

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 cover.

Delivering Trade Potential

The EBC Report on the Japanese Business Environment 2012

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

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The EBC Report on the Japanese Business Environment
2012

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The European (EU) Chamber of Commerce in Japan

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The European Business Council (EBC) is the trade policy arm of the 17 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents some 3,000 local European companies and individuals who are members of their national chambers of commerce. Around 400 company executives participate directly in the EBC's 30 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

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

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

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Message from the Chairman

The shattering events of March 2011, when the Great East Japan earthquake and its aftermath destroyed lives and livelihoods across swathes of the country, marked a turning point for Japan, lending extraordinary poignancy and purpose to a host of initiatives to revitalise the Japanese economy. So much now depends on these initiatives. The aim of this, the 2012 annual report of the European Business Council in Japan (EBC), is to contribute our ideas for their success.

It should be said that, even before March 2011, Japan faced significant challenges. For years, its economy dipped in and out of recession. Competition in its traditional markets was intensifying, just as its shrinking and ageing population placed increasing strains on public finances. Then in 2008 came the global financial crisis, leading to a collapse in demand for exports, made worse by a surge in the value of the yen, with domestic demand proving too weak to take up the slack. Against this background, it was very clear that a new approach was needed.

The announcement of a new Growth Strategy was a welcome sign that the Government was serious about changing direction. Reinforced by the work of the Cabinet's Revitalisation Unit, it provides a roadmap not only for reconstructing areas affected by the March 2011 disaster but also for boosting the entire economy, with clear priorities for reform and investment.

The Growth Strategy recognises the crucial role to be played by international trade and by policies that promote high-level economic partnerships between countries. The EBC shares this view. We are convinced that opening up trade and attracting more foreign capital will be crucial to Japan's future prosperity. Without doubt, this will require considerable improvement to the regulatory environment, which continues to be plagued with unclear administrative practices, unique Japanese standards, and protracted product approval and certification processes. This report includes multiple examples of such barriers to trade. We believe that removing them would promote the inflow of foreign direct investment, enriching the Japanese economy with new products and business approaches, as well creating new jobs. It would also be invaluable in stimulating domestic companies to become more innovative and competitive in global markets.

Accordingly, we were delighted that the EU-Japan Summit in May 2011 resolved "to deepen bilateral relations from a comprehensive and long-term perspective" and to launch a process that has ultimately paved the way for "a deep and comprehensive Free Trade Agreement (FTA)/Economic Partnership Agreement (EPA)". On November 29, 2012, the European Council took the historic step of approving the start of negotiations for an EU-Japan FTA/EPA. For forty years, the EBC has been calling on the EU and Japan to improve their mutual trade environment yet, until now, the opportunity had never been grasped. Every attempt at achieving a step change in EU-Japan trade, through dialogue, meetings and Summits, had met with failure. The impact of such failure was felt throughout business, not just by companies struggling to expand into overseas markets or finding promising opportunities strangled by red tape, but also by the many companies deterred from even trying. The news that leaders of the EU and Japan have finally changed all that is not just welcome – it makes sense.

The EBC has much to offer to the debate on how to take Japan forward. Following our detailed input to the EU-Japan Scoping exercise in 2011 in preparation for the FTA/EPA negotiations, our 2012 report pinpoints key areas where we believe reform is most urgently needed and makes priority recommendations for change. Many reforms simply require unilateral action by a determined Government, while others call for international cooperation and would greatly benefit from the framework of an EU-Japan FTA/EPA. The conclusion is clear: Japan's future prosperity depends on its ability to thrive in the global economy. Now is the time to deliver trade potential.

Duco Delgorge
Chairman, European Business Council in Japan
(President, MIE PROJECT Co., Ltd.)

Message from the Executive Director

The European Business Council in Japan (EBC) is pleased to present its 2012 Report on the Japanese business environment: *Delivering Trade Potential*.



This report appears at a time when Japan is still recovering from the tragedy of March 2011 and struggling to return to economic growth in the wake of the global financial crisis. Moreover, the country is facing fierce competition in export markets and increasing pressure on public finance, exposing fundamental weaknesses in many business sectors. For forty years, the European Business Council in Japan (EBC) has been urging successive Japanese Governments to address such weaknesses, not simply to help European firms here, but Japanese firms as well. Continuing low levels of foreign direct investment damage Japan's competitiveness. Domestic companies remain unchallenged, with little incentive to increase productivity and poor prospects for growth. The Japanese economy misses out on fresh ideas, capital and jobs. Customers miss out on innovative products. And in some cases, patients may even miss out on new, life-saving treatments.

Our aim in this report is to identify issues that, in the view of European business in Japan, hold back prospects for economic revival, and to make practical recommendations on how such issues should be addressed. A key focus is the role of regulation in determining the business climate and we highlight the benefits of bringing domestic rules into line with international norms, not simply to help European firms to trade with Japan, but also to help Japanese firms trade with the world. The negotiations towards an EU-Japan FTA/EPA will significantly increase the prospect of successfully resolving these issues as well as putting Japan and the EU on course for sustained economic growth.

The recommendations in this report are 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 based on inputs from the EBC's sectoral Committees and reflect their considerable knowledge and experience of operating businesses both in Japan and other markets. We are indebted to them for their valued expertise, as well as to our Committee Chairmen, many member companies, and key stakeholders - the European National Chambers of Commerce and other business organisations represented in Japan. The final document is a tribute to the commitment of the EBC Policy Director, Bjorn Kongstad, in collecting, coordinating and combining their myriad inputs.

On behalf of the EBC, I would also like to thank the Delegation of the European Union to Japan and the European national embassies in Tokyo for their continued support for the work of the EBC. Last but by no means least, I am grateful to all the 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 that the EBC report could make a significant contribution to the Japanese Government's work to find solutions to Japan's economic challenges. EBC members have Japan as the base of their business and are employing Japanese people. They constitute a crucial part of the Japanese market and work hard to encourage their respective headquarters to continuously engage and invest in Japan. Their personal commitment to Japan is strong and their recommendations sincere.

The EBC remains convinced that improving market access in Japan will lead to new opportunities for business growth, increased employment and prosperity for all. Our report offers a wealth of ideas on how to achieve this. We therefore commend the report to all our readers and look forward to opportunities to discuss our recommendations in further detail.

Alison Murray
Executive Director
European Business Council in Japan

Introduction



INTRODUCTION

Two eventful years have passed since the publication of the last EBC report on the business environment in Japan. During that time, the country has experienced one of its worst ever natural (and manmade) disasters, one more Prime Minister has come and gone, we have seen a consistent trade deficit (2.5 trillion yen in 2011), and major strategies have been launched to put the economy on a new course. So setting the scene for this new EBC report is quite a challenge, although the real question is not what has happened, but has anything really changed?

At a political level, there are certainly some new faces in Government. While the Democratic Party of Japan has now been in overall power since August 2009, the premiership of Naoto Kan (June 2010 – September 2011) was succeeded by that of Yoshihiko Noda. Prime Minister Noda had the unenviable task of trying to steer Japan through a period of intense debate and disagreement over economic and foreign policy and finally decided to put his leadership to the vote. As this report goes to press, the country is gearing up for a December general election. However, no matter who wins in December, the main challenges will remain the same.

The Tohoku disaster in March 2011 gave massive impetus to the Government's efforts to revive Japan's stagnant economy, a challenge that has remained unsolved for many years. The Cabinet Office estimated the cost of the physical damage alone to be close to 17 trillion yen. On top of that, many companies discovered they were completely dependent on suppliers located in the Tohoku region and had insufficient inventory to continue production. Exports and consumer confidence fell, not helped by concerns that products may be contaminated by radiation. Meanwhile, the shutdown of the Fukushima I Nuclear Power Plant led to power shortages so industry and homes alike endured power cuts. One very striking lesson from the disaster was that Japan needed to re-think its energy policy as all Japanese reactors were taken out of action for urgent safety checks, and even now only a handful are back up and running. The absence of nuclear power has increased costs for energy producers, forced to seek alternative supplies – costs that have been passed on to customers, both industrial and domestic.

The Government's Growth Strategy has a strong outward focus, aiming to promote Japan as Asia's regional business hub and to re-launch existing programmes encouraging inward investment. Even more significantly, it envisages high-level economic partnerships between Japan and major trade partners such as China and South Korea, and may lead to Japan joining the TransPacific Partnership agreement (albeit a politically divisive issue) and signing a Free Trade Agreement with the European Union. The strategy is clearly ambitious and a special Governmental Revitalisation Unit (GRU) has been established to oversee its translation into reality. The Unit sits within the Cabinet Office and the Cabinet itself signs off each new initiative before it is sent to the relevant Ministry for implementation. The strength of this approach is that it throws the Cabinet's weight behind each reform, something that hopefully will help it to overcome the notoriously independent-minded ministries.

From an EBC perspective, the GRU report was a welcome initiative and we watch the roll-out of each element with intense interest and in the hope that, this time, Japan will really change for the better. As this report reveals, EBC members have themselves identified numerous reforms that would improve the current environment for doing business and so lead to higher growth. Some important advances slated for action in the GRU report and others already implemented in areas where we had previously called for action include:

- Further harmonisation of regulations governing the approval of vehicles
- Expansion of the product scope for self-verification in the telecommunications equipment sector.
- A new 5-year-plan for medical innovation, intended to deliver a more efficient environment for clinical trials, an improved safety review process and more adequate recognition of innovation.
- Approval of a series of new, innovative vaccines, long available in other industrialised countries.
- Faster approval of food additives
- Revising of the zoning law deciding which areas can be used for large scale retailing.
- Faster examination of new healthcare products for possible sale in Japan, through increases in professional resources at the Pharmaceuticals and Medical Devices Agency.



- Removal of unnecessary restrictions on Wholesale Liquor Licensing.
- A first step towards public tendering for railway-related projects in the form of a call from JR East for a signalling system in Japan.
- Introduction of a Feed-In Tariff scheme to encourage investment in renewable energy, requiring utilities to buy power from solar, wind, geothermal, hydropower and biomass sources at a fixed tariff.
- Changes to the re-entry permit system, to remove unnecessary bureaucracy and obstacles to the successful immigration of foreign professionals.

Although these advances represent a step in the right direction, the EBC believes that the overall scope and pace of change is insufficient to address and reverse the weaknesses in the Japanese economy. To this end, the major themes underlying the EBC's 2012 report call for Japan to introduce the following changes:

- Closer collaboration with EU authorities towards mutual recognition of standards, product certifications and marketing authorisations, and adoption of international standards – for example in the medical equipment, passenger cars, environmental technology, retail and food sectors;
- Lifting of barriers such as high costs and unnecessary bureaucracy that prevent or delay products from reaching the market - for example, by eliminating tariffs in the food sector; streamlining procedures for the import of organic foods; and removing Japan-only product labelling requirements;
- Increased vigilance to ensure fair competition and the fair and equal treatment of all companies, domestic and foreign – for example, by removing regulatory and fiscal privileges for *kei* cars; by improving the access granted to European airlines at Haneda Airport; by ensuring that the bail-out of JAL does not lead to unfair competitive advantage; and by ensuring a level playing field for all competitors of Japan Post;
- More fair and open competition in services - for example, by improving network access for foreign telecoms carriers and in the tendering of public procurement contracts, such as in the defence and construction sectors;
- Improved conditions for foreign direct investment – for example in the banking and asset management sectors, by removing requirements unique to Japan and incompatible with global organisational structures;
- Enhanced incentives for investment in R&D – for example, through reimbursement schemes in the healthcare sector that both recognise and reward innovation.

The individual sections of this report offer further sector-specific details and more precise recommendations for action that could bring about the real change in the economy that Japan now seeks. They also highlight areas that might best be addressed in the negotiations towards the EU-Japan Free Trade Agreement/Economic Partnership Agreement. The possibility of such an agreement was raised at the EU-Japan Summit of May 2011. Since then, a Scoping Exercise, to which the EBC contributed a detailed set of recommendations, identified the range and type of issues to be tackled in the negotiations and the outcome each side would seek. On this basis, the European Commission recommended that negotiations should be opened and the matter was taken to the European Council, which took the historic decision on November 29, 2012 to approve the start of the trade negotiations. The EBC will make every effort to ensure that its members' interests will be addressed in the FTA/EPA. It is clear that there is a huge amount of untapped potential in the EU-Japan trade relationship and neither side can afford to forego the prospect this agreement will offer of greater prosperity and economic stability. It is for this reason that we have called this report "Delivering Trade Potential".

How this report is organised

This introduction, prepared by the EBC's Policy Director, introduces some of the main factors identified by the EBC as influencing the current business environment in Japan. It also offers an overview of the key themes of this report. The introduction is followed by 31 chapters, each addressing the concerns of a specific EBC sector committee. These chapters are written by the committee members, based on their insights and benefitting from their extensive first-hand experience in operating businesses in Japan, combined with deep personal knowledge of European and other markets. The chapters summarise issues and developments impacting their sector over the past year, followed by a series of recommendations for further regulatory reform.

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. Several forecasts suggest that the population of Japan will be halved by 2050. Although we are still far from such a situation, we are already seeing signs of an ever-decreasing working population. The EBC sees only four ways to combat this decline: increasing productivity, introducing more women into the labour force, increasing the birth rate and/or increasing the number of immigrants. The EBC believes that policies in all four areas are needed to retain a skilled and competitive workforce.

Of highest priority is the desperate need to motivate and facilitate the return of Japan's female population 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 remain unwilling to enter the workforce because they feel unable to commit to becoming a regular employee (*seishain*). This can only be described as a waste of available resources.

In July 2012, the Alien Registration Law was abolished through a merger with the Immigration Control Act, bringing the control of all immigration information together under the Immigration Bureau of the Ministry of Justice (MoJ). The EBC commends the MoJ and the Japanese Government on the changes, which generally benefit the greater foreign population of Japan. The new system, especially the change to the re-entry permit system, has improved the attractiveness of Japan for foreign professionals. Although the system has only been in place for a short period of time, and the EBC has received some reports of confusion, we believe that a major step forward has been taken. It is essential that continued improvements are made to immigration policy if Japan is to compete on the global market.

Revisions to labour laws over recent years have been successful in creating greater flexibility in terms of working hours, compensation, pension schemes and contracts for employees, 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. From 2013, the Japanese Government will be introducing legislation that places part-timers and contracted employees, who have worked for 5 years or more for the same company, on an equal footing with full-time *seishain* employees. For employees such changes are encouraging, but the continued strengthening of employee protection weighs heavily on the competitiveness of Japanese companies, limiting their ability to control labour costs and make changes when the economic, political or social situation demands adjustment. Furthermore, the Worker Dispatching Act is also earmarked for change to protect workers from being expelled from their jobs by their temporary worker dispatch agencies during economic downturns. If implemented, this will leave companies with very little flexibility in terms of managing their workforce of skilled labour. Such a situation would likely demotivate companies from entering into new employment contracts, which will not assist in motivating female participation in the Japanese workforce, nor help with the increasing unemployment rate of new graduates.

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 expatriate workers leaving Japan to be expanded from the current amount, which is limited to the last three years of premium payments. 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, Hungary and Sweden. The Government of Japan should act quickly to conclude social security agreements with all remaining EU Member States as well as with Norway and Iceland. The comprehensive FTA/EPA 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 visas and work permit requirements between the EU and Japan with a view to creating a more integrated labour market extending to both regions.

Key Issues and Recommendations

■ Immigration, re-entry permits and the new “Resident Card”

Yearly status report: good progress. The merging of the Immigration Control Act and the Alien Registration Law, and the introduction of the “Resident Card” were passed by Parliament in July 2009, and the new system entered into force on 9 July 2012. There are still some glitches to be resolved, but the EBC applauds the Government for its work and views this development as an exemplary case demonstrating how policies can be improved.

Recommendations:

- Acknowledge the inconvenience of regular trips to Immigration Bureau Offices due to their limited locations and implement application systems that allow changes to “Resident Card” details to be made on-line and by post.
- Eliminate the re-entry permit system entirely.
- Further revise immigration policy to encourage the entry of skilled labour to Japan. For example, many visa categories require a minimum of ten years’ experience in “the industry” in the absence of a university degree. Such policies cause skilled labour, for which sufficient experience can often be gained in less than five years, to by-pass Japan for other developed or developing nations with less stringent requirements.
- Automatically grant work permits to spouse visa holders so that multinational companies can attract the best talent to postings in Japan.

■ Work place diversity

Yearly status report: no progress. Japan’s future prosperity depends greatly on maintaining a workforce sufficient to support its ageing population and drive its economy. By far the easiest way to increase the working population would be to increase female participation. 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 household and child-rearing activities.

Recommendations:

- Remove the “spouse special income tax credit (*haigusha-tokubetsu-kojo*)” which 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 to ensure sufficient child-care facilities, systems and staffing to support female participation in the workforce and male participation in the home.
- Introduce employment legislation that encourages the creation of a competitive workforce based upon performance and not on long-term employment. Adequate protection of employees is required, but employers also need a legal framework within which to remove non-performing workers.

■ 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, Hungary and Sweden. Japan is also contemplating agreements with Slovakia and Austria. For the nationals of countries without an agreement, refunds of mandatory contributions to Japanese pension plans remain capped at a maximum of three years.

Recommendations:

- Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers. Additionally, benefits should be paid out 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 and EU Members States should swiftly conclude mutual social security agreements.

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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 trade in counterfeit goods. Most fake products entering and circulating in Japan are nowadays sold through Internet websites. The problem stems from Japan's legal system, which regrettably allows the import of fake goods as long as they are for personal use. Accordingly, there is an inflow of counterfeit sales through mid-sized auction websites based overseas, which are outside Japanese jurisdiction and targeted at Japanese people. Moreover, although major auction websites or shopping malls can easily remove obvious counterfeit products, their removal is more difficult when the information on the screen provides no prima facie evidence of infringement. It is thought that over 20% of goods sold in this way as well-known brands are in fact counterfeit.

In the last few years, the Japanese authorities have started to more pro-actively counteract violations of intellectual property rights. Reform of the Act on Specified Commercial Transactions has resulted in improvements. This measure aims to strengthen control of the identity of vendors on Internet auction sites by compelling them to furnish their complete identity data when selling twenty or more luxury brand goods. If a vendor does not comply with this obligation, the Ministry of Economy, Trade and Industry (METI) may demand that the relevant vendor is banned from selling goods on the auction website. This is an effective tool, but its potential will only be realised if it is used more systematically. Furthermore, in 2007 it became possible under the Customs Act for rights holders to request that an image of a suspect product be sent to them by e-mail for checking, rather than their being required to visit the Custom Offices to check the product in person, as was previously the rule. Moreover, the maximum limit of ten products imposed on suspect items for sending information by e-mail, much criticised by rights holders, has been removed.

However, notwithstanding important legal improvements and encouraging results following intensified surveillance over the past few years, crucial issues remain unresolved. The EBC believes that the Japanese authorities should seriously look for solutions to deal with outstanding issues, such as the very high number of counterfeit goods of which only a relatively small percentage are being handled by the Japanese Customs Authorities every year. In 2011, Japanese Customs seized 567,107 counterfeit products, representing just the tip of the iceberg, as not all of imported products are effectively checked by Customs, showing that additional resources should be allocated.

Major auction websites such as Yahoo! Japan, Rakuten and DeNa play an important role through their management in the fight against counterfeit goods. Yahoo! Japan has, for example, built a system using 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 rights holders' associations. Rakuten and DeNa are also making a greater effort to raise their corporate standards. Whenever major auction websites identify counterfeit goods from the information on their screens, they remove them, resulting in a ratio of counterfeit items to genuine goods of approximately 1%. These companies have also strengthened their controls and anyone who has ever offered a counterfeit product for sale is banned and unable to acquire a new registration ID.

Hence, in terms of removal of 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 Japanese regulations still prove inadequate in terms of prohibiting all types of trademark violation. This is demonstrated by the absence of prohibition of the import of counterfeit goods for "personal use", together with the persistent acceptance of parallel imports, which imply inadequate border control of importation and facilitate the entrance of fake goods into Japanese territory. The Japanese police and prosecutors face, moreover, tremendous difficulties in proving that an importer is aware that the distributed goods are fake, which currently is a prerequisite for taking action. This difficulty in proving awareness allows some importers to continue importing counterfeits unpunished.

