all distribution channels.

Recommendations:

- The Government should implement the announced changes in a fast and efficient way.
- Japan should consider the possibility of having the final (total) consumer price, including taxes and fees, published in all distribution channels.

■ JAL restructuring

Yearly status report: new issue. Since January 2010, JAL has been under the protection of bankruptcy law. The Government should carefully consider the competition implications of any further re-capitalisation of JAL.

Recommendations:

- The Government should closely monitor the implementation of JAL’s rehabilitation plan and intervene if market distortion develops, especially in the fields of capacity and pricing.
- The Government should also reduce entrance barriers for European carriers to Haneda airport, especially in the light of JAL’s declaration that utilisation of new and convenient slots at Haneda will be a major factor in its envisaged turn-around.

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BUSINESS AVIATION

Introduction

The business aviation industry is experiencing a slowdown worldwide, though forecasts indicate that demand for business aircraft will increase over the next few years. With new airline safety and security requirements in place at all international airports, many business people and governments are chartering aircraft or considering buying or leasing a corporate jet to increase the efficiency of their respective operations. There are still relatively few business aircraft in Japan considering the country'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 a few flights were operated by Japan-registered aircraft. However, with the increase in slots at Haneda and Narita airports, business aviation now has the opportunity to grow.

A range of issues and factors accounts for the slow development of business aviation in Japan. It includes still the application of restrictive Extended-range Twin-engine Operational Performance Standards (ETOPS) requirements to diversion flight times, even though an increase from 60 to 180 minutes is envisioned. Added to this is a lack of suitable airports and infrastructure, difficulties in obtaining slots for landing at Haneda and Narita (the number is increasing, but is still too low), high landing fees and navigation costs, the lack of Fixed Base Operators (FBOs), and a lack of understanding within businesses and the government about the efficiency gains that can be achieved through private aviation. VIP clearances, that make it more efficient to get to the aircraft and through security and customs, need to be implemented at all suitable airports.

Despite these problems, 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 and Transportation (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 slow and in some cases the business environment is deteriorating. Business opportunities are being lost.

The lack of a prosperous business aviation industry puts Japan at a disadvantage relative 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: progress. Japan does not yet have an adequate regulatory framework specific to business aviation and on-demand charter flights. The policy of applying the same complicated and strict rules created for operations involving several hundred passengers to operations requiring high flexibility is excessive and effectively hinders the development of the business aviation sector 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 globally for chartered and private flights. The Japanese situation is unique in that ETOPS requirements are applied to privately owned jets even though, internationally, the limits have been increased yet proven to still guarantee safety. This results in Japan-registered airplanes having to make detours while others can fly more 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 Japan to establish a regulatory regime enabling greater use of business aviation and on-demand charter flights. A taskforce including international business aviation experts is highly recommended.

■ Infrastructure for business aviation

Yearly status report: some 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. Typically, the cost of such services, if kept within reasonable limits, could be borne by the business jet users and operators.

Recommendations:

- The Government of Japan should establish a taskforce, including international experts, 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. Foreign investments would benefit Japan.

■ Maintenance and airworthiness

Yearly status report: limited progress. Certificates of airworthiness need to be renewed annually 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 (on demand). Furthermore, Japanese maintenance requirements are out of line with international practice, exemplified in the type-certified mechanics system. Moreover, replacement parts have to be pre-certified making maintenance very slow, especially overseas, where Japanese certified parts are not accessible. Unnecessarily rigorous and Japan-specific regulations increase costs to such an extent that it makes little economic sense to own a business aircraft in Japan.

Recommendations:

- Regulations covering airworthiness and maintenance requirements should be brought in line with global best practice exemplified by the US Federal Aviation Administration (FAA) or the European Aviation Safety Agency (EASA).
- 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. European carriers and forwarding companies in Japan struggle with high costs, an inadequate infrastructure at international airports, and rigid custom clearance procedures. They also have to deal with outdated restrictions on foreign-owned companies engaging in domestic freight forwarding business in Japan, and distorted competition caused by differences in the rules and regulations applied to carriers providing the same services, thereby leading to inefficiencies and higher prices for users.

Japan Post, which is currently restructuring, 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. While the EBC recognises the need for a universal service obligation to meet certain socio-economic goals, Japan Post is competing with private-sector express carriers on an unlevel playing field through its Express Mail Service (EMS), a special value-added international express package that today accounts for around 20% of the outbound express market. A major issue of concern to the private sector is that EMS is not subject to the strict regulations applied to other express services (as detailed on the following page), hence the expansion threatens to distort competition and will negatively affect not only foreign private operators but also Japanese companies.

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, therefore, should be regulated like regular letter mail. However, this argument disregards the fact that with EMS, Japan Post is indeed directly competing with private-sector operators. Accordingly EMS should be removed from the universal postal service, just as Japan Post's domestic parcel service ("Yu-Pack") was removed in 2005. In addition, it was clearly acknowledged that EMS is in fact similar to private express delivery services in a press release of the Kahala Post Group, which is a collaborative international network of postal administrations accounting for almost half of the world's total EMS traffic, and which was chaired at the time by the CEO of Japan Post.

The EBC applauds the newly signed mutual recognition agreement on Authorised Economic Operators (AEO). As the freight and logistics sector is directly affected by various customs policies, the EBC is very much looking forward to the practical result of this agreement. Furthermore, the EBC believes that additional cooperation can be achieved under a future EU-Japan Economic Integration Agreement (EIA) that would cover additional customs areas. An EIA should also open up the sector further for the equal treatment of Japanese and European operators, particularly in eliminating the ban on foreign freight forwarders engaging directly in the domestic air freight forwarding business.

Key Issues and Recommendations

■ Customs clearance and declaration

Yearly status report: no progress. Currently the minimum threshold value for dutiable import shipments is 10,000 yen. Compared with other major developed countries, this value is somewhat low; in the EU, the minimum is 150 euro. By increasing the minimum value, the burden on customs offices and brokers would decrease and importers would benefit from reduced duty payments. Customs declaration procedures should also be improved. Currently, declarations are lodged at a customs clearance operation physically located within the territory of the responsible customs office. However, if submissions could be lodged at locations independent of the territory of the responsible customs office, flexibility would increase and capacity planning for operators would improve.

Recommendations:

- The Government of Japan should increase the minimum threshold value for dutiable import shipments to 20,000 yen.
- The Government of Japan should introduce freedom in terms of the customs declaration location, independent of the territory of the responsible customs office.
- The EBC requests greater flexibility in terms of where quarantine shipments can be checked. Checks carried out in special bonded warehouses should be facilitated.

■ 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 airports, in stark contrast to the thorough check of packages arriving with private operators.

Recommendations:

- The Government of Japan should ensure a level playing field by (1) applying the same threshold for customs declarations to both EMS and private express deliveries, (2) applying the Parking Law equally to all parties, and (3) implementing transparent accounting procedures for Japan Post.
- The Government of Japan should remedy the situation whereby EMS quarantine shipments can be moved outside international airport facilities, whereas those of private express delivery services cannot.

■ Establishment of reference group

Yearly status report: new issue. Since customs clearance is such a vital process for a company involved in international logistics, good and close relations with customs authorities as well as a clear understanding of new customs-related policies are crucial. Accordingly, the EBC believes that a reference group should be set up by the Ministry of Finance and Japan Customs together with foreign companies in order to foster a better understanding of each other's needs and wishes. The group could also be used by Japan Customs to present draft proposals as well as new ideas coming from within the customs authorities and for foreign companies to provide input to the Government. There are, indeed, examples within the EU where such reference groups have been very successful.

Recommendation:

- The Ministry of Finance should establish a reference group, including foreign companies, to foster a better environment for imports and exports.

■ Ban on foreign operations

Yearly status report: no progress. The Freight Forwarding Business Law defines “foreigners” and forbids them to engage directly in domestic air freight forwarding business. From July 2008, foreign freight forwarders have been allowed to contract air freight services through Japanese freight forwarders. Although a welcome step, the discriminatory legal proscription of foreign freight forwarders contracting air freight services directly still exists.

Recommendation:

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

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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 Japanese National Railways (JNR), which was privatised in 1987. All in all, there are approximately 68,000 cars running on the 32,000 kilometre-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. Although it is currently not growing like other markets in Asia, the Japanese market remains one of the biggest in the world with an estimated average value of 6 to 7 billion euro per year over the next 5 years, according to the latest data from UNIFE (European Rail Industry Association), yet foreign penetration is negligible.

Part of the reason is the strong position held by the operators, the JR companies in particular, which have traditionally only purchased products and solutions from manufacturers who develop them exclusively for Japanese buyers. This means that not only is it extremely difficult for foreign suppliers to break into the Japanese market but also products developed in Japan can only be exported as part 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 use of harmonised international standards. Japan-specific standards deny Japanese manufacturers interoperability and opportunities to export. These standards are often not made public, but are provided by the buyer. It is therefore imperative that the Government of Japan takes a stronger lead in implementing and encouraging the use of internationally acknowledged standards. The Government should also enforce already existing public guidelines equally for all players. This will not only increase competition, but also increase the use of new and improved technology leading to lower operational, maintenance and procurement costs in Japan. This will be beneficial for European companies in Japan, but will also enhance the capability of Japanese companies to access international markets. In short it will result in greater trade between Japan and the rest of the world in the rail transport sector.

Although the basic situation since the EBC Railways Committee was established remains unchanged, the EBC is pleased to have had the opportunity to engage in meaningful discussions and exchange with government officials, railway operators and industry. We are also encouraged to note that some market players have started to look abroad for advanced technology and partners in the EU fitting their requirements.

The global transport sector is a major producer of CO₂ emissions, already accounting for over one-fifth of CO₂ emissions worldwide. If policies remain unchanged, emissions are projected to double within just 40 years. By virtue of railways providing better energy efficiency in terms of consumption per passenger kilometre and having relatively low carbon emissions, they 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 the 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. Under an EU-Japan Economic Integration Agreement (EIA), Japan could work jointly with Europe through open integrated systems built on harmonised standards, and by willingly offering reciprocal market access to Europe, be able to benefit from the best technologies available in Europe, and export its own products to the rest of the world. Under an EIA, test data from internationally recognised organisations should be accepted without further delay and references from Europe should be fully recognised and accepted.

