

A large, stylized yellow map of Japan, including the four main islands (Honshu, Shikoku, Kyushu, and Hokkaido) and surrounding smaller islands, positioned in the background of the cover.

Taking Action

The EBC Report on the Japanese Business Environment 2014

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

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The European Business Council (EBC) is the trade policy arm of the 16 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents some 2,500 local European companies and individuals who are members of their national chambers of commerce. Around 350 company executives participate directly in the EBC's 28 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

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

The EBC works closely with the Delegation of the European Union 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

Welcome to the 2014 EBC Report on the Japanese Business Environment. This is the latest in a long line of annual reports, identifying the barriers faced by European companies in Japan and recommending ways to make this a more vibrant and welcoming place to do business. So why is this report in particular entitled *Taking Action?* The answer is that, in our view, the case for reform is clear; the challenges are understood; the Prime Minister himself has set out a new strategy for growth. What is missing is specific, detailed, determined implementation. Put simply, it's time to walk the talk.

Much has been made of Prime Minister Abe's Growth Strategy, launched within weeks of his return to office and designed to pull Japan out of decades of economic stagnation and deflation. The initial focus was on boosting GDP and raising inflation through short-term fiscal stimulus and monetary easing. Some 10.3 trillion yen was earmarked for new infrastructure projects; plans were made to stimulate private investment; the Bank of Japan agreed to double its inflation target (to 2 percent) and to increase its purchase of government bonds. The short-term results were remarkable: in the space of one year, the yen fell in value, export profits boomed, the stock market rose, new jobs were created, inflation turned positive and GDP grew; even wages increased, at least in some larger corporations. Unfortunately, however, the era of sustained prosperity had yet to dawn.

Events in 2014 have demonstrated the fragility of Japan's new-found economic success. Shortages of skilled workers have held back investments in regional infrastructure as well as job creation; an increase in consumption tax has dampened household spending; stock prices have proved vulnerable to both global and domestic instability; and the rate of GDP growth has fallen. All is not lost, but it is obvious that fiscal stimulus and monetary easing alone are not enough to mend the economy: Japan also urgently needs structural reform.

Finally, then, in June 2014 Prime Minister Abe turned the spotlight on policies to tackle over-regulation, modernise the labour market and support investment in the private sector. His proposals range from lowering the corporate tax rate, reducing energy costs, encouraging targeted immigration and increasing female participation in the workforce, to improving corporate governance and boosting key industries, such as healthcare. Moreover, the crucial role of trade in providing new and expanded markets for Japanese goods is recognised. To be frank, none of these ideas is really new: many have been recommended year after year in EBC reports and featured in previous Government programmes. It would be different this time, if they actually led to action.

The EBC acknowledges the many obstacles faced by the Prime Minister in his efforts to translate his strategy into reality, not least the resistance from various industry sectors and interest groups and their allies within his own party. Such resistance should not, however, be allowed to jeopardise reform: the interests of Japan's future prosperity must prevail.

The EBC is greatly encouraged that the Government has recognised the considerable contribution of potential new trade agreements to its Growth Strategy. Current negotiations towards an EU-Japan Free Trade Agreement / Economic Partnership Agreement (FTA/EPA) offer an important vehicle for progress. Many of the issues on the table point towards the action needed to reform the economy, lift trade relations to a new level and set both Japan and the EU on a path to greater prosperity. This report provides background to these issues and recommendations for change, based on the considerable experience and expertise of EBC sectoral committees. Addressing their concerns is vital, not only to bringing the FTA/EPA negotiations to a swift and successful conclusion but also to ensuring it can deliver the benefits foreseen in Europe and in Japan.

Prime Minister Abe has recognised that Japan's economic future is in the balance: the challenges are many; the urgency is clear. Now is the time for taking action.

Danny Risberg
Chairman, European Business Council in Japan
The European (EU) Chamber of Commerce in Japan
(President & CEO, Philips Electronics Japan, Ltd.)

Message from the Executive Director

The European Business Council in Japan (EBC) is pleased to present its 2014 Report on the Japanese Business Environment: *Taking Action*.

2014 has been a year of significant ups and downs for the Japanese economy, which remains fragile and overly dependent on exports. While the Government will almost certainly try to mask this with stimulus measures at home, and possibly more quantitative easing, it cannot continue to do so indefinitely. It needs urgently to address the structural and regulatory obstacles that are holding back the economy.

As early as April 2013, Prime Minister Abe announced his intention to restructure industry, reform regulation, modernise the labour market and strengthen trade relationships. However, intention is not the same as action and in practice, very little changed for business on the ground. Announcements in June 2014 served to add more specific measures, but still the rate of progress is too slow. Tellingly, foreign direct investment (FDI) into Japan continues to languish, while last year, according to JETRO, Japanese outward FDI reached a record high.

For the EBC, this is particularly frustrating. We have long believed that Japan has huge potential as a world-leader in innovative, quality products, as a global financial centre, and as a regional transport hub. For years now, our sectoral committees have been highlighting obstacles to reaching these goals and recommending specific, concrete remedies, based on their considerable expertise and experience operating in Japan and other markets. Yet far too few of their recommendations have been taken up to make a difference: successive Governments have seemed more interested in talking than taking action.

Our earnest hope is that in 2015, things will be different. Prime Minister has reinforced his strategy for growth with a commitment to strengthen Japan's trade links. Negotiations towards an EU-Japan Free Trade Agreement / Economic Partnership Agreement are in full swing. If sufficiently ambitious and comprehensive, this FTA/EPA could remove barriers to competitiveness, unlock unfulfilled potential in the EU-Japan trade relationship, and promote renewed and sustainable prosperity. Yet there is still a long way to go and success depends on both sides remaining committed to the negotiations, to resolving all the issues on the table and to following up with rigorous implementation. The EBC will continue to support the process and commends this report to both sides as a reminder of what must be achieved.

I would like to thank all those who have contributed to the report, especially the members of the EBC Committees, and indeed all EBC member companies and stakeholders. I also wish to thank the EBC Policy Director, Bjorn Kongstad, not only for collecting and coordinating the many disparate inputs to this report but also for providing an insightful introduction to its findings.

The EBC greatly appreciates the continuing support of the Delegation of the European Union to Japan and the European national embassies in Tokyo. We also gratefully acknowledge all those EBC Members whose generosity has made this publication possible and who are listed in the sponsors and supporters sections at the end of the report.

The EBC report contains a wealth of valuable ideas to help Japan achieve long-term prosperity. We look forward to an opportunity to discuss them soon with the Government and all those committed to building a brighter economic future. May 2015 truly be a year of taking action.

Alison Murray
Executive Director
European Business Council in Japan
The European (EU) Chamber of Commerce in Japan



Introduction



INTRODUCTION

It is two years since Shinzo Abe returned to office as Prime Minister in a landslide victory for the Liberal Democratic Party of Japan. Barely had the dust settled on his victory than he announced a flurry of measures to pull the country out of its long cycle of stagnation and recession. His ambitious growth strategy, nick-named “Abenomics,” grabbed headlines around the world. It launched actions in three key areas or “arrows”: monetary policy, fiscal stimulus and structural reform. So, two years on, the question is: is it on target?

Certainly, Abenomics has made an impact. The Government has pumped money into stimulus measures, including major infrastructure projects, and the Bank of Japan has expanded money supply. By mid-2013 the value of the yen had fallen, exports risen, and the stock market rallied. Money had begun to flow into the regions, creating jobs, especially in the construction industry. There was evidence of improved business confidence and even wage rises in some quarters. It seemed that Abenomics was working.

Unfortunately, the impression did not last. Initial improvements, though notable, were not enough to change Japan’s overall economic trajectory. A long-expected rise in consumption tax in April 2014, designed to help relieve increasing Government debt, prompted a spike in sales in the first quarter, as canny consumers sought to pre-empt price increases, followed by an inevitable slump. Wage rises were simply too patchy and weak to sustain higher household spending. Meanwhile, uncertainty in overseas markets had begun to dampen demand for Japanese goods. For a country so dependent on exports, the result was highly predictable: GDP growth went into reverse.

The truth is that stimulus packages and quantitative easing alone are not enough to change the long-term course of the Japanese economy. They offer short-term fixes, useful in terms of buying time for longer-term restructuring to take effect, but useless as a substitute for such restructuring.

To his credit, Prime Minister Abe acknowledges this. The third arrow of his economic strategy is all about structural reform. Initially, the details were rather thin: a June 2013 announcement was long on intention - to boost private sector competitiveness, reform labour markets, and promote growth industries - but short on concrete action. What followed was months of consultations and studies on what might be done. On the positive side, these discussions were refreshingly open to new inputs and ideas, and EBC Committees were pleased to be invited to participate, including on healthcare reform and measures to promote the medical industry in Japan. Clearly, any major change must be well thought-out and it makes perfect sense to involve experienced experts. Still, the need for significant action remained.

The EBC therefore welcomed a second round of announcements from the Prime Minister in June 2014, giving more detail of what precisely was to be done and tackling a number of the issues long highlighted by EBC Committees as barriers to a truly competitive business environment. In particular, we noted proposals for:

- Further reduction of the Corporate Tax rate, towards a level closer to that of other developed economies;
- A new code of Corporate Governance for listed companies;
- Measures to enable more skilled professionals from overseas to work in Japan;
- Measures to boost female participation in the workforce;
- Further reform of healthcare, expanding provision including preventative healthcare services;
- Revision of the policy asset mix of the Government Pension Investment Fund;
- Liberalisation of the agricultural sector.