The Intellectual Property Rights Committee believes that the EU-Japan negotiations towards an FTA/EPA should cover IPR in order 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 type of sale by strengthening measures against repeat counterfeiters, such as increasing surveillance and removing fake items on the basis of information provided by rights holders. However, the scope of the Act on Specified Commercial Transactions is too limited, hence enforcement 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 wider in scope and more systematically enforced and the system of corporate guidance and coordination between auction websites should be strengthened.
- The Japanese Government is encouraged to urgently seek closer cooperation with overseas authorities on the shutting down of websites offering counterfeit goods aimed at the Japanese market.

■ 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 abandoned the counterfeit goods they had ordered upon receiving such a letter, but the efficiency of the system is gradually being eroded with an increasing number of importers becoming aware that the goods can be imported under the guise of “for personal use” and that these letters are non-binding.

Recommendations:

- The Trademark Law should be revised 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.
- Alternatively, improvements could be made by requiring the importer, whoever he/she is, to prove conclusively that it is an import for personal use.

■ 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 level of protection enjoyed in Europe and most other markets.

Recommendations:

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

Mr. Francesco Formiconi

Chair, Retail & Wholesale Committee

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RETAIL & WHOLESALE

Introduction

The Japanese retail market is one of the largest and most vibrant in the world. After many years during which the presence of European retailers was more or less limited to the luxury sector, the last five to six years have seen the rapid establishment of new European retailers in Japan, both in fast fashion and home interiors. Their success clearly benefits Japanese consumers by offering greater choice, often better prices and, frequently, 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 helps to revitalise many cities that were previously in a dire condition. Japanese retailers and wholesalers gain from the presence of European competition as it provides incentives to further strengthen their global competitive edge. Very concrete examples of this are Uniqlo and Nitori, which are today stronger than ever.

Despite recent successes, European wholesalers and retailers still face considerable barriers in the Japanese market. Firstly, while there has been 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. Secondly, the process of developing and opening new retail outlets remains fraught with restrictions, inefficiencies and delays. Thirdly, although the EBC Retail & Wholesale Committee understands and shares the Government of Japan's concerns regarding consumer protection, it believes that European rules more than adequately address these same concerns, ensuring safe and good-quality products. Hence, applying Japan's rules and regulations to products that have already met European standards serves only to create barriers to trade. Examples of such barriers are Japan's unique labelling rules, inflexible food sanitation rules that are not related to the safety standards themselves, and non-recognition of global standards or European approvals. These barriers are particularly damaging to companies with a global supply chain. Moreover, 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 problem affects several areas, as described in the recommendations that follow.

Japan is vigorous in enforcing copyright, trademark, and other intellectual property laws and regulations. Japan Customs is screening and stopping many counterfeit items at the border, but as indicated in the IPR section of this report, much more could be done in this regard. Japan has also adopted some of the world's most lenient rules and regulations pertaining to the import and distribution of 'grey market' goods (i.e. genuine goods authorised for sale and distribution outside Japan but whose distribution within Japan has not been authorised by an intellectual property owner or other responsible party). This permissive attitude toward grey market items creates confusion among authorised Japanese distributors, wholesalers and retailers adding an unnecessary challenge to brand management and marketing. Importantly, many importers of grey market items manage to side-step safety testing requirements, thus at times endangering the Japanese consumer.

However, not all is doom and gloom in this sector. The EU-Japan Scoping Exercise and the Japanese Governmental Revitalisation Unit (GRU) have highlighted a number of issues for fast-track reform. The EBC is optimistic that the issue of Wholesale Liquor Licensing might, after many years of discussion, be resolved by end 2012. The GRU also has in its sights the matter of the City Planning Law relating to large-scale retailing, which has made it more difficult for large retailers to procure land for the establishment of large shops. Although the latter issue is not at the time of printing completely resolved, the EBC applauds the progress made so far and will continue to monitor developments closely.

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 & Wholesale Committee believes that the EU and Japan should swiftly move through the FTA/EPA to establish mutual acceptance of standards and certification, which will benefit companies in both markets.

Key Issues and Recommendations

■ 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. The EBC, while understanding the need to ensure the safety of the consumer, specifically requests the Japanese Government to revise its legislation applying to products with food contact and the related import system to facilitate smoother trade. Products covered by the Food Sanitation Law can only be tested in either the country of exportation or in Japan, an unnecessary restriction that serves no safety purpose.

Recommendations:

- Japan and the EU should mutually accept regulations governing the application process for importing and selling/using products to lessen the need for re-testing.
- Japan should enable “food contact” products to be tested in any laboratory approved by the Japanese Government regardless of the country of export.

■ Labelling of household products

Yearly status report: some progress. The Household Goods Quality Labelling Act regulates how household goods within the scope of the Act are labelled. The legislation requires 90 specified product categories, grouped into four areas (textile goods, plastic manufactured goods, electric appliances and miscellaneous manufactured goods), to be labelled with information defined by the Act. The EBC welcomes the Consumer Affairs Agency’s (CAA) recent activities considering possible amendment of the law. The CAA plans a two-step process: short-term revision of the Act within its current framework, and a longer-term revision of the framework itself. However, the EBC believes this process lacks a sufficiently comprehensive approach.

Recommendation:

- The long-term revision should focus on aligning the information required to the actual product. The CAA should take the needs of global companies supplying markets all over the world into better consideration. This will, without hurting the Japanese consumer, also be beneficial to Japanese companies operating in foreign markets.

■ Shoe quota

Yearly status report: new issue. Various shoe tariff lines are covered by quotas. By means of these quotas, imported shoes can benefit from a lower tariff. The allocation is partially based upon historical import figures while part of the total volume is dedicated to “newcomers”. The major problem with the current system is the lack of transparency and that companies not truly involved in the shoe business retain quotas, which they “sell” to other companies. This behavior is illegal, but still persists.

Recommendation:

- The Ministry of Economy, Trade and Industry (METI) should improve monitoring of the situation to turn down applications from entities that are not properly trading shoes and to release their quotas. It is further recommended that METI should implement stricter penalties for companies taking advantage of the system.

■ Superior bargaining power

Yearly status report: new issue. The Antimonopoly Act (AMA) contains legislation covering the abuse of a superior bargaining position to protect weaker companies (often SMEs) and penalise larger companies that force other entities to agree to undesirable action. This is an issue for both domestic and foreign companies. Unfortunately, it is difficult to comply with the legislation, which is vague, and the Japan Fair Trade Commission (JFTC), in its eagerness to protect weaker companies, is contradicting business practices that are common in Europe and the United States, especially on the issue of shared loss-taking.

Recommendation:

- The EBC requests that the AMA is amended to take global business practices into better consideration. While the EBC fully understands the background to the legislation - to protect a weaker company from being forced into taking undesirable action - we request that the AMA be changed to allow shared loss, where both parties are in agreement on the issue.

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LEGAL SERVICES

Introduction

After a gap of one year when both the Japanese and EU authorities were focused on the Scoping Exercise for the EU-Japan FTA/EPA, we return to the White Paper. This is unfortunately against a background when not much has changed in the field of Legal Services since the White Paper of two years ago – in fact if anything, things have gone backwards.

Two years ago, there were positive developments to report, even if of a limited kind. There had been moves by the Ministry of Justice (MoJ) to streamline the application process, and a report of the Foreign Lawyers System Study Group, set up to consider the ability of foreign lawyers to establish *bengoshi hojin* (corporations) and thereby operate in Japan through more than one branch, had adopted the more liberal of the regimes under discussion. This latter point addressed an issue identified a number of years ago by the EBC as involving clearly discriminatory treatment for foreign lawyers, though it had not been among the main issues troubling foreign lawyers, which continue to be the time required for registration and the three-year experience rule.

Since then, an attempt by the Japan Federation of Bar Associations (*Nichibenren*) to reverse the Ministry's streamlining efforts appears to have been unsuccessful. However the legislation relating to *bengoshi hojin* has been opposed by the Association of Japanese Patent Attorneys (*benrishikai*) for no obvious reason, and it seems that the relevant legislation, when enacted, will permit law firms in Japan comprised entirely of foreign lawyers to establish a corporation and so open a branch, but those comprised of both foreign and Japanese lawyers will not be able to do so. This distinction has no rational basis, and will reduce the already limited usefulness of the new measures.

From a broader perspective, the 25th anniversary of the foreign lawyer (*gaiben*) law coming into effect offers an opportunity to consider how this legislation might be developed better to fit the types of law firms now establishing themselves in Japan and to take account of the way the *gaiben* registration system has developed to date. This would solve most of the issues on which it seems that otherwise no progress will be made in the short term. Moreover, the fact that many Japanese firms are dealing with downturns in work levels, following the global financial crisis and the reduction of foreign investment into Japan, makes it even more important for the Japanese authorities to liberalise the legal services market to avoid further recession in the sector.

One way forward would be to include the legal services sector in the negotiations on an FTA/EPA. The EBC Legal Services Committee believes this would benefit both foreign companies as well as Japanese legal firms with 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.

EBC Legal Services Committee Member Companies

Allen & Overy	Herbert Smith Freehills
ARQIS Foreign Law Office	Hogan Lovells
Ashurst	Linklaters
Baker & McKenzie	Norton Rose
Clifford Chance Law Office	Sonderhoff & Einsel Law and Patent Office
Cotty Vivant Marchisio & Lauzeral	Squire, Sanders & Dempsey L.L.P.
Freshfields Bruckhaus Deringer	White & Case LLP

Key Issues and Recommendations

■ Recognition and approval as a foreign lawyer in Japan

Yearly status report: questionable progress. In order to become registered as a *gaiben* 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 home jurisdiction law, not where it is practiced. The procedure for admitting foreign lawyers as *gaiben* also still imposes undue costs on foreign firms and individuals. A streamlined application form has, in general, shortened the process, but the requirements for approvals from both the MoJ and committees at the *Nichibenren* and local bar associations inevitably give rise to delays.

After 25 years of operation, the *gaiben* system is in need of a thorough overhaul. Changes in the system could solve a number of the current frustrations.

Recommendations:

- The rule requiring a specific number of post-qualification years of experience should be abolished. As an immediate first step, while a more thorough overhaul is completed, the legislation should be amended such that all, 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: no progress – backward movement. 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*.

In December 2009 the final report of the Foreign Lawyers System Study Group was published. This committee recommended that *gaiben* should be able to establish corporations with other *gaiben*, and also with *bengoshi*. Draft legislation was introduced to implement the report: however it has been opposed in the Diet and revised so that *gaiben* will now not be able to establish a corporation with *bengoshi*. This may limit its usefulness still further.

Recommendation:

- The proposed legislation should be amended to its original status and enacted as soon as possible. An even 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. The EBC continues to recommend the introduction of a limited liability structure for lawyers in Japan, for the benefit not only of foreign but also Japanese lawyers. It has been considered fair to permit professionals in many other parts of the world to take advantage of these structures. For foreign lawyers, this could be achieved by permitting them to operate through a branch of their home entity, rather than as separate individuals, which only an overhaul of the existing system could achieve.

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

In an increasingly globalised world of dwindling natural resources and escalating social tensions, the appeal launched in the 1987 report of the Brundtland Commission (the World Commission on Environment and Development 1987 appeal to balance the needs of the present with those of future generations appears to be an ever more daunting challenge. Harnessing the innovative potential of business across all industries to address the issues of sustainable development and climate change is imperative for the survival of the broader system that enables life and business as we know it.

The EBC Sustainable Development Committee reflects the commitment of European companies to contribute to sustainable development and aims to facilitate their access to the Japanese market. This includes efforts to remove any trade or investment barriers that may block such progress. 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 in Japan remains far short of what is required, if the country is to meet its environmental targets.

While Japan has tended to focus on environmental technology and innovation, business practices and consumer behaviour have not followed this lead with the same sense of urgency. The continued use of excessive packaging, which in the rest of the world is proactively discouraged, is one of the most visible examples of this. As far as construction is concerned, Japan's environmental requirements tend to be 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 technologies and materials are adopted and implemented.

Japan is lagging behind 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 offer some of the best solutions on the market, but increased efforts are needed to reduce 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, if Japan is to reach its environmental goals, it will need to demonstrate a dramatic acceleration of progress in all the areas indicated above. The EU-Japan FTA/EPA will create a key vehicle for further cooperation and coordination in the area of sustainable development.

Key Issues and Recommendations

■ Improved sustainable development awareness and behaviour

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

Recommendations:

- The Government should raise public awareness regarding the benefits of sustainable development. The EBC believes that this will 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 the EU-Japan FTA/EPA.

■ 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. This situation is clearly undesirable from both an environmental and consumer perspective. 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 remove the need for supplementary organic certificates from EU Embassies for organic food that requires Organic-JAS Mark labelling in Japan as part of the FTA/EPA 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 (since organic food already carries a price premium, tariffs only serve to make such food exorbitantly expensive, thereby discouraging their purchase by consumers and growth of the organic food sector).
- 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 an incentive system to make sustainable and green buildings more attractive to construction companies and consumers.
- 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 stimulation given to the Japanese economy by reducing the corporate tax rate to 38% as of April 2012 and 35% as of 2015, thus bringing the rate closer to international levels. This will improve the competitiveness of Japan for the benefit of both Japanese and foreign companies. The magnitude of the challenges still ahead for the Government, however, cannot be exaggerated. The uncertain outlook of the world economy, in combination with the Japanese public's lack of confidence in their social welfare system, is suppressing consumption below already low levels. Increasing the consumption tax in steps to 8% and then 10% in April 2014 and April 2015, respectively, should help to restore the finances of and confidence in the social welfare system at least.

Aware of the severe fiscal constraints the Japanese Government is facing, the EBC's recommendations address the fact that insufficient transparency and predictability in tax rules create uncertainty and lead to lower investment and economic activity. We believe that addressing transparency issues thoroughly and 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 - hence tax revenue would remain the same. Unfortunately, attempts made so far by the Government of Japan to improve the transparency and predictability of the tax regime have been inadequate and, as a result, the situation has not substantially changed. Improvements made to the formal tax ruling system, *Bunsho Kaito*, did not lead to a significantly higher number of tax rulings. While the EBC is pleased to see that some progress has been made regarding secret comparables in transfer pricing, we are disappointed to note that confidential taxpayer information is still leaked and that the press is still reporting on ongoing tax audits, making references to sources within the tax authorities. The EBC recommends that the Government reviews recent changes in the way in which the relationship between taxpayer and tax inspector is organised in European jurisdictions like The Netherlands and the UK and how these changes have improved transparency, reliability and predictability for the taxpayer and the tax administration alike.

When considering how to boost bilateral trade and investment, the EU and Japan should strive to mutually eliminate double taxation and withholding tax on dividends, royalties and interest, as provided for in tax treaties concluded between Japan and the UK, France, The Netherlands, Switzerland and the US. The EU-Japan FTA/EPA 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 FTA/EPA should also provide for a mandatory arbitration clause to ensure that double taxation will effectively be solved between Japan and the individual EU Member States if the tax treaty text itself does not avoid double taxation in effect.

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

Key Issues and Recommendations

■ Research and Development Tax Incentives

Yearly status report: progress. The EBC is pleased to note that recent and planned tax reforms continue to include R&D tax incentives. Nevertheless, overseas investors are discriminated against by the Japanese R&D tax incentive regime. While Japanese rules give tax consideration to R&D expenses incurred by Japanese multinational enterprises even when undertaken overseas, no credit is given to foreign investors conducting R&D in Japan, unless the related expenses are borne locally. This discrepancy is due mainly to the focus of the tax rules on Japanese domestic enterprises that naturally take the cost of R&D at the level of their Japanese headquarters, a practice that is not very common among foreign subsidiaries in Japan.

Recommendation:

- Research and Development conducted in Japan by a foreign investor should be eligible for tax benefits here, even when the associated expenses are not borne by the investor's Japanese subsidiary.

■ 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 in the domestic tax regime 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 number of tax audits on which information has leaked is unprecedented in comparison to any EU Member State. The press often makes reference in news articles on such audits to sources within 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 and providing transparency and certainty is vital for investors to be willing to invest and for governments to collect the applicable revenues and maintain the tax base in the most efficient way possible. To this end, the Dutch and British governments have introduced systems in their tax collection processes comprising 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. In return, the tax authorities undertake to provide timely advice and clearance regarding their position on disclosures, and to respond faster to any questions and take clear positions. Moreover, tax audits are carried out on a less frequent basis and are less detailed. The use of Horizontal Monitoring, Risk Rating, and Senior Accounting Officers offers a far more efficient way for taxpayers and tax authorities to work together. The overall approach provides certainty to the taxpayer, while maintaining the same amount of tax revenue for the government.

Recommendations:

- The tax authorities in Japan 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 ensure that the press is not given access to confidential tax audit data. The tax administration should be held accountable for secrecy duty violations, if any such leakage comes from their side.
- The Government should consider the merits of introducing a system offering 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.

■ 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 needed to facilitate foreign direct investments into Japan.

Criteria that are complex and in practice difficult to meet in tax qualified restructurings are adverse to the natural goals of foreign-affiliated and domestic companies to reduce the number of peripheral legal entities and infrastructure costs. Removing potential obstacles in administration, including tax, should therefore be the aim of tax policy makers.

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 simplified and clarified to reduce both the cost and 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 Netherlands 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

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Banking
Insurance**

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ASSET MANAGEMENT

Introduction

The professional investment management industry in Japan continues to provide important benefits to society by helping to prepare investors for their financial future. Due to the ageing of the population and to stubbornly low birth rates, the burden on social security and pension systems continues to swell. Moreover, the prolonged low interest rate environment precipitated by the global financial crisis of 2008, coupled with the continued strength of the Japanese yen vis-à-vis other major currencies, has driven public and private investment pools to seek higher returns from financial products both from within and from outside Japan. The demand for increasingly sophisticated investment expertise has continued in 2012. The importance of basic operational controls and proper oversight of fiduciary responsibilities has been reemphasised by unfortunate cases of malfeasance.

To meet the critical needs of users of investment management services, it is imperative that the Government of Japan and in particular the Financial Services Agency (FSA) continue with reform measures designed to provide the investing public with appropriate products, both new and innovative, in a flexible, user-friendly investment management framework that promotes growth and avoids hampering expansion. The EBC is therefore looking forward to the new initiative on Individual Savings Accounts. We believe that it is important for the Government of Japan to introduce a system with a sufficiently long period of tax exemption, to ensure that a broad range of investment options are allowed, and to incentivise banks and other market participants to support and give robustness to the new scheme.

The EBC continues to believe that further development of a “free, fair and global” market is the only way forward for Japan to become an international financial centre. The regulatory environment in Japan continues to impose unnecessary and costly burdens on investment management service providers, which ultimately hurts Japanese consumers. A primary example is the recent creation of yet another industry association with regulatory responsibilities, this one for companies licensed as Tier 2 entities under the Financial Instrument and Exchange Law (FIEL). This proposal flies in the face of demands to merge the existing two industry associations, the Investment Trust Association, Japan (JITA) and the Japan Securities Investment Advisers Association (JSIAA): their merger had been agreed and was to be implemented but was thwarted by a late-stage impasse brought on by the industry associations themselves. Such regulatory burdens stifle innovation and yield inefficiencies in resource allocation.

The advances made by the EU in investment management, as well as in other areas of financial services, are recognised as leading edge and, by working together, Japan and the EU can extend the benefits of these advances to the Japanese investing public. The EBC strongly recommends that the EU and Japan include such issues in the bilateral FTA/EPA.

Key Issues and Recommendations

■ 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 large shareholdings (FIEL Chapter II-3) is helpful in promoting fairness and transparency in boardroom battles between shareholders and managers. However, if an investment management company that is subject to regulatory supervision files a statement affirming no intention to actively contest, 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, which include measures to accommodate employees transferred to Japan from foreign countries, to reconcile certain differences in taxation schemes applicable to investment products, and to unify financial services regulation through the introduction of the Financial Instruments and Exchange Act (FIEA). However, many impediments remain, and the pace of change has been too slow to attract positive attention from the international community. The FSA's effort to push reform measures within its control is highly commendable, but without a holistic approach that encompasses 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.