Key Issues and Recommendations

■ Introduction of open integrated railway systems

Yearly status report: limited progress. 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.

Recommendations:

- The Government of Japan should promote and encourage open-ended integrated railway systems, in which operators set only the performance criteria and manufacturers develop and provide the solutions, as a way to boost competition on the domestic market and boost export prospects for Japanese manufacturers.
- The EBC welcomes continued dialogue and exchange of opinions with government officials, research institutes, the railway operators and industry.

■ Harmonisation of standards and mutual recognition of certification and references

Yearly status report: limited progress. 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.

Recommendations:

- Test data from internationally recognised organisations should be accepted without further delay.
- References from Europe should be fully recognised and accepted.

■ GPA - definition of the operational safety clause and its scope

Yearly status report: no progress. Japan and the EU are both signatories of the WTO's Plurilateral Agreement on Government Procurement (GPA). The agreement stipulates which entities, including the JR companies, have to follow the agreed rules when procuring new equipment. In the framework of the agreement, Japan negotiated a specific clause applicable to rail (the operational safety clause), which stipulates that procurement related to the operational safety of transportation is excluded. In practice this means that the prescribed procedures are rarely, if ever, followed in the rail sector. The EBC regrets that this safety clause is used to hinder a proper tendering system where every supplier should be given the chance to offer its products irrespective of its country of origin.

Recommendations:

- The EBC requests a clear definition of the operational safety clause and its scope in order to enable all companies to meet or exceed the requirements.
- Performance criteria related to traffic density and earthquake resistance, which seem to be of concern to the operators, should be made publicly available.

■ Investment in railways, revitalisation of Japan and enforcement of environmental standards

Yearly status report: little progress. For environmental reasons, the increase in transport by train is widely welcomed. The Government of Japan must invest further in the railway system, especially for cargo, if it is to fulfil its ambitious CO₂ reduction target. 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. Plans to invest in tramway lines which could contribute dramatically to the local economy and the revitalisation of mid-size Japanese cities have been considered for years, but very little progress has been made.

Recommendations:

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

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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 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 of 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 – the “New Competition Promotion Program 2010”. The main objective of the programme 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 ten specific measures in the programme and plans to commence discussions on the restructuring of NTT in 2010 to enhance fair competition in the telecommunications industry in Japan.

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

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 the 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 regulatory authority. The EBC believes that the new committee should be truly independent and 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 Parliament, and not to the MIC.

■ NTT re-organisation

Yearly status report: no progress. In 2006, the Koizumi cabinet and then the Liberal Democratic Party 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 by 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 its competitors. 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 Government of Japan should engage in 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 108 billion euros. 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 further 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 MRA remains low and the SVC still applies only to wired telecommunications terminals, with limited application to wireless/radio equipment.

Currently, in the Japanese market, handsets are sold tied to a specific telecommunications service provider. This means that a customer cannot independently choose one handset and then a service provider or vice-versa. This is not the result of any guidelines or legislative framework, but rather the result of the business practice that has evolved in Japan. However, the result remains the same: a market without free competition since handset makers cannot directly provide consumers with their products, but are instead bound to the technology offered by each service provider. The EBC believes that it should be in the interest of the MIC to remedy this situation and offer Japanese consumers the very same choices and benefits that consumers have in Europe. At the same time, the EBC acknowledges the efforts of the MIC, especially in discussions related to potential changes leading to the un-locking of SIM-cards.

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 (EIA) 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, lead 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 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 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. This could be achieved through an EIA.
- 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 international standards should be accepted in Japan.

■ Harmonisation of spectrum for IMT (IMT-2000 and IMT-Advanced)

Yearly status report: some progress. The International Telecom Union identified spectrum for international mobile telecommunications (IMT-2000 and IMT-Advanced) according to Agenda Item 1.4 of the 2007 World Radio Communication Conference. The EBC acknowledges that the Government of Japan has been active in identifying 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. In addition, the EBC has observed that there is an opportunity to achieve harmonised spectrum allocation and arrangement for IMT systems at the band of 700 MHz/900 MHz in the recent consultation carried out by MIC.

Recommendations:

- The Government should work jointly with other governments to achieve a globally harmonised spectrum allocation for IMT systems in line with the findings of the 2007 World Radio Communication Conference.
- The Government should take all possible measures to achieve harmonised spectrum allocation and arrangement for IMT systems at the band of 700 MHz/900 MHz taking into account the results in the AWF (Asia Pacific Telecommunity Wireless Forum) for harmonised usage of the UHF digital dividend.

■ Improving market conditions

Yearly status report: new issue. Handsets in Japan are, as a rule, sold through a telecommunications service provider and the handset cannot access a different service provider without serious limitation of the service. This has long been the business practice in Japan and has unfortunately led to a market where service providers are all too dominant at the expense of handset manufacturers and also Japanese consumers. The EBC, therefore, requests the Government of Japan to establish guidelines to facilitate the selling of handsets to consumers without an obligatory tie-up with a particular service provider. This will foster better competition and will offer consumers the ability to choose the handset and service provider independently.

Recommendations:

- MIC should take further actions to facilitate an open market where consumers can choose both the handset and service provider independently, as the current improvements, while commendable, are not enough.
- MIC should also introduce guidelines to implement solutions to avoid the problems with platform incompatibility between different service providers.

Health Science

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

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ANIMAL HEALTH

Introduction

While Japan has in the past been an important market for animal health products for European companies, low growth rates and many years of deflationary tendencies for agricultural products are eating away at the attractiveness of this market. With the EU and the US each representing 30% of the global market, Japan at 3-4% is now of much less overall importance. This means that unique registration and production requirements for Japan are often second-line priorities that will be addressed only after the top priority needs are met. The resulting delayed access to new technologies is hurting the competitiveness of Japan's animal health market. Stringent requirements in respect of the safety, efficacy and quality of any new veterinary medicinal product make the cost of development and registration high. While these new veterinary medicinal products go through a rigorous review process in Europe and the US 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. Without prompt access to new vaccines and medicines the Japanese livestock market will not remain competitive, which might lead to calls for an increase in agricultural 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 without coordination; moreover, the review takes a very long time.

International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH), in which Japan, Europe and the US participate, has accelerated the harmonisation process by generating harmonised study guidelines to avoid the repetition of similar studies. However, the VICH guidelines are not always interpreted or implemented consistently in different countries. In its charter, VICH mandates that, once adopted, its guidelines replace corresponding regional requirements. While global companies normally comply with the VICH guidelines, MAFF continues to maintain obsolete local guidelines for the registration of domestic products, creating dual standards. 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, there are some cases where product specifications have to be rewritten 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 solely for the Japanese market.

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

MAFF has been very slow in implementing measures to improve the predictability, quality, and speed of the registration process. Consequently, there are delays in the review process for most product segments. An EU-Japan Economic Integration Agreement (EIA) should aim for mutual recognition of European and Japanese marketing authorisations for veterinary products, by starting off with mutual recognition of GMP certification for veterinary medicines. Harmonisation of regulations for 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: limited 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 an obvious scientific rationale create serious animal welfare concerns. While MAFF is implementing some reforms, including the acceptance of reports in English, the applicant is still required to answer questions of little relevance to the safety and efficacy of the product. It seems some application reviewers still lack a proper understanding of the VICH guidelines. Since three different regulatory authorities (MAFF, FSC and MHLW) are involved, the registration of products for food-producing animals can take an extremely long time, despite a standard administrative review process of 12 months having been set by MAFF. Although MAFF is positively considering reducing the requirement for the translation of English reports, concrete implementation remains uncertain.

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. The VICH guidelines should completely replace obsolete regional guidelines.
- In view of animal welfare concerns, requirements for additional animal studies should be minimised where similar studies are already available in other countries.
- Reviews of food animal products by MAFF, MHLW and FSC should be conducted in parallel to shorten the overall review period for veterinary medicinal products for food-producing animals.
- MAFF should accept technical reports written in English as soon as possible.

■ Seed-lot system and national assay of vaccines

Yearly status report: limited progress. The seed-lot system enables the production of vaccines using a working seed virus or bacteria derived from an established master seed virus or bacteria. Thanks to the MAFF initiative to introduce the seed-lot system, some animal vaccines no longer require a national assay for batch release. However, some European vaccines cannot enjoy this benefit due to additional unique testing requirements, such as in-process testing that does not exist in the internationally recognised seed-lot system. An inactivation test on the finished product is required only for imported inactivated vaccines and not for similar domestically produced inactivated vaccines, creating a discriminatory non-tariff barrier. 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 with 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.

■ Restriction on use of oil adjuvant vaccines requiring long withholding period

Yearly status report: no progress. MAFF approval of an oil adjuvant vaccine for food producing animals usually requires an extremely long withholding period compared with that of the US (usually 21 days) or the EU where there is usually no withholding period. Considering the fact that meat produced from animals treated with the same vaccine in the US or EU with a shorter withholding period is imported into Japan, such use restriction does not make sense and is unduly depriving Japanese producers of the opportunity to use innovative oil adjuvant vaccines.

Recommendation:

- Regulations concerning the withholding period should be aligned with international standards.

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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. They are essential in many clinical facilities, playing an important role in preventing sickness, detecting and diagnosing diseases, monitoring treatment, and ascertaining the side effects of drug therapy. Medical diagnostic reagents and equipment thus improve patient quality of life and reduce total healthcare costs. Repeated cuts to reimbursement prices have reduced the prices of medical diagnostic reagents and equipment in Japan below those of comparable overseas markets.

The EBC welcomes the national health insurance reviews in 2008 and 2010 through which the reimbursement price for in vitro diagnostics (IVD) was improved significantly, and encourages the Government of Japan to continue addressing structural issues. The current approach is one of revision and value judgment, where medical diagnostics are treated only as another expense and reimbursement prices are set without consideration of the added-value of the product and inspection. This 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 eventually, excessive healthcare costs. Structural reform is essential in this respect. The EBC is encouraged to see that the issue 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.