Although the translation of these proposals into action is only just getting underway, they do at least offer real hope of a step change in Japan’s business environment. Moreover, EBC Committees have already seen some improvements on the ground, which will help to boost competition in the Japanese marketplace and attract foreign investors. Among the examples included in this report:



- The start of revision of the Household Goods Quality Labelling Act by the Consumer Affairs Agency after the EBC advocated improvements for a number of years. As one example, the JIS standard regulating washing symbols have already been amended to now mirror the applicable ISO standard.
- Measures that will increase efficiency and transparency in the financial services sector, clarifying the Financial Services Agency's annual inspection programme and, in some cases, providing pre-notification of inspections.
- An "Action Plan for Speedy Examination of In Vitro Diagnostics" aiming to shorten the time period required for regulatory approval of new products.
- Clarification of the evaluation policy for quasi-drugs, through release of a model template for ordinary quasi-drug application documents and a Q&A notice.
- Introduction of a more scientifically informed approach to food imports, distinguishing between foods that support the growth of *Listeria monocytogenes* and foods that do not.

These and other measures address the issue of competitiveness which has long dogged Japan. While the country has many world-class innovative firms, it has often relied on booming export demand to keep them profitable and to postpone much needed, but possibly painful, productivity improvements. Moreover, it has consistently shielded some sectors from any competition at all. Recent policies driving down the value of the yen have merely compounded the problem: Japanese exports have become cheaper, thus stimulating demand abroad and once again allowing inefficient domestic companies to survive unchallenged. Yet, there is ample evidence that relying so heavily on external demand exposes Japan's economy to too many risks beyond its own control: it can only follow where other countries lead. This approach is not only high risk: it is also unnecessary.

So the time has come for Japan to take more control of its economic destiny. Granting the realities of global markets, there is still much more that Japan could and should be doing in its drive for sustainable growth, from casting aside layers of unnecessary regulation and protectionist bureaucracy, to opening the door to real, invigorating competition and foreign investment. This EBC report highlights some of the many sticking points and suggests concrete reforms, based on the first-hand operational experience of EBC expert Committees. Their recommendations include:

- Mutual recognition of standards, product certifications and marketing authorisations, and adoption of international standards, for example in terms of medical equipment, environmental technology, consumer products, cars, and food.
- Lifting of barriers, such as high costs and unnecessary bureaucracy that prevent or delay products from reaching the market – for example, in terms of tariffs on certain foods, and Japan-only product labelling requirements.
- Ensuring fair competition and fair and equal treatment of all companies, domestic and foreign, for example in the airline, express delivery and insurance sectors.
- Ensuring fairer and more open competition in services and government projects, for example by introducing truly open tendering for public procurement contracts, and improved network access for foreign telecom carriers.
- Improving conditions for foreign direct investment, including requirements unique to Japan in the banking and asset management sectors.
- Enhancing incentives for investment in R&D, including reimbursement schemes in the healthcare sector that fully recognise and reward innovation.

The EBC recommendations go to the heart of Prime Minister Abe's desire to revitalise the Japanese economy. They are also central to current negotiations towards an EU-Japan Free Trade Agreement / Economic Partnership Agreement (FTA/EPA). Mr Abe has acknowledged the key role played by international trade and investment in his growth strategy and an agreement with the European Union is surely vital to its success. In 2013, the EU ranked as Japan's third largest trading partner, accounting for 10 per cent of its exports, and 9.7 per cent of its total trade.

Moreover, there is evidence that this trade relationship has considerable upwards potential. To make sure this potential is realised, the EBC urges the authorities in Japan and the EU to ensure that all the recommendations in this report are taken up in the FTA/EPA negotiations, and to deliver a final agreement capable of setting their economies on a new path to success.

A more open, fairer, and more competitive business environment in Japan is not simply in the interest of European firms. As Prime Minister Abe has recognised, it would contribute significantly to the country's long-term economic growth. The recommendations in this report provide not just inspiration but also specific details for how to move forward. They offer Japan the prospect of a dynamic home market that is a platform for greater prosperity and counterbalance to the vagaries of overseas markets. None of this will happen if all the Government does is talk. Consultations, studies and negotiations are not enough. As this report makes clear, the future is in Japan's hands. Now is the time for taking action.

How this report is organised

Following this introduction, prepared by the EBC's Policy Director, there are 31 chapters, each addressing the concerns of a specific EBC sector / expert committee. The chapters summarise key issues and developments of the past year, and are accompanied by concrete recommendations for regulatory reform.

We trust the information, ideas and recommendations in this report will prove to be a positive contribution to the thinking of the Government of Japan and all other authorities, including in the European Union, who genuinely wish to see the EU-Japan trade relationship reach its full potential.

Business

Fundamentals

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

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FINANCIAL REPORTING

Introduction

2014 saw encouraging reinvigoration of Japan's attempts to introduce a single set of accounting standards that would enhance the cross-border comparability of companies' consolidated financial statements. Earlier, Japan had committed to make the use of International Financial Reporting Standards (IFRS) mandatory for most domestic filers meeting relevant criteria. However, Japan reversed that decision after the Great East Japan Earthquake, which led to a decrease in the number of companies adopting IFRS on a voluntary basis. Now, driven by the economic recovery of the past 12 months, Japan is once again talking about mandatory use of IFRS. Unlike the big bang approach taken in Europe that required all listed companies to use IFRS in their consolidated financial statements from 2005, Japan appears to be moving towards a more gradual approach. Encouraged by stronger results and the easing of the criteria for voluntary use, many Japanese multinationals are currently in the process of adopting IFRS.

The EBC's Financial Reporting Committee is encouraged by this renewed drive towards the adoption of IFRS, which is expected to enhance transparency in the financial reporting of Japan's global corporations with Europeans and other peers. However, challenges remain for multinational companies headquartered in Europe that have significant subsidiaries domiciled in Japan, because these subsidiaries will likely continue to report under local Japanese Generally Accepted Accounting Principles (J-GAAP) as published by the Accounting Standards Board in Japan (ASBJ) for statutory reporting purposes and reconcile to IFRS for group reporting by their parent. Any reduction in the need for reconciliation between local accounting standards and IFRS would decrease the administrative burden on these subsidiaries without compromising the quality or transparency of the reporting process. Therefore, the EBC recommends that more efforts be made to reduce such reconciliations. There are many ways to achieve this objective; they range from the use of full IFRS or endorsed IFRS in the separate financial statements of subsidiaries with foreign parent entities, to further convergence of J-GAAP with IFRS. We acknowledge that any effort in this direction needs to be carefully considered in the light of corporate and tax laws in Japan. The EBC will continue its efforts to identify the areas in which differences in accounting exist and which are especially burdensome in practice, as a basis for further discussion.

The issuance of new key standards under IFRS poses significant challenges for the aforementioned convergence efforts. In some cases they may reduce differences with J-GAAP, in others increase them. Often the compatibility of the new standards with J-GAAP is unclear. The objective of the EBC is to promote the convergence of financial reporting towards internationally accepted standards and to help clarify compatibility between different accounting frameworks. We look to the local standard setting and regulatory bodies to support these efforts and so encourage foreign investment in Japan.

Japanese subsidiaries of European multinationals also have to deal with local tax reporting, which requires adjustments to comply with tax laws and regulations. Such subsidiaries often try to minimise these adjustments to limit costs and enhance transparency, within the boundaries of optimising their tax position. Alignment efforts are hindered where tax and financial reporting requirements are incompatible. The EBC recommends that regulators avoid unfavourable tax consequences (from time, cost and tax perspectives) when converging J-GAAP with IFRS and consider adjusting tax and company laws to facilitate financial reporting convergence where there are close ties between them.

Key Issues and Recommendations

■ Financial instruments

While the EBC notes many similarities between the accounting standards of financial instruments under IFRS and J-GAAP, there is one area where further alignment is recommended. Under J-GAAP, certain securities such as non-listed equity securities are generally recognised at historical cost. The EBC recommends that all investments in equity securities be measured at fair value, as in IFRS. Changes in fair value would be recognised in Other Comprehensive Income for investments not held for trading, similar to the debt securities under J-GAAP and the available-for-sale category under IFRS. A comprehensive analysis should also consider new accounting guidance under IFRS 9. The EBC believes that the valuation of all securities at fair value improves the relevance and transparency of financial statements, providing stakeholders with an assessment of investment decisions of management in deploying the balance sheet. By aligning the accounting treatment under J-GAAP with IFRS, the EBC expects efficiency gains for issuers of financial statements who need to prepare financial statements under both regimes. The EBC notes that the recently published exposure draft regarding Japanese Modified IFRS does not seek an exemption for the measurement of investments in equity instruments.

Recommendation:

- Japan should align J-GAAP with IFRS to require all equity investments to be accounted for at fair value.

■ Goodwill

J-GAAP and IFRS differ significantly in the guidance provided on how to account for goodwill arising in a business combination. While IFRS mandates the impairment-only approach, J-GAAP requires amortisation over a maximum period of 20 years if the goodwill amount is not negligible, and otherwise no impairment is required. The impairment-only approach has led to substantial criticism in Europe, with goodwill growing to significant amounts, as it opens the door to potential earnings management. It remains to be seen if the standard setter for IFRS, the IASB, will yield to this criticism and revert to systematic amortisation. The EBC appreciates the arguments that can be made to support both views and advocates that the ASBJ should work closely with the IASB to come to a position that results in alignment of J-GAAP and IFRS in this area.

Recommendation:

- The ASBJ should revisit the conceptual and practical merits of alternative subsequent accounting methods for goodwill and work closely with the IASB to resolve the issue on a global basis.

■ Vacation accruals

IFRS requires vacation accruals to be recognised. J-GAAP does not, partly due to the labour market's low rate of vacation usage in Japan and the fact that such entitlements are generally not paid out when the employee leaves. IFRS requires an entity to recognise vacation accruals because a liability is created when an employee has provided service in exchange for employee benefits to be paid at a later date and an expense is incurred when the entity consumes the economic benefits from services provided by an employee.

Recommendation:

- Japan should require recognition of vacation accruals under J-GAAP.

■ Property, Plant & Equipment (PPE)

Many companies use tax regulation to determine residual value and useful life of PPE for J-GAAP reporting. Depreciation methods must be reasonable and applied systematically every year. In practice, a significant number of J-GAAP filers use the double-declining method, which avoids reconciling differences between financial and tax reporting and generally achieves greater tax deductions in earlier years. However, it creates differences with IFRS, which generally prohibits using this method as default and uses residual life and useful life assumptions that reflect usage patterns rather than tax tables. The EBC recommends the IFRS approach to provide readers of financial statements with a more accurate reflection of usage patterns and related costs, and enable companies to maintain existing tax advantages, even if this results in a new reconciling item with tax reporting.