Recommendation:

- To further promote Japan as an international financial centre, the Government should develop a more holistic plan for reform that encompasses all relevant and key functions, including tax and industry associations, in order to strengthen the competitiveness of the local financial sector and to 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.

■ Japan-version Individual Savings Accounts (J-ISAs)

Yearly status report: new issue. The EBC believes that the Government's recent approval of the Japan-version Individual Savings Account (ISA) Law, which establishes a framework for a new form of individual savings and investment account from 2014, is an important step toward encouraging savings and investment. The law's stated goal is to reverse lower savings rates among individuals and to provide an additional channel for long-term asset growth, through long-term and diversified investment in listed stocks and publicly-offered stock investment trusts. However, the new law as approved allows for investment contributions of only 1 million yen per year in the period 2014 - 2016, each such contribution being tax exempt for 10 years. As with the Japan 401k scheme, such limited contribution allowances provide limited benefit to individuals and even less incentive to the industry participants expected to administer the scheme. The FSA has proposed that the ISA law be amended to add two more years of contributions (2018 and 2019). The EBC supports the FSA's proposal and encourages the Government to avoid the mistakes of the 401k system by making adjustments to ensure that the new ISA scheme is effective.

Recommendation:

- To ensure that the new ISA scheme meets the stated goal of helping individuals grow their assets through long-term and diversified investment, the Government should amend the ISA law prior to implementation to (a) allow sufficient contribution amounts to provide material benefit to individuals, (b) make the investment period permanent, or at least of sufficient length to provide material benefit, for example, until age 65, and (c) provide for the new scheme's robustness and smooth implementation by ensuring that market participants who will administer it can benefit from scale and business opportunities.

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BANKING

Introduction

Japan's relative prosperity has decreased considerably in recent years and, although Japanese consumers have continued to save throughout this period, their return on capital has been the lowest in the industrial world. At the same time, it is obvious that Japan has weathered the latest financial crisis much better than many other countries. Japanese capital markets were strong enough to raise substantial funds during 2009 and 2010. Therefore, Japan still remains one of the largest financial markets in the world with high savings rates.

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 leadership of Prime Minister Koizumi. 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. The Japanese Government and, in particular, the Financial Services Agency (FSA) have pushed through some easing of firewalls allowing, in some cases, double-hatting of back-room functions.

However, the EBC believes that Japan could still benefit from further improvements to its banking system. The Government cannot afford to relax in a world where competition for capital is ever fiercer: a strong and healthy financial services sector is vital to attract investment in Japan. In 2012, the Global Financial Centre Index (GFCI), which ranks the competitiveness of financial centres, ranked Tokyo 7th, down two places from the previous survey, and behind Seoul. It is, therefore, of the utmost importance that the authorities and Japan’s political leadership realise what could happen if they do not act swiftly.

The EBC advocates a regulatory framework that recognises and reflects the differences in business models between retail banking and commercial banking. While there is an understandable need for strong consumer protection measures in the retail sector, in view of the imbalance in information and knowledge that exists between retail banks and their individual clients, the same cannot be said of banks in the commercial sector and their clients, who are generally other financial institutions or corporations. The EBC is not arguing against having a regulatory framework for the commercial banking sector, but believes regulation should avoid placing an unwarranted burden upon commercial banks. This issue is particularly relevant to the expansion of the deposit insurance system, which was established to protect the accounts of depositors in the event that a bank defaults.

Following the March 2011 earthquake and its aftermath, Business Continuity Management (BCM) has been placed high on the agenda of the banking community. Among the key issues is the need to secure and access information in the event of Japan’s communication infrastructure becoming inaccessible. One natural solution would be to duplicate or relocate the information in an offshore location. Unfortunately, current law either, in some cases, expressly forbids such action or fails to provide guidance on how it should be carried out.

Finally, working under the auspices of the FTA/EPA 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.

Key Issues and Recommendations

■ Deposit insurance system

Yearly status report: new issue. Foreign banks have in the past been excluded from the deposit insurance system because most are branches and not subsidiaries. During 2012, several statements by the Japanese authorities have indicated an intention to include foreign branches. Such an approach would not take into sufficient consideration the differences in business models between most Japanese banks and European banks in Japan, the latter being almost exclusively focused on commercial and corporate banking where client knowledge is very different from that of the customers of the retail sector.

Recommendation:

- The Japanese Government should take into consideration differences in business models and customer profiles, before expanding the deposit insurance 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 increase efficiency and transparency and welcomed the FSA's decision to release its 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:

- The extensive requirements for reporting to regulators and self-regulatory organisations should be re-evaluated, and reduced to a level consistent with sound, but not excessive, supervision.
- 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 financial services markets by operating on the basis of published general principles for good governance.

■ Banking agency system

Yearly status report: no progress. 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.

Recommendations:

- The FSA should further clarify and streamline the application process for banking agency licences.
- The FSA should introduce a system whereby European branches do not have to apply for a special business licence each time they introduce a new product.

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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 include 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, which will drive a need for products dealing with extended retirement, changes to family structure and rising demand for medical products. Through a principles-based regulatory regime, where the regulator strikes a careful balance between innovation and regulation, focusing on risk management, and allowing 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.

Currently, the single most influential issue affecting the insurance sector is, without doubt, the changes to Japan Post. Since former Prime Minister Koizumi launched the privatisation of Japan Post, it has indeed been a bumpy road. 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. The bill later passed the two houses of parliament after some amendments and entered into force in April 2012. The bill has given 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 is exempted from a wide range of provisions under the Insurance Business Law and Banking Law, including licensing and inspection requirements. Moreover, JPI will be given near-exclusive access to most Japanese consumers through the post office network. The EBC has repeatedly advocated that JPI should not be allowed to introduce new or modified products as long as the playing field is not level. This is the concern not only of European insurers, but also of domestic insurance companies. The EBC is also concerned that Japan should adhere to 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.

More widely, enhancing the regulatory environment for the insurance industry in Japan will be critical to its future development. Convergence of Japanese regulations with global methodologies in terms of market-based solvency (Solvency II) and International Financial Reporting Standards (IFRS) is vital to improve risk management and understanding among insurers, provide confidence to the market, and reduce the costs of operating across different territories. The EBC therefore urges the FSA to continue to move towards harmonisation as it develops its new solvency regulations. We also believe that a permanent, post-funded scheme should be established for the Policyholder Protection Corporation (PPC). 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, would contribute to Japan's recovery from the financial crisis. This would also benefit 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. The EU-Japan FTA/EPA 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, the agreement should include 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: no progress – backward movement. With the introduction of the bill on postal reform, JPI has been 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 is already the world's largest financial institution. JPI has already indicated an interest in expanding its product portfolio. As a signatory to the WTO General Agreement on Trade in Services (GATS), the Government of Japan is obliged to ensure all market players enjoy equal treatment.

Recommendations:

- The Government of Japan should establish a level playing field before JPI is allowed to introduce new products.
- The Government of Japan should adhere to its commitments made under the GATS.

■ Kyosai

Yearly status report: no progress. *Kyosai* are mutual aid cooperatives providing insurance products. Under commitments made by the Japanese Government, these organisations should be governed by the same rules and regulations as foreign insurance companies, but this is currently not the case, as *kyosai* are not subject to 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 and be covered by the Insurance Business Law and should not be allowed to expand their businesses 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 would 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 aimed 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.

■ Product approvals

Yearly status report: some progress. The FSA product approval process is overly lengthy and FSA's resources are limited. This results in product development delays and makes effective planning for insurance companies difficult. Furthermore, approvals, when granted, are not flexible enough to enable adaption to ever-changing markets. In the long term, a "file-and-use" system should be introduced. The EBC notes with concern that JPI enjoys different and preferential treatment which distorts competition in its favour.

Recommendations:

- The FSA should improve its product approval process.
- The FSA should make greater use of EU approvals, either by recognising these approvals or by recognising the approval process thereby benefitting from robust EU procedures and speeding up its own process without increasing risk.

Transportation & Communications

Airlines
Logistics & freight
Railways
Telecommunications carriers
Telecommunications equipment

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AIRLINES

Introduction

The Japanese aviation industry is of global significance. About 5.5% of global traffic is connected to Japan, generating 11% of the industry's revenues. Moreover, air transportation is critical to Japan as a catalyst for economic growth.

However, as a consequence of the catastrophic events of March 11th, 2011, the number of inbound travellers from Europe fell drastically and the reduction lasted for more than 15 months. Whilst leisure-driven demand from Japan returned to normal levels after a short period, business travel to Europe was negatively influenced by the strong appreciation of the Japanese yen. Combined with peaking kerosene prices and high airport costs, this situation has had a substantial negative impact on European airlines operating to and from Japan. After the H1N1 flu outbreak and the global financial crisis of 2009, the aviation industry in Japan has again been subject to adverse external factors beyond its control.

The EBC urges the Government of Japan to continually work towards reducing charges at all Japanese airports, especially for those offering 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 prohibitive landing fees, navigation charges, airport terminal rent, airport terminal common user charges, and cargo handling fees as well as indirectly paying security fees, which should be borne by the Government and not by the airlines. According to the World Economic Forum's competitiveness ranking for Travel and Tourism, Japan ranks 106th in the world in terms of airport and ticket charges (by way of comparison, the Republic of Korea ranks 33rd).

Healthy competition is a pre-requisite for establishing a vibrant market driven by an economic rather than political rationale. While welcoming the opening up of Haneda Airport for intercontinental flights following completion of its new runway and international terminal in 2010, the EBC urges the Government to ensure that access is provided on equal terms to all carriers. Currently, only a limited window of operations (22:00 - 07:00) is allocated to traffic to and from non-Asian destinations. Because flights from Europe are not permitted to land before 22.00 hrs, European carriers are denied the possibility of connecting with the domestic networks of their Japanese and Asian competitors, which do not operate domestic flights after 22:00. While European carriers are restricted to serving the Tokyo metropolitan area at very inconvenient times, Japanese and Asian carriers can depart from and land in Japan at hours that easily allow them to be fed by and feed connections to practically every Japanese domestic airport. Until a level playing field is established, Hanada will not be able to play the role of a truly international hub as envisaged by the Government, and local cities will not benefit from the business potential that a fully fledged hub airport could provide.

The Government should also carefully consider the competition implications of the government-supported bail-out process and recapitalisation of Japan Airlines (JAL). The Enterprise Turnaround Initiative Corporation (ETIC) has guaranteed various commercial transfers so that JAL can survive and be restructured in a controlled fashion. However, the protection umbrella organised by the Government, such as long-lasting tax breaks and access to valuable slots at Haneda Airport, will distort competition not only within the Japanese airline industry, but also with European carriers which, due to the strict framework applied within EU bail-out legislation, do not benefit from any comparable advantages. In the interests of fair competition, Japan Airlines should not be allowed to conduct price dumping or capacity increases while receiving favourable government treatment .

Key Issues and Recommendations

■ High costs

Yearly status report: no progress. A new round of negotiations is underway in 2012 to determine charges at Narita Airport. After slightly lowering its charges in 2009, and despite achieving a substantial profit, in March 2012 the Airport put most of its charges back up. The EBC believes that with improved profitability and a more streamlined process leading to lower costs, a permanent fee decrease should be feasible. In the meantime, Narita is considering giving discounts to airlines serving the Airport for the first time or increasing capacity. Such an approach would greatly disadvantage incumbent carriers, which have for years paid high prices. Furthermore, Japan's Airport Development Special Accounts have unfortunately had the effect of subsidising unprofitable airports by taxing major airports, which are the very facilities used by European airliners. The EBC believes this approach is not only unfair but also unsustainable and that, where there is little public value in operating an airport, it should either be closed or consolidated. If Narita is to remain competitive with other hubs in Asia, a new approach, leading to reductions in airport costs by as much as 50%, will be necessary. The decision to integrate Kansai International Airport and Itami Airport into one holding company is welcomed. However a substantial reduction of the high user fees at Kansai Airport is essential in order to stabilise the long-term presence of major airlines in this market.

Recommendations:

- Fees have to be lowered if Japan is serious about becoming a true tourist destination in Asia.
- The competent authorities should make certain that no differentiation is made between new and incumbent airlines.
- The cost of security measures at airports should not be levied on airlines, but should be absorbed by the respective airport or, if requested by the Police Authorities as in the case of Narita, be borne by the Government.
- The Airport Development Special Accounts should be abolished to pave the way for the lowering of fees.

■ Airport infrastructure

Yearly status report: limited progress. At Haneda, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has allocated some 60,000 new slots to international routes and now permits flights to and from non-Asian destinations, but only during the night-time (22:00 – 07:00). The Government should consider the implications for competition between local airports and also between airlines. It is essential that all airlines should be able to use the airport on a commercially viable and practical basis. Haneda Airport cannot be considered to be a hub, if European Airlines cannot feed and defeed traffic into/from the domestic Japanese network.

Recommendation:

- Japan should establish a plan for efficient use of all available airport infrastructure. Haneda Airport should be fully opened up to all international traffic, including flights to/from Europe, on a non-discriminatory basis. A reduction of night curfew hours at Narita Airport should be considered due to the much lower noise levels of modern airplanes and their reduced environmental impact on the local community.

■ JAL Restructuring

Yearly status report: no progress. The Government should carefully consider the competition implications of the government-supported bail-out process and recapitalisation of JAL. The EBC believes that proper surveillance should be carried out so that healthy competition and a level playing field are ensured. JAL cannot be allowed to expand and conduct price dumping while receiving government assistance.

Recommendations:

- The Government of Japan should not allow JAL to distort competition by benefitting from long-term tax breaks whilst, at the same time, gaining access to valuable slots at Haneda.
- The Government of Japan should reduce entrance barriers for European carriers to Haneda Airport, taking into consideration that JAL has declared the utilisation of new and convenient slots at Haneda as key to the success of its envisaged turnaround.

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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, depend on efficient end-to-end supply chain services both domestically and across borders.

European companies have successfully brought to Japanese consumers the benefits of access to their worldwide logistics operations, but still face serious and significant regulatory challenges. European forwarding and express companies struggle with Japan's high cost base and inadequate infrastructure, as well as very restricted aircraft operation time windows at international airports, especially in the Tokyo area, as well as rigid custom clearance procedures. They also have to deal with outdated restrictions on foreign-owned companies engaging in the domestic freight forwarding business, 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. Heavy congestion in and around the port of Tokyo is also an issue, leading to low utilisation and long waiting times for bringing containers in and out of the container yards in the port area.

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 free 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 uneven playing field through its Express Mail Service (EMS), a special value-added international express package that today accounts for more than 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 its expansion threatens further to distort competition and will negatively affect not only foreign private operators, but also Japanese companies and individuals.

Operators expected the introduction of the Authorised Economic Operator (AEO) concept to lead to simplification of many of the transport and customs processes they need to undertake in order to provide their services. Unfortunately, the EBC believes that the new system has missed this target since, instead of benefitting from a streamlining of the process, many companies have been burdened by an increase in administrative tasks and compliance requirements in order to achieve AEO status. They have reached the conclusion that, although beneficial in theory, the advantages of AEO status have not justified the investment.

On the other hand, the EBC applauds the newly signed EU-Japan 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, we believe that the EU-Japan FTA/EPA could further enhance trade by extending co-operation to additional customs areas. The FTA/EPA should also open up the sector by establishing equal treatment of Japanese and European operators, in particular eliminating the ban on foreign freight forwarders engaging directly in Japan's domestic air freight forwarding business.

Key Issues and Recommendations

■ Customs clearance and declaration

Yearly status report: no progress. Currently, declarations can only be lodged at a customs clearance operation physically located within the territory of the responsible customs office. Deregulation of customs jurisdictions, allowing remote filing of clearances at locations independent of the territory of the responsible customs office, would increase flexibility and improve capacity planning for customs brokerage operators. The current set-up makes it difficult for foreign logistics companies, and also small and mid-sized Japanese companies, to expand the reach and coverage of their customs clearance businesses in Japan. Moreover, administrative practices and interpretations vary considerably between the different customs territories in Japan. This often causes problems and uncertainty for logistics companies and importers. The EBC, therefore, believes that better alignment between local customs offices is of the outmost importance.

Recommendations:

- Allow companies freedom to choose the customs declaration location, independent of the territory of the responsible customs office.
- Enable greater flexibility in terms of where quarantine shipments can be checked. Checks carried out in special bonded warehouses should be facilitated.
- Remove the caps on customs clearance charges currently in place and allow free and fair pricing to be set by the market.
- Streamline the reporting and administration requirements of the various customs authorities to provide more standardised interpretation and application of customs rules and reporting requirements.
- Increase the minimum threshold value for dutiable import shipments to 20,000 yen.

■ 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 materials such as quarantine-related goods, which are subject to control by various regulations (*tahourei*) other than the Customs Law, are not checked by government offices at airports, in stark contrast to the thorough checking 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 Japan Post's EMS shipments of goods regulated by *tahourei* can be moved outside international airport facilities, whereas those of private express delivery services cannot.

■ Authorised Economic Operator

Yearly status report: new issue. The current system of AEO has unfortunately not led to the simplifications that many operators had hoped for. On the contrary, in many cases the administrative burden has increased. The EBC seeks a system that gives companies a simplified process and extended power to handle matters without the involvement of the authorities in every single case, provided that the operator can demonstrate sufficient control over the flow, and that a traceability mechanism is in place.

Recommendations:

- The AEO concept should focus more on offering simplifications if the operator meets the agreed criteria for tracing each product and adhering to the agreed process flow.
- The Government of Japan should introduce more benefits for imports by AEOs, including but not limited to :
 - ◇ Deregulating customs clearance beyond the local customs jurisdiction territories
 - ◇ Reducing the physical examination of shipments for Authorised Economic Operators

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RAILWAYS

Introduction

On 11 March, 2011 a major earthquake hit the Tohoku region of Japan. With it, a tsunami swept away homes, buildings and people, and also destroyed several kilometres of railroad tracks and rolling stock. While the reparable tracks are more or less back to normal operation, some that were completely destroyed have not yet been replaced. Sources indicate that as of March 2012, ten stations and 370 km of tracks were still missing. This has affected not only industry, but also the people living in this region where the station and the train represented an important part of their transportation and communication network. The EBC is, therefore, concerned that some operators have indicated they will replace railways and trains with a Bus Rapid Transit (BRT) system. We believe that the situation instead presents a perfect opportunity to introduce the so-called Light Rail Transit (LRT).

Some 72% of Japan's railway network is operated by Japan Railways (JR Group), while the rest is operated by 190 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 28,000 kilometre-long Japanese railway network, 75% being Electric Multiple Units (EMU) and high-speed Shinkansen trains. Approximately 1,800 cars were built in 2011, out of which about 500 were exported. The Japanese market is one of the biggest in the world, yet foreign penetration is negligible.

Part of the reason for this negligible penetration 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 has created a situation where other products, even if tested and certified according to international standards, will not be considered by Japanese operators without further extensive testing.

On the other hand, Japanese companies in the railway field have realised that growth can only be achieved by accessing overseas markets. This has also been recognised by the relevant ministries. METI (the Ministry of Economy, Trade and Industry) and MLIT (the Ministry of Land, Infrastructure, Transport and Tourism) are actively supporting such companies in gaining access to overseas markets. This requires Japanese companies to comply with international regulations and standards.

Japan does not have a third-party certification scheme related to the railway industry in place. Operators have their own testing and certification schemes and do not accept overseas certification. Therefore, to meet overseas client's requirements, Japanese manufacturers must rely on certification bodies in Europe and other countries. In order to address this issue METI, MLIT, related organisations and enterprises have been promoting the establishment of a Japanese certification body for the railway industry, with the aim of certifying products for international markets. Although the current certification and testing programme has the objective of helping Japanese railway-related manufacturers to export their products overseas, it fosters an appreciation of international standards, testing and certification bodies. We believe that it is now crucial for the Japanese Government and operators to recognise testing and certification carried out by European approved bodies. The EBC is, therefore, looking at recent events with a positive outlook. We are also encouraged to note that some market players have started to look to the EU for advanced technology and partners fitting their requirements.