However, not all changes have been positive, as reimbursement prices have been cut by 50% on a cumulative basis since 1998. In addition, medical fee reimbursement cuts have led to continuous and significant 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. On the other hand, 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 (PAL) 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 risk classification methodologies and data storage requirements that are unique to Japan. Furthermore, European products are hampered by lengthy application periods due to the amount of re-testing and re-certification that are required.

The EBC can see no reason why products that have undergone thorough tests in Europe and are certified with CE (conformité européenne) marking for the European market must undergo additional tests for Japan. It is important and necessary to make available advanced medicines and products to clinical facilities and patients as soon as possible. Moreover, the use of advanced products will greatly reduce the total medical costs of the nation.

Mutual acceptance of standards and certification between the EU and Japan would not only bring a wider range of products more quickly to Japanese consumers, but also provide significant business opportunities 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 (EIA).

Key Issues and Recommendations

■ Product approval and smooth introduction

Yearly status report: no progress. The introduction of third-party certification and a self-certification system, as part of the revised PAL, are important steps in the right direction, but still fall 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. Substantial delays in approval procedures experienced in the past few years highlight the need to establish organisational countermeasures and plans for improvement in addition to improving system operation. Under the current circumstances, many producers are unable to initiate application procedures for their products, and approval of products is substantially delayed; this situation should be remedied immediately.

Recommendations:

- 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. In particular, application data requirements unique to Japan should be eliminated.

■ Reimbursement

Yearly status report: progress. The EBC welcomes the national health insurance review in 2008 and 2010 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. This would reduce the number of inspections undertaken in respect of products of low medical contribution, and improve the medical contribution per reimbursement cost.

■ 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. Relaxation of the conditions for introducing and the rules for operating DPC in recent years has prompted many hospitals to introduce this system. As a result, measures to prioritise cost reduction have prevailed, eroding the underlying infrastructure for diagnostic testing which is essential for medical care. If this situation persists, the quality of medical care is likely to worsen.

Recommendations:

- 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.
- As part of the above efforts, an expert medical diagnostics committee should be set up in the Central Social Insurance Medical Council and clearly show the Government's determination to enhance the quality of medical care from the institutional aspect.

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MEDICAL EQUIPMENT

Introduction

Healthcare in Japan is generally of a high standard, as might be expected in a 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. The Japanese people 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 individual patients 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 patients 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, giving rise to a serious device-gap in medical equipment.

The EBC has long called for a reduction in the time and costs associated with introducing innovative new equipment to the Japanese healthcare system. Despite the Government's original intent of using the revision of the Pharmaceutical Affairs Law (PAL) to shorten approval procedures and bring Japanese pharmaceutical 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 related to Good Clinical Practice (GCP) and Quality Management Systems (QMS).

As a condition of authorisation and market introduction 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 failure of Japan to accept foreign clinical investigation data is non-compliance with MHLW's GCP requirements. Whereas the international standard ISO14155 is generally accepted in Europe and elsewhere as GCP for clinical trials of medical devices, 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 QMS 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 QMS guidance for medical devices substantially based on, and compatible with, ISO13485. The Japanese system, however, requires a QMS compliance survey for the respective items, hence manufacturers are plagued with duplicate fees and inspections. In Japan, because marketing authorisation of a medical device is tied to, and dependent amongst other conditions on timing of QMS audits by the Pharmaceuticals and Medical Devices Agency (PMDA), this often leads to delays in authorisation and considerable loss for the manufacturer and patients who may be denied access to new technologies already in use in the EU.

An Economic Integration Agreement (EIA) between the EU and Japan should work towards ensuring that products certified in one market are 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 European standards (EN standards). Special focus should be placed on the mutual acceptance of certifications for medical equipment by establishing common GCP and QMS regulations.

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Biotronik Japan	Lima Japan
Coloplast	Molnlycke Health Care
Dornier MedTech Japan	Nippon BXI
Draeger Medical Japan	Nobel Biocare Japan
Edaptechnomed	Philips Electronics Japan
Elekta	Radiometer
Gambro	Sata
Intersurgical Japan	Senko Medical Trading
Japan Life Line	Siemens Japan
Japan MDC	Smith & Nephew Wound Management
JIMRO	Sorin Biomedica Japan
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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 with international standards, as recommended by the “Global Harmonisation Task Force.” However, GCP and QMS were not implemented in a manner completely consistent with international standards. ISO14155 is specific to medical device clinical trials, whereas the Japanese GCP guidance for medical devices is basically a duplicate of that for medicinal products, and inappropriate for medical devices. This creates slightly different requirements and results in the need for foreign manufacturers to 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 GMP of 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 stages through marketing and obsolescence. Conformity with QMS requirements is an obligation of 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. Moreover, in the meantime, the Government should work towards regarding clinical data generated according to European standards as also 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, and should actively use them.

■ Reimbursement prices

Yearly status report: no progress. The 2006 revision of prices paid out under the reimbursement scheme resulted in price reductions for medical materials equivalent to 60 billion yen. The equivalent figure for the 2008 revision was 39 billion yen. Another reduction of about 50 billion yen for medical materials was decided in the 2010 revision, although total medical fees were revised upwards for the first time in 10 years. The purported reason for the cuts was to correct price differences between Japan and foreign markets, but the merits of directly comparing market 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 pursuit of further reductions. In the long run, this will only undermine the interest of foreign manufacturers in the Japanese market. In view of continually decreasing reimbursement prices, and delays in obtaining approvals (contributing to a device-lag), as well as expensive PAL approval costs, high business costs, and an unattractive medical fee environment, medical equipment manufactured and marketed in the EU and the US continues to be withheld from the Japanese market, exacerbating the “device-gap”.

Recommendation:

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

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PHARMACEUTICALS

Introduction

Japan's national expenditure on medical care in FY2009 was an estimated 35.3 trillion yen, up 3.5% from the previous year. This was a record-high in terms of level and growth rate, driven by ageing of the population and more sophisticated medical care. In contrast, expenditure on drugs, currently accounting for about 21% of medical expenditure, has increased by just 3% over the past ten years. This is due to the periodic drug price decrease that occurs every other year. Furthermore, the Government of Japan has been actively promoting generic drugs as a way to save costs, with the goal of generics accounting for 30% of the market by 2012. Moreover, the creation of innovative drugs has been delayed, thereby creating Japan's "drug-lag".

Japan's previous National Health Insurance (NHI) drug system, designed to continually reduce the prices of most drugs even if innovative and new, was a huge problem for pharmaceutical companies, as the system was an impediment to the early recovery of their massive investment. In 2008, the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) proposed "Exceptional Treatment for Maintenance of NHI Drug Prices" at the Special Committee on Drug Prices of the Central Social Insurance Medical Council (Chuikyo). In April 2010, a new drug price system (based on premiums to promote new drug creation and resolution of unapproved drugs/indications) that could maintain NHI prices for new drugs under certain conditions and reinvigorate investment in new drug development and unapproved drugs/indications was introduced on a trial basis. While the system should help to promote innovation and eliminate Japan's drug-lag, the EBC requests evolution from a trial system to establishment as a permanent system.

The Pharmaceuticals and Medical Devices Agency (PMDA) increased the number of examiners and engaged in human resources development to reduce the review time for new drug approval and improve the quality of the process. The agency has also become more active in upgrading safety measures by increasing staff and setting up various working groups. The Ministry of Health, Labour and Welfare (MHLW) is encouraging improvement of the clinical trial environment in Japan and active participation in international cooperation on drug development. The EBC supports these efforts and will maintain dialogue with the authorities, carefully monitoring progress to see that goals are met.

The global pharmaceutical industry has increased its focus on global research and development. Many Japanese pharmaceutical companies now recognise the merits of this approach, since 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 of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH). However, there has been no progress in extending the scope of the existing mutual recognition agreement (MRA) for EU and Japanese Good Manufacturing Practice (GMP); the MRA remains limited to oral solid preparations, so inspections of manufacturing facilities for other products still continue, although essentially redundant, and the process of launching any new product is potentially time-consuming with increased costs.

While welcoming the PMDA's initiatives, the EBC also requests the Government to actively use data and evaluations already guaranteed by the European Medicines Agency (EMA) concerning drugs distributed in the EU. It also suggests that many of the EU guidelines 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, resolve the problem of unapproved drugs/indications, and benefit patients, industry, and society as a whole. 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 is still needed to develop 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 these goals. The EU and Japan should promote an EU-Japan Economic Integration Agreement (EIA) that covers the harmonisation of 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: progress. In April 2010, a new industry-proposed NHI drug price system was introduced on a trial basis from the perspective of rewarding innovation. The new system will ease the periodic drug price reduction under certain conditions (drugs must be within 15 years of their initial NHI drug price listing, have no generic counterparts on the market and no sales with average discounting). Continuation of the new system will allow early recovery of research and development costs in Japan and promote the development of innovative new drugs and unapproved drugs and indications.

Recommendation:

- The Government of Japan should establish the new drug price system, introduced in 2010 on a trial basis, as a permanent system so that innovation is rewarded and the value of drugs more appropriately evaluated.

■ Upgrading of clinical trial 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, and Science and MHLW in 2007, is important for improving the clinical trial implementation environment. Three years after its publication, positive changes, though limited, can be seen in the simplification of clinical trial procedures, the 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. Further development is anticipated.

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 (Source Data Verification) should be discussed. Greater effort is needed to increase and upgrade the convenience of the clinical trial network. Discussion is needed on the calculation method in connection with reasonable clinical trial costs.

■ Improvement of approval examination environment / MRA

Yearly status report: limited progress. To increase the speed of examinations, the PMDA announced a plan to expand its staff by hiring 236 new full-time staff members from the year 2007. By June 2010, 176 new recruits had been hired. The effect of the staff increase on the speed and quality of examinations should be monitored. The working group consisting of PMDA representatives and industrial players also discussed issues concerning clinical trial consultation, approval examination and GCP investigation, and achieved improvements in clinical trial consultation and approval examination. An Office Memo entitled “Points to Consider in Relation to Applications for Reduction of Total Time Required for Approval Examination of New Drugs” dated 9 June 2010 clearly set the target median time periods required for the entire approval examination at 12 months for ordinary items and 9 months for priority review items. The EBC anticipates fulfilment of these targets through the efforts of both the competent authority and corporations. The number of PMDA personnel in charge of post-marketing safety measures has been sharply increased. Moreover, various government-private sector joint task forces have started reviewing safety measures. The EBC anticipates these efforts will have positive effects. Less positively, the scope of the existing EU-Japan MRA on 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 the use of IT, as well as increased transparency in 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 existing EU-Japan MRA concerning GMP should be expanded to include non-solid preparations.