Recommendation:

- Japan should align accounting for PPE under J-GAAP with IFRS while considering implications for taxation.

Mr. Steve Burson

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HUMAN RESOURCES

Introduction

The EBC Human Resources Committee has for many years been concerned at Japan's bleak demographic outlook. 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 halve by 2050. 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.

Prime Minister Abe's "third arrow" for economic growth includes policies that directly impact human resource capital. EBC believes this to be a good start, but more needs to be done. Currently the low level of international experience within many Japanese companies, exacerbated by their failure to capitalise on the knowledge and experience gained by students who have studied abroad is a concern. This unfortunately discourages students from pursuing opportunities to go abroad, at a time when global exposure is vital. The EBC understands that the Government is attempting to resolve this situation, especially through internationalisation of the universities, and feels that significant changes will be required for measures to be effective.

Of high priority is the desperate need to motivate and facilitate the return of Japan's female population to the workforce. Initiatives such as the "Short-Time Regular Employee System" (*tanjikan-kinmu-no-seishain seido*) have been introduced, but are not generally well-known or utilised. As a result, many of Japan's housewives remain unwilling to enter the workforce, in the mistaken belief that to do so would require a commitment to becoming a regular employee (*seishain*). This can only be described as a waste of available resources. Prime Minister Abe has raised the issue of increasing female participation in the labour market as part of his growth strategy. The EBC is also encouraged by signals from the Government that it is considering an overhaul of the income tax break for tax payers with spouses who do not work, or work only limited hours. This will remove the incentive for spouses to work only part-time. Furthermore, the EBC believes that greater efforts should be made to support women and men in the workplace, for instance by offering more public child care centres and also private child-minding services. More also needs to be done to support and encourage men to take child care leave.

On a positive note, the EBC commends the Ministry of Justice and the Japanese Government on the changes they have introduced related to re-entry permits and extension of visa periods. The new system has improved the attractiveness of Japan for foreign professionals. The Government is continuing to try to admit greater numbers of highly skilled persons.

On the pension side, Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees. Discussions on lowering the minimum period of pension premium payments are also encouraging. However, amendments are still required to enable the refund in full of all mandatory Japanese pension fund contributions to expatriate workers leaving Japan, abolishing the current limit of the last three years of premium payments. 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 to lessen the burden on both employers and employees and to avoid double payments. A comprehensive FTA/EPA between the EU and Japan should aim to streamline the process of brokering multiple bilateral agreements on social security pension reimbursement and also include equal treatment in the area of social support. It would also provide an opportunity to revise all visa and work permit requirements between the EU and Japan with a view to creating a more integrated labour market.

Key Issues and Recommendations

■ Immigration policies

Yearly status report: good progress. With the amendment to the Immigration Control Act leading to effective removal, in practice, of the re-entry permit, Japan has made considerable improvements to the visa process. There are, however, some areas that can still be improved.

Recommendations:

The Government of Japan should:

- Introduce on-line applications.
- Further revise immigration policy to encourage the entry of skilled labour to Japan. For example, in the absence of an applicable university degree, lower the unnecessarily high requirement for ten years experience “in the industry” to five years.
- Expand the Technical Intern Training Programme to include vehicle mechanics.
- Automatically grant work permits to spouse visa holders so that multinational companies can attract the best talent to postings in Japan.
- Create a new category for permanent-residence holders eligible for the benefits of “highly skilled professionals”.

■ Work place diversity

Yearly status report: some progress. Japan’s future prosperity depends greatly on maintaining an adequate workforce that can 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, and consider other incentives that encourage more participation in the workforce.
- 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, while discontinuing any consideration of extending child care leave.
- 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 several European countries to the benefit of citizens from these countries. For the nationals of countries without an agreement, refunds of mandatory contributions to Japanese pension plans remain capped at a maximum of three years. Regarding the minimum period of contributions before being eligible to receive a pension, the EBC is encouraged by talks on lowering the current mandatory 25 years to 10.

Recommendations:

- Swiftly implement the policy that 10 years of contribution should be sufficient to receive a pension.
- 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.

Mr. Laurent Dubois

Chair, Intellectual Property Rights Committee

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INTELLECTUAL PROPERTY

Introduction

In Japan, luxury products reach consumers via one of two sales channels: either regular outlets and distributors, or dealers in parallel imports. The sale of parallel imported goods is not illegal under current Japanese law. Consequently, while luxury brands strive to protect the prestigious image of their products and are reluctant to engage in e-commerce through their regular outlets and distributors, the online marketing and sale of their brands in the form of allegedly authentic “parallel imports” is growing.

Today, an increasing respect for intellectual property rights and a slight weakening in demand for luxury brands mean that fewer consumers are enticed into buying items that are obviously fake. However, more and more counterfeit luxury products are flowing into the Japanese market via dealers from other Asian countries who disregard Intellectual Property Rights (IPR).

The problems that Japan currently faces in this field are as follows:

- An influx of counterfeits through websites targeting Japanese consumers and which are hosted by foreign servers beyond the control of the Japanese judicial authority;
- Sale of counterfeits purporting to be “parallel imports” and hence marketed as “authentic” brand items through major online malls;
- Sale of counterfeits via emerging online auctions without a proper framework for protection of IPR;
- Sale of counterfeits in Tsuruhashi, Osaka.

In 2013, some 628,187 fake items were stopped at the border by Japan Customs. However, given that it is impossible for Customs to examine all imported items, it can be assumed that large numbers of counterfeit products still make it through the border. The top exporter of counterfeits to Japan is China, accounting for 91.9% of the known total.

The Japanese Government is making a considerable effort to protect IPR, including by implementing new laws and amending existing legislation. For example, gradual easing of the obligation for rights holders to go to Customs offices to check each imported item suspected of being fake began with the Customs Circular Notice of 2007, and the requirement was totally removed by last year’s circular notice (albeit conditional on the number of items, distance between the rights holders and the Customs office, etc.).

The operators of major online auctions and shopping websites, Yahoo, Rakuten and DeNA, also play an important role in combating counterfeits. Yahoo, for example, is successfully policing its auction service through a team of 200 staff members and a regular exchange of information on counterfeits and criminal dealers with major brands via rights holders’ associations. Such information allows the operator to detect and eliminate a large part of uploaded data identified as being related to fake products (about 1% of all posted items are counterfeits). Rakuten is also active in the “purification” of its auction website. When a product posted on Rakuten is suspected of being a counterfeit because, for instance, of a particularly low price, the operator makes a test purchase of the item to verify its authenticity. If the item turns out to be fake, the posting dealer is banned from the website.

Driven by a strong will to combat fraud against consumers, Japan is making concerted efforts to set up a framework for eliminating counterfeits. Some of its approaches are even more advanced than those applied in Europe or the USA. However, a number of problems remain because of delays in reforming fundamental areas of regulation. Specifically, Japan needs to strengthen control of parallel imports, to develop partnerships with foreign regulatory bodies and internet service providers (ISPs), to build up a proper social system for protecting consumers and to control by law the possession of counterfeits for personal use.

Finally, the EBC calls on the EU and Japan to ensure that IPR issues are taken up in their mutual FTA/EPA negotiations with a view to improving the current situation and creating common rules that may provide solutions to some of the problems described above.

Key Issues and Recommendations

■ Influx of counterfeits through websites hosted outside Japan

Yearly status report: no progress. A number of (mainly Chinese) counterfeit dealers banned from major Japanese websites have their own websites in Japanese, hosted by foreign servers, enabling them to continue selling counterfeits to Japanese consumers. Even though such websites often exhibit typical features of sites selling counterfeits, including very low prices, unnatural Japanese language and inaccurate information on the dealer, many online shoppers are unaware that these are fraudulent sites. Several countermeasures have already been taken by Japanese regulatory bodies and executive authorities (such as confiscation of goods at Customs, the freezing of bank accounts, alerts by security software and the publication of a list of fraudulent URLs on the website of the Consumer Affairs Agency). Fundamental solutions are yet to be found given that the operators of such websites are located overseas and beyond the control of the Japanese judicial authority.

Recommendations:

- A way should be found to eliminate counterfeit sales websites hosted by foreign servers, especially via strengthened partnerships with foreign regulatory bodies and authorities. Japan should also work with other jurisdictions to ensure all necessary action, including legal, can be taken against the operators of such websites.
- More rigorous application of the Act on Specified Commercial Transactions is needed, as well as thorough enforcement of the obligation for dealers to post their identification data. Consumers should be urged to verify the credibility of such data posted by dealers.

■ Sale of counterfeits via online auctions sites

Yearly status report: some progress. “Rakuten Ichiba”, the top online shopping mall in Japan, has put in place a system of test purchase by the operator to check the authenticity of posted items. If an item turns out to be fake, the posting dealer is banned from the website. Although “Yahoo Shopping” and “DeNA” have followed Rakuten’s example in this field, they are not yet fully effective because of the unrestricted admission for dealers (Yahoo) and the late introduction of the checking process (DeNA). Moreover, another major global online mall is not paying enough attention to applicable laws, nor preparing any countermeasures against the posting of fake goods. The rapid multiplication of auction websites accessible via smartphone applications, whose countermeasures against fake products are often imperfect or even non-existent, also requires a prompt response from the Japanese authorities.

Recommendation:

- While the control of online auctions is on the right track, further efforts must be made by Japanese ISPs and relevant government ministries to develop closer partnerships and cooperation with rights holders, engage ISPs currently not involved, and promote the discussion and implementation of specific actions.

■ Sale of counterfeits in Tsuruhashi, Osaka

Yearly status report: new issue. Most of the 30 stores lining the shopping street in the Tsuruhashi area of Osaka are selling counterfeit goods. Efforts by the Japanese police to ban such stores (with around 10 cases detected each year) have had little impact on the situation, as closed premises are often taken over by other counterfeit dealers.