The EU-Japan FTA/EPA should enable Japan to work jointly with Europe to promote open integrated systems built on harmonised standards. Furthermore under the FTA/EPA, test data from internationally recognised certification bodies should be accepted without further delay and references from Europe should be fully recognised and accepted.

Since its inauguration, the EBC Railways Committee has developed close contacts not only with MLIT, but also with related governmental organisations such as testing and standard-related bodies. The Committee is very pleased with the improved channels of communication with several Japanese operators and wishes to develop these further.

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

■ Mutual recognition of testing and certification, and harmonisation of standards

Yearly status report: limited progress. For years, the EU railway industry has been lobbying Japan to increase transparency in its approval and certification requirements. The EBC is pleased that the Japanese Government has taken initial steps towards establishing mechanisms that would introduce third-party certification to the Japanese railway industry. Even though the current certification and testing programme has the objective of helping Japanese railway-related manufacturers to export their products overseas, the EBC believes it is crucial for the Japanese Government and operators to recognise the testing results and certifications carried out by European approved bodies to facilitate bilateral trade in the sector.

Recommendations:

- Fully recognise and accept testing results and certifications from overseas accredited certification bodies under the International Accreditation Forum (IAF)/Pacific Accreditation Cooperation (PAC)/International Laboratory Accreditation Cooperation (ILAC) umbrella.
- Establish a certification programme for the railway field based on international and/or Japan Industrial Standards (JIS).
- Establish appointment criteria for certification bodies based on the IAF/PAC/ILAC accreditation framework.

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

Yearly status report: progress. Japan and the EU are both signatories to the WTO's Plurilateral Agreement on Government Procurement (GPA). In the framework of the agreement, Japan negotiated a specific clause applicable to transport (the operational safety clause), which stipulates that procurement related to the operational safety of transportation is excluded. In practice this means that the prescribed GPA procedures are rarely, if ever, followed in the rail sector. The EBC regrets that this safety clause is used to avoid a proper tendering system which would give every supplier 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.
- The EU and Japan should continue the positive discussion that has been undertaken under the auspices of the Scoping Exercise.

■ Tenders

Yearly status report: new issue. Japan has never had a system of tendering for railway-related projects. Part of the reason for this lies in its effective exclusion of the transport sector from the GPA. The EBC, however, notes the recent call by JR East for a signalling system in Japan. While not yet having had an opportunity to study the plans in depth, the EBC believes this is a major step in the right direction and commends JR East for its initiative.

Recommendation:

- The EBC requests that the Government of Japan promotes the use of tendering as this will improve competition in the Japanese market, leading to safer, cheaper and better products for Japanese operators which will in turn benefit passengers in Japan. Other operators should also follow the lead set by JR East.

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TELECOMMUNICATIONS CARRIERS

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, the EBC believes there are still some areas that can be improved.

The notion of an independent electronic communications regulator has been widely discussed in Japan, including in political debates. Independence of the regulatory process is considered good practice to promote decision-making that is objective, transparent and accountable, and to build trust and credibility within the industry in order for various viewpoints and interests, including economic, social, and political objectives to be duly considered. This balance should be reflected in the institutional organisation and in the system of checks and balances.

Whilst the Ministry of Internal Affairs and Communications (MIC) has made tremendous progress in advancing the Information and Communication Technology (ICT) industry, the EBC believes that an oversight body with a majority of independent members and due transparency of its proceedings and decisions should be created. This is particularly important in light of Japan's transition to the model of equivalence, non-discrimination and functional separation. We believe that such a measure could provide more explicit assurances of fair treatment to customers, incumbents and competitors.

The functional separation of NTT, which became effective in November 2011, was much applauded by the EBC. We hope that Japan will be able to reap the full benefits of this development. There are, however, some issues requiring further consideration. We believe that a more holistic approach is needed. The MIC has focused on introducing functional separation by mainly changing the existing laws on interconnection deals between NTT and competitors with reference to a firewall, account separation, and monitoring of NTT's operation. The EBC believes that the MIC should issue a statement announcing that a full review will be implemented in 2015 covering key principles, such as transparency, non-discrimination, and fair competition, and that it will provide telecom companies with further guiding principles related to the operational and behavioural aspects of the functional separation.

Benchmark studies indicate that prices in Japan are high relative to other comparable jurisdictions such as Singapore, Australia and Hong Kong. A reduction in the price of telecom input should have the knock-on effect of driving down prices charged to customers, which is good for jobs and growth in the wider economy. The EBC, therefore, suggests that the MIC undertakes a study to assess how access pricing in Japan compares to other major advanced Asia Pacific jurisdictions. This study should include business-grade products and services. Where prices are found to be comparatively high, the MIC should look to reduce prices via appropriate forms of pro-competitive regulation. 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, access fees have remained high compared to other OECD countries. Accordingly, the EBC believes that there is much scope to reduce access prices in Japan.

The EBC Telecommunications Carriers Committee has high hopes for the benefits of the FTA/EPA between Japan and the EU, and believes that telecom issues should be included. We would, therefore, like to see an overall ambitious FTA/EPA that covers detailed commitments and pro-competitive rules for the telecom and ICT services sectors serving business and end users. Those commitments should go beyond those made under the WTO Basic Telecoms Agreement of 1998 and its annexed Reference Paper and, in particular, cover wholesale access regulation. It is also worth exploring whether there is a case for enshrining EU-Japan ICT policy and regulatory principles in the Agreement, given the existence of EU-US and US-Japan ICT principles. It may also be instructive to consider if such broad principles can be agreed in future regulatory harmonisation in important hi-tech related areas, such as cloud computing, transborder data flows, data privacy, and cyber-security.

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 Democratic Party of Japan (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 the rapid introduction of innovative new services 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: some progress. In 2006, the Koizumi cabinet and the Liberal Democratic Party (LDP) agreed to re-open discussion on the organisation of NTT in 2010. The new Government led by the DPJ announced its intention to re-consider this decision from the perspective of global competitiveness. Network-based competition requires a 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.

Recommendations:

- Conduct a stocktaking review during 2013 on the current approach to functional separation against issues raised by industry.
- Create clear evaluation criteria to monitor progress or to assess whether functional separation is achieving its objectives.
- Adopt a specific regulatory focus on access within the wholesale market.

■ Access prices

Yearly status report: some progress. Prices are still relatively high compared to other countries in the region, such as Singapore, Australia and Hong Kong. A reduction in the price of telecom input should have the knock-on effect of the driving down the price charged to customers. In 2009, the Asia Pacific Carriers’ Coalition (APCC) commissioned an access pricing benchmark study across 14 economies in the Asia Pacific region, including Japan. Among the conclusions drawn for Japan was that the prices of simple leased circuits are relatively high compared to other developed Asia Pacific countries. The EBC believes that the significant price differential suggests there is scope to further drive down prices through regulatory intervention

Recommendation:

- Undertake benchmarking of access prices in Japan and use regulatory measures to drive down prices that are found to be relatively high.

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TELECOMMUNICATIONS EQUIPMENT

Introduction

Japan has the second largest telecommunications equipment market in the world. Telecommunications equipment accounts for 12.5% of Japan's total industrial output, worth an estimated 11 trillion yen. Structural reforms under the Government of Japan's ICT Strategy have supported the introduction of high-speed, large-capacity ICT infrastructure, the lowering of communications costs, and the development of e-commerce and e-government. Internet access costs have decreased dramatically and access to broadband is now amongst the most developed in the world. 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 now 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 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. The EBC is pleased that these issues have been taken up by the Government Revitalisation Unit (GRU). We are continuing to follow progress in the GRU and its cooperation with MIC. Not surprisingly, the EBC is very much looking forward to a successful outcome.

In the area of spectrum allocation, Japan has in recent times allocated both the 700 and 900 MHz band for mobile telephony by a process requiring each applicant company to submit information on its planned use of the band in terms of investments in both infrastructure and availability to consumers, upgrades and so on. The EBC is pleased to see that the bands mirror mobile telephony best practice in other large markets, such as the EU and the US.

The continuing importance of Japan's commitment to an industry-led, global approach cannot be over-stated. The world is already highly connected and this trend is increasing. Today, there are about six billion mobile subscriptions worldwide. As devices of all kinds become connected, there will be more mobile subscriptions than people on the planet. It is expected that the number of connected devices will increase by a factor of 10 over the coming decade. Solutions for connected devices have been available for many years, but now we are entering a new phase of rapid growth in Machine-to-Machine (M2M) services and consumer-device connectivity. The cost of connected devices is decreasing and the value of connectivity is rising for individuals, businesses and society in general. M2M connectivity offers an increasingly attractive way of adding value, improving productivity and reducing costs in a wide range of industrial and business processes, such as Smart City, Smart Grid, e-Health and so forth. The Intelligent Transport System (ITS) integrates information and communications technologies (ICT) with transport infrastructure, vehicles and users. The overall purpose of ITS is to improve safety and security, increase efficiency and reduce the environmental impact of transport systems. Mobile network technologies are major enablers for critical ITS applications, offering attractive economies of scale and speed of deployment. The Government of Japan should cooperate with the European Commission and the EU Member States to lead the international harmonisation of M2M (Machine-to-Machine) communication and ITS (Intelligent Transport Systems), including standardisation for technical specifications.

The EBC believes that to facilitate trade between the EU and Japan, the current duplication of product certifications for telecommunications equipment sold on both the European and Japanese markets should be eliminated. The FTA/EPA between the EU and Japan should establish true mutual acceptance in which telecommunications equipment products certified for either the European or Japanese market 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 the FTA/EPA.

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 include 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 the FTA/EPA.
- 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".

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

Yearly status report: some progress. The EBC acknowledges that the Government of Japan has been active in trying to identify a globally harmonised spectrum for International Mobile Telecommunications (IMT) systems. This would bring enormous benefits to the industry and consumers by eliminating the need to develop local variations of new telecommunications equipment. It would also create economies of scale, bringing down the prices of products and facilitating international roaming. In addition, the EBC was pleased to note that in 2010, the MIC presented a plan to allocate the 300 MHz band to wireless broadband including IMT by 2015, and awarded licences for the 700 MHz and 900 MHz bands in 2012 with the possibility of achieving harmonised spectrum allocation and arrangement for IMT systems. The EBC also notes that MIC is now studying the technical requirements for IMT-advanced especially in the band between 3,400 MHz and 3,600 MHz.

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 World Radio Communication Conference in 2007. This should include the bands of 700 MHz, 2,300 MHz and 3,400-3,600 MHz.
- The Government of Japan should work actively in accordance with agenda item 1.1 of the World Radio Communication Conference in 2015, in order to identify new harmonised IMT spectrum systems.

■ **Harmonisation between the EU and Japan on M2M and ITS**

Yearly status report: new issue. M2M connectivity offers an increasingly attractive way of adding value, improving productivity and reducing costs in a wide range of industrial and business processes, such as Smart City, Smart Grid, e-Health and so forth. ITS integrates information and communications technologies (ICT) with transport infrastructure, vehicles and users. The overall purpose of ITS is to improve safety and security, increase efficiency and reduce the environmental impact of transport systems. Mobile network technologies are major enablers of critical ITS applications, offering attractive economies of scale and speed of deployment.

Recommendation:

- The Government of Japan together with the European Commission and the EU Member States should cooperate and lead the international harmonisation of M2M (Machine-to-Machine) communication and ITS (Intelligent Transport Systems) including standardisation for technical specifications.

Health Science

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

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ANIMAL HEALTH

Introduction

The animal health product market in Japan is worth approximately 100 billion yen, and ranks 6th in the world. In the past, it has been an important market for European companies. Japan has, however, lost its attractiveness in recent years due to low growth rates and the high cost of doing business. The Japanese animal health market is, like that of Europe or the USA, highly regulated. Japan belongs to the trilateral (EU-Japan-USA) programme of the VICH (International Cooperation on Harmonization of Technical Requirements for Registration of Veterinary Medicinal Products), a veterinary equivalent of the International Conference on Harmonisation (ICH) for human medicine, which aims to harmonise registration requirements for animal health products at the global level. This has helped to some extent in the reduction of registration costs for globally developed products. There are, however, still some requirements that are unique to Japan and often prevent or delay access to innovative and useful animal health products for animal owners, veterinarians and consumers. This is particularly regrettable, since these products will have gone through a rigorous review process in Europe and the USA prior to registration and so their efficacy, safety and quality are assured. Japan's regulatory requirements for innovative veterinary medicinal products based on biotechnology are especially stringent and, therefore, products readily available in Europe are often not available here. Increased harmonisation of regulatory requirements would certainly improve access to innovative animal health products. More rapid access to new animal vaccines and medicines is also necessary for the Japanese livestock industry to remain competitive with foreign producers. If producers in Japan cannot maintain competitiveness, Japan will continue to become increasingly dependent on imported animal products or may have to expand its agriculture subsidies.

Marketing authorisation of a veterinary medicinal product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal drug intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labour and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process for food-producing animal health products is complex and often inefficient, lacking good coordination and taking a very long time before a product becomes available to livestock producers.

In the case of biological products, most of the specification items are unique to Japan, including the requirement for a serological potency test on live vaccines. Product specifications have to be established purely for the Japanese market and each batch of vaccine has to be released based on these unique specifications, often requiring duplicate testing at the manufacturing site.

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

For the last few years, MAFF has been implementing various measures to improve the predictability, quality, and speed of the registration process and these are improving to some extent, but there are still delays in the review process for some product segments. The EU-Japan FTA/EPA should aim for mutual recognition of European and Japanese marketing authorisations for veterinary products, starting with mutual recognition of GMP certification for veterinary medicines.

Key Issues and Recommendations

■ Product approvals

Yearly status report: Limited progress. Products already approved in the EU, especially veterinary biological products, 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. The applicant is still required to answer questions of little relevance to the safety and efficacy of the product. Since three different regulatory authorities (MAFF, FSC and MHLW) are involved, the registration of food-producing animal products can take an extremely long time, despite the standard administrative review process of 12 months set by MAFF, and the process is very unpredictable.

Recommendations:

- The Government of Japan should use all measures available to speed up product approvals, including mutual recognition of product registration schemes, and fully harmonise domestic regulations with international practices. 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.

■ Seed-lot system and national assay of vaccines

Yearly status report: Progress. The seed-lot system enables the production of vaccines using a working seed virus/bacteria derived from an established master seed virus/bacteria. 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. Japan requires an inactivation test on the finished product only for imported inactivated vaccines and not for similar domestically produced inactivated vaccines, thereby creating a non-tariff barrier to trade. 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 to be included in 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.
- Recombinant vaccines should also be eligible for inclusion in the seed-lot system.

■ Slaughter withholding period of post-vaccinated food producing animals

Yearly status report: No progress. The withholding period prior to shipment for the slaughter of food-producing animals vaccinated with an oil-adjuvanted vaccine is significantly longer in Japan compared with reference countries. Oil adjuvant is mostly made of ingredients that are listed as food additives, and their safety has been well established. The long withholding period, which is a burden for producers, means that some innovative and useful vaccines used in the EU or the USA cannot be used practically in Japan. Having fewer alternatives results in higher costs to producers and ultimately to consumers.

Recommendation:

- Align the withholding period of post-vaccinated food producing animals with that approved in Europe or the USA, based on scientific justification and appropriate risk assessment.

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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 therapies. Medical diagnostic reagents and equipment thus improve patient quality of life and reduce total healthcare costs. Yet their valuable contribution is threatened by repeated cuts to reimbursement prices, which have reduced the prices paid in Japan for medical diagnostic reagents and equipment to below those in comparable overseas markets. The current system of biennial revisions to reimbursement prices for medical diagnostics have delivered continuous and significant price cuts, 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. Altogether, 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. Hence the EBC welcomed the National Health Insurance (NHI) reviews of 2008, 2010 and 2012, through which the reimbursement price for in vitro diagnostics (IVD) was improved significantly. Nevertheless, in general, the current approach remains one of revision and value judgment, where medical diagnostics are treated only as another expense and reimbursement prices are set without considering the added value of the product. This may ultimately lead to medical practitioners failing to use the most advanced technology due to inadequate reimbursement, thus risking misdiagnoses and unnecessary or inappropriate treatment, and eventually, excessive healthcare costs.

In this respect, structural reform of the reimbursement regime is essential. 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.

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 classification. 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.

The merits of quickly delivering higher-level medical products to medical practitioners, hospitals and clinics, and patients, thereby contributing to the reduction of healthcare costs, are clear. Soaring medical expenditure is of serious concern to the Japanese Government. Such costs could be reduced by alleviating the adverse effects associated with certain drugs through the use of companion diagnostics. Selective use of companion diagnostics with specific patients to determine the dose of their drug that will deliver the maximum efficacy would also contribute to reducing medical expenses.

The EBC believes that 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 therefore be part of the EU-Japan FTA/EPA.

Key Issues and Recommendations

■ Product approval and smooth introduction of products

Yearly status report: no progress. Introduction of the ministerial authorisation system, third-party certification and a self-certification system intended for risk classification and reinforced safety measures as part of the revised PAL are important steps in the right direction, but still fall short of what is needed. Risk classification methodologies and data requirements that are unique to Japan make the application and review process technically slow and/or redundant. In addition, the past few years have seen substantial delays in product approval, and 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 to make the product approval process more efficient.
- The EBC proposes the introduction of a periodic performance review of the process from application through to approval of the product, to identify and remove obstacles to quick delivery of the clinical value of new products to hospitals and clinics, which enhances their contribution to healthcare.
- The EBC requests simultaneous approval of companion diagnostics and their corresponding drugs.

■ Reimbursement

Yearly status report: progress. The EBC welcomed the NHI reviews of 2008, 2010 and 2012 through which the reimbursement of IVD was improved significantly following greater Government recognition of its value. The Government, however, 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 and laboratory certification), speed (emergency response and urgent tests for outpatients), and contribution to comprehensive patient care (infection control, risk management and qualitative indications).
- The Government of Japan should establish a periodic 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 vis-a-vis reimbursement cost.
- Reimbursement prices for companion diagnostics of high added value to be used with certain drugs should better reflect the value of the medical diagnostics.

■ Diagnosis procedure combination (DPC)

Yearly status report: some 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. 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. At the same time, the EBC welcomed the comprehensive measures adopted in the 2010 revision, including the introduction of New Function evaluation coefficients, increased NHI points for inspection room facility requirements and the addition of quick outpatient testing.

Recommendations:

- Guidelines should be established based on consultation within 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 to clearly show the Government's determination to enhance the quality of medical care from an institutional perspective.

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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 in the world and one of the lowest infant mortality rates. However, the system suffers from inefficiencies, including a high rate of hospital visits, unparalleled long hospital stays, and a shortage of medical staff. In 2010, the national cost of medical care reached 37.4 trillion yen, up by more than one trillion yen from the previous year, reflecting a society that is rapidly ageing and placing increasing demands on health services. These demands will continue to grow as public expectations of medical care rise and the system comes under increasing strain in the years ahead. Efficient medical equipment could make a major contribution to easing this strain, being an investment that not only offers individual patients a substantially higher quality of life, but also offers a reduction in total expenditure on medical care over time. However, Japan's current regulatory structure and reimbursement regime frustrate the introduction of such equipment to the Japanese market and thus deprive patients of access to products and treatments readily available in other countries, including China and South Korea. Indeed 50% of state-of-the-art medical equipment manufactured and sold in the EU and the US is not yet available in Japan, giving rise to a serious device-gap.

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 2005 revision of the Pharmaceutical Affairs Law (PAL) to shorten approval procedures and bring Japanese pharmaceutical rules in line with global standards, the revised law actually resulted in longer approval times, because regulations applying to pharmaceuticals were extended to also apply to medical equipment, a fundamentally different product.

Another cause of approval delays is the discrepancy between international standards and Japanese guidelines relating to clinical evaluation and quality management systems (QMS). In both the EU and Japan, the authorisation and market introduction of medical equipment is conditional on satisfactory evidence of clinical safety and effectiveness. Information from the Japanese Ministry of Health, Labour and Welfare (MHLW) indicates that in 70% of all cases where the introduction of new medical equipment is subject to authorisation, clinical investigation data gathered outside Japan are accepted as the sole or primary source of evidence. However, when such data are determined to be insufficient, a new and/or additional clinical investigation must be conducted in Japan, leading to significant additional delay and expense. Moreover, there is a lack of clear guidelines enabling companies to predict whether or not such new/additional investigations will be necessary.