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VACCINES

Introduction

The A/H1N1 influenza pandemic broke out in Mexico in 2009 and quickly spread across the globe. In June 2009, the WHO declared the highest pandemic alert phase (Phase 6), calling for worldwide efforts to prevent the pandemic influenza by manufacturing vaccines as quickly as possible, and recommending treatment with antivirals. In response, vaccines containing novel influenza virus as the antigen were produced rapidly in various countries. In Japan, four domestic manufacturers produced monovalent novel influenza vaccines using the manufacturing method and manufacturing facilities used every year to produce seasonal influenza vaccines. Moreover, the Japanese Government made the landmark decision to import vaccines from two European manufacturers, assuming that domestic vaccines alone could not protect all of the Japanese people due to limitations in production capacity. Such importation of vaccines had never been approved in the past and the decision was indeed a special measure restricted to the A/H1N1 novel influenza vaccine, and not approving the import of other pandemic influenza vaccines or seasonal influenza vaccines, which leaves problems for the future.

Accordingly, vaccines produced in Japan account for 98% or more of the domestic vaccine market. However, due to the A/H1N1 novel influenza pandemic and the urgent need to import and approve foreign vaccines against it, the Government of Japan has been showing increasing interest in the latest vaccines accessible in other industrialised countries. In addition, the Ministry of Health, Labour and Welfare (MHLW) has approved the HPV (human papillomavirus) vaccine and the pneumococcal 7v vaccine. In line with these changes, an Immunisation Committee has been established under the MHLW and specific discussions on revising Japan's Immunisation Law and securing funds have been started, in order to eliminate the vaccine-gap between Japan and other industrialised countries.

Japan was well behind other countries in terms of the environment surrounding the development of new vaccines but is now catching up thanks to an MHLW research project. Official guidelines on non-clinical and clinical developments of vaccines have been announced, and discussions regarding guidelines on adjuvants are ongoing. In addition, a review of the minimum requirements for biological products and for certifying foreign product standards is under consideration, and efforts to increase opportunities to develop vaccines in Japan have been gradually made.

The EBC requests the Government of Japan to promote these dialogues, and implement the reforms needed to encourage Japanese and foreign vaccine manufacturers to invest in the development and production of innovative vaccines that can contribute to the improvement of preventive medicine for the Japanese people. Japan's guidelines on non-clinical and clinical developments were created by referring to the European Medicines Agency's (EMA) guidelines on clinical development. Harmonisation of the guidelines on adjuvants and biological preparation standards should also be carried out by referring to EU examples. Harmonisation of clinical development guidelines and biological preparation standards should be included in an EU-Japan Economic Integration Agreement (EIA) and, accordingly, vaccines approved by the EU should be accessible in Japan. In the meantime, the EBC anticipates beneficial outcomes of the MHLW's research project, which is currently in progress with the aim of harmonisation.

Key Issues and Recommendations

■ Vaccine-gap

Yearly status report: progress. Three vaccines (HPV vaccine, pneumococcal 7v vaccine and novel influenza vaccine) among many vaccines widely used and easily obtained in other countries have been approved. In addition, activities of the MHLW's Immunisation Committee have started at the level of Government with the aim of eliminating the vaccine-gap.

Recommendation:

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

■ Harmonisation of clinical development guidelines and biological preparation standards with the EU

Yearly status report: progress. The development of non-clinical and clinical guidelines for vaccines was completed with examples taken from the EMA as a reference. Discussions aimed at establishing guidelines for adjuvants are ongoing. With a view to drastically revising the "Minimum Requirements for Biological Products" (MRBP), an MHLW research project is in progress, led by Japanese and foreign vaccine manufacturers in addition to representatives from the Government and academia.

Recommendation:

- Similar to the non-clinical and clinical guidelines, guidelines for adjuvants should also be developed quickly using EMA examples as a reference. Repetition of unnecessary specification tests should be avoided by revising the MRBP and accepting the certification of foreign product standards.

■ Securing public funds for new vaccines

Yearly status report: some progress. The MHLW minister stated in the Budget Committee of Japan's House of Councillors that public funding for the HPV vaccine is being considered under the Cancer Control Act rather than under the Immunisation Law. MHLW's Immunisation Committee has started discussions on revision of the Immunisation Law with a view to securing public funds. Only 40% of the vaccines available in Japan are covered by public funds for vaccination fees. Since local governments and not the central government provide the funds, the inevitable consequences include regional disparity and lower immunisation coverage in regions with financially-pressed local governments. On the other hand, the National Health Insurance (NHI) system is already established as the means by which contributions are made to cover standard medical expenditure on drugs, and is accepted by the Japanese people, healthcare professionals and the pharmaceutical industry. The NHI system is designed to provide medical care on an egalitarian basis without regard to social disparity, and is not affected by the financial position of local governments, as is currently the case with vaccines.

Recommendation:

- In Japan, the NHI system does not cover vaccines. Consequently, those people who need vaccines most may not be able to receive them. Vaccine coverage should be incorporated into the National Health Insurance system that has a more consistent approach and is superior to the current system for vaccines funded by local governments.

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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 that include helping to keep their bodies clean and healthy, by protecting against the damaging effects of extreme weather, by preventing decay and the spread of germs, and by 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 (GVP) and Good Quality Practice (GQP).

Japan is the second largest market for cosmetics in the world with 2009 sales of 1.4 trillion yen. Japan imported 154 billion yen and exported 108 billion yen's worth of cosmetics in 2009, including 72 billion yen of imports from Europe and 10 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 insufficient regulatory transparency in Japan, as well as a low degree of harmonisation with standards used in other parts of the world, and unnecessarily complex approval and manufacturing requirements. 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 active and inactive ingredients in Japan that have already been approved is very limited. The EU and Japan maintain different rules governing what ingredients are allowed in cosmetics through negative and positive lists. Even if 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 of products meeting existing approval standards is delegated to prefectural authorities, but different prefectural offices often have inconsistent interpretations of how the approval standards should 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 the claims can be supported by clinical data.

Globalisation has brought unprecedented benefits to consumers world-wide, in terms of new product benefits, greater variety, higher quality and lower prices. However, European companies need 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. An Economic Integration Agreement (EIA) would prove to be an important vehicle for this. We also strongly support greater leadership by the EU and Japan in the International Cooperation on Cosmetic Regulation (ICCR). The ICCR is an international group of cosmetic regulatory authorities from the United States, 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 of the quasi-drug approval system

Yearly status report: no progress. The Ministry of Health, Labour and Welfare (MHLW) cooperated with industry in disclosing a list of approved ingredients for medicated cosmetic-type quasi-drugs in December 2008. However, regulatory transparency remains insufficient and product reviews are slow.

Recommendations:

- Review times for quasi-drugs should be reduced: The EBC recommends a streamlined and expedited product approval and partial change process in Japan for quasi-drugs, especially for products using active ingredients that have been previously approved for use in similar products. This would allow reviewers to spend more time on products that present a higher risk.
- Quasi-drug transparency should be increased: Japan should further increase transparency by establishing a clear process and schedule for regularly updating and expanding the list of approved active and inactive ingredients.

■ Expansion of efficacy claims for cosmetics

Yearly status report: no progress. The scope of the 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.”

■ Elimination of non-tariff barriers for cosmetic and quasi-drug imports

Yearly status report: no progress. The Pharmaceutical Affairs Law unnecessarily requires companies to submit the same import notification documentation to the MHLW after obtaining product approval or submitting a product notification. The MHLW has also announced that the importers of cosmetics and quasi-drugs need to re-submit these documents whenever they renew their business licence. Moreover, because previous versions of a quasi-drug cannot go through the quality check process after a partial change request has been approved, and given the difficulty in predicting approval timing, sea freight importers must hold large amounts of excess stock in Japan to ensure a stable supply. This results in unnecessary costs.

Recommendations:

- The requirement for resubmission of import notification documentation should be eliminated in order to reduce unnecessary paperwork and the time required to import products.
- After partial change approvals, there should be a grace period during which the previous version of imported products can undergo quality checks and be sold.

■ Increased transparency for cosmetic ingredients

Yearly status report: no 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 maintenance of positive and negative lists remains unaddressed.

Recommendation:

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

■ Application of the same legal standards to parallel importers

Yearly status report: no progress. Manufacturers and importers of cosmetics and quasi-drugs are legally required to observe GVP and GQP in order to secure safety and quality. However, parallel importers do not comply with these requirements, sometimes illegally using registered trademarks, sometimes importing versions of products that use ingredients not approved in Japan, and sometimes selling products with damaged or missing labels or that are past the expiration dates. For example, some parallel importers do not provide legally required safety information and others ignore their legal obligation to protect consumers, by stating on their websites: “we are not responsible for skin problems that may occur after use of this product”.

Recommendation:

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

■ Establishing of 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 the system of the Japanese Center for the Validation of Alternative Methods (JaCVAM) and establish animal protection environments based on the 3R concept (reduce, reuse, recycle).

■ Avoidance of confusing carbon footprint labels

Yearly status report: no progress. Japan has begun certifying methodologies for calculating and displaying numerical carbon footprints on product labels. However, insufficient validated datasets make it difficult to generate accurate numerical labels, and methodologies that are inconsistent with those of other countries could become a trade barrier. Moreover, the labels could shift 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.

Consumer Goods

**Liquor
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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 value, foreign imports in 2009 accounted for less than 3%, at 170 billion yen (Japan Customs), of the total Japanese liquor market, including beer and beer-like products. 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 (*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. Moreover, 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 (MOF) 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, US 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.