Recommendation:

- As the current action has not led to elimination of counterfeit businesses from Tsuruhashi, the police should launch a fullscale control operation under the Penal Code.

■ No regulations on the importation and purchase of counterfeits for personal use

Yearly status report: no progress. The fact that the importation and purchase of counterfeits for “personal use” are lawful in Japan offers a loophole to dealers importing fake goods commercially.

Recommendation:

- The importation and purchase of counterfeits, even for “personal use”, should be controlled under the law.

Vacant

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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 ten 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 them 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 decline. Japanese retailers and wholesalers gain from the presence of European competition as it provides incentives to further strengthen their global competitive edge. 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. It has proved difficult for foreign wholesalers and 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. Added to this, there are related sales restrictions. 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, the Government's insistence on 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, non-acceptance of non-SI units (International System of Units), 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 again to Japan insisting on additional product testing against specifically Japanese standards, even where products are already covered by international and European standards. It is encouraging that the Japanese authorities have recently shown that they are prepared to introduce more international standards in certain areas. The EBC believes that this will benefit not only foreign retailers and wholesalers looking to enter or expand in the Japanese market, but also Japanese retailers expanding into foreign markets, as their labelling costs will be reduced as well.

The EBC earnestly hopes that, in the process of the negotiations towards an EU-Japan FTA/EPA, many of the barriers met by European retailers and wholesalers will be removed. In particular, the EBC can see no reason why products already certified for the European market should have to undergo testing and certification anew if they are to be sold in Japan, or vice versa. The FTA/EPA negotiations offer an excellent opportunity to establish definitively that there is no practical purpose or benefit in such re-testing. The EBC therefore calls on the EU and Japan to move swiftly to establish mutual acceptance of standards and certification, which will benefit companies and consumers in both markets.

Key Issues and Recommendations

■ Prohibitive import, testing and certification procedures

Yearly status report: some progress. Japan's reluctance to accept EN (European standards) and ISO standards or CE (conformité européenne) markings delays the introduction of new products to the Japanese 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 to measuring devices and the related import systems, to facilitate smoother trade.

Recommendations:

- Japan and the EU should mutually accept each other's regulations governing the application process for importing and selling/using products to eliminate the need for re-testing.
- Japan should clarify its rules relating to where testing for pre-registration (*Hinmoku toroku*) of food contact products can be carried out. The EBC requests that test reports prepared by approved test laboratories overseas be accepted.
- Japan should accept inclusion of common non-SI units on measuring devices when SI units are also used.

■ Labelling

Yearly status report: progress. The Household Goods Quality Labelling Act regulates how household goods within the scope of the Act are labelled. The EBC appreciates the work of the Regulatory Reform Office with the Cabinet Office and looks forward to working closely with the Consumer Affairs Agency (CAA) to bring about meaningful reform. The EBC also commends the Ministry of Economy, Trade and Industry (METI) for its work on harmonising care instructions for textiles and clothes, and hopes that implementation will be carried out without deviation from the ISO standard.

Recommendations:

- The CAA should without delay commence the task of reviewing and reforming the Labelling Act.
- The CAA should adopt the new ISO-aligned JIS (Japanese Industrial Standard) wash and care instruction symbols, as proposed by METI, without any additional requirements or deviations.

■ Shoe quota

Yearly status report: no progress. 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 behaviour is illegal, but still persists.

Recommendation:

- METI should improve monitoring of the situation to reject applications from entities that are not properly trading shoes and release their quotas. It is also recommended that METI should implement stricter penalties for companies taking unfair advantage of the system.

■ Limitations on selling liquor via telecommunication channels

Yearly status report: new issue. Although improvements were made to the liquor wholesale licence scheme some years ago (albeit for in-store liquor sales only), the sale of liquor on the retail market remains heavily restricted, even for sales to registered professionals. In particular, the restrictions limit sales conducted across prefectural borders via any telecommunication channel (internet, fax, e-mail, etc.) and lead to higher transaction costs and inefficiencies. This especially hurts small businesses attempting to overcome limited resources by utilising the internet to purchase liquor. It should, furthermore, be pointed out that very old licences do not have this limitation (grandfathered licences), which creates an imbalance between new and old licence holders.

Recommendations:

- Japan should abolish the telecommunication channel limitation within the liquor retail licence system.
- Japan should, as an interim solution, immediately permit liquor sales through telecommunication channels, including the internet, over prefectural borders to registered professionals (still categorised as retail under the law).

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LEGAL SERVICES

Introduction

This year, the Government of Japan finally passed legislation permitting a *gaiben* (foreign lawyer) law firm to incorporate itself as a *hojin* (corporation), and so open more than one branch. This option has been available to *bengoshi* (Japanese lawyers) for about 10 years. It should become available to *gaiben* in 2015, once the *Nichibenren* (Japan Federation of Bar Associations) and local bar associations have adopted the necessary rules. However, contrary to the recommendations of the final report of the Foreign Lawyers System Study Group in December 2009, the new legislation will not permit *gaiben* and *bengoshi* to establish a *hojin* together. This limitation will severely restrict the usefulness of the new legislation.

In other respects, the EBC's recommendations in respect of Legal Services in Japan remain the same as last year's, because nothing else has changed. However, the Cabinet's Regulatory Reform Plan, approved on 24 June 2014, gives hope that the Japanese system will be shaken up or at least subjected to a decent airing. The Plan suggests the following in respect of the regulations applicable to *gaiben*:

1. Setting up a study group to discuss the *gaiben* system: this will be set up under the responsibility of the Ministry of Justice within this fiscal year. With the increase in demand for international legal services, this study group will among other things review the requirement to have certain work experience (i.e. the 3 year requirement) in order to register as a *gaiben*, with the involvement of *gaiben*;
2. Transparency of the *gaiben* registration system: this will start to be considered this fiscal year under the responsibility of the Ministry of Justice. With a view to making the registration process and timing more transparent, and improving the user-friendliness for registrants, a forum will be set up for discussions between the Ministry of Justice and the *Nichibenren* taking into account opinions from registrants as necessary; and
3. Making the *gaiben* registration process simpler: this will start to be considered this fiscal year under the responsibility of the Ministry of Justice. With a view to making the registration process simpler and faster, a forum will be set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary.

The EBC will be taking a close interest in the roll-out of this Plan, not least because its credibility and ultimate success will depend on the process being conducted fairly, with proper participation by foreign lawyers and due consideration given to the views of the foreign legal community.

The EBC urges Japan and the EU to ensure that their bilateral FTA/EPA negotiations tackle both the issue of mutually recognising the status of lawyers so as to alleviate the cumbersome registration process in Japan, and the need to improve market access for firms with both *gaiben* and *bengoshi* with regard to setting up branches.

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, a foreign lawyer must have three years of professional experience in his/her respective home law, out of which two have to be obtained outside Japan. This rule is in stark contrast to the rules governing *bengoshi* who are not required to have any post qualification experience before being recognised. The EBC believes that this practice is not only discriminatory, but also makes little sense, as foreign lawyers are already acknowledged by their jurisdiction of qualification. If there is to 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 requirement for approvals from both the Ministry of Justice and committees at the *Nichibenren* and local bar associations inevitably gives rise to delays. After over 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. At the very least, experience in home jurisdiction law should be recognised regardless of where it has been practiced.
- 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 to 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: some progress, but of limited application. Legislation has now finally been passed permitting a *gaiben* law firm to incorporate itself as a *hojin*, and thereby become eligible to open more than one branch. However, the new legislation does not permit *gaiben* and *bengoshi* together to establish a *hojin*. The effect is to severely limit the usefulness of the new legislation.

Recommendation:

- Amend the legislation to permit *gaiben* and *bengoshi* to establish a *hojin* together. Even better, 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, in line with the practice in many other countries, for the benefit not only of foreign but also Japanese lawyers. 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

Harnessing the innovative potential of business across all industries to address the issues of sustainable development and climate change is imperative to meet the challenge defined in the 1987 UN Brundtland Commission report, to balance the needs of the present with those of future generations.

The EBC Sustainable Development Committee was formed by European companies from a variety of industries, including food, energy, water and construction, each committed to contributing to sustainable development. Reflecting their commitment, these companies have developed products that have already proven successful in Europe and other markets. These same products could also help Japan to achieve its goal of promoting a sustainable future. So to improve access to these products, the EBC recommends that the Government of Japan adopt a two-pronged approach. First barriers that inhibit market entry should be removed. These often take the form of a non-tariff barrier: a lack of acceptance of European standards that positively impact sustainable development. Second, standards and regulations which create perverse incentives or discourage the use of sustainable products, whether imported or not, should also be removed and replaced with a regulatory environment that promotes sustainable solutions.

The goals of EU sustainability policies are: 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 buy products and services that do not damage the environment; expand the market in technologies and innovations that are environmentally-friendly; and improve the welfare of animals both within the EU and beyond. 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 - infrastructure, business practices, and consumer behaviour. To take one example, in Japan, as in other advanced countries, buildings are the foremost producers of greenhouse gases, accounting for up to 40% of greenhouse-gas emissions. The construction sector, therefore, provides a prime opportunity to improve Japan's sustainability. Reducing the energy consumption of buildings would make a major contribution to reducing adverse impacts on the environment. Many private developers and building owners are keenly aware of the economic impact of reducing their energy consumption, and are taking action accordingly. Nonetheless, government legislation that encourages or mandates the use of energy-saving equipment and energy-efficient materials would provide an added boost.

One of the reasons the construction and real estate markets in Japan lag behind other countries in the widespread adoption of sustainable solutions is the relatively lax regulatory environment. Examples include the still widespread use of single glazing (Europe has moved to double and even triple glazing) and the lack of mandatory strict insulation standards for buildings and houses (reducing thermal losses is a requirement for building in Europe). Buildings should be constructed in such a way that they do not require a lot of energy to heat and cool in the first place. Building envelopes should be well-insulated and use components that mitigate heat gain in summer and heat loss in winter. European manufacturers offer some of the best solutions on the market - including insulation, spectrally selective glass, and curtain wall systems that prevent thermal bridging.