In the EU, medical equipment manufacturers are obliged to ensure conformity with QMS requirements by inspection of their manufacturing sites. They can generally satisfy this requirement by demonstrating compliance with International Standard ISO13485. In Japan, the MHLW has issued QMS guidelines for medical equipment based on, and compatible with, ISO13485. However, the Japanese system requires a separate QMS compliance survey for each category of product listed under the "Japanese Medical Equipment Nomenclature". Furthermore, the Japanese compliance inspection authority comprises three parties drawn from both the public and private sectors. This makes it difficult for companies to share the results of investigations, and the manufacturers are forced into duplicate inspections and fees.

In June 2012, the Japanese Government announced a 5-year-plan for medical innovation as part of a suite of measures to revitalise the economy. For medical equipment, this includes the creation of an efficient environment for clinical studies and trials; rationalisation, facilitation and improvement of the processes for review and reinforcement of safety measures; and adequate evaluation of innovation. The plan stresses the need to address problems in these fields, which is an important first step for solving the problems. The EBC will carefully monitor the progress of these initiatives.

The FTA/EPA between the EU and Japan will help in ensuring that products certified in one market are automatically accepted in the other. This would lower costs and, in the long term, eliminate the device-lag and device-gap between Japan and other industrialised countries, as virtually all equipment on the world market today is certified in accordance with European (EN) standards. The EBC believes special emphasis should be placed on introducing mutual acceptance of certifications for medical equipment by establishing common Good Clinical Practice (GCP) and QMS regulations.

B.Braun Aesculap Japan	Maquet Japan
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Draeger Medical Japan	Otto Bock Japan
Edaptechnomed	Philips Electronics Japan
Elekta	Radiometer
Gambro	Sata
Japan Lifeline	Senko Medical Trading
Japan MDC	Siemens Japan
JIMRO	Smith & Nephew Wound Management
Laerdal Medical Japan	Sorin Group Japan
Lima Japan	Teijin Pharma

Key Issues and Recommendations

■ Clinical evaluation, and mutual recognition and alignment of QMS

Yearly status report: slight progress. The alignment of Japan's GCP with ISO14155 has advanced the process of clinical evaluation considerably and clinical test results obtained in Europe and the US are now accepted in Japan for several types of medical equipment. However, although the clinical evaluation standards themselves are now aligned, clinical tests in Japan still present a number of unresolved issues. For example: (1) many more product items are subject to testing in Japan than in Europe and the US; (2) Japan differs from the EU and US in the regulatory treatment of applications to extend the use of approved products to additional diseases; and (3) clinical tests are often required even for equipment that has simply been modified or improved. Even after approval, the ongoing deployment of medical equipment is subject to surveys on its actual use, to further review and to other regulatory requirements that do not exist in the EU or US. This necessitates additional expenditure and personnel, resulting in fewer European products being launched on the Japanese market.

MHLW notifications issued in 2011 include helpful clarification of the differences between ISO13485 and the Japanese QMS. However, problems persist in the investigation of manufacturing sites and in QMS compliance inspections, which are applied on a multitude of Japanese product categories instead of one inspection site. Therefore, both equipment manufacturers and compliance inspection authorities must conduct excessive and unnecessary QMS compliance investigations, leading to duplicate inspections, increased cost and significant delays in market introduction because of the Japanese focus on product categories rather than on manufacturing site (as in the EU).

Recommendations:

- The Government of Japan should expand the range of products for which clinical tests are not required, building on the systems in Europe and the US. Where medical equipment is already available on the European or US market, the Japanese authorities should evaluate the clinical records of actual use and relevant clinical literature in order to avoid further unnecessary clinical testing.
- The Government of Japan should acknowledge that QMS audits conducted by competent third parties (notified bodies) in the EU provide sufficient evidence of compliance with quality management system requirements, and accept them as such. We recommend that the Government recognises the ISO13485 investigation methods of the EU and adopt a similar approach in its own examinations of the quality systems of manufacturing sites.

■ Reimbursement prices

Yearly status report: slight progress. The 2012 revision of the reimbursement scheme resulted in an increase in medical fee reimbursement equivalent to 550 billion yen (+1.38%). However, this increase was offset by decreases in the prices reimbursed for drugs and medical materials equivalent to 500 billion yen and 50 billion yen, respectively. The Government's continuing tactic of thus balancing its healthcare budget by reducing drug and materials prices to compensate for increasing medical fees is undermining the medical industry and patient care. Despite this, the EBC was pleased to note that, in line with its recommendations, new prices have been set for two key items: 64 multi-slice CT imaging equipment and MRI equipment of 3 Tesla or above. In another positive development recommended by the EBC, the existing reimbursement category for medical materials for small markets such as paediatrics has been defined in more detail to include new subcategories. However, Japan still lacks a system for revising or increasing prices that would motivate and drive business toward eliminating the core problems of device-lag and device-gap. As a result, price negotiations for products in categories C1 (new function) or C2 (new function and technique) are likely to become ever more drawn-out and complicated.

Recommendations:

- Further reforms should be introduced to allow price increases for diagnostic imaging, new fees for new techniques, and more function subcategories for price differentiation. Japan should establish concrete standards for identifying the functions that need to be further subdivided into subcategories.
- Following the Great East Japan Earthquake and the 2011 floods in Thailand, Japan's authorities have urged business to ensure stable supply to the markets in times of need. The associated cost, in terms of diversifying supply lines and increasing inventory, should be reflected in future reimbursement prices.

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PHARMACEUTICALS

Introduction

Japan's national expenditure on medical care in fiscal year 2011 was an estimated 37.8 trillion yen, up 3.1% from the previous year. The expenditure on a per capita basis was 296,000 yen. Whereas the expenditure by persons below 70 years of age was 179,000 yen, for those aged 70 or more years, it was as much as 806,000 yen, approximately 4.5 times greater. While expenditure on drugs has increased by about 3% annually over the past 10 years, the proportion of total medical care expenses accounted for by drug expenditure has remained relatively stable at about 21% over the years. Regular biennial drug price reductions and the Japanese Government's active promotion of generic drugs, with the goal of generics accounting for 30% of the market by the end of fiscal year 2012, have contributed to relative control of drug expenditure growth in spite of an ageing population with access to ever more sophisticated medical care.

In 2008, the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) proposed "Exceptional Treatment for Maintenance of NHI (National Health Insurance) Drug Prices" to the Special Committee on Drug Prices of the Central Social Insurance Medical Council (*Chuikyo*). In April 2010, a new drug price system was introduced on a trial basis. Based on premiums to promote the development of new drugs and eliminate unapproved off-label use (in treating diseases other than NHI-approved indications), the system will maintain NHI prices for new drugs under certain conditions and reinvigorate investment in the development of new drugs and as yet unapproved drugs, and the expansion of approved indications of certain drugs currently in use for unapproved indications (currently unapproved off-label use). Following the introduction of this new system, early data from European R&D-based pharmaceutical companies indicate that the measures are beginning to accelerate access to innovation and contribute to the elimination of the so-called Japan drug-lag. EFPIA and the EBC request that this system become permanent on the basis of these positive results observed during the trial period. Consideration should also be given to eliminating arbitrary re-pricing measures for market expansion as well as improved recognition of drug health benefits brought by pharmaceuticals.

In May 2012, discussions on the possible introduction of Health Technology Assessments (HTA) for drug evaluation were formally started by the *Chuikyo*. While HTA has had mixed results in Europe, it is expected that Japan will develop its own system, preserving the fundamentals of the healthcare environment for its citizens, among which access to innovation through universal, high quality, affordable healthcare is internationally recognised as a key asset. In introducing HTA to Japan, it will be necessary to conduct thorough surveys and studies involving all concerned parties, including research-oriented pharmaceutical companies. Moreover, it should be clearly noted that elements of HTA are already included in the current system in Japan and are functioning appropriately. EFPIA and the EBC recommend that discussions on HTA should start from existing principles and consider using post-approval data collection as an opportunity to gather a real-life data set. This would avoid the creation of a new drug lag and maintain Japan as a leading country in the recognition of innovation.

The Pharmaceuticals and Medical Devices Agency (PMDA) has increased the number of examiners and embarked on human resources training to reduce the review time for new drug approval and improve the quality of the process. PMDA is also more actively engaged with trade associations, setting up joint working groups. Regarding clinical trials, Japanese Good Clinical Practice (GCP), which used to differ in many aspects from global standards, is steadily moving forward through the promotion of ICH goals (International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use). We support these efforts. 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). Limiting the MRA to solid oral preparations leads to duplicate inspections of manufacturing facilities for other products, making the process of launching any such new product unnecessarily time-consuming and expensive.

While the "policy dialogue" between Government and industry resumed in December 2011, the format and rarity of such interaction shows the need for improvements. In 2012, a consumption tax hike was decided from 2014 as part of the "Comprehensive Reform of Social Security and Tax", but essential specific measures for social security, including medical care, will need clarification. Moving the debate from pricing to funding of the healthcare system should become a priority for the Government and EFPIA members would be willing to contribute to this debate.

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 to reward innovation. The new system will ease the periodic drug price reduction so long as the drug meets certain conditions, such as having no generic counterpart on the market and no sales with average discounting, and being on the NHI drug price list for no more than 15 years. Continuation of the new system will allow early recovery of research and development costs in Japan and promote the simultaneous development of innovative new drugs and as yet unapproved drugs. Also consideration should be given to the elimination of re-pricing measures for market expansion. Moreover, the restriction imposed on all new drugs in the first year after their launch of a maximum prescription length of 14 days hinders patient access. Patients on such medication who are suffering from chronic diseases and expected to have stable symptoms for a certain period are nevertheless required to visit hospital once every two weeks to get a new prescription, which imposes a significant burden on them and on the resources of healthcare providers.

Recommendations:

- The Government of Japan should make the new drug price system permanent so that innovation is rewarded and the value of drugs more appropriately evaluated.
- Re-pricing measures for market expansion should be eliminated.
- The Government of Japan should abolish the 14-day prescription restriction for new drugs.

■ Health Technology Assessments in the Japanese context

Yearly status report: limited progress. In May 2012, the Government established an HTA subcommittee under the *Chuikyo* and has started official discussions on HTA. These discussions, however, have remained technical and have left consideration of the fundamental implications of HTA on the backburner. For example, there has been no focus on the design of a Japan-specific system, and no recognition of the merits of the existing system or any attempt to build on them. Moreover, the discussion has not looked into the practical implications of gathering data, including the need for a unique social security number identification. Issues related to patient access to innovative drugs should be a priority in the discussions.

Recommendation:

- The Government of Japan should preserve the level and share of pharmaceutical spending, the visible advantage of shorter periods between the approval of drugs and their reimbursement, the benefits of an advanced post-marketing surveillance system, and the merits of the new drug pricing system, which has already shown efficacy in increasing R&D activities. Contradictory and controversial results of HTA policies in the rest of the world should be carefully studied to prevent access delays for patients. EPFIA member companies are ready to participate in the dialogue to design a Japan-specific HTA system.

■ Improvement of the approval examination environment / MRA

Yearly status report: limited progress. To increase the speed of examinations, the PMDA increased its staff to about 300 people from 2008 to April 2012 and during the last fiscal year the number was increased by a further 43. The effect of the staff increase on the speed and quality of examinations should be continuously monitored. A working group consisting of PMDA representatives and industry players also discussed issues concerning clinical trial consultation, approval examination and GCP investigation, and achieved some improvements at least in clinical trial consultation and approval examination. EPFIA anticipates further improvements in these areas through the combined efforts of both the competent authority and industry. Moreover, various government-private sector joint task forces have started to review safety measures. We believe that these efforts will have positive effects. On the other hand, 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 on the risk evaluation of drugs.
- The scope of the existing EU-Japan MRA should be expanded to include non-solid preparations.

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VACCINES

Introduction

Japan's vaccine market is expanding rapidly as a series of new, innovative vaccines, long approved and marketed in other industrialised countries, have now been approved and increasingly made available in Japan. These include the Hib, human papillomavirus, pneumococcal 7-valent and rotavirus vaccines. The approval and marketing of a series of others, such as the MR (measles and rubella), inactivated poliovirus and quadruple combination (DtaP-IPV) vaccines, have also increased access in Japan to the latest products.

The situation in Japan has improved significantly as Japan catches up with the US and Europe in the number of antigen types approved. However, many of the paediatric combination vaccines that are needed to prevent infectious diseases in infants, who represent the future of Japan, have not yet been approved. According to the immunisation schedule for infants recommended by the National Institute of Infectious Diseases (NIID), a sizeable number of vaccinations is required within 18 months of birth to provide adequate protection. Paediatric combination vaccines containing several different types of virus strains are essential to meeting the NIID-recommended schedule. In other countries, a variety of paediatric combination vaccines has been approved and used for more than 10 years. However, Japan lags behind those countries when it comes to introducing and routinely administering paediatric combination vaccines. For example, the DtaP-IPV combination vaccine was finally approved this year, whereas it has been readily available for 15 or more years in Europe and the US.

The quality standard for vaccines imported from Europe and other foreign countries is defined in Japan's Minimum Requirements for Biological Products (MRBP), which are unique to Japan. These requirements often lead to issues in harmonising the quality specification for a vaccine in the manufacturing country and the specification in Japan (MRBP). Items that are not tested by the manufacturer, or for which testing is not required in the country of manufacture and is required only in Japan, are usually added to the MRBP, contributing to the delay in approval and supply processes. As a result, the quality of imported vaccines is examined through three separate, but very similar and hence increasingly redundant stages of lot testing, undertaken by the overseas manufacturer, the domestic marketing authorisation holder and the National Institute of Infectious Diseases (via the National Control Test).

The Government of Japan has established a subcommittee for regulatory and system reform in the Government Revitalisation Unit of the Cabinet Office. After discussions and consideration, the Cabinet decided on the following four actions: (1) expansion of the scope of the EU-Japan MRA to include biological products including vaccines, (2) exemption of vaccines from redundant in-house tests in Japan, (3) periodic review of the MRBP, and (4) routine vaccination with vaccines recommended by the World Health Organisation.

The Ministry of Health, Labour and Welfare (MHLW) also considers vaccines as a central pillar of preventive medicine. It has made efforts to improve the current situation by establishing the "Vaccine Industry Vision" as well as introducing innovative vaccines developed overseas and taking measures against pandemics. EPFIA and the EBC applaud the Government of Japan for taking this step in addition to the above mentioned decisions, which will lead to increased access to innovative vaccines in Japan.

EFPIA and the EBC request the Japanese Government to promote dialogue and implement the reform necessary to encourage Japanese and foreign vaccine manufacturers to invest in the development and production of vaccines (especially paediatric combination vaccines) that can contribute to the improvement of preventive medicine for the Japanese people. To this end, EFPIA and the EBC call on the MHLW to act on the Cabinet decision and work toward the reform of regulations and systems, as well as the revision of non-clinical and clinical guidelines for preventive vaccines against infectious diseases and the establishment of adjuvant guidelines in Japan.

Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	Lundbeck Japan
Bayer Yakuhin	Merck Serono
Bracco-Eisai	Nihon Servier
Chugai Pharmaceutical	Nippon Boehringer Ingelheim
CSL Behring	Novartis Pharma
Ferring Pharmaceuticals	Novo Nordisk Pharma
Galderma	Pierre Fabre Japon
GE Healthcare Japan	sanofi-aventis
GlaxoSmithKline	UCB Japan
Guerbet Japan	

Key Issues and Recommendations

■ Vaccine gap

Yearly status report: progress. The notion that the “Japanese are unique” and “it is only conventional regulatory practice” have long acted as barriers to introducing into Japan paediatric combination vaccines that have been used in other countries for many years and whose efficacy and safety have been proved. Such barriers considerably delay the approval process, thereby leading to the vaccine gap.

Recommendation:

- The vaccine gap should be eliminated by establishing and executing a system that can supply the Japanese people with the vaccines they need, whether of domestic or foreign origin, based on scientific grounds, promptly and at low cost.

■ Harmonisation of clinical guidelines and Minimum Requirements for Biological Products with the EU equivalent

Yearly status report: progress. In 2010, the guidelines on clinical trials for preventive vaccines against infectious diseases came into effect, but give no clear explanation why dose-response studies using Japanese subjects are required. The argument that the dosage regimen used worldwide should be different for Japanese people is not convincing. In Japan, additional tests are added for vaccines whose quality has been already ensured through adequate testing in Europe, requiring all tests to be performed again after importation. In parallel, the vaccines are required to go through the Japanese National Control Test based on the MRBP. Vaccines cannot be released without passing this test.

Recommendations:

- EFPIA and the EBC request that the MRBP should be integrated into the Japanese Pharmacopoeia as we believe this to be essential for the harmonisation process.
- The guidelines on clinical trials for preventive vaccines against infectious diseases should be reviewed to eliminate the unnecessary dose-response study. In addition, in order to provide the Japanese people with the vaccines they need promptly and at reasonable cost, the redundant quality control test items should be removed and a system established to ensure quality that meets today’s standard. This will help in eliminating the vaccine gap, which is currently having a severe negative effect on access to innovative vaccines in Japan.

■ Increase in vaccination coverage

Yearly status report: slight progress. While vaccines are administered to individuals to protect them from infectious diseases, another major goal is to protect the entire community and thus the entire Japanese population from infectious diseases and epidemics through mass vaccination. Japan faces the issue of seeing only marginal increases in immunisation rates, with rates for several approved vaccines at only 30% or less. Such a low rate means that the full benefit of an immunisation programme cannot be reaped.

Recommendations:

- All approved vaccines should be included in the routine vaccination programme to provide maximum protection from infectious diseases, and the adverse reaction compensation system should be expanded.
- EFPIA and the EBC support further active public education on the importance of vaccination and of vaccines to improve the health and growth potential of the population.

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COSMETICS

Introduction

European companies produce a wide variety of innovative and safe cosmetic and quasi-drug products that consumers value and enjoy. The products improve their daily lives in many ways, helping them to keep their bodies clean and healthy, protecting them against the damaging effects of extreme weather, preventing dental cavities and the spread of harmful microorganisms, and improving the way they look. EU cosmetics companies work to ensure the quality, efficacy, safety and environmental sustainability of cosmetics by investing in the research and development of new ingredients and technology, conducting clinical studies on efficacy and safety, monitoring global developments in scientific knowledge, providing information to consumers and meeting or exceeding strict post-marketing surveillance and control requirements in accordance with Good Vigilance Practice (GVP) and Good Quality Practice (GQP).

Japan is the second largest market for cosmetics in the world with sales of 1,609 billion yen in 2010. Japan imported cosmetics valued at 185 billion yen that year, of which cosmetics from the EU accounted for 75 billion yen. European cosmetic and quasi-drug products comprise a large share of imports because Japanese consumers recognise their value. However, European companies face challenges in bringing cosmetic and quasi-drug products to them in an efficient manner due to Japan's lack of regulatory transparency, the low degree of harmonisation between its product standards and those used in other parts of the world, and its unnecessarily complex approval and manufacturing requirements. As a result, the launch of many European cosmetic products in Japan is severely delayed, despite the fact the same products are already in global use and have clinically proven efficacy. Some quasi-drugs even 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 is very limited in Japan on which active and inactive ingredients have already been approved. The EU and Japan maintain different rules governing which ingredients are allowed in cosmetics, expressed respectively in terms of negative and positive lists. Even if an ingredient does not require regulatory approval in Japan when used in a cosmetic, the use of the same active ingredient in a quasi-drug often requires a lengthy approval process. Moreover, approval of products meeting existing approval standards is delegated to the prefectural authorities, but different prefectural offices often have inconsistent interpretations of how the approval standards should be met.

Globalisation has brought unprecedented benefits to consumers world-wide, in terms of new product benefits, greater variety, higher quality and lower prices. However, in any country where the product approval process deviates from international standards and practices, there is an inevitable and significant increase in the complexity of that process and its associated cost. Increasing transparency, streamlining the approval process, and promoting greater regulatory harmonisation between Japan and the EU would make it easier to bring more high value-added products to Japanese consumers in a timely manner.