Japan continues to impose tariffs on both sparkling wine (182 yen/litre) and still wine (125 yen/litre), which are around five and three times higher, respectively, than the levels in the EU. In addition, the EBC cannot understand why there is a discrepancy between the tariffs imposed on sparkling and still wine - Japan has almost no production of sparkling wine, yet it carries a higher tariff than still wine.

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 (EIA).

Lastly, in contrast to the EU, US and Australia, Japan has yet to legislate in favour of traceability codes featured on the packaging of imported (or domestic) liquor products. The Government of Japan should introduce such legislation in order to protect the interests of consumers.

Key Issues and Recommendations

■ Traceability

Yearly status report: new issue. European manufacturers of liquor as well as food producers have a tracing system that has been in place in the EU since 1990. This enables the producer to easily trace a particular batch or a particular production site. Furthermore, it makes it possible to know at what time the product was produced. This helps both the producer and the authorities to identify and recall a defective product. However, some third party importers, usually parallel importers or grey market importers, make a habit of erasing the code. While the EBC understands that in Japan, parallel importation is legal and that such products are permitted on the Japanese market, we wish to make the Japanese Government aware of the risks and problems that arise from the removal or the traceability codes.

Recommendation:

- The Government of Japan should amend its legislation to make it illegal to tamper with traceability codes.

■ 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. Of particular interest is the discrepancy between still wine and sparkling wine. Japan has almost no production of sparkling wine, yet it carries a higher tariff than still wine. The Japanese tariff on sparkling wine is twice the US duty and almost five times the EU tariff.

Recommendations:

- The EBC urges the Government of Japan to continue working towards the eventual elimination of tariffs on imported liquor products.
- Dismantling of all liquor-related tariffs should be included in the negotiations on an EU-Japan Economic Integration Agreement.

■ 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 US and endorsed by the International Federation of Wines and Spirits.

■ 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 MOF 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 US, which distinguish between spirits, beer, wines and intermediate products.

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FOOD

Introduction

Generally speaking, Japan's regulatory environment favours the import of raw materials for use by the domestic processing industry, but hampers the import of packaged food (processed or not). The relative scarcity of imported packaged food in Japanese supermarkets compared to other developed countries bears witness to this. Indeed imported it can generally only be found in a relatively small number of gourmet and upscale supermarkets and seldom in larger supermarket chains.

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, in accordance with international practice, Japan's sufficiency rate is 66%, which is lower than for Italy (89%) and Germany (73%) but higher than, for instance, the United Kingdom (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 United Kingdom (\$756), to mention just a few.

Overall, there are three factors underlying these statistics. The first, which is a significant issue in the food sector, is that tariffs are imposed on imported foods. Food is purchased everyday and so price is a key decision factor for food shoppers. European packaged food will never reach competitive price levels if tariffs persist.

The second factor is that a large number of non-tariff barriers have a serious impact on the amount of food imported from Europe, in terms of the volume and variety of trade. For example, many food additives recognised as safe in most parts of the world are still not authorised in Japan and the approval process for "new" food additives in Japan is slow. There are differences in standards for the use of key additives even for authorised substances, as the maximum level of use may be set much lower than in the EU, thereby precluding the import of foods containing them. Japan does not recognise the EU regulatory approach of distinguishing foods that support the growth of *Listeria monocytogenes* from foods that do not. Despite the recent recognition of the organic certifications of the new Member States of the EU, the Organic-Japanese Agriculture Standards (Organic-JAS) logo still cannot be used for many EU certified organic products, and there is a lack of comprehensive legislation for several categories of agricultural products (such as honey). Japan has only accepted scientific evaluations by international bodies such as The Joint FAO/WHO Expert Committee on Food Additives (JECFA) and Codex Alimentarius (CODEX) to a limited extent, and bans the import of products of bovine origin from the EU, while all other origins of the world are authorised.

The third factor is that Japanese food culture is deeply rooted in society and even if the country's doors were fully open to imported foods, supermarket shelves in Japan may never look identical to their counterparts in Europe. However, the Japanese people are genuinely curious which suggests that a wider availability of affordable European food products would stimulate the food sector greatly.

Accordingly, 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 and positive change, to support the goal of providing consumers in Japan with a much wider variety of safe, high-quality food. We believe that our closely shared principles strongly support the establishment of an EU-Japan Economic Integration Agreement (EIA). Under such an agreement, tariffs should be abolished, standards harmonised and market authorisations of both regions mutually recognised, without compromising on food safety. The EBC Food Committee believes such an agreement would lead to more choice in supermarkets and stimulate healthy competition in the food and agricultural sectors of both zones.

The EBC would like the following issues to be addressed with high priority.

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. Examples include butter (with an import duty rate of 35% plus 1,159 yen/kg), cheese (26-40%), chocolate for professional use (29.8%), confectionery (25%), syrup (24% plus sugar tax), fruit juice and fruit puree for babies (21.3%), and herbal tea (15%).

Recommendation:

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

■ Food additives

Yearly status report: slow progress. In December 2002, the Ministry of Health, Labour and Welfare (MHLW) prepared a list of 46 food additives not approved in Japan that “have been proven safe and are widely used in the world”. At the time of writing, more than one-third of these 46 additives have still not been approved. Moreover, the list has now increased to 73 entries (with the addition of many new flavouring agents), including six substances whose evaluation by the expert committee of the Food Safety Commission was stopped around 2008. We note that eight entries have been dropped from the initial list, but see no reason for their removal. The total number of additives listed now demonstrates that there is still a need to approve more additives without delay. The EBC must also point out that, relative to the EU, some widely used additives (especially preservatives), such as sulphur dioxide (SO₂) and sorbic acid (potassium sorbate), have significantly different allowed usage levels in Japan, based on food category. For sulphur dioxide, the allowed usage level can be as high as 5 g/kg for designated food categories, or as low as 0.3 g/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 sorbic acid as for this substance, the “other foods” category does not exist, meaning that even a trace (possibly even a carry-over) of sorbic acid found, would result in the total recall of that food, despite there being absolutely no health risk whatsoever.

Recommendations:

- The Food Safety Commission should start to process the eight additives dropped from the initial list, and approve as soon as possible the six additives for which the evaluation process started in 2007 and stopped in 2008. The complete list as of September 2010 should therefore have 81 entries and work on the additives not yet processed should start without delay.
- Beyond this list, the EBC strongly recommends a review of the standards of use for food additives. Standards of use for common preservatives, such as sulphur dioxide (SO₂) and sorbic acid (potassium sorbate), should be modified to allow usage levels in line with European standards and international best practice.

■ Products of bovine origin (meat, gelatine, etc.)

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 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 received from MAFF and MHLW and have already submitted data. The process is extremely slow and still remains only at the discussion level. Consequently, imports of all products from the EU using ingredients of bovine origin (such as meat, any sausage made with bovine gelatine, cosmetic products, etc.) are completely banned in Japan.

Recommendation

- Considering the high level of safety and traceability in the beef industry in the EU, and also given the fact that the ban on US beef was lifted more than 3 years ago, the EBC recommends that MAFF and MHLW give the green light to authorise the resumption of imports of products of bovine origin from the EU.

■ **Listeria Monocytogenes in ready-to-eat food products**

Yearly status report: some 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 ready-to-eat (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 the US Food and Drug Administration (FDA). This would improve food safety by focusing attention and action only on those products that pose a health risk.

■ **Supplementary embassy certificates for organic products to be labelled in Japan**

Yearly status report: no progress. Products that have the Japanese label (Organic-JAS) affixed in Japan (which is often the case when small quantities are imported) are subject to a time-consuming, costly, wasteful bureaucratic process. 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). This process alone is already a burden, but then the importer must send that original certificate to the relevant embassy of the country from which the products were imported, together with the invoice, packing list and waybill. The embassy must then issue a “supplementary certificate” to the importer in order to have the products labelled Organic-JAS in Japan.

Recommendation:

- The Government of Japan should abolish the need for issuing all these certificates. It should be sufficient for the importer to be Organic-JAS certified (and as such inspected once a year), as well as to keep a file copy of annual organic certificates or imported products.

■ **Food safety**

Yearly status report: no progress. In 2009, there was a public debate about the possibility of adding labels to foods listing the origin of all ingredients, in the name of consumer safety. In today’s global world, it would be near impossible for most food manufacturers (Japanese especially) to abide by such a rule, and in no way would it increase consumer safety.

Recommendations:

- In the field of Food Safety, EU legislation has made significant progress in recent years. We urge the Government of Japan to liaise as much as possible with relevant bodies in the EU. In particular, the EBC recommends that Japan’s Food Safety Commission liaises with the EFSA (European Food Safety Authority).
- The newly created Consumer Agency of Japan should interact with the Food Safety Commission when considering the most effective actions to ensure consumer safety and to reduce the incidence of accidents and fraud in the food sector.

Industry

Automobiles
Automotive components
Aeronautics
Space
Defence
Construction
Materials
Environmental technology

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AUTOMOBILES

Introduction

Import car sales began to recover from the full impact of the global financial crisis towards the end of 2009, a trend that has continued in 2010. However, the recovery remains weak. Imports in the first half of 2010 were still some 15% lower than in the pre-crisis year of 2008. Unfortunately, the pace of recovery of imports is slower than that for the passenger car market as whole, with the result that the import share of the domestic market has dropped to a level not seen in the last 20 years.

The slow recovery of imports is largely attributable to the distortion of the domestic market created by the Japanese Government's sales incentive schemes introduced in April 2009 in response to the financial crisis. As noted in last year's EBC annual report, these schemes are nominally open to all, but differences between Japan and the EU in fuel efficiency and emissions testing cycles used to assess eligibility for the subsidies and incentives largely disqualify European imports. In spite of the absence of any lead time between the announcement of the eco-car incentive schemes and their implementation, some European importers have succeeded in launching eligible models. Making the necessary engineering changes in short order, however, is not a practical proposition for small volume importers. Even though few imports have benefited from eco-car subsidies, there is a considerable risk that European imports will be caught in the inevitable market down-turn when the current incentive schemes expire.

The threat of a double-dip in the domestic automobile market underlines the importance of the Japanese Government's carrying out of a comprehensive review of the system of taxation of automobiles in order to provide for the future stable growth of the market. The EBC Automobile Committee will continue to work closely with the Japan Automobile Importers Association and other automobile related organisations to promote the tax reform proposals set out in our recommendations.