In summary, many European companies operating in Japan are world leaders in sustainability, but they are often confronted with a conservative business environment that is slow to embrace the opportunities of a more sustainable business model. This stands in sharp contrast to Japanese consumers, who polls have shown are generally supportive of sustainable initiatives. Put another way, consumers are open to change, but their sustainable choices are constrained. European business is keen to promote a dialogue with Japanese society, government and business to encourage reforms that would concretise Japan's commitment to sustainability and benefit all businesses that view sustainability as a key component of their future growth. Furthermore, 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 - infrastructure, business practices, and consumer behaviour. In addition to individual reform initiatives, the EU-Japan FTA/EPA offers an opportunity to promote sustainable development in a comprehensive fashion.

Key Issues and Recommendations

■ Improved sustainable development awareness and behaviour

Yearly status report: no progress. Japanese consumers exhibit a high level of environmental consciousness, and Japanese businesses are among world leaders in manufacturing energy-efficient technologies, such as energy-conserving equipment. However, there are few incentives to encourage consumers to demand environmentally-friendly products or for businesses to invest in and produce more environmentally friendly products.

Recommendations:

- The Government of Japan should raise public awareness regarding the benefits of sustainable development.
- 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 0.4% of all food sold in Japan. This is about 10 times lower than in Europe and possibly the lowest percentage among all developed countries. Japanese agriculture is still overly reliant on chemical inputs, such as pesticides, fertilisers and hormones. This situation is undesirable from both an environmental and consumer perspective. As such, the EBC recommends that Japan should take measures to encourage the production of more organic food by promoting the development of local organic and sustainable agriculture. The EBC is pleased that supplementary certificates from EU embassies are no longer needed. The requirement that every shipment of imported organic food must be accompanied by an individual organic certificate, however, remains an administrative hurdle that discourages both imports and exports of organic foods.

Recommendations:

- Abolish the need for individual organic certificates for every shipment. An annual certificate should suffice.
- Expand the organic JAS (Japanese Agricultural Standard) to include animal-based products.
- Abolish tariffs on organic food. (Organic food is already priced higher, so that tariffs make such food exorbitantly expensive, further discouraging consumers from buying it and slowing the growth of the organic food sector.)
- Encourage more sustainable farming practices by reviewing and revising regulations that encourage or require the use of pesticides and antibiotics.

■ Sustainable building design and construction materials

Yearly status report: some progress. Because the environmental impact of buildings collectively is so significant, standards and certifications governing building design, individual building materials and components, construction practices, and operations and maintenance procedures should be reviewed and revised in order to promote lower emissions of greenhouse gases and other environmental impacts. The foremost goal should be to reduce the energy consumption of buildings. To speed up implementation of sustainable building solutions, Japan should reduce barriers to the import of foreign materials. The acceptance of foreign environmental standards would remove the most significant non-tariff barrier in this area.

Recommendations:

- Introduce incentives or requirements to increase the demand for sustainable and green buildings.
- Adopt as soon as possible a mandatory high level insulation standard for buildings and houses with a total floor area of less than 300m².
- Require achievement of a specific rating level under CASBEE (Japan's Comprehensive Assessment System for Built Environment Efficiency) before issuing a building permit.
- Recognise ratings under foreign green building rating systems, such as LEED (US), BREEAM (UK), DGNB (Germany) and Green Star (Australia), as equivalent to CASBEE ratings in respect of local green building requirements.
- Facilitate the testing and certification of European building materials with sustainable properties, or accept foreign certifications as equivalent to comparable local standards.

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TAX

Introduction

The EBC welcomes the stimulus given to the Japanese economy by the reduction of the corporate tax rate to 35.6% as of April 2014, thus bringing the rate closer to international levels. The Government's announcement that it aims to continue bringing down the effective corporate tax rate over the coming years to around 30% is also promising, as it will improve Japan's competitiveness for the benefit of both domestic and foreign companies. The benefits of reduced tax rates should not be outweighed by the accompanying measures to broaden the tax benefits such as reduced tax incentives and the further restriction of the loss carry forward. 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, have suppressed consumption below already low levels. On the other hand, the increase in consumption tax to 8% in April 2014 has helped to restore the finances of and to some extent at least, confidence in the social welfare system. It will be crucial to see whether the Government will follow through with the October 2015 consumption tax increase to 10%. Meanwhile, if, as announced, cross-border services are to be made more widely subject to consumption tax, it will be imperative for the tax authorities to provide clear definitions of taxable events.

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. Unfortunately, attempts made so far by the Government 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. 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. The EBC also calls for the cost of tax compliance, inflated under currently inefficient tax filing rules, to be brought down and at the same time for the unreasonable pressure created by overly tight filing deadlines to be reduced, which would be beneficial to working parents. Both targets could easily be achieved by relaxing outdated and unduly short Japanese tax filing periods, and again would have no negative impact on tax revenues.

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. Any EU-Japan Free Trade Agreement / Economic Partnership Agreement (FTA/EPA) should include a mandatory arbitration clause to ensure that double taxation will effectively be resolved between Japan and individual EU Member States if a tax treaty text itself does not avoid double taxation in effect. The EU-Japan FTA/EPA should, furthermore, enable employers' and employees' contributions to social security systems within the EU and Japan to be treated as tax deductible on a mutual basis.

In short, the EBC considers that the tax reforms undertaken so far by the Japanese Government have been too piecemeal and a new, more coherent approach is needed. The EBC encourages the Government 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

■ Extended tax return filing periods

Yearly status report: new issue. Japanese tax filing rules cause very high tax compliance costs and put unreasonable pressure on taxpaying companies, their staff and service providers to file tax returns no later than two to three months after the end of the calendar or fiscal year. In Europe and elsewhere, an average period of nine months is allowed, and sometimes up to one year. The extremely short filing periods in Japan compromise the quality of tax filings and the working lives of those preparing the returns, while driving up expenditure on overtime. In the case of tax professionals serving both companies with a calendar year end and others with a March 31 year end, their work/life balance is even more impaired. The inescapable long hours leave no time for home life, a situation irreconcilable with being a working mother, thus forcing many women to either quit the job or never return to their profession after having children. Companies have no choice but to comply with labour laws and are held accountable for managing the overtime of their employees, so are forced to hire additional part-time staff on short-term contracts (a form of employment which is not necessarily in the public interest in Japan) and to give preference to those willing to work excessive hours. Not surprisingly, international comparison of the cost incurred for tax compliance shows that Japan has the highest level among developed countries.

Recommendation:

- Tax filing periods should be extended to one year in order to reduce the current unduly high cost of tax compliance. Any negative impact on public finances could be avoided as long as the tax rules continue to allow for prepayments and impose interest in the case of insufficient prepayments.

■ Research and Development tax incentives

Yearly status report: no progress. While Japanese rules give tax consideration to R&D expenses incurred by Japanese multinational enterprises, even when the R&D is 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 uncommon among foreign subsidiaries in Japan. The announced cuts in R&D tax incentives will reduce the relative financial disadvantage for overseas investors but the underlying discriminatory treatment will remain.

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. As a result of changes made to the *Bunsho Kaito* system, taxpayers may now seek written clarification of specific transactions. Yet despite this improvement, an overall lack of transparency and systematic accountability in the domestic tax regime still impedes the development of business in Japan. European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. The press often publishes news articles on audits, making reference 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 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: no progress. The Japanese tax authorities continue to use the domestic corporate tax rules relating to donations to make assessments in relation to transfer pricing matters. This has been done ostensibly to avoid the mutual agreement procedures arising under Japan's tax treaty network.

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.
- Any changes to domestic transfer pricing legislation in response to the OECD's ongoing Base Erosion and Profit Shifting ("BEPS") initiative should be introduced in a manner that minimises the additional administrative burden placed on tax payers.

■ 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 recently concluded new tax treaties with Switzerland and the UK. Japan is still 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.

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 issue of withholding tax on royalties and qualified dividends and interest.

Financial Services

**Asset management
Banking
Insurance**

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ASSET MANAGEMENT

Introduction

The professional investment management industry in Japan provides important benefits to society by helping investors to prepare 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, has driven public and private investment pools to seek higher returns from financial products, both from within and from outside Japan. The EBC welcomes plans by the Japanese Government to introduce changes to the mandate for the Government Pension Investment Fund. The demand for increasingly sophisticated investment expertise has continued in 2014.

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 was, therefore, encouraged by the launch of Nippon Individual Savings Accounts (NISA), introducing many investors to the savings market. However, efforts are still needed to reach investors who traditionally have never participated on the stock market or invested using a financial instrument, especially the younger generation. We also believe that the maximum limit allowed per year in the NISA scheme should be raised to further increase its attractiveness and give it the appropriate robustness.

The EBC is convinced 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 imposes unnecessary and costly burdens on investment management service providers, which stifle innovation and yield inefficiencies in resource allocation, to the detriment of Japanese consumers. It was, therefore, disappointing that despite the benefits of a planned merger between the two existing industry associations, the Investment Trust Association, Japan (JITA) and the Japan Securities Investment Advisers Association (JSIAA), the merger was derailed by a late-stage impasse brought on by the industry associations themselves.

Japan has long lacked proper rules on corporate governance. The EBC is therefore delighted to see guidance on a Stewardship Code published. We regard stewardship as integral to the investment process. Good stewardship is important for understanding the sustainable value of the companies in which equity is held on behalf of investors and provides a standard of behaviour that encourages protection of the assets of clients of asset management companies. Well managed enterprises will deliver sustainable competitive advantage and long-term shareholder value. Consequently, provision of insight into a company’s financial performance, the quality of its management structures, the suitability of its internal controls and the ability of its board to manage operational performance, environmental and social risks and opportunities will affect the stock valuation and selection strategies.

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 negotiations towards a bilateral FTA/EPA.