The EBC believes that the EU and Japan should lead the way by bilaterally negotiating harmonised regulations for quasi-drugs, expanding efficacy claims, and aligning their respective positive and negative lists. The EU-Japan FTA/EPA should be an important vehicle for this process. The EBC also strongly supports greater leadership by the EU and Japan in the International Cooperation on Cosmetic Regulation (ICCR), an international group of cosmetic regulatory authorities from the 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, 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 establish a clear process and schedule for regularly updating and expanding the list of approved active and inactive ingredients.

■ Expansion of efficacy claims for cosmetics and quasi-drugs

Yearly status report: some progress. A scheme for specifying the efficacy of cosmetics was presented in the “Notification on Enforcement of Pharmaceutical Affairs Law” of 1961. Subsequently, 55 efficacy claims were defined for cosmetics in the “Notification on Revision of the Scope of Efficacy Claims for Cosmetics” of 2000. In 2011, the efficacy claim of “making fine wrinkles due to dryness less noticeable” was added to the list after many years of advocacy from the Japan Cosmetic Industry Association (JCIA), supported by the earlier establishment and publication of the “Guidelines for the Method for Evaluating the Functions of Cosmetic Products” by the Japanese Cosmetic Science Society. This development marks significant progress for the cosmetics industry as it is the first step in harmonising Japanese efficacy claims for cosmetics with those of other countries. The EBC hopes that, at the level of quasi-drugs, an application expanding the efficacy claim of “fine wrinkles” to “wrinkles” will be approved. The scope of efficacy claims approved in Japan is still narrower than in other countries, which hinders the entry of foreign-made cosmetics to the Japanese market. Further expansion of the scope of efficacy claims is required to reflect advancing research and technology and accommodate consumer demand for cosmetics and quasi-drugs.

Recommendation:

- The scope of positive efficacy claims for cosmetics and quasi-drugs should be expanded to harmonise the range of efficacy claims in Japan with those of foreign countries. In particular, the EBC requests that the claim of “preventing photo-ageing caused by exposure to ultra violet light,” which is proposed by the JCIA, be approved.

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

Yearly status report: no progress. Every time a company imports a particular cosmetic product, it is required, under the Pharmaceutical Affairs Law, to re-submit the original import notification documentation, obtained when the product was first approved or its product notification submitted. This requirement is wholly unnecessary yet time-consuming to fulfil. Now the MHLW has announced that importers of cosmetics and quasi-drugs will also 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 still 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 product 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 harmonisation of regulations on ingredients.

■ Application of the same legal standards to parallel importers

Yearly status report: no progress. While the administrative authorities have charged some illegal traders with the import and sale of cosmetics without authorisation, or the distribution of products that do not carry the legally required labelling, illegal products are still distributed and marketed by parallel importers on internet marketing sites beyond the reach of administrative supervision and enforcement. There are cases of the import and sale of products without legal labels, products deviating from Japanese regulations, and counterfeit products. These products do not comply with the requirements in place to protect consumers and they also impair fair competition, to the detriment of law-abiding manufacturers and authorised importers.

Recommendation:

- The Japanese Authorities should conduct more effective surveillance and better enforce existing laws related to the import and sale of cosmetic products.

■ Establishing of alternatives to animal testing

Yearly status report: some progress. Use of alternatives to animal testing was officially recommended in the February 2011 MHLW Administrative Circular. In April 2012, guidance on the effective use of alternatives for the safety evaluation of cosmetics and quasi-drugs was issued for the Local Lymph Node Assay (LLNA) (Organisation of Economic Co-operation and Development (OECD) Test Guideline 429) and the *in vitro* 3T3 Neutral Red Uptake (NRU) phototoxicity test (OECD Test Guideline 432) to replace the skin sensitisation test and conventional phototoxicity test, respectively. Six years have passed since the MHLW issued its “Administrative Circular on Alternatives” in July 2006, indicating that test reports based on the OECD alternatives or their equivalent might be used in applications for approval of quasi-drugs. Issuance of further guidance is expected for other alternatives. The Japanese regulatory authorities have already agreed to continue to cooperate and coordinate with and support the activities of the International Cooperation on Alternative Test Methods (ICATM) in the International Cooperation on Cosmetic Regulation (ICCR).

Recommendations:

- The Japanese authorities should issue similar guidance for, and promote the use of, other alternatives that have already been adopted by the OECD and other organisations and for which The Japanese Centre for the Validation of Alternative Methods (JaCVAM) has completed an evaluation and sent a proposal for adoption to the Government.
- Japan should establish an animal protection environment based on the 3R (reduce, reuse, recycle) principle, and abide by its international commitment to protection of humans and the environment.

Consumer Goods

**Liquor
Food**

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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 sales of 6 trillion yen and growing wine consumption. Despite such figures, in terms of value, foreign imports in 2009, at 170 billion yen (Japan Customs), accounted for less than 3% 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. Directly related to this, 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. 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 contravention of the 1998 WTO ruling, which prescribes that the overriding determinant when setting tax categories for alcoholic beverages should be the level of substitutability in terms of production and consumption. 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 imposed in the EU. In addition, the EBC cannot understand why there is a difference 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.

In Japan, the use of lot codes (traceability information) is not compulsory under the Food Sanitation Law, although it is recommended in the Ministry of Health, Welfare and Labour (MHLW) administrative guidelines. By contrast, the EU makes it obligatory to display lot codes on food and beverage products, as they fulfil an important role in any effective and efficient product recall or withdrawal process. Whilst most importers of EU liquor products ensure that lot codes are in good order when products are marketed and put into distribution in Japan, it is common practice for opportunistic traders, prioritising business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up. The EBC urges the Japanese Government to take more proactive measures to protect the health and safety of Japanese consumers by:

1. forbidding the sale of liquor with lot codes that have been erased, covered up or tampered with, and
2. introducing penalties for the wholesale or retail of liquor bottles whose lot codes have been erased, tampered with or covered up.

It is believed that the establishment of penalties will be effective. As the examples of EU countries and the US demonstrate, fines ensure effective implementation of the law without any additional administrative burden.

The lack of accurate Geographical Indicator (GI) definitions in Japan's Liquor Tax Law has been a great concern for the EU. In the long term, it may hinder the ability of European businesses to compete in the Japanese market. The EU and Japan should adopt common definitions within the context of the EU-Japan FTA/EPA.

Key Issues and Recommendations

■ Traceability

Yearly status report: no progress. Lot codes (traceability information) fulfil an important role in any effective and efficient product recall or withdrawal process. In the case of a serious health threat, delays to such processes could endanger consumers: a rapid, targeted and efficient response is vital in order to protect them and preserve their confidence in the supply chain.

Whilst most importers of EU liquor products ensure that lot codes are in good order when products are marketed and put into distribution in Japan, it is common practice for opportunistic traders, prioritising business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up.

Recommendation:

- The Government of Japan should issue an administrative guideline, reinforced by penalties, that forbids the wholesale or retail of liquor bottles whose lot codes have been erased, tampered with or covered up.

■ Tariff on wine

Yearly status report: no progress. Japanese wine duty is arbitrarily high in comparison with the duty applied to beer, brandy and whisky, which was reduced to zero in 2002 (in accordance with agreements reached at the 1998 WTO panel).

Recommendation:

- The EBC urges Japan to completely remove all tariffs on wine.

■ Tariff on white spirits

Yearly status report: no progress. Japan committed to apply a tariff of zero from 1 April 2002 on spirits for WTO members. However, whereas the zero-tariff on whisky and brandy is permanent, the reduction for other spirits, notably, rum, gin, vodka and liqueurs is applied only on a temporary basis.

Recommendation:

- The EBC urges Japan to change the applicable tariff lines for white spirits to become permanently zero.

■ Additives

Yearly status report: no progress. The list of additives approved by the Japanese authorities for inclusion in liquor is outdated and differs greatly from the lists of other industrialised countries. In addition, the process for having additives declared safe is both very costly and time-consuming.

Recommendation:

- Japan should swiftly approve additives that are in common use among industrialised countries.

■ Wine definition

Yearly status report: no progress. The Japanese definition of wine is too broad. The loose wine definition opens the door for different products to be sold as “wine”, misleading Japanese consumers and creating unfair competition for European wines, which meet the internationally accepted definition.

Recommendation:

- Wine definitions 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.

■ Geographical Indicators

Yearly status report: no progress. GI terminology in Japan is not compatible with the EU-origin concept and rules.

Recommendation:

- The EBC urges the Japanese Government to reinforce the GI rules in its Liquor Tax Law in line with EU definitions.

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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, whether processed or not. The relative scarcity of imported packaged food in Japanese supermarkets compared to other developed countries bears witness to this. It can indeed be found in regular supermarkets, but the assortment is, with few exceptions, limited to only a fraction of the potential. The situation is better in upscale and gourmet specialised shops, where price matters less. However, there is no reason why imported European food should be either so expensive or exclusively upscale.

There are two main factors behind the current situation. The first and most important is tariffs. Food is purchased everyday and therefore price is a key decision factor for consumers when choosing what to buy. European packaged food is at a clear disadvantage as it is subject to tariffs that can represent a large proportion of the price, and in some cases the tariff is effectively even more than 100%. Ordinary butter is an example of this anomaly.

The second factor is the large number of non-tariff barriers that have a serious impact on the amount of food imported from Europe, in terms of both volume and variety. For example, Japan remains "out of sync" with other countries as the majority of food additives declared safe by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) are still not approved in Japan, while many approved additives in Japan are not accepted by the Joint FAO/WHO Expert Committee on Food Additives (JECFA). Accordingly, Japan has only accepted scientific evaluations by international bodies such as JECFA and the Codex Alimentarius Commission (CODEX) to a limited extent, which has led to approval procedures in Japan being both time-consuming and overly costly.

Another example of a non-tariff barrier to trade is that Japan does not recognise the EU regulatory approach of distinguishing between foods that support the growth of *Listeria monocytogenes* and foods that do not. The EBC believes that food products that do not support the growth of listeria and contain only a non-harmful level of listeria should be approved for import.

Last but not least, despite Japan's recent recognition of organic certifications issued by the new EU Member States, and the EU's recognition of organic certifications issued by Japan, the Organic-JAS (Japan Agricultural Standard) Mark still cannot be used for many EU certified organic products. Moreover, Japan lacks comprehensive legislation for several categories of agricultural products (such as honey). Due to the complexity of obtaining the Organic-JAS Mark and the limitations in product scope, organic food in Japan lags far behind that in other developed markets in terms of market share.

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. European food products in subsectors that are not hampered by high tariffs or non-tariff barriers are very popular in Japan, clearly indicating the demand for European food. We believe that our closely shared principles strongly support the potential for success of the EU-Japan FTA/EPA. Under the agreement, tariffs should be abolished, standards harmonised and market authorisations of both regions mutually recognised, without compromising food safety. The EBC Food Committee believes the agreement will lead to more choice in supermarkets and stimulate healthy competition in the food and agricultural sectors of both zones and to European food being more accessible, something we know Japanese consumers would appreciate.

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

Key Issues and Recommendations

■ Tariffs & quotas

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 related to quota), fruit juice and fruit puree for babies (21.3%), and herbal tea (15%). Quotas also exist, for example for dairy products and sugar, and add a further tax to be paid when importing food containing such ingredients.

Recommendations:

- The Government of Japan and the EU should abolish tariffs on food products as part of the EU-Japan FTA/EPA.
- The quota system should be abolished, especially for dairy products and sugar and its derivatives.

■ Food additives – Lecithin of sunflower origin

Yearly status report: slow progress. Lecithin is a food additive used worldwide and has no associated health or safety issues. JECFA evaluated the safety of lecithin for use in foods in 1973 and established an Acceptable Daily Intake (ADI) evaluation of “not limited.” The safety of lecithin in foods is widely recognised by regulatory authorities in other countries, but remains prohibited in Japan. Sunflower lecithin safety can be established based on its substantial equivalence with soybean lecithin. In the US, it is approved by the US Food and Drug Administration (FDA); in the EU, it is approved as a food additive (Commission Directive 2008/84/EC) with no reference to the lecithin source.

Recommendation:

- The EBC continues to request that the Ministry of Health, Labour and Welfare (MHLW), in cooperation with the Food Safety Commission (FSC), swiftly approves lecithin of sunflower origin.

■ Food additives – List of 45 additives (since December 2002)

Yearly status report: slow progress. In December 2002, based on input from the EU and US, MHLW prepared a list of 46 food additives (today 45) that are not approved in Japan, but “have been proven safe and are widely used in the rest of the world” and agreed to fast-track them through the approval process. As of today, 15 of these remain to be approved by the FSC. The EBC understands that MHLW will issue a road-map to speed up approval of these 15 additives.

Recommendation:

- The FSC should start the approval process for the 15 remaining additives without further delay.

■ Food additives – Standard of use

Yearly status report: no progress. The EBC consistently notes that some widely used additives (especially preservatives), such as sulphur dioxide (SO₂) and sorbic acid (potassium sorbate), have widely varying “allowed usage levels” in Japan, depending on the food category in which they occur. For SO₂, the allowed usage level can be as high as 5 g/kg for designated food categories, or as low as 0.03 g/kg for “other foods”. For sorbic acid, there is no “other foods” category.

Recommendation:

- 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.

■ Beef and beef derivatives (casings, gelatines)

Yearly status report: progress. In 2012, the FSC issued a recommendation for the removal of the ban on meat imports from France and The Netherlands. Imports will re-open in 2013 for these countries for animals under 30 months of age (fresh and frozen meat). It has, however, been indicated that processed food containing beef and bovine gelatines will remain banned. It is noted that in 2013, Japan will be granted “negligible risk” status by the World Organisation for Animal Health (no new BSE cases found in the last 11 years), giving a guaranteed boost to exports of Japanese beef.

Recommendations:

- The EBC recommends that the FSC speeds up the process for EU Member States that have already submitted data to the Ministry of Agriculture, Forestry and Fisheries (MAFF) and MHLW.
- The EBC recommends that processed food containing beef, bovine gelatines, or products made with beef casings, should also be approved for import as they are widely used in the European food industry, which has already established high safety standards.

■ Listeria Monocytogenes

Yearly status report: no progress. Listeria monocytogenes is a widespread pathogenic bacterium. If allowed to grow, it can contaminate food 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 food that supports growth of the bacteria, whilst accepting minute levels of L. monocytogenes (less than or equal to 100 cfu/g) in food not supporting growth of the bacteria due to particular characteristics (e.g. pH, water activity, certain processes or treatment). However, Japan makes no such distinction and bans all foods that contain L. monocytogenes

Recommendation:

- Japan should review its position on L. monocytogenes and consider aligning regulations with the “double approach” adopted by the EU, Canada and other countries, and also supported by the principles of CODEX and the FDA.

■ Tests of Caesium contamination for selected European products

Yearly status report: new issue. A new law on caesium levels was passed in Japan in April 2012, reducing the yearly maximum dose for humans from 5 to 1 millisievert and the maximum general level in food from 500 to 100 Becquerel per kilogram. Customs is now required to conduct tests on a number of specific products, especially processed food containing berries from Ukraine, Poland and Sweden. Currently, tests have to be conducted in Japan for each shipment.

Recommendation:

- Certificates issued at the country of origin should suffice to ensure that the food is compliant with the new Japanese regulation on radioactivity levels.

■ Yearly analysis (additives, bacteriological) at Customs

Yearly status report: new issue. At present, food imported into Japan requires analysis on a regular basis (at least once per year). As food safety standards in the European Union are as high as in Japan, there should be no need for Customs to conduct additional analyses of EU food imports. Such analyses cost time and money and do not help in improving consumer safety, especially since they are carried out on a random basis.

Recommendation:

- Eliminate the need for a yearly analysis of EU foods (additives, bacteriological) at Customs.

■ Organic food – Full equivalence between EU and Japan

Yearly status report: slow progress. Despite the fact that the EU and Japan now mutually and fully recognise each other's organic labels (the Organic-JAS Mark has been recognised by the EU since 2011), the development of the organic food market in Japan remains very slow overall for both foreign and domestic organic products. The EBC believes the reason lies in the incomplete certification system in Japan.

There are currently two main groups of products, in addition to honey, related to the Organic-JAS Certification system:

- I. Organic agricultural products – the product must qualify for an Organic-JAS Mark, which must be affixed in order to show the product is “organic”;
- II. Animal products – The Organic-JAS Certification system does not apply to these products. A voluntary system exists where producers or importers can nevertheless claim their product is “organic” without using the Organic-JAS Mark;
- III. Honey, which is neither an agricultural product nor an animal product and so a claim can be made that the product is “organic” without reference to any Organic-JAS Mark.

As a direct consequence, a product with mixed ingredients, like chocolate with milk or jam with honey, cannot acquire the Organic-JAS Mark, if it contains more than 5% of milk or honey. The complex and incomplete regulatory framework of the Organic-JAS Certification system (the Organic-JAS law itself) fails to inspire confidence in consumers, who cannot rely on a single and comprehensive reference (the Organic-JAS Mark). Consequently, producers and importers of organic foods cannot convey the full value of their products to consumers, hampering expansion of this market segment.

Recommendations:

- Remove the need for supplementary organic certificates from EU Embassies for organic food that requires Organic-JAS Mark labelling in Japan.
- Allow EU organic food producers, who are organic certified by a recognised EU organic certifier, to affix Japanese labels with the Organic-JAS Mark without requiring Organic-JAS certification, provided they export to an Organic-JAS certified importer in Japan.
- Additives that are allowed in organic food in the EU should also be allowed in organic food in Japan.
- MAFF should declare full equivalence between Organic-JAS and Organic-EU. This will be beneficial not only for EU producers, but also for Japanese producers.

Industry

Automobiles
Automotive components
Aeronautics
Space
Defence & Security
Construction
Materials
Environmental technology
Energy

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AUTOMOBILES

Introduction

The Japanese domestic passenger car market has rebounded strongly from the disruptions of 2011 to levels last seen before the 2008 financial crisis. European imports have shared in the recovery. In the first 9 months of 2012, sales have risen by 21% to 167,000 units. This increase has, however, not been sufficient to prevent an erosion of the European share of the domestic market.

While the overall recovery is welcome, the market continues to be distorted by the operation of the Government's eco-incentive and subsidy schemes. As noted in previous EBC Annual Reports, these schemes are nominally open to all, but the differences between Japan and the EU in fuel efficiency and emissions testing cycles used to assess eligibility for the subsidies and incentives raise the cost to European importers of qualifying for the benefits. The short lead time between the announcement of the new schemes at the end of 2011 and their implementation gave small volume importers little opportunity to make the necessary engineering changes to qualify. Nor was it commercially viable for them to do so. Whereas some 80% of domestic models have qualified for incentives and subsidies, only 60% of imports have done so. Now that the eco-subsidy has expired, there are already signs that the market has once again begun to recede.

The Japanese passenger car market is further distorted by the inexorable growth of the kei car segment. "Kei" or mini-cars are a vehicle classification unique to Japan: such vehicles are restricted to a maximum length of 3.4 m, a width of 1.48 m, a height of 2 m and an engine displacement of 660 cc and below. Kei cars benefit from lower automobile-related taxes, automobile liability insurance and motorway tolls and are subject to less stringent overnight guaranteeing requirements. No foreign model qualifies for kei car designation, an artificial construct of the Japanese regulatory system. In the first nine months of 2012, kei cars accounted for 34% of the domestic passenger car market. The Japan Automobile Dealers Association forecasts that this share will grow to 40% by 2020. The regulatory and fiscal privileges enjoyed by kei cars substantially restrict the market available to European compact and subcompact imports with a comparable performance and pre-tax purchase price.

In the longer term, the Japanese domestic car market faces the prospect of prolonged decline owing to demographic changes. Mitsubishi Research Institute has forecast on behalf of the Japan Automobile Manufacturers Association that by 2020 the car market will shrink by 660,000 units relative to 2010. Even to be able to maintain the current level of sales, European importers will need significantly to increase their market share.