The Japanese Government can also help stimulate import car sales by speeding up the international harmonisation of vehicle standards. The EBC Automobile Committee welcomes the initiative that Japan has taken in Working Party 29 (WP29) of the United Nations Economic Committee for Europe (UN-ECE), the global body for setting vehicle standards, to introduce an International Whole Vehicle Type Approval System (IWVTA), which would make possible the mutual adoption of vehicle certification between the EU and Japan. This would benefit both domestic manufacturers and importers. Importers have a special interest in the harmonisation of standards since meeting Japan's unique regulatory requirements imposes a higher unit cost of compliance on imports, with their lower volumes, than on domestically produced vehicles. As new power-train technologies - electric vehicles, hybrid vehicles and fuel-cell vehicles - are developed, the EBC Automobile Committee urges the Japanese government to seize the opportunity to establish with its trading partners internationally harmonised technical requirements that will encourage the smooth market adoption of these new environmentally friendly technologies.

"*Kei*" or mini-cars are those vehicles legally restricted to a maximum length of 3.4m, a width of 1.48m, a height of 2m, and to an engine displacement of 660cc and below. *Kei* cars benefit from lower automobile-related taxes, automobile liability insurance and motorway tolls and are subject to less stringent overnight garaging requirements. The continued existence of the privileges enjoyed by *kei* cars is an anachronism, which distorts the competition with imported compact and subcompact cars sold in other global markets, which do not enjoy the same prerogatives as *kei* cars in Japan, even though their performance and specifications hardly differ.

The agreement reached in July 2010 between the European Commission and Japan on streamlining the procedure for approving the use in Japan of European advanced safety devices sets a good precedent. It demonstrates that with determination, persistence and good will on both sides the EU and Japan can overcome non-tariff obstacles to trade. The EBC Automobile Committee hopes that in this spirit the EU and Japan will work closely together to promote the further international harmonisation of automobile standards.

Key Issues and Recommendations

■ Tax reform

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

Recommendations:

The Government of Japan 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.
- Conduct a comprehensive review of the taxation on fuels from the perspective of environmental policy.
- Adopt and implement as early as possible 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. The EBC Automobile Committee welcomes Japan's proposals in WP29 in Geneva for 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:

- Accelerate 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 Government of Japan should put *kei* cars and other motor vehicles on the same footing.

■ Technical guidelines for new safety technologies

Yearly status report: some progress. The European Commission and Japan have reached an agreement of principle on the introduction of "more transparent, streamlined and inclusively consultative procedures for the administration of technical guidelines in relation to new automotive safety technologies." The agreement takes into account many, but not all, of the proposals made by EBC Automobile Committee members. It should pave the way for the more rapid market introduction in Japan of proven European advanced safety technologies.

Recommendation:

- The Government of Japan should implement promptly the terms of the agreement reached with the EU.

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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, and continue to favour traditional suppliers for product design and production. There is indeed a lack of transparency in a situation where standard business practice for Japanese automobile manufacturers is to request an exact product instead of setting up a framework of open standards to fulfil, thus defying the global trend towards single platform development and volume production. The EBC feels that Japan is looking inwards in not using international technology. The lack of English use unfortunately also shows that Japan still has some way to go to truly become a global market.

The process of globalisation and intense competitive pressures have meant that the outsourcing of automobile component development and supply has emerged as a clear trend in the European automobile industry. The European system offers low risks, reasonable 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 automotive components market in the world, but European automotive manufacturing companies hold only a small share of the local market. The European component manufacturers offer competitive advantages, which are yet to translate into significant new opportunities to supply the Japanese automobile industry. As both sides are gearing up for the implementation of new technology, the EBC requests Japan to ensure that its standards and technical regulations fall within the framework of international standards in order to avoid distorting trade flows.

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. 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. Nevertheless, European automotive component and system manufacturers continue to face numerous challenges in promoting European technical expertise to automobile manufacturers in Japan. In this respect the traditional concept of affiliated companies (*keiretsu*) still exists, presenting obstacles and leading to the distortion of competition. Free and open competition would lead to more innovative and better quality products, something that would benefit Japanese manufacturers. Japan-specific requirements are common, and it is not unusual for specifications to differ between domestic and overseas production, even within the same company. It is, therefore, of crucial importance that Japan harmonises its regulatory framework to better accommodate globalisation of the automotive components sector.

Recommendations:

- 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.
- The EBC recommends the application of free and open competition and the avoidance of excessive reliance on *keiretsu* companies.
- Japan should recognise foreign test results to avoid the necessity of re-testing for the Japanese market.

■ 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 18-20 May 2011 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 a "negative" list like that of the EU's Restriction of Hazardous Substances Directive (RoHS).

Recommendations:

- The EBC urges the Japanese automobile industry to adhere to accepted international practices when setting procurement requirements.
- Japan should recognise conformity to RoHS as equivalent to the Japanese rules.

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AERONAUTICS

Introduction

It is unclear how far the reformist attitude of Japan's leaders since September 2009 will support a review of Japan's policies in aeronautics. Although the aeronautics sector is particularly subject to political influence, business reality lies elsewhere. While respecting Japan's policies in aeronautics, the EBC wishes to reiterate its strong belief that a rapprochement with Europe in aeronautics business and project development would result in more gains for Japanese industry than have occurred in decades of Japanese national industrial policy. We can see that recent disappointment with outdated, exclusively pro-US policies is causing a shift in attitude, but nothing tangible has changed as yet in terms of Europe-Japan aeronautics business.

The Japanese market for commercial aircraft and helicopters is one of the largest in the world, and has historically been dominated by US manufacturers. The EBC suggests that Japanese airlines and other aircraft operators should recognise the benefits of competition, the risk of depending on a single source, and the advantages of diversifying suppliers. European companies provide state-of-the-art technology, highest-quality products and goods, as well as second-to-none customer support services. For instance, the availability on the market of the 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 programme and the cooperation between KHI/Mitsubishi Heavy Industries (MHI) and Rolls-Royce on the Trent 1000 and XWB engines are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. In commercial aircraft, Airbus has been trying to forge ties with the Japanese aerospace industry since the 1980s, with disappointing results. A change may be in the offing, however, as Japanese equipment manufacturers, disappointed with the lack of success in supplying their traditional foreign customers, begin showing interest in Europe. An EU-Japan Aeronautics Industry Workshop took place in November 2009 and met with encouraging success. However, due to its long-standing relationship with North American companies and dismissal of Europe as a plausible competitor, Japan's aerospace industry is often still reluctant to work with European companies. Such loyalty may be understandable in the Japanese context, but it should be kept in mind that US and European aeronautics suppliers routinely cooperate and supply prime contractors of the other side on a large scale (typically 30 %) in virtually all major aircraft programmes, making Japanese loyalty look moot at best.

Needless to say this is also certainly not a time to perpetuate an all-Japan-team attitude that may be easy for Japan's Government to manage in the short term, but goes against all lessons learned from worldwide experience. Proactive collaboration with successful European companies will enable Japanese companies to strengthen their position in commercial aeronautics. By joining a wider range of projects, Japanese firms will 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 Japan's Government and aerospace industry to continue giving 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 attempt at modernising its air traffic management system. 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 deplores 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 cooperation

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 a single aircraft development with Europe. METI's support for the Boeing 787 programme 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 recently signed EU-Japan S&T Cooperation Agreement 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 the Japan Aerospace Exploration Agency (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, which should be examined further by both sides.
- 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

How deeply the reformist attitude of Japan's leaders since September 2009 will reshape its Space policies is unclear. Budget realities, however, call for change. While respecting Japan's Space policies, the EBC believes that more cooperation with Europe would result in significant budgetary savings and large technological and industrial gains. Unfortunately, Japan has so far ignored most European cooperation overtures and capabilities. As a result, Europe, while hoping for a different Japanese attitude in the future, now concentrates on more receptive countries. The onus is on Japan to reverse this trend, which should be easier to do under the 2008 Basic Space Law than before, as it laid the groundwork for unified and budget-saving policies. Yet few steps in that direction have occurred. The May 2010 Space policy report issued by Japan's Strategic Headquarters for Space Policy tends to consider Japan in isolation and only regards the outside world as a market.

Japan has changed its attitude to Space as it now (1) makes strategic budget choices, (2) regards space not only as science and technology but also as business, (3) is significantly expanding private financing initiative programmes, and (4) is promoting exports as part of its "New Growth Strategy", with the goal of a 100% increase in industry revenues within 10 years.

The Ministry of Economy, Trade and Industry (METI) assists the Japanese industry in supplying developing countries with all-Japan satellite systems financed through Japanese Official Development Assistance (ODA). The packages include satellites, launches, operations, data analysis, maintenance, personnel training, and technology transfers. A remote sensing system for Vietnam is the first successful case. Contrary to EU policy, Japan's policy is that ODA contracts must be awarded to Japanese industry, resulting in a distorted market. The scale of METI's satellite export project is 15 satellites over the next 5 years.

The private satellite market is open to all suppliers and reached the level of 2 communications or broadcasting satellites a year, but it is now experiencing a trough due to a broadcasting industry merger and the general state of the economy. Moreover, satellites for government- and quasi-government-use applications have been put to international tender since 1990. These include the Multi-functional Transport Satellite (MTSAT) series and the BSAT broadcasting series. The former NTT Group's NSTAR series was terminated. The EBC notes that participation in the government satellite tender process is difficult for foreign companies, due largely to the contract language, unlimited liability, other unrealistic clauses, and currency problems.

No-tender government satellite programmes are science and technology satellites funded by the Japan Aerospace Exploration Agency (JAXA), a small number of programmes under METI, and the defence-purpose remote-sensing Information Gathering Satellite (IGS) series. There has not yet been a dedicated defence communications satellite. Japan's cooperation in satellite and other development programmes remains biased towards the US, whose past political influence has had an adverse effect on the development of both the Japanese and European space industries in Japan.