Key Issues and Recommendations

■ Stewardship Code

Yearly status report: new issue. In accordance with the guidance from “The Council of Experts Concerning the Japanese Version of the Stewardship Code”, published on 27th February 2014, Japanese equity investment managers in Japan have issued and disclosed every individual company’s stewardship code. We regard stewardship as integral to our investment process. Good stewardship is important for understanding the sustainable value of the companies in which equity is held on behalf of clients and provides a standard of behaviour that encourages the protection of the assets of investors. Well managed companies will deliver sustainable competitive advantage and long-term shareholder value, and the provision of insight into a company’s financial performance, the quality of its management structures, the suitability of its internal controls and the ability of its board to manage operational performance, environmental and social risks and opportunities will affect the stock valuation and selection strategies.

Recommendations:

- The Government of Japan should encourage boards and executives of equity issuing companies to fully implement the Stewardship Code by considering and reviewing the strategy, operating performance, quality of leadership and internal controls of the companies they direct in line with the Stewardship Code guidelines in order to produce the returns sought by investors.
- The Japanese authorities should ensure that the Corporate Governance Code, which is under discussion by “The Council of Experts Concerning the Japanese version of the Corporate Governance Code”, is effective in progressing the corporate governance discussion amongst equity issuing companies.

■ 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 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, real structural change is lacking. The bulk of capital still orbits around low interest government bonds. The EBC believes that there is a need to re-balance the investment portfolio to better achieve the goal of becoming an international financial centre.

Recommendations:

- Japan should prepare a more holistic plan for reform.
- Japan should encourage diversification of portfolios to support more high return products.
- Japan should swiftly introduce the new mandate for the Government Pension Investment Fund.

■ Nippon Individual Savings Accounts

Yearly status report: progress. The EBC believes that the introduction of NISA has been very beneficial to both the industry and investors and has produced a considerable amount of new investments. The 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 underpinning legislation as approved allows for investment contributions of only 1 million yen per year for five years, each such contribution being tax exempt for five 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 EBC supports the basic aim of the scheme and hopes that it can be expanded in the near future, just as the system has evolved in the United Kingdom, the first country to introduce Individual Savings Accounts.

Recommendations:

- Increase the maximum amount that can be invested.
- Continue to promote the scheme with a special focus on the younger generation and investors with no previous experience.
- Consider making the system permanent.

Vacant

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BANKING

Introduction

Japan's relative prosperity has decreased considerably in recent years and, although Japanese consumers have continued to save, their return on capital has been the lowest in the industrial world. On the other hand, Japan has weathered the various financial crises that have occurred during this period much better than many other countries; Japanese capital markets were strong enough to raise substantial funds even during 2009 and 2010. Japan thus remains one of the largest financial markets in the world with high savings rates. European banks have much to offer this market, bringing not only global networks but also valuable expertise in cross-border M&As.

After some years of flagging attractiveness as a financial centre, Tokyo has started to bounce back. The Economist newspaper now lists Tokyo in sixth place on its Global Financial Centre Index (GFCI), which ranks the competitiveness of such centres. No doubt much of this is due to “Abenomics” which has had its biggest impact on the stock market, with the Nikkei 225 index rising dramatically since the programme started in early 2013. It is, however, now crucial for structural reform to be introduced to convert this short-term gain into sustainable growth. So far Prime Minister Abe's reform plan for the financial sector has not impressed. While the banking sector has seen more movement in capital, especially in the area of securities, lending and projects are still underperforming. The EBC therefore believes a more radical approach is needed to create a financial environment enabling Tokyo to become a true financial centre.

In this context, the EBC is particularly interested in the amendments to the mandate of the Government Pension Investment Fund (GPIF). We very much welcome the shift from almost exclusively low-yield investments to more advanced products with chances of a higher return. Since a large amount of capital is tied to the Fund, we believe that such a shift will help to revitalise the capital market in Japan and, therefore, also boost the banking sector.

Meanwhile, further effort is needed to provide an appropriate regulatory framework for cross-border transactions. The banking agency system introduced in 2008 requires Japanese branches of European banks to apply for a special business licence each time they plan to introduce any new banking service that will be provided by another banking entity, even if that entity is simply an overseas branch of the same financial group. 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 FSA has published a Q&A on who is covered by the banking agency system and who is not, a lack of clarity persists.

Anti-Money Laundering (AML) and Know Your Customer (KYC) regulations are core parts of the global regime to tackle financial crime. This is a major issue for regulators and also for financial institutions. The standard setter for global regulations is the Financial Action Task Force (FATF) and its recommendations are endorsed by the International Monetary Fund. FATF has criticised Japan for not introducing a regime that complies with its recommendations, notably in a press release issued in June 2014. The Japanese Government has started to take legislative action in response to this criticism. The biggest gap between Japanese and the global standards is the failure by the Japanese regime to fully implement a risk-based approach throughout the processes of customer due diligence and customer management. For example, identification of the ultimate beneficiary of ownership of a transaction (UBOs) and politically exposed persons (PEPs) have been left unaddressed in Japan, while at the same time formalistic KYC requirements are rigidly applied without giving consideration to the underlying risk. The EBC welcomed recent activities and progress in this area and encourages the Government in its efforts to introduce an anti-money laundering regime compatible with international standards.

Key Issues and Recommendations

■ Revitalisation of the financial market

Yearly status report: new issue. The introduction of the first two “arrows” of Abenomics (focussed on fiscal stimulus and monetary easing) led to a flurry of activity in the financial market in Japan. Now, two years later, this activity has subsided and the market is waiting for a more permanent improvement: long-term reform on the macro level is required. The EBC especially looks forward to implementation of the new mandate for the GPIF and is, furthermore, cautiously optimistic about the newly introduced Stewardship Code guidelines, which should lead to improved transparency and lowered risk.

Recommendations:

- Japan should expand the mandate of the GPIF as announced and encourage the move in the GPIF from low-yield investments to investments with higher returns.
- Japan should swiftly implement the proposed Stewardship Code without diluting its content

■ 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 so welcomed the FSA’s decision to release its annual inspection programme, which clarifies the focus issues for the year, and to provide pre-notification of inspections in certain cases.

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.
- Special consideration should be given to companies already regulated due to their designation as Global Systemically Important Financial Institutions, in order to avoid an unnecessary administrative burden.
- FSA rules and regulations should be applied consistently in accordance with 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: progress. The banking agency system requires Japanese branches of European banks to apply for a special business licence each time they introduce any new banking services provided by another banking entity, even if that entity is a branch 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. While clarity improved when the FSA published a Q&A on who is covered by the banking agency system, further efforts to provide a more appropriate regulatory framework for cross-border transactions is needed.

Recommendations:

- The FSA should further clarify and streamline the application process for banking agency licences.
- The FSA should introduce a system whereby branches of European banks in Japan do not have to apply for a special business licence each time they introduce a new product.
- The FSA should provide a more appropriate regulatory framework to facilitate cross-border transactions.

■ Anti-money laundering

Yearly status report: new issue. To date, foreign banks in Japan and Japanese banks with overseas operations, have in some cases had to operate two different systems to meet two different risk management requirements (Japanese and ex-Japan). This has cost implications for firms and introduces a risk of non-compliance. Non-compliance with global FATF rules can lead to blacklisting by FATF. We welcome and encourage the Government’s efforts to introduce an anti-money laundering regime compatible with international standards.

Recommendation:

- Japan should promptly align its legislation with international standards to avoid deviating from FATF.

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INSURANCE

Introduction

The Japanese insurance market is the second largest in the world after the USA. While the market share of foreign affiliates in Japan is increasing, they continue to encounter regulatory obstacles that can limit efficient development of their businesses. Examples include the issue of privatisation of Japan Post, non-equal footing with mutual aid cooperatives (*Kyosai*), reserving and solvency regulations that are inconsistent with, for example, European solvency requirements, and the lengthy, non-transparent 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.

The EBC has in previous White Papers repeatedly drawn attention to Japan Post and the preferential treatment it receives. Japan Post Insurance (JPI) is currently conducting life insurance business under Japan Post Holdings. JPI is now allowed to launch new life insurance products subject to regulatory approval under the amended Postal Service Privatization Act even though privatisation has not been completed and a level playing field among JPI and private insurers has not been secured. The EBC repeats its position that JPI should fall under the same rules as private insurers and that there should be more transparency as regards JPI's access to and relationship with Japan Post's network. The EBC is following with interest recent developments regarding business alliances between JPI and private insurers. However, the EBC wants to clearly point out that this does not completely resolve the issue and that it is vital for the Government of Japan to comply with its obligations under the WTO General Agreement on Trade in Services (GATS).

In response to the global financial crisis, the International Association of Insurance Supervisors (IAIS) consigned by G20 and the Financial Stability Board (FSB), designated nine insurers as global systemically important insurers (G-SIIs). The FSB/IAIS are advocating that such insurance companies maintain certain minimum capital requirements, adopt a market-based solvency measurement methodology such as Solvency II, implement certain risk management strategies, and develop substantial resolution plans amongst other measures. Additionally, they are proposing that national insurance regulatory bodies in each country increase information sharing with other regulators across borders. As the regulator of Japan's financial market, the FSA would need to adopt many of the proposed policy measures before they could become effective in Japan.

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 lengthy in comparison with other financial markets 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: some progress. 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 introduced a limited number of products and has 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 swiftly carry out the privatisation process in accordance with its previous commitments.
- The Government should, furthermore, better explain obligations under the universal service requirement.
- The Government should set up guidelines for the Japan Post Network on how it selects which products to market and sell.
- 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 Government of Japan, 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*. The EBC would also like to point out that the original purpose of *kyosai* of supporting only a well-defined group like farmers or police officers has in many cases been abolished and today more or less any person, irrespective of affiliation, can sign up for a policy. For example, *Tomin kyosai* only requires the customer to live in Tokyo and the Central Union of Agricultural Cooperation (JA) can to a certain extent sell to non-JA members.

Recommendations:

- *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.
- *Kyosai* should only be allowed to sell insurance to the members of their own well-defined group.