At a time when Japan is pressing the EU to open negotiations on a bilateral Free Trade Agreement, it is all the more important that the Japanese Government should take the necessary steps to create a level playing field in the trade in cars between the EU and Japan. The Impact Assessment of a Free Trade Agreement published by the European Commission on 18 July estimated that the Non-Tariff Barriers faced by the European automobile industry in Japan were the equivalent of a tariff of 12.5%. The EBC Automobile Committee has welcomed Japan's proposal to develop an International Whole Vehicle Type Approval (IWVTA) system within the framework of the United Nations Economic Commission for Europe (UNECE). The EBC Automobile Committee hopes that Japan and the EU, additionally, will set an example to other participants in the IWVTA process by bringing forward the implementation on a bilateral basis of the mutual recognition of automobile standards and certification procedures based on UNECE regulations, so that any vehicle which has been tested and certificated in the EU can be sold in Japan without the need for further testing or modification.

Key Issues and Recommendations

■ Harmonisation of technical standards and certification procedures

Yearly status report: some progress. The EBC Automobile Committee welcomes Japan's proposals in the UNECE for the adoption by 2016 of an International Whole Vehicle Type Approval (IWVTA) system and calls for its earlier implementation on a bilateral basis. This would make mutual recognition of vehicle certification possible between Japan and the EU.

Recommendations:

The Government of Japan should:

- Accelerate the adoption of existing UNECE Regulations in areas where Japan retains unique national requirements.
- Work closely with EU Member States and the European Commission to implement on a bilateral basis the proposal for an International Whole Vehicle Type Approval system.

■ 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.
- Take advantage of the revision of the Consumption Tax to simplify the structure of the taxation of automobiles and to 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.

■ 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 regulatory and fiscal footing.

■ High Pressure Gas Safety Act

Yearly status report: new issue. The High Pressure Gas Safety Act acts as an impediment to the introduction into the Japanese market of new environmental and safety technologies such as fuel cell, LPG and CNG vehicles, hydrogen airbags and refrigerants with a low global-warming potential for car air-conditioning units, which are already in use in the EU and elsewhere.

Recommendation:

- The Government of Japan should take the necessary steps to allow the use of these technologies with the minimum administrative burden.

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AUTOMOTIVE COMPONENTS

Introduction

Mentioning the Tohoku disaster is unavoidable when dealing with the automotive components sector. While the sector shared the human tragedy, it also became apparent that its supply chain was very vulnerable. Several Japanese companies had depended on a single supplier based in the affected region, and this severely hurt production upstream. This, together with the strong yen, has changed the business environment in the vehicle components sector. Japanese vehicle manufacturers are today more open to doing business with foreign companies, both from a monetary perspective and to spread the risk via a second supplier.

At the same time, the process of globalisation and intense competitive pressures have together caused the outsourcing of automobile component development and supply to emerge as a clear trend in the European automobile industry. The European system now offers low risks, reasonable prices and flexibility. In the past, European component manufacturers that had enjoyed success with Japanese transplants in Europe had seldom been able to build on this base to become suppliers of the parent company in Japan. However, European firms are finding that, as a result of recent changes in the Japanese automobile manufacturing sector, new opportunities are surfacing and more and more are now dedicating resources to attracting business in Japan, investing in local infrastructure and improving technical competence, with the goal of promoting more direct contact and closer relationships with Japanese clients. 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.

As it stands, however, Japanese firms are still uneasy about divulging proprietary information to outsiders, and continue to favour traditional suppliers for product design and production. It is standard business practice for Japanese automobile manufacturers to request an exact product instead of setting up a framework of open standards to fulfil, which reflects their lack of transparency and reluctance to consider new inputs, thus defying the global trend towards single platform development and volume production. The EBC feels that Japan's failure to use international technology makes its industry overly inward-looking, a situation unfortunately reinforced by the lack of English use. Japan still has some way to go to become a truly global market.

Japan is a member of Working Party 29 on transport issues within the United Nations Economic Commission for Europe (UNECE) and has recognised regulations related to tyres: Regulation no. 30 (Passenger Car), 54 (Light Truck, Truck & Bus) and 75 (Motorcycle). There are some slight differences between the Japanese regulation and the UNECE regulation, but the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has repeatedly confirmed that tyres fulfilling UNECE (E marked tyre) requirements are fully legal in Japan because Japan ratified the UNECE 58 Agreement in 1998. However, *Jisha* 502 (MLIT Notification in 1982) specifies that every approved tyre for the Japanese market has to be listed in the Japan Automobile Tyre Manufacturers' Association's (JATMA) Year Book. In order to be listed in the Year Book, a tyre must comply in detail with Japanese regulations. Any product that complies with UNECE regulations, but not with the precise Japanese regulations, is therefore not listed. This puts such tyres at a disadvantage in the market where some retailers will not carry them.

The EBC also notes the almost oligopolistic situation in the tyre market. Brand-exclusive networks make it very difficult for outsiders to penetrate the market, leading to less competition, which does not benefit the consumer who has to pay higher prices while only having access to a limited variety of tyres.

Key Issues and Recommendations

■ Globalisation of the automobile industry

Yearly status report: 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 Japanese practice of working with affiliated companies presents obstacles and leads 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 the 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 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 affiliated 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 considerable potential value in the Japan Society of Automotive Engineers' (JSAE) Automotive Engineering Exhibition and the annual congress/paper presentation scheduled for 22–24 May, 2013 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 car manufacturers. The EBC also hopes that the scope of these meetings will be expanded in the future to include Japanese venues.

■ Tyres

Yearly status report: new issue. Jisha 502 specifies that every approved tyre has to be listed in JATMA's Year Book. Although tyres fulfilling the applicable UNECE regulation are perfectly legal, and of course safe, in Japan, JATMA refuses to include tyres that are not in complete compliance with Japanese regulations. This puts European tyres at a disadvantage.

Recommendation:

- JATMA should without delay include UNECE-compliant tyres.

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AERONAUTICS

Introduction

Despite the professed commitment of Japan's current leadership to reform, there is still no clear sign of the much-needed review of Japan's policies in the field of aeronautics. These policies have long influenced the direction of the aeronautics industry in Japan, ignoring business realities far beyond the reach of politicians. The Japanese aeronautics industry should be given the freedom to benefit from closer cooperation with European aeronautics companies. The EBC therefore calls on the Government to focus its efforts on fostering such collaborations.

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 recommends that Japanese airlines and other aircraft operators consider the benefits of increasing competition, the inherent risk of depending on a single source, and the advantages of diversifying suppliers. European companies provide state-of-the-art technology and highest-quality products and goods, as well as customer support services that are second-to-none. For instance, the Airbus A380 commercial aircraft offers unprecedented opportunities to airlines in Japan to provide 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. Japanese equipment manufacturers, disappointed with their lack of success in supplying their traditional foreign customers, are showing increasing interest in Europe. An EU-Japan Aeronautics Industry Workshop, which took place in November 2009, enjoyed an encouraging response. However, cooperation in commercial aircraft development in Japan is still heavily biased in favour of North America, hence Japan's aerospace industry is often still reluctant to work with European companies. Such loyalty may at first sight be understandable but, given that US and European aeronautics suppliers routinely cooperate in virtually all major aircraft programmes and supply each others' prime contractors on a large scale (typically 30%), it now looks somewhat misplaced.

However, not all is doom and gloom. With new Japanese and foreign airlines now flying in Japanese airspace, opportunities have opened up for the European aeronautics industry. In the last two years it has seen an increase in both the lease and purchase of European aeroplanes. In 2012, Peach Aviation and Jetstar Japan, as well as AirAsia Japan, all had operations flying Airbus aeroplanes. The EBC was pleased to see that Japan's "era of Low Cost Carriers" took off with the Airbus A320, and we hope that these first successes will pave the way for further progress.

The EBC believes that, while an "all-Japan-team" attitude may be easy for Japan's Government to manage in the short term, it is unfit for this new era of competition and goes against all the lessons learned in other countries. Proactive collaboration with successful European companies would enable Japanese companies to strengthen their position in commercial aeronautics. By joining a wider range of projects, Japanese firms would be able to expand their international business opportunities and further develop their technological base. The EBC feels that there is considerable scope 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 seize the opportunity to develop 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 smaller than its average share worldwide. The Japanese aeronautical sector is afflicted by a general lack of transparency in the way it undertakes equipment procurement, as exemplified by the attempt at modernising its air traffic management system. European companies are recognised worldwide as setting state-of-the-art standards, yet 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. We also urge the Japanese authorities to facilitate greater use of equipment from foreign manufacturers who can help them 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. Yet 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 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 search for innovative solutions to meet future needs in civil aviation. The EBC considers these challenges as an opportunity to enlarge the scope of cooperation between Japan and Europe and encourages METI and relevant government-affiliated institutions to openly promote and fund collaboration with European companies as they do 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

The political leadership that came to power in Japan in 2009 has continued to implement the progressive and significant reform of the country's space activity jurisdiction that started a decade ago. The context is a broader recognition of the space sector as critical for national security, which together with severe budgetary constraints, is making effective unification of space policies across Japan's ministries a more pressing necessity. The strategic need to maintain a healthy domestic space industry has led Japan's administration to more actively seek growth in export markets, although it is still mostly geared towards domestic government contracts.

The overall changes in recent years are significant. Japan is now forced to make strategic budgetary choices and regards space not only as an arena for science and technology, but also for national security and business. It is, furthermore, proactively helping its domestic industry to seek growth in overseas markets through ad hoc, all-Japanese industry consortia. The Ministry of Economy, Trade and Industry (METI) assists the Japanese space industry in supplying emerging countries with all-Japanese satellite systems, through funding tied to Official Development Assistance (ODA). The packages include satellites, their launch service, operations, data analysis, maintenance, personnel training, technology transfers, and other services. Contrary to EU policy, Japan's ODA contracts must be awarded to its domestic industry, resulting in a distorted and uncompetitive market.

The EBC cautiously supports Japan's administrative reform as it makes space jurisdiction more transparent and, to some extent, the market more accessible to foreign companies. While generally respecting Japan's space policies, the EBC believes that fewer all-Japanese consortia and more cooperation with Europe in this sector would bring significant advantages to Japan in terms of budgetary savings and enhanced national security, research and development, and commercial success on the global market. Since Japan has for several decades consistently ignored most European overtures and capabilities in the space sector, we hope that negotiations on the FTA/EPA will lead to Japan's claims of market opening finally being realised. The EBC believes that Japan to reverse the current negative situation.

The private satellite market is ostensibly open to all suppliers. There used to be at least one launch of a communications or a broadcasting satellite a year, but the market has lapsed into a continuing trough due to the general state of the economy. Satellites with business and practical applications of former government monopolies have been procured through international tenders since 1990. These now only relate to the Multi-functional Transport Satellite (MTSAT) series and the broadcasting satellite (BSAT) series. Despite the apparent openness of the market, participation in government tenders is very difficult for European companies, due largely to the contract language, unlimited liability, other unrealistic clauses, and currency problems.

No-tender government programmes include the science and technology satellites of the Japan Aerospace Exploration Agency (JAXA), a small number of programmes under METI, and the defence-purpose remote-sensing Information Gathering Satellites (IGS). A new dedicated defence communications satellite programme is underway. Japan's willingness to cooperate in satellite development programmes, however, remains biased towards the US, whose political influence has had an adverse effect on the development of both the Japanese and EU space industries in Japan.

Ariane launchers are successful in Japan and could play a broader role in cooperation. Arianespace and Mitsubishi Heavy Industries already allow commercial customers to shift satellites from Ariane 5 to H-IIA and vice-versa to avoid launch delays due to technical mishaps. However, talks between the Japanese and European space authorities towards a mutual back-up of government launch missions have stopped. In addition, a future Space Activities Act may require Japanese commercial customers to seek government approval before procuring foreign launch services. Any need to apply and wait for government approval would be 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: new issue. A new Office of National Space Policy has been created in the Cabinet Office with a greater level of empowerment than previous setups. The political will to allow Japan's independent ministries to follow consistent space policies will be put to the test. The EBC advocates policies that make mutually beneficial trade and balanced cooperation possible. More openness towards EU industry would benefit the Japanese Government's industry space plans, as Europe provides better and cheaper technology in a cooperative way, free from "black-box" policies of concealing technologies from the buyer. Japan is also toying with Private Finance Initiative (PFI) ideas, where satellites would serve both public and commercial purposes but would be regarded as governmental as far as building and launching them is concerned. As a result, foreign satellite makers and launchers would be excluded from Japan's commercial market in a piecemeal fashion.

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 encourage more cooperation between the Japanese and European space industries.
- The EBC recommends mutual recognition of Japanese and European export control procedures.
- The EBC recommends Europe-Japan coordination and cooperation in space-related ODA worldwide.
- PFI projects should not exclude European participation.

■ Satellites

Yearly status report: no progress. Japanese policy mostly ignores Europe's satellite technology. The space agencies of both sides cooperate in science and research, but do not achieve much in terms of industrially meaningful cooperation.

Recommendations:

- The EBC advocates closer space agency cooperation in satellite technology development and applications, with pro-active promotion and execution of industrially and commercially meaningful cooperation projects.
- The Government of Japan should increase cooperation with Europe through the procurement of high-quality satellite systems or equipment in fields related to national security. This includes the joint development of high-quality sensors or their production by Japanese industry under licensing arrangements.
- Government procurement methods, terms and conditions should not place European makers at a disadvantage.

■ Launchers

Yearly status report: no progress. Currently Japan and the EU are not backing up each other's government-related launches. Doing this would reduce launch delays and prevent loss of business to third countries with no possibility of providing such back-up. Such measures were suggested to Japan's space authorities in 2002, but still no agreement is in sight. For technical and cost reasons a backup agreement must be comprehensive and systematic to be successful. Currently, however, political leadership is missing on this issue.

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 satellite launchers.
- The EBC stresses the importance for Japan's satellite communications and broadcasting industry of eliminating administrative burdens, difficulties and delays when acquiring foreign launch services.

■ Ground equipment

Yearly status report: no progress. As Japan's international procurement activities in this area generally exclude entire systems and remain limited to subsystems and components, foreign suppliers are placed at a disadvantage.

Recommendation:

- Japan's international procurement of ground equipment should include whole systems. The procurement process for standard ground processing products should not place European suppliers at a disadvantage.

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DEFENCE & SECURITY

Introduction

Despite recent economic difficulties and political drift, Japan remains the world's third largest economy and an important ally for the US and NATO (North Atlantic Treaty Organisation), sharing common values and interests in the Asia Pacific region and globally.

The security environment surrounding Japan remains complex. North Korea has launched several missiles during the past few years, the latest being in April 2012. China continues to strongly and actively assert its claims on the Senkaku Islands by use of non-military action. To avoid further escalation, the US has openly stated that the security of the Senkaku Islands is subject to the US-Japan Security Treaty. Russia has continued to assert its right to the Northern Island chain. The Republic of Korea and Japan are in dispute over the Takeshima Islands.

The Japan-US alliance remains the cornerstone of Japan's national security policy after the transition from long-term Liberal Democratic Party (LDP) rule to the current Democratic Party of Japan (DPJ) Government. The 2010 National Defence Program Guideline focuses on strengthening Japan-US cooperation and protecting Japanese maritime sovereignty through the "dynamic defence" concept that involves greater defence capabilities in the southern island chain near Okinawa. Furthermore, in recent years, a number of major procurement decisions have been made in favour of US manufacturers or Japanese manufacturers working under US licences, choosing Lockheed as opposed to the Eurofighter consortium on the FX programme, and Mitsubishi Heavy/Sikorsky as opposed to Eurocopter on the ASDF (Air Self-Defence Force) UH-X (rescue helicopter) programme.

On the other hand, Japan realises that it must reach beyond the US if it is to play a greater role on the global stage and it has started broadening cooperation with other maritime powers such as Australia and India. The Joint Statement on the UK-Japan Defence relationship that was agreed between Prime Minister Cameron and Prime Minister Noda, during Cameron's visit in April 2012, is an attempt to forge closer links between Japan and the UK. Other nations in Europe and NATO, including France, are in discussions with the Japanese authorities for the same purpose.

The Japanese defence industry is the major supplier to the nation's own Self-Defence Forces. Production costs are, however, high due to the low rates of production, independent research and development and the perceived importance of securing national self-sustainability. On the industrial side, difficult times continue for Japan's defence contractors, with the defence budget having decreased for a number of years and several Japanese defence-related companies having exited the market during this period. In June 2012, the Defence Production and Technology Base Research Committee submitted an alarming report to the Defence Minister on the state of Japan's defence industry. The production of fighter aircraft, sub-assemblies and systems has been the pillar of the aircraft industry for a long time and is decreasing. In addition F-2 fighter production was terminated last year with little work deriving from the FX (fighter aeroplane) programme to replace it.

On March 11, 2011 Japan experienced the largest earthquake in its history. The Japanese Self-Defence Forces gained great respect from the Japanese people for their outstanding efforts in the ensuing earthquake and tsunami recovery operations. Many Japanese were highly impressed with their devotion and efficiency at a time of uncertainty and as a result have altered their perception as to the need for a National Security and Defence Force.

On December 27, 2011, the Japanese Government announced new Guidelines for Overseas Transfer of Defence Equipment. These revised guidelines permit the overseas transfer of defence equipment under certain conditions, by allowing comprehensive exemption measures under the Three Principles on Arms Exports. The EBC welcomed these changes and the opportunity to meet representatives from the Ministry of Defence (MoD), Ministry of Foreign Affairs (MOFA) and Ministry of Economy, Trade and Industry (METI) to discuss the new guidelines. Meetings were also held with the Defence Production Committee of the Japan Business Federation (Nippon Keidanren) to explore the implications for EU-Japan industrial partnerships.

Key Issues and Recommendations

■ Procurement

Yearly status report: some progress. The MoD has made an attempt to improve the transparency of its procurement decision-making process by declaring a point system to determine the winner and providing a debrief as to how the decision was made. However, the point system is not very clear and debriefs need to be more detailed to have any real value. The EBC would also encourage the MoD to create an appeal process. The MoD should also send a clear message to suppliers that if they do not fulfil the contract on the basis of their selection there will be serious consequences and/or cancellation of the contract.

A greater emphasis on Life Cycle Costs (LCCs) is also welcome. EU companies have considerable experience in modelling and predicting LCCs and are confident about their ability to guarantee predictions and enter into fixed price contracts. This prevents price shocks and escalations. LCC models used in the EU can be shared with Japan, as they are based on the same features in areas such as manpower, equipment levels and training policies.

Recommendations:

- Japan should improve transparency towards foreign suppliers by making the Statement of Requirements (SOR) for procurement processes more widely available and placing more emphasis on LCCs.
- The MoD should consider adopting NATO standards for the initial research and development phase of each defence project to strengthen competition and reduce development risks.
- The Government of Japan should 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 MoD should also implement a multiyear contract scheme for weapon acquisition in order to obtain the best conditions in terms of prices and local content from foreign manufacturers.

■ Industrial partnerships

Yearly status report: some progress. EU industry can assist the MoD in meeting cost-reduction targets by offering 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 both very experienced in and open to technology and know-how transfers to partner companies of allied countries, such as Japan.

Recommendations:

- Japan should enter into agreements with EU countries to ease technology and information exchange at both a government-to-government level and an industrial level.
- Intellectual property rights must at all times be respected if partnerships are to be successful.
- 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 among Japan's political and administrative leaders.
- The Government of Japan should provide a stimulus package to encourage cooperation with European industry given the current paucity of defence relationships between Japan and the EU.

■ Defence exports

Yearly status report: no progress. The European defence industry has a large share of the global defence market through both direct sales and cooperation with foreign governments and industries. European defence companies are eager to work with the Japanese defence industry to develop programmes which have a broader market application and are capable of export by the partnership. However there needs to be a clearer defence exports policy. The current *ad hoc* arrangement between the MoD, METI and MOFA makes it too difficult for industry to assess the potential market for a product.

Recommendation:

- The Japanese Government should develop a better defined defence export policy.