Ariane launchers are successful in Japan and play a role in cooperation. Arianespace and Mitsubishi Heavy Industries let customers shift satellites from Ariane 5 to H-IIA and vice-versa to avoid launch delays due to technical problems. However, talks between the Japanese and European space authorities towards mutual back-up of government launch missions have stopped due to a lack of unified policies across Japanese ministries. Moreover, a future Space Activities Act may require Japanese commercial customers to seek government approval before procuring foreign launch services. The need to apply and wait for government approval may become a hindrance to growth in this time-sensitive business.

Japanese investment in ground equipment has been spurred by its 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. In addition, homeland security-type applications enhance defence capability. Protectionist procurement methods are still being used in this area to the disadvantage of foreign suppliers.

Key Issues and Recommendations

■ General environment

Yearly status report: no progress. Japan's space policies largely ignore Europe. Not surprisingly, Europe now looks elsewhere. 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 that excludes the “black-box” policies of concealing the technology from the buyers.

Recommendations:

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

■ Satellites

Yearly status report: no progress. Japanese policy continues to ignore Europe's satellite technology. Both sides' space agencies continue meeting, but they do not achieve much progress in 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 the procurement of satellite systems or satellite equipment in fields related to national security.
- METI and the Ministry of Defence should be open to procuring the high-quality European sensors they need or have Japanese industry produce them in Japan under a licensing arrangement.
- Government procurement methods, terms and conditions must not place European makers at a disadvantage.

■ Launchers

Yearly status report: no progress. 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 on both sides. This suggestion was first presented to the Japanese space authorities in 2002, but no agreement is in sight. For technical and cost reasons, this cooperation must be comprehensive and systematic to succeed. Unfortunately political leadership has been missing. In addition, a new Space Activities Act may make it more difficult for Japanese satellite-operating companies to launch satellites urgently needed in a timely manner.

Recommendations:

- New government satellite programmes will require more timely launches. The EBC urges Japan to bring about effective, formal back-up cooperation between Japanese and European heavy-lift launchers.
- The EBC stresses the importance for Japan's satellite communications 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 requests that Japan's international procurement in ground equipment includes whole systems, and that the procurement process for standard ground processing products does not place European suppliers at a disadvantage.

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DEFENCE

Introduction

It has been encouraging to note that the Democratic Party of Japan (DPJ) is reassessing all aspects of Japan's government spending. Yet, in the area of defence procurement, Japan still has some distance to travel to take full advantage of the opportunities and benefits that Europe's defence companies can offer. The EBC believes that more cooperation with Europe would result in mutually beneficial outcomes, bringing Japan large budget savings and considerable technological gain.

According to the 2010 Yearbook of the Stockholm International Peace Research Institute (SIPRI), Japan's 2009 defence budget accounted for 0.9% of GDP and was the world's 6th largest in terms of amount, based on current exchange rates. This marked a year-on-year fall equivalent to 0.1% of GDP. Like many other countries, Japan will face difficult financial choices and more efficient use of the budget will be increasingly necessary. Sourcing decisions based on country of origin limit opportunities for cost saving; open competition from a range of competent suppliers, all of whom already operate in the US market, would offer greater capability choices and cost savings.

It is clear that changes are occurring: (1) Japan's defence industry, whose technological level is rising steadily, increasingly recognises the need to change; (2) Japanese public opinion is more aware of the need for improved defence in response to increased capabilities in North Korea and China and the recognised need for Japan to contribute more to international stability; (3) New political leaders are more open to the benefits of diversifying defence sourcing; (4) The high performance defence systems that Japan needs can only be developed, built and procured through international cooperation; (5) Financial constraints can no longer be ignored.

Last year, Japan's next five-year defence plan was postponed for a year and will be finalised in late 2010. The Ministry of Defence (MoD) is considering new procurement methods to meet defence needs without reducing capability or harming domestic industry. Japan could make huge cost savings in maintenance by diversifying methods and practices. Cost Plus local procurement may give way to efficient fixed-price open tenders. This thinking is welcome, but its effects may not be sufficient to strengthen Japan's defence industrial capability. Japan has many similarities with Europe, including budget levels and mission requirements, and would benefit from greater international cooperation. Areas where particularly large potential budget savings and technology gains can be made include new aircraft (fixed-wing and helicopters) including retrofitting, maintenance and repair, radars, missiles, unmanned aerial vehicles, electronics and optoelectronics systems, space-based services, and technology development in all these areas.

The Japan Business Federation (Keidanren) and the DPJ are now cooperating on the latter's New Growth Strategy, including for the defence industry. Relaxation of Japan's "Three Principles on Arms Exports", which effectively prevent Japan's participation in international collaborative projects, is under consideration. The goals are to maintain the capabilities of Japan's defence industry and enable participation in international development programmes. We support these goals and strongly encourage Japan to ensure their implementation and to include working with Europe.

There remains insufficient recognition in Japan that European industry's products are fully interoperable with those of the US. This interoperability makes European industry ideal for Japan as a supplier and as a partner in joint development. For Japan, advantages of this collaboration would be both budgetary and technological. To foster this mutually beneficial collaboration, we encourage the use of procurement processes based on internationally developed practices, including: (1) a clear statement of the requirement; (2) adherence to the statement, or total transparency as to the rationale for any change; (3) a clear statement of timelines and adherence thereto; (4) a clear statement of the evaluation criteria, to include any weighting given to industrial and security relationships; (5) processes to be conducted in English; (6) the application of NATO standards; (7) the basis of award and the evaluation to be made public; and (8) an opportunity to appeal award decisions.

Key Issues and Recommendations

■ Increased competition

Yearly status report: some progress. The EBC welcomes the steps being taken by the MoD to increase competition in the procurement process, opening it up to foreign suppliers. Publishing the Statement of Requirements (SOR) increases transparency and the level of competition. It is crucial that the Cabinet and ministers set priorities for each important tender. A greater emphasis on Life Cycle Costs (LCCs) is also welcome. EU companies have great experience in modelling and predicting LCCs and are confident about their ability to guarantee predictions or enter into fixed price contracts. This prevents price shocks and escalations. LCC models used in the EU can be shared with Japan. They are more relevant than those used by the US, which has vastly higher manpower and equipment levels, requiring different maintenance and training policies.

Recommendations:

- Japan should improve transparency towards foreign suppliers by making the SOR for procurement processes more widely available and placing more emphasis on LCCs. The MoD should adopt NATO standards from the initial research and development phase to strengthen competition and reduce development risk, as this would encourage more diverse inputs and an increased number of partners.
- The EBC strongly urges the Government to repeal unlimited liability in the terms and conditions of public tenders, since this puts foreign bidders at a considerable disadvantage vis-à-vis Japanese contenders.
- The success of a better procurement system is contingent on serious consideration and actual granting of major contracts to European suppliers. Barring this, weak competition would preclude any cost reductions.

■ Industrial partnerships

Yearly status report: some progress. EU industry can assist the MoD in meeting cost reduction targets with Performance Based Logistics (PBL), Private Finance Initiatives (PFI), commercial off-the-shelf solutions, leasing schemes, and procurement techniques to minimise costs. Examples of progress achieved by LCC models through an initial phase of performance-based logistic support or through a fully integrated operational support programme can be demonstrated by European Governments already partnering with industry and familiar with through-life cost benefits. Access to several decades of European experience in using an International Integrated Project Team (IIPT) could be a great asset for Japan. EU industry is very experienced in and open to technology and know-how transfers to partner companies of allied countries, such as Japan. Regulated by a proper government agreement, this could contribute to making the EU defence industry an even more attractive partner, as it would allow Japan's defence industry to improve its capabilities.

Recommendations:

- Japan should enter into agreements with EU countries to ease technology and information exchange. This would enable joint development and cost sharing, and provide greatly improved technological solutions.
- The Government of Japan should introduce innovative procurement approaches, such as partnerships with industry, to reduce procurement costs, place more emphasis on LCCs, and promote the IIPT approach.
- Simple measures such as planning more defence study missions to Europe would improve the level of knowledge and understanding of European achievements by Japan's political and administrative leaders.
- Having more than one MoD official based in Europe would be helpful. There are 15 MoD officials posted to the US.

■ New security policy

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

Recommendation:

- The Three Principles on Arms Exports should be relaxed.

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CONSTRUCTION

Introduction

The severe impact of the economic slowdown on the construction sector continues, as a sharp reduction in property investment forces restructuring within the domestic property industry, while a number of international participants have chosen to retreat from the Japanese market. 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 (363 billion euros in 2006) makes it one of the largest in the world, and it therefore remains important. However, it is not seen as having obvious growth potential relative to other Asian markets. It should be noted that despite this harsh situation, a number of European-affiliated enterprises in the construction sector are maintaining their long-standing commitment to Japan. Having built a presence over a long period, the character and concerns of these businesses in many ways align with domestic companies. Integrated into the Japanese economy with a strong local workforce, these businesses have the capacity to deliver quality products and services, making a valuable contribution to the growth of the Japanese economy, now and in the future.

The Government of Japan has made enormous efforts to stimulate the economy through supplemental budget provisions, but effectiveness within the construction market has been limited by difficult conditions in the financial markets for private sector investment, and clouded by drawn-out investigations into public works irregularities. Recently, some analysts have suggested that the declining property market is bottoming out, however such optimism is dependent upon stimulation of the overall economy and favourable property investment policies. Leveraging new technologies and project delivery methods will be key to unlocking new growth potential. One such area is sustainability. Given that 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, the activities of the construction and property management industry will fall under close scrutiny if the targets for reduction of carbon emissions (25% by 2020 compared to 1990 levels) set by the Japanese Government are to be achieved. This is an area where European experience can be applied, and is a high priority for the EBC.

Whilst regulations on energy efficiency 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 (*kensetsugyo kyokasho*) to be a contractor or a direct subcontractor of a general contractor for projects that are worth over 5 million yen (roughly 40,000 euros) in value. To obtain this permit, the company must have a resident management staff member with more than five years of relevant experience in the same company or in another company in the same field. Innovative 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.

The public works procurement process continues to limit opportunities for European firms to participate and increases the cost of public works for the Japanese taxpayer. To promote competition, the Government should abolish the ceiling price system (*yotei kakaku*) for public tenders and relax requirements for bid participation. 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 (World Trade Organisation) minimum threshold, a manipulation that contravenes the WTO Government Procurement Agreement (GPA).