■ Harmonisation with global solvency and other regulatory standards

Yearly status report: progress. The EBC welcomes the update of the Solvency Margin methodology 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 local regulatory 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 FSA and insurers - and hopefully reduce the overall regulatory reporting burden on insurers conducting business in multiple jurisdictions.

Recommendations:

- The Government of Japan should accelerate reforms aimed at attaining convergence between Japanese and global solvency standards by establishing a roadmap for convergence with Solvency II.
- The market-based Solvency Margin calculation methodology should be further aligned with Solvency II.
- The Government of Japan should continue to fully participate in the development by the FSB/IAIS of enhanced regulatory measures for systemically important insurers and internationally active insurance groups.
- In adopting any or all of the FSB/IAIS proposed policy measures for the Japanese market, the Government of Japan should consider the burden that such risk management reporting and capital adequacy requirements could impose on these businesses and minimise any conflicting cross-border jurisdictional requirements.

■ 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 adaptation to ever-changing markets. In the long term, a "file-and-use" system should be introduced so that reputable companies do not have to start from scratch when introducing a product that is already on the market. The EBC is however encouraged to see that FSA acknowledges the need for strengthened resourcing.

Recommendations:

- The FSA should improve and clarify its product approval process to avoid uncertainties. One way forward could be to set up a task force, with members from both the authority and industry, the latter comprising both domestic and foreign companies.
- The FSA should, furthermore, introduce a simplified approval system for products that are either fully or partially on the market already.

■ Bancassurance or bank sales channel

Yearly status report: limited progress. It is common practice for insurance companies to use banks, and especially the physical network of the banks, to better market and sell various insurance policies. Although the market has been liberalised, some areas of the market cannot be accessed through this sales channel – notably sales of insurance to employees of companies with less than 50 employees where the company is a borrowing customer of the bank. While the EBC understands that the rationale behind this policy is to prevent banks from using their superior bargaining power to force clients to buy unnecessary or inappropriate insurance policies, we would like to point out that such behaviour is already prohibited by anti-trust law and the banks' codes of conduct. The EBC, furthermore, remains unaware of any major complaints from consumers about banks mis-selling insurance policies.

Recommendation:

- The FSA should further liberalise bancassurance to make it possible for banks to sell insurance to any company employee regardless of the relationship between the bank and the company.

■ Policyholder Protection Corporation (PPC)

Yearly status report: some progress. While the framework for PPC has long been discussed, very little has happened, and the system is still pre-funded. This situation exists even though the funds have not been used for several years. In addition, neither the total amount of the funds nor the annual assessment have been adjusted to better mirror the current more stable situation of the insurance market. The EBC would prefer a system that is post-funded to remove the risk of moral hazard among companies. We would also like to remind the authorities that some European insurers are already designated as Global Systemically Important Insurers (G-SIIs) with further requirements of enhanced supervision and higher loss absorption (HLA).

Recommendations:

- The FSA should amend PPC so that it becomes a post-funded system and at the same time introduce provisions for the system to better mirror the current market situation regarding the total funding and annual assessment.
- The EBC requests that the Japanese authorities take into consideration the situation of the G-SIIs when amending the PPC system.

Transportation & Communications

**Airlines
Railways
Telecommunications carriers
Telecommunications equipment
Logistics & freight**

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AIRLINES

Introduction

The Japanese aviation sector continues to be of global significance, with about 5% of global traffic flying in and out of Japan. More than ever, air transportation is critical as a catalyst for economic growth. However, Japan still ranks low in terms of the quality of its air transport infrastructure, placed just 46th in World Economic Forum (WEF) rankings. International flights connect Narita and Haneda Airports with only 88 cities, while Seoul, Hong Kong and Singapore each have more than 130 international routes. The Japanese Government intends to increase the combined number of annual slots at both airports from the current 747,000 to 830,000 prior to the Olympic Games in 2020 by introducing new flight routes above Tokyo. Unfortunately, domestic demand for leisure travel has fallen recently, following a substantial weakening of the Japanese currency and an increase in the rate of consumption tax from April 2014, together leading to increased package tour prices and cautious consumer spending behaviour. While inbound travel from Europe has increased, it cannot compensate for weaker demand from the bigger Japanese market. Revitalisation of outbound leisure traffic from Japan to external markets, especially to Europe, is therefore of great importance. The capacities planned by the Government for the Olympics can only be provided if outbound demand can support them, not least on Japan-Europe routes.

The EBC again urges the Government of Japan to reduce charges at Japanese airports, especially for those airports offering vital links to and from international markets, so that the Government's ambitious growth targets can be achieved. 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 WEF's competitiveness ranking for Travel and Tourism, Japan ranks 113th in terms of airport and ticket charges. The new Narita Airport fee structure introduced in 2013 has not succeeded in producing any substantial cost reductions for users. Landing fees were indeed lowered, but rents and baggage handling system costs were increased. As a consequence, the real beneficiary of the changes has been Narita Airport, which shows healthy profits on its balance sheet.

The EBC is closely following the construction and opening of the new terminal at Narita for Low Cost Carriers (LCC). We are still seeking a transparent explanation of the cost structure for this terminal and reassurance that the complete cost will be borne by the users of this specific terminal, the LCC themselves. No cross subsidy should take place between existing terminals financed and used by the incumbent airlines and the new project. Airport user charges at Haneda exceed even those applied at Narita although the infrastructure for users is totally inadequate. For example, the infrastructure for catering and cargo cannot meet demand and creates substantial hidden costs for airlines. Given the plans to develop further capacity for international flights to take off and land at Haneda, we urge the Government to earmark the necessary space to accommodate production/storage facilities for vital airline suppliers. Furthermore, while welcoming the opening up of Haneda Airport for intercontinental flights following completion of its new runway and international terminal in 2010, the EBC again urges the Government to ensure that access is provided on equal terms to all carriers. Healthy competition is a prerequisite for establishing a functioning market driven by an economic rather than political rationale. In order to avoid unhealthy and unsustainable excess capacity, the Government should engage in developing flexible solutions that do not require carriers serving Haneda Airport to also maintain flights at Narita.

Finally, the EBC urges the Government to consider carefully 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 transactions 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 (9 years) and access to valuable slots at Haneda Airport, has impacted 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. The Japanese Government should, therefore, closely monitor the competitive situation and ensure that European airlines can enjoy a fair and level playing field.

Key Issues and Recommendations

■ High costs

Yearly status report: limited progress. The revised Narita Airport fee structure did not produce the expected substantial cost reduction for users – the lowering of landing fees was accompanied by an increase in rental and baggage handling system costs. In the meantime, Narita has announced that it will give 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. In addition, Japan's Airport Development Special Accounts have had the effect of subsidising unprofitable airports by taxing major airports, which are the very facilities used by European airlines. The EBC believes this approach is unfair and also unsustainable. If Narita is to remain competitive with other hubs in Asia, reduction in airport costs by as much as 50% will be necessary.

Recommendations:

- Airport fees should be lowered if Japan is serious about becoming a true tourist destination in Asia.
- The authorities should ensure that no differentiation in fees is made between new and incumbent airlines.
- The authorities should ensure that the announced lower fee for LCCs is not subsidised by mainline carriers.
- The perimeter security control at Narita should be abolished and replaced by a more efficient and passenger-friendly process, and the consequent savings shared with the airlines, who currently pay for this.
- Airport Development Special Accounts should be abolished to pave the way for the lowering of fees.
- The Japanese Government should proceed with privatising airport management, as in Osaka, giving the new managers sufficient flexibility to achieve higher cost efficiency and lower charges for airlines.

■ Airport infrastructure

Yearly status report: limited progress. As of summer 2014, 30,000 new daytime slots for international routes had been assigned at Haneda. Some operational restrictions on the utilisation of the airport had been removed.

Recommendations:

- Japan should establish a plan for efficient use of all available airport infrastructure, including identification and assignment of space for airline suppliers in the Catering/Cargo sector to reduce costs for airport users.
- 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.
- The expensive *early gear down* policy should be abolished after careful explanation to the local community.
- Haneda Airport should accept all aircraft types.

■ Revitalisation of outbound tourism

Yearly status report: limited progress. Japan is allocating substantial efforts and funds to promoting Japan as an inbound destination. However the capacity increase required between Europe and Japan for the 2020 Olympics can only be provided if there is an increase in the volume of Japanese customers travelling outbound to Europe.

Recommendations:

- The Japanese Government should facilitate and promote outbound travel, especially to Europe.
- The cost of first passport issuance should be reduced and travel encouraged, especially for younger people.

■ JAL Restructuring

Yearly status report: limited progress. The Government should carefully consider the competition implications of the government-supported bail-out process and recapitalisation of JAL.

Recommendations:

- The Government of Japan should make sure that competition is not distorted by the effects of long-term tax breaks as well as guaranteed loans for Japan Airlines.
- During the next round of slot allocations at Haneda Airport, European airlines should be treated favourably.

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RAILWAYS

Introduction

Japan, being an island nation, is not connected to any neighbouring countries by rail. The EBC Railways Committee believes that this presents challenges for its railway industry, depriving it of the competitive stimulus and commercial opportunities that direct connections with neighbouring countries provide. Examples of such direct connections abound in Europe, from the rail and road tunnel linking the island nation of the U.K. to France to the integrated network of high speed TGV and ICE train services running between France and Germany. In Istanbul, Turkey, a railway has even been built under the Bosphorus to connect the trans-continental networks of Asia and Europe. None of these connections would exist without the countries involved recognising the opportunities integration can offer and investing the time and effort to harmonise their rules and regulations and thus make it possible. Creating an open framework for ensuring the safety and conformity of railway products and services has greatly benefited Europe, from the perspective of manufacturers, operators and users alike. The EBC commends this approach and hopes that the railway sector in Japan will itself choose to take a similar route, mirroring the sea and air related sectors here, which have chosen to benefit from a global market and moved towards adopting more open and comprehensive legislation for approvals and recognitions.

More than three years have passed since the Tohoku Earthquake, yet many railway tracks still remain damaged and will take another year or more to be rebuilt. The EBC Railways Committee, with its particular expertise in urban planning and rail technology, believes that a Light Rail Transit (LRT) system should be introduced. While some rail-bound operations have been replaced by bus services, the roll-out of LRT would contribute to the long-term revitalisation, commercial development and well-being of people in what is currently an ageing and depopulated region.

The total value of rolling stock produced in Japan in 2013 was 197 billion yen, up 14.6% from the previous year. The figure includes new production, remodelling and repairs. In comparison, the value of rolling stock imported from abroad was extremely low, amounting to only 7.1 billion yen. The value of railway-related parts production in Japan in 2013 was 252 billion yen, up 7.4% from the previous year, whereas the value of imported parts was just 6.8 billion yen. Although production increased in 2013, the level of imports remained more or less the same as in 2012. The EBC is still of the opinion that Japan represents a large market with good potential for European manufacturers and service providers, and we would welcome more openness to imports.

In Japan, unless products are sourced from specific manufacturers, traditionally they are not considered by Japanese railway operators without further extensive yet unnecessary testing, even if already tested and certified according to international standards. The EBC strongly requests the Japanese Government to improve the legal environment to facilitate smooth imports and exports, while minimising wasted costs and time.

The EBC welcomes the EU-Japan FTA/EPA negotiations and the progress made to-date. We note that Japan requested the removal of three JR companies from the list covered by the World Trade Organisation's (WTO) Plurilateral Agreement on Government Procurement (GPA), and that this request was approved when the EU removed its reservation. One of the conditions for accepting this request is that there must be transparency in respect of materials procurement. Moreover, the definition of the Operational Safety Clause (OSC) has always been an important part of this process. The EBC still does not understand why the Japanese Government believes that safety concerns can be grounds for not following the guidelines of the GPA, as Japan and its operators would still be allowed to set their own safety-related standards. The EBC therefore looks forward to improved clarity regarding the definition of the OSC, and requests the Japanese Government to continue its efforts to enhance the transparency of materials procurement. We urge the EU and Japanese negotiators to recognise that the EU and Japan have comparable safety standards and to agree on the elimination of the OSC during the second year of the FTA/EPA negotiations and to eliminate all remaining non-tariff barriers in the sector.

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 and vertically integrated 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, as a way to boost competition in the domestic market and export prospects for Japanese manufacturers.
- The EBC would welcome continued dialogue on this theme with Japanese government officials, research institutes, the railway operators and industry.

■ Conformity assessment and mutual recognition of testing and certification

Yearly status report: no progress. In 2012, the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) established a Railway Certification Center under its National Traffic Safety and Environment Laboratory, with the objective of certifying Japanese products for overseas markets. Japan is indeed an active participant in various international standardisation bodies, but there is very little movement to apply common standards across its domestic railway market. Moreover, Japan lacks a common conformity assessment scheme for this industry. The EBC believes that it is crucial and mutually beneficial for Japanese operators to work together with the EBC Railways Committee to define common requirements. With this important first step, a roadmap could define how to move towards a common conformity assessment scheme.

Recommendations:

- Japan should establish a working group with the participation of the JR groups and other major Japanese operators to identify minimum common requirements acceptable to all operators.
- The Japanese authorities should take a more active role in setting up a conformity assessment scheme.

■ GPA - definition of the Operational Safety Clause and its scope

Yearly status report: some progress. Japan and the EU are both signatories to the WTO's Plurilateral Agreement on Government Procurement (GPA). Within the agreement's framework, Japan negotiated an OSC applicable to its transport sector, stipulating that procurement related to the operational safety of transportation is excluded, resulting in very few calls for tenders in this sector. While Japan committed to define the OSC, as part of the delisting of the three JR companies, there is still doubt whether this will result in real change, as current information indicates that Japan is formulating a very wide definition.

Recommendations:

- Japan should make certain that the new definition of the OSC is not a catch-all, but will lead to real change and that government entities covered by the GPA truly follow the agreement.
- The Government of Japan should ensure that when planning new railway projects (LRT), local cities abide by or use the GPA as guidance to set up a proper public procurement scheme, and not apply the OSC.

■ Tenders

Yearly status report: slight progress. Japan has never had a system of tendering for railway-related projects. The EBC, however, would like to commend JR East for its recent call for tenders for diesel rolling stock. The EBC believes there is a clear business case for tendering and so hopes that Japanese operators will start to use tendering procedures as the main method for procurement of railway-related products and services. We also hope the voluntary code on publishing procurement plans, issued by the three major JR companies, will result in more transparency and better access to technical specifications as well as information on how to meet and exceed any set requirements. The strict adherence of the three JR companies to their voluntary codes of conduct remains a critical issue for the EU suppliers and the Government needs to ensure full compliance with these codes.

Recommendation:

- The Government of Japan should encourage other operators to follow the example of JR East and promote the use of tendering as this will improve competition in the Japanese market, benefiting both operators and passengers.

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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 creating an independent electronic communications regulator has been widely discussed in Japan, including in political debates. The EBC regards independence of the regulatory process to be good practice in order to promote decision-making that is objective, transparent and accountable, and to build trust and credibility within the industry in order for different viewpoints and interests, including economic, social, and political objectives to be duly considered. The EBC believes such independence should be reflected in the institutional organisation in Japan and in its system of checks and balances. The resulting regulator should, furthermore, report directly to the Japanese Parliament.

Whilst recognising that the Ministry of Internal Affairs and Communications (MIC) has made tremendous progress in advancing the Information and Communication Technology (ICT) industry, the EBC nevertheless believes there is a need for an oversight body with a majority of independent members and due transparency of its proceedings and decisions. This is particularly important in the 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 EBC has long argued that ensuring fair competition is essential if Japan is to remain a vibrant telecom market. Creating an independent regulator is crucial, but only one of many elements that need to be put in place. There is also a need for better transparency in the cost mechanism for interconnection charges. Moreover, universal service obligations should reflect actual costs, thus helping to avoid unfair cross-subsidy. Japan has relatively high access prices compared to neighbouring East Asian countries so it is important that a much more holistic approach is taken in order to maximise competition in the market.

As large transfers of personal data between servers are becoming common and involve an increasing number of companies as well as administrations both as users and as providers, authorities are looking into how big data should be regulated. While by no means a new issue, the last couple of years have seen an immense increase in the volume of data. The EBC fully understands the need for regulating this field, emphasising, however, that any regulation should be designed so as to fulfil the security requirements, while avoiding placing companies under an excessive compliance burden. The EBC believes that it is of the utmost importance for there to be flexibility and pragmatism and for new rights and definitions to be clear. The process of formulating the regulations must be transparent and open to comments from outsiders. Special care should be taken regarding the issue of international transfers of information, so that companies can make full use of the advantages of cloud technologies. An appropriate balance should, therefore, be struck between protecting and informing consumers and providing the right environment for companies to conduct business. As such, it is crucial that authorities do not work in isolation, but constantly communicate with each other worldwide to learn from best practices.

The EBC Telecommunications Carriers Committee has high hopes of the benefits that an ambitious FTA/EPA between Japan and the EU can bring, and strongly believes that telecom issues should be covered, including detailed commitments and pro-competitive rules for the telecommunications and ICT services sector for business and end users. These commitments should go beyond those made under the WTO Basic Telecoms Agreement of 1998 and its annexed Reference Paper. They should, in particular, cover wholesale access regulation. The negotiations should also explore 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. The EBC believes that it is inappropriate for the Government of Japan to act as both the regulator and a major shareholder in the Japanese telecommunications sector. Currently, however, MIC continues to enjoy wide-ranging statutory powers of intervention and control. The issue of independence was raised by the previous Government, but so far no discussion has taken place under the current Government. The EBC recommends the creation of an independent government committee as an independent regulatory authority, with a mandate to monitor regulation and business practice 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 enables 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 the Government and the committee should report directly to Parliament, and not to the MIC.

■ Data protection for big data

Yearly status report: new issue. With vast amounts of personal data being sent between servers daily, authorities have realised that there is a need to regulate this area. The EBC is keen to contribute to the policy debate, believing that any changes should be straightforward and practical. Regulation should strike a careful balance between protecting individual privacy and creating an environment that supports innovation of new products and services driving economic growth and employment in Japan.

Recommendations:

- New obligations on data processors should be clear and any definitions must provide clarity.
- The authorities should avoid overly complex regulation that could inadvertently lead to increased cost and so off-set the advantages of offering data processing.
- Any new regulation should also provide a balanced approach to minimise the inherent conflict between privacy for individuals and the need for companies to use information.
- Special focus is needed on international transfers of data to make certain that data flows are not “stopped” at the border, while at the same time introducing best practice to make certain that data are kept safe.

■ Fair competition

Yearly status report: some progress. MIC started reviewing fair competition rules in 2014, having already finished its initial research and public comment procedure. There are many items on the agenda including crucial topics such as the functional separation of NTT. The EBC believes it is of utmost importance to follow fair competition principles based on global practices. These principles will ensure that future discussions on fair competition rules will be successful.

Recommendations:

- The Japanese Government should ensure the transparency and efficiency of the regulatory process, including providing adequate time for consultation.
- The Japanese Government should introduce open and simple licencing procedures with minimum service and regulatory obligations.
- Incumbent carriers should be obligated not to discriminate on price or other conditions between their own businesses and those of competitors and to provide suitably separated published accounts.
- There should be transparent control by the regulator of access to the radio frequency spectrum, to physical rights of way and to the numbering plan.
- There should be proactive regulatory oversight of the implementation of any schemes for “equal access” and number portability to support newcomers to the market.
- To help avoid unfair cross-subsidisation, operators with significant market power should keep transparent, publicly available, separate accounts.

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TELECOMMUNICATIONS EQUIPMENT

Introduction

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, and in 2009 the same organisation set up the "i-Japan Strategy 2015" with the goal of providing broadband to everybody, everywhere and at any time. An additional goal is to improve health-care and education through ICT, as well