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CONSTRUCTION

Introduction

Construction remains a challenging market in Japan, as the industry faces pressure to undertake a massive re-building effort in the Tohoku region following the March 2011 disaster, while struggling with demographic changes in the workforce and a generally sluggish economy.

Prolonged recession and economic uncertainty, combined with government efforts to cut back public works to reduce the deficit, sent overall investment in construction into decline from 1990 onwards. However, this trend was reversed in fiscal year 2011, with investment reaching 46.5 trillion yen. Moreover, total imports of building products to Japan increased by 6.5% over fiscal year 2010, to 110.7 billion yen. Accordingly, Japan is still one of the largest construction markets in the world, but it is not seen as having obvious long-term growth potential relative to other Asian markets. The Government of Japan has made enormous efforts to stimulate the economy through supplemental budget provisions primarily focused on Tohoku reconstruction, but a positive effect on the construction market has been limited by demographic change placing pressure on the availability of skilled labour and hence on profitability for contractors. In theory, reconstruction of the Tohoku region appears to offer unlimited opportunities for construction companies, but in reality, due to the sensitivities of these projects, profitability remains an issue. The EBC understands the urgency of these reconstruction projects, but believes the best way to deliver solutions to the needs of Tohoku in an efficient, economic and environmentally responsible manner is to ensure that an open and transparent procurement process is maintained, so that global best practices can be realised. The EBC also believes that, as part of a broader immigration policy, the Japanese Government should consider expanding opportunities for construction companies to hire internationally qualified trade labour (such as carpenters, plumbers, electricians, and plasterers), which may ease the recruitment difficulties they face.

Recently, some analysts have suggested that the property market decline 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 critical 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, a figure that continues to increase, the activities of the construction and property management industry will fall under close scrutiny, especially as Japan addresses long-term power supply issues. In particular, in the wake of the Tohoku disaster and the resulting energy shortages, suppliers, authorities, and individual consumers have shown a renewed focus on sustainability and energy efficiency.

Many regulatory initiatives are made at municipal level via the administrative guidance process. This places the authorities in a difficult position when required to make fair and technically informed decisions on compliance without reference to international standards. It also makes it difficult even for domestic companies to keep track of all the relevant guidelines. Furthermore, much of the documentation is available only in the Japanese language. This reduces transparency and hampers access to information by European companies, making it difficult for them to recognise opportunities or deliver goods and/or services in compliance with the latest regulations, even if they have the relevant technical capacity. The EBC encourages the Japanese Government to treat the strengthening of policies geared towards sustainable practices as a high priority and advocates standardisation of regulations and application of global equivalencies and internationally recognised assessment techniques as an alternative to the current unhelpful mix of local and proprietary incentives or quasi-mandatory administrative guidance.

The EU-Japan FTA/EPA should include mutual acceptance of standards and certifications for construction product convergence, so that EN (European Standards) standards and CE-marking (*Conformité Européenne*) can be used interchangeably with JIS/JAS (Japan Industrial Standards/Japan Agricultural Standards) standards. It should also ensure improved transparency, 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: no progress. European firms could make a significant contribution to the development of Japan's construction market in terms of innovative designs, technology, materials and methods, but attracting them will require the reform of over-prescriptive regulations, a shift in the attitude of local officials resistant to change, and rationalisation of unnecessarily complicated procedures for obtaining mandatory approvals. Alignment of standards and testing methods across industries and across borders will be essential to achieve the benefits anticipated for Japan. Currently, 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 JAS/JIS and EN standards for building materials. CE marking of construction products should suffice as a guarantee of their high quality and safety when sold in Japan. Non-harmonisation is unfortunately still common, examples being in the flooring sector and for roofing sheets.
- Relevant foreign experience should be recognised as equivalent to domestic experience when granting a general construction licence (*kensetsugyo kyokasho*).

■ Promotion of environmentally friendly construction

Yearly status report: some progress. Improved building insulation is one of the simplest and most effective ways to reduce energy use, and also generates a positive monetary return (source: McKinsey Greenhouse Gas curve). While Japan has now put regulations in 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.

Recommendations:

- The Government of Japan should continue to strengthen regulations aimed at promoting energy efficiency in residential and commercial buildings as a way to fulfil its international commitment to cut carbon emissions, with a view to applying the best available technologies in an integrated systems approach and transparent methods for measuring performance achievement.
- 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.

■ Transparency and accessibility of information and regulations

Yearly status report: new issue. Currently much of the interpretation of construction-related legislation and guidelines is left to the discretion of local authorities. This has created a situation of uncertainty with questionable decisions in some cases being made. It appears that that, in some circumstances, local authorities lack the necessary knowledge to properly interpret legislation.

Recommendations:

- The competent national authorities should take appropriate action to rationalise the patchwork of local regulations that exist today.
- The Government of Japan should facilitate educational programmes for the local authorities geared to increasing knowledge at the level of construction project implementation and clarifying the legal framework.

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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 adopts a strategy based on security of supply at competitive prices, which can only be achieved by allowing overseas suppliers unrestricted access to its domestic market. 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, however, their competitiveness is compromised because these tariffs have to be passed on to their customers.

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 in South Korea and China. The same situation applies to fused aluminium oxide (artificial corundum) and to silicon carbide, both of which are widely used in the refractory and abrasive industries 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.

To get round the problem, in the case of silicon carbide, Japan has traditionally imported 90% of its requirements from a single country, which enjoyed a tariff exemption. Once this exemption is removed, however, the full impact of the tariff will be felt by Japanese industry. Manganous manganic oxide or Mn_3O_4 is another case in point. 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, in conformity with stringent environmental regulations and could guarantee a safe and stable supply on a long-term basis to Japanese industry. Yet the import tariffs imposed on Belgian Mn_3O_4 have led Japanese companies to become dependent instead on Chinese suppliers, threatening the longer-term future of their industry.

Semi-fabricated aluminium, such as flat-rolled aluminium products, is subject to a tariff of 7.5%. The protection this gives to the Japanese aluminium industry, in combination with its continued concentration, is detrimental to downstream sectors such as the automotive, construction, electronics, packaging and food industries. The costs of imported plastics and industrial polymers such as low-density polyethylene (LDPE), widely used for packaging, films, bags and moulding applications, are similarly inflated. End users are found in strategic Japanese industries such as food and agriculture and, in the case of LDPE, which is used increasingly as a coating and packaging, medical products. Today, polymers of ethylene, propylene and other olefins, in primary forms, are subject to tariffs of 6.5%. The Government of Japan should allow its domestic industry to procure raw materials from all sources, with zero duty.

Tariffs are not the only barrier to increasing the business potential between Europe and Japan. Non-tariff barriers in the form of administrative burdens, regional differences in registration procedures and inconsistent use of classifications make doing business in Japan unnecessarily costly and difficult for foreign companies. The benefits of eliminating tariffs and of harmonisation and simplification would be felt not only by European suppliers, but even more by Japanese industry, making it more competitive. The EBC is hopeful that the EU-Japan FTA/EPA will address these issues by including the removal of tariffs on all material related products, both raw materials as well as processed products.

Key Issues and Recommendations

■ Tariff issues

Yearly status report: no progress. Approximately 60% of total stainless steel production contains nickel, corresponding to roughly 40% of the 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. The impact of tariff rates on refined nickel is a significant increase in costs for domestic users, particularly in the stainless steel industry. Removal of import tariffs is imperative for Japan to retain its competitive edge.

With the increased use of renewable energy and battery technology, it makes little sense for Japan to retain tariffs on cathode materials, which are needed for its battery and hybrid industry. The EBC believes that further investments would be possible in this sector if input materials could be imported duty-free. With regard to silicon carbide and manganous manganic oxide, almost all imports come from only one country. This vulnerability is of particular concern considering the limited capacity of domestic production, which is estimated to be only 10% of demand, even when run at maximum capacity.

Japan also retains tariffs on common items, such as certain aluminium products used as input materials in many industries. The same is also valid for polymers where high quality products are used for sensitive and perishable products like food and beverages.

Recommendation:

- The Government of Japan should remove import tariffs from all industrial raw materials, including:
 - ◇ nickel products and aluminium, such as semi-fabricated and flat-rolled aluminium,
 - ◇ fused aluminium oxide, silicon carbide, and manganous manganic oxide, and
 - ◇ non-organic chemicals and polymers.

■ Tariff classifications

Yearly status report: no progress. Supplies of industrial materials to Japan are occasionally subjected to arbitrary tariff classifications and revisions. Regional Customs offices do not apply classification rules on a consistent basis and the appeal mechanism is both time-consuming and costly without any guarantee that the outcome will be in line with international practice. 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 regional Customs offices in classification rulings, and to strengthen and simplify dispute resolution mechanisms.

■ Chemical Substance Control Law

Yearly status report: new issue. With both the EU and Japan now having introduced a chemical substance registration system, producers, exporters and importers are faced with re-testing, double submissions and an increased administrative burden to fulfil their respective regulations. On top of this, the EBC is also concerned that in some cases in Japan, sensitive confidential information has to be handed over to competitors, in order for a product to be tested and approved. This gives an unfair advantage to the competitor, upsets the level playing field and creates unbalanced competition.

Recommendation:

- The EBC recommends that Japan and the EU harmonise their registration systems or mutually recognise test results and supporting documents to avoid re-testing and unnecessary administrative burdens.

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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 change 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. Since the introduction of the "The Act on Special Measures concerning the Procurement of Renewable Electric Energy by Operators of Electric Utilities" and the announcement of the related Feed-in-Tariffs, there is a tool at hand for industry and society at large to promote environmental technologies, based on the detail now available on related technology, finance and legal issues.

Japan will need massive investment in clean and renewable energy sources to reach its greenhouse gas reduction targets and should make further efforts to open up to international companies willing to invest technology, expertise and funds in its energy market.

Although the RPS Law was intended to promote renewable energy in Japan, and deregulation of the electricity market was intended to encourage new entrants, there are still a number of significant regulatory hurdles that prohibit free market access and the utilisation 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 (three million yen). There is, therefore, very little incentive for the power companies to promote renewable energy sources. Furthermore, grid access regulations and marginal regional transmission capacity prohibit market access for independent power producers (IPPs).

More competition in the energy market will benefit Japanese energy users through lower prices and better service. An increase in the use of renewable energy will give further benefits by helping Japan reduce its reliance on imported fuels, and boost its energy security, and will act as a buffer against rising oil, coal and gas prices.

In view of the above, it is important that the regulations are structured, worded and implemented in ways that facilitate the application of new technology and solutions, thereby also stimulating and enabling further innovation.

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", 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 the 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 of environmental regulations and standards and cooperation should be part of the FTA/EPA between the EU and Japan. This will not only benefit the environment, but will also give companies in the two regions mutual access to new technologies and new research.

Key Issues and Recommendations

■ Environmental standards

Yearly status report: No progress. 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: Some progress. The EBC welcomes the Feed-in-Tariff system for alternative energy sources introduced in July 2012. However, we still believe that Japan will benefit from further opening its energy market to new entrants and encourage 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, and result in higher costs to build wind energy projects. The EBC considers that the regulatory regime for wind energy should be substantially simplified and harmonised with existing International Electrotechnical Commission (IEC) standards. 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 re-attract European wind energy firms to Japan and to increase prospects for Japanese engineering companies and wind farm developers in 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 the priority of a renewable energy portfolio for power utilities; unbundling the power companies into energy production, transmission and retail businesses; and increasing transmission grid access for IPPs.
- The Government should also revise its technical standards for wind energy in line with IEC standards, hence increasing competition and free trade.

■ Packaging waste management

Yearly status report: No progress. Laws and regulations on waste management should set targets and parameters and assign responsibilities, with which relevant local authorities and industry participants must comply. It is important that these responsibilities and the related financial burden, fairly reflect the environmental impact of each stakeholder, such as municipalities, producers, distributors and retailers. In addition, and to be effective, these entities as well as consumers must be provided with incentives to participate in resource saving activities. Moreover, if the regulations specify in too much detail what particular technologies or processes should be used, the potential benefits of new technologies and solutions may be restricted or their use even prevented. The "Containers and Packaging Recycling Law" is one example of the latter type of regulation.

Recommendation:

- The EBC recommends that the Japanese authorities follow the example of European environmental regulators and apply laws and regulations based on clear principles and with strong incentives for all entities to take part in the handling of waste. This will encourage the development of new and enhanced technology as well as an effective use of natural resources.

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ENERGY

Introduction

The Japanese utility industry is run by ten regional private power companies that have a virtual monopoly on power generation, transmission and distribution in each area. In March 2000, partial liberalisation of the power retail supply for extra high voltage users was introduced. The Electricity Industry Committee, an Advisory Committee for Natural Resources and Energy, a consultative body to the Minister of Economy, Trade and Industry, decided upon a limited model of liberalisation, where the vertical integration of generation, transmission and distribution was maintained in order to secure a stable supply of electricity. In the area of price setting, the “cost+” model, which was already in use before the partial liberalisation, has been reviewed various times, but has remained intact ever since.

Japan is highly dependent upon imports for gas, oil and coal. Following the oil crisis of the 1970s, Japan set out to reduce this dependency through increased use of nuclear energy. The 2010 power generation energy mix consisted of: 26% nuclear, 11% renewables, 57% fossil fuel and 6% combined heat & power. However, after the March 2011 Tohoku disaster and related Fukushima nuclear accident, Japan’s nuclear plants were shut down and most are still not operating. Accordingly, Japan’s dependence on imported fossil energy resources has increased again.

Japan’s energy policy is enacted in the Basic Act on Energy Policy, which sets the following goals:

1. Securing of a stable energy supply
2. Environmental sustainability
3. Use of market mechanisms, which should however remain consistent with the first two basic goals.

After the March 2011 nuclear disaster, Japan’s utility model was placed under review. A committee of the Ministry of Economy, Trade and Industry (METI) on industry reform is currently examining two proposals for splitting off power generation from transmission operations. Both proposals are premised on launching a nationwide entity to manage major power lines. Currently, Japan’s transmission network is centred around the production sites, with the main transmission at 500kV. Three convertor stations connect the 50Hz and 60Hz networks. (European and US grids are based on the mesh concept, which is a more efficient transmission network, but is also more difficult to operate and control.)

Besides the overall model, the energy mix was and continues to be reviewed. Whereas the pre-disaster plan proposed an increase in nuclear energy, the latest options all show either a similar level or a reduction. Three scenarios were considered: 0% nuclear, 15% nuclear or 20-25% nuclear, with renewables in all options growing to between 25% to 35% and energy saving accounting for 20%. As a result of the discussion on these scenarios, the Japanese Cabinet has decided to move towards becoming independent of nuclear power by the 2030s.

In July 2012, the new Feed-In Tariff (FIT) scheme for renewable energy sources came into effect, requiring the utilities to buy power derived from solar, wind, geothermal, hydropower and biomass sources at a fixed tariff and allowing them to pass on such cost to consumers. The aim is to further promote investment in the renewable energy field as part of the “Green Growth Strategy” laid out by the Government’s Energy and Environment Council.

Adding to the already established 3GW of residential installations, solar energy is projected to increase rapidly from new utilities and commercial-grade photovoltaic power plants. At present there are over 560MW of projects in the pipeline for completion in 2012 to 2013. Industry analysts have forecast that the domestic solar power market will reach an annual level of between 1.7 to 2.5 gigawatt-hrs in 2012 growing to a cumulative capacity of 17,900 gigawatt-hrs by 2016 in line with METI targets, accounting for slightly less than 2% of Japan’s electricity consumption.

The EBC expects energy to be discussed in the FTA/EPA negotiations in order to further strengthen the ties between Japan and EU in this area, where there is so much that we could learn from each other.

Key Issues and Recommendations

■ Stability of supply versus cost

Stability of supply must remain the first priority for the Japanese economy. However, the “cost+” model may not be providing adequate incentives to the utility companies to reduce costs and increase efficiency. Fossil fuels are and will most likely remain the key pillars of the energy mix, but their costs are currently unsustainable and will remain so in the short-term for Japanese utilities, thereby affecting the competitiveness of Japanese industry in general in the global market.

Recommendations:

- The utility companies should accept international standard products and solutions, which can drastically reduce both Capital Expenditure (CAPEX) and Operational Expenditure (OPEX).
- Transparency in procurement should be increased in line with the World Trade Organisation’s guidelines.
- Among the fossil fuels, the use of natural gas should be increased and gas-fired thermal power plants should be preferred for future investments in power generation, in order to reduce greenhouse gases.
- Nuclear energy could also remain a core constituent of the Japanese energy mix, as it plays an important role in providing industry and citizens with competitively priced electricity. Its long-term sustainability depends on clear confirmation of the closed fuel cycle policy (waste volume reduction). However, it would be necessary to deal with the ageing of existing plants, improve facility utilisation rates, and properly manage the nuclear fuel cycle.
- The development of renewable energies must be carried out with ambitious, albeit realistic targets, aiming at increasing the safety and reliability of the energy supply. Achieving grid parity is essential; however it must not be pursued to the detriment of industry competitiveness.

■ Separation of generation, transmission and distribution

The current situation does not provide the transparency and cost efficiency required. Security of supply is also not guaranteed, with limited interconnections between utility companies as well as between the 50Hz and 60Hz networks.

Recommendations:

- Separate generation from transmission to allow the required investments in the transmission grid, while providing transparency and efficiency in terms of cost.
- Use the latest international High Voltage Direct Current (HVDC) solutions to connect to the 50Hz and 60Hz networks.
- Use the latest international HVDC and Flexible Alternate Current Transmission System (FACTS) solutions to strengthen the transmission grid and increase capacity to integrate renewable energy sources more efficiently.

■ Nuclear safety

In the wake of the Fukushima accident, Japan has reformed its nuclear safety regulator, which is now an entity with enhanced independence. Currently Japan is reassessing its nuclear safety standards, which will result in safety improvements by the nuclear power plant operators. The EBC believes it is of the utmost importance for the new safety rules, which are to be issued by the newly created NRA (Nuclear Regulation Authority) in the upcoming months, to be properly implemented by the Japanese power utilities.

Recommendations:

- Continuously increase the level of safety of nuclear energy under the scrutiny of an independent regulatory committee such as the recently created NRA, consisting, among others, of nuclear energy experts.
- Review safety measures at individual plants with support from international inspectors and implement recommendations before any restart.
- Use international standards and procedures as minimum requirements.
- Share best practices and establish common safety requirements through international cooperation.

■ Wind energy

Wind energy is a proven way for Japan to reduce its reliance on imported fossil fuels, and to make use of one of its own local energy sources. Furthermore it will help Japan reach its emissions targets without the pollution or safety risks of many other fuel sources. It is, therefore, unfortunate that Japan still does not properly promote the use of both on-shore as well as off-shore wind farms. Modern wind turbines now contain sophisticated technology that works well with established power grids of all kinds, such as large transmissions systems or isolated local grids. The EBC also recommends that the Japanese Government takes note of the work technical standards for wind energy being carried out by the International Electrotechnical Commission (IEC).

Recommendations:

- Reduce the number of unnecessary regulations that add to the cost of wind farm development, a cost that ultimately is paid by the Japanese population.
- Revise environmental impact assessment requirements applicable to wind farm development to a more appropriate level that enables wind farm development within a reasonable time frame.
- Adopt internationally accepted certification standards for wind turbines and their componentry in Japan rather than existing local certification standards. This will prove vital both to facilitate increased investment and improve the potential for Japanese technology exports.

■ Solar energy

Principal impediments to sustainable growth of utility and commercial-grade solar energy are the cumbersome procedure for obtaining special permits for land re-zoning for non-agricultural uses, sourcing engineering and construction firms with the potential to acquire financing, and obtaining project financing for mega-PV (photovoltaic) projects. Additional challenges that Japanese utility companies may soon encounter are managing cost effective solutions to integrate decentralised and intermittent renewable generations into the existing power grid.

Recommendations:

- Streamline the process to re-classify special permitted lands for renewable power generation.
- Adopt internationally accepted certification standards for solar modules and system components rather than enforce existing “Japan-only” certification standards.
- Increase Government support to drive the adoption of standard criteria for Japan’s megabanks and regional banks to provide debt financing.
- Create incentive programmes for the power utilities to contract PV project construction to an emerging class of Japanese engineering and design companies.

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