An EU-Japan Economic Integration Agreement (EIA) 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

■ Harmonisation of building material standards and contractor qualifications

Yearly status report: limited progress. Creating opportunities for European firms to use innovative designs, imported materials and modern construction methods - the key to their competitive advantage - will require reform of over-prescriptive regulations, of the attitude of local officials resistant to change and of complicated procedures for obtaining the necessary approvals. Alignment of standards and testing methods across industries and across borders will be essential to achieve the benefit anticipated for Japan. 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.

Recommendations:

- The Japanese and EU authorities should work towards mutual recognition of Japan Agricultural Standards/Japan Industrial Standards (JAS/JIS) and EN (European standards) standards for building materials. CE (*conformité européenne*) marking of construction products should suffice as a guarantor of their high quality and safety when sold in Japan.
- With regards to the *kensetsugyo kyokasho*, the EBC requests that similar foreign experience be recognised as equivalent to domestic experience.

■ Promotion of environmentally friendly construction

Yearly status report: some progress. The EBC applauds the Government of Japan's ambitious CO₂ emissions reduction target, and will eagerly monitor the effectiveness of the Tokyo Metropolitan Government's Carbon Cap and Trade programme, which was implemented from April 2010. The Science Council of Japan, as a member of the global Interacademy Council along with other similar bodies from G8 countries, 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 Greenhouse Gas curve). While regulations are put into place to drive higher performance from new buildings, emphasis must also be placed on improving the efficiency of existing building stock through incentives geared to stimulate the renovation market. Opportunities may span from simple component replacements such as double-glazed windows, high-efficiency air conditioners or installation of insulation in walls and ceilings, to the application of new technologies for on-site energy recovery, water treatment and other conservation strategies. The EBC sees great potential in the recently introduced eco-point system as a first step in this direction. We encourage the Japanese Government to expand this programme taking a holistic view of not just stimulating the sale of energy-efficient products, but also linking rewards with overall reduction of energy consumption through integrated design strategies and life-cycle cost evaluations.

Recommendations:

- 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, with a view to applying best available technologies in an integrated systems approach and transparent methods for measuring performance achievements.
- The Government of Japan should mandate the introduction of much stricter insulation standards for buildings, as current requirements are well behind those of advanced European countries. Rating tools such as CASBEE (Comprehensive Assessment System for Built Environment Efficiency), and schemes such as the Energy Efficiency Standard for Houses and the PAL/CEC (Perimeter Annual Load/Coefficient for Energy Consumption) assessment for larger office buildings, are heading in the right direction, but produce buildings that are not yet up to international standards.
- The Government of Japan should facilitate educational programmes geared to increasing awareness at the level of construction project implementation and establish clear methods to ensure that objectives are met.

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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 those used to produce rechargeable batteries for hybrid vehicles, nanotechnologies for manufacturing semiconductors, and various products related to environmental technology, among others. 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 the 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 for overseas suppliers. A shift in strategy among Japanese companies has already taken place to minimise risk and dependency on unstable sources, leading them to diversify purchases despite existing tariffs. Ultimately, the tariffs must be paid by Japanese companies.

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). With the breakdown of the 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, was a welcome step of major importance.

Tariffs damage competitiveness and threaten the future of Japan's domestic 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), and to silicon carbide, 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 annual demand. While consumers can currently import much of their fused aluminium oxide 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. There have also been some indications that China may be removed from the list of recipients of GSP preferences. In addition, China is introducing export tariffs, export quotas and even in practice, export bans! It is therefore important that the Government of Japan allows its domestic industry to procure raw materials from all sources, with zero duty.

In the case of silicon carbide, Japan imports 90% 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 and stable supply on a long-term basis to Japanese industry. Import tariffs increase the dependency of Japan on Chinese suppliers and threaten the future of Japanese industry.

The EBC strongly believes that Japan will benefit from removing tariffs on materials in order to facilitate the continued competitive edge of Japanese companies in key growth industries. An example of this is in nickel. There are projections indicating that, in 2020, demand from the battery industry (for electrical vehicles) alone will be 30,000 tonnes for cathodes produced in Japan. Today Japan imports 60,000 tonnes of nickel and nickel refined products. An EU-Japan Economic Integration Agreement (EIA) 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 tariff rates on refined nickel is a significant increase in costs for domestic users, particularly in the stainless steel industry. 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. This is imperative for Japan to retain its competitive edge.

■ 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 processed in Japan. This increases the price of imported fused aluminium oxide (artificial corundum, tariff codes: 281810010 sized grain and 281810090 non-sized grain) in addition to silicon carbide (tariff codes: 284920010 sized grain and 284920090 others) 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 country. In this context, such dependency on only one source makes Japan vulnerable to supply shortages or market control attempts. This is of particular concern considering the limited capacity of domestic production, which is estimated to be only 15% of demand, even when run at maximum capacity.

Recommendation:

- The Government of Japan should remove import tariffs on all industrial raw materials including fused 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

The Government of Japan has, since the turn of the millennium, announced various schemes and ambitious targets for environmental protection, energy efficiency, recycling, renewable energy, and climate control countermeasures. The Renewable Portfolio Standards (RPS) Law of 2003, former Prime Minister Abe's Cool Earth proposal, the Basic Act on Global Warming Countermeasures, and the recently announced New Growth Strategy all have ambitious targets, but offer very little detail in terms of the technological, financial and legal measures required to meet these targets.

Japan will need massive investment in clean and renewable energy sources to reach the CO₂ emission targets set by the current Government and should make efforts to open its energy market to European and other companies willing to invest in the market with technology, expertise and finance. Although the RPS Law was intended to promote renewable energy in Japan, and deregulation of the electricity market was intended to promote new entrants, when compared to European energy markets, there are still a number of significant regulatory hurdles that prohibit free market access and implementation of renewable energy. For example: the minimum amount of renewable energy in each energy producer's portfolio is set at only 1.35% according to the RPS Law, and the penalty for not reaching this target is very small (3 million yen). There is, therefore, very little incentive for the power companies to promote renewable energy sources. Furthermore, the grid access regulations and marginal regional transmission capacity prohibit market access for independent power producers (IPPs). The feed-in tariffs (FIT) for renewable energy are not technology-indifferent, but largely skewed, towards photovoltaic energy rather than wind energy, for example.

In view of the above, it is important that the regulations are structured, worded and applied in ways that facilitate application of new technology and solutions, thereby also stimulating and enabling further innovation. Laws and regulations should set targets and parameters, and assign responsibilities, with which relevant industries and industry participants have to comply. However, if the regulations specify in too much detail what particular technologies or processes should be used, or the regulations are applied too rigidly, new technologies and solutions may be restricted or their use even prevented if and when available. The 'Packaging Waste Management Law', first implemented in 1997, is one example of the latter type of regulation.

A lack of environmental standards in a number of areas - or if they exist, a lack of clarity - is also an impediment to many European companies offering innovative and high quality environmental technology and products. For example, a number of voluntary and often unregulated environmental labelling schemes exist, frequently created by one or a few companies on their own. Such schemes may denote a given product or process as "environmentally friendly", or as an "Eco Product" and the like, without any basis in a clear, defined and commonly recognised standard. This makes it difficult, if not impossible, for consumers and industrial buyers alike to verify the claims that products and services are "Eco-friendly" and to compare products and solutions from different providers in terms of their environmental impact.

The EBC believes that further harmonisation and cooperation should be part of an Economic Integration Agreement (EIA) between the EU and Japan. This will not only benefit the environment, but will also give companies of the two regions mutual access to new technologies and new research.

Key Issues and Recommendations

■ Environmental standards

Yearly status report: new issue. The EBC strongly encourages the Japanese authorities to focus more attention and efforts on ensuring that clear and robust environmental standards are introduced, especially for products and services relevant to important areas such as energy efficiency, renewable energy, and greenhouse gas emissions. It will be in Japan's best interest to align these as much as possible with applicable international standards.

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.

■ Alternative energy

Yearly status report: no progress. The EBC believes that Japan will benefit from opening its energy market to new entrants from Europe and encourages the Japanese Government to rationalise its regulatory environment to promote innovation, competition and efficiency. The current standards and regulations for constructing and operating wind farms in Japan are very complex compared to best practice in Europe. The EBC feels that in order to realise the target announced by former Prime Minister Hatoyama of achieving 10,000-MW wind energy in Japan by 2020 (of which three-quarters is to be derived offshore), the regulatory regime for wind energy should be substantially simplified and harmonised with existing International (IEC) regulations. Indeed, one of the aims of a new technical committee (TC88/MT22-J), established under the umbrella of the "Japan Electrical Manufacturers' Association" (JEMA), is to achieve internationally harmonised procedures. The EBC believes that this is necessary in order to attract European wind energy firms to Japan and also to enable Japanese engineering companies and wind farm developers to enter the European markets where these international regulations and standards already apply.

Recommendations:

- The Japanese Government should accelerate Japanese electricity market reforms to encourage IPPs. This includes: stipulating a higher renewable energy portfolio share for power utilities; unbundling the power companies into energy production, transmission and retail businesses; and increasing transmission grid access for IPPs.
- The Japanese Government should implement a "carbon pricing" system in the form of a CO₂ tax or an emission trading scheme or a combination of the two.
- The authorities should ensure technology indifference with respect to feed-in-tariffs and other subsidies to promote renewable energy sources.
- The EBC recommends harmonisation and alignment of standards and regulations with respect to new energy sources, such as wind and photovoltaic energy.

■ Packaging waste management

Yearly status report: new issue. Laws and regulations should set targets and parameters and assign responsibilities, with which relevant industries and industry participants must comply. However, if the regulations specify in too much detail what particular technologies or processes should be used, or the regulations are applied too rigidly, new technologies and solutions may be restricted or their use even prevented if and when available. The "Packaging Waste Management Law", first implemented in 1997, is one example of the latter type of regulation.

Recommendation:

- The EBC recommends that Japanese authorities follow the example of European environmental regulations and apply laws and regulations based on principles. This will encourage the development of new and enhanced technology.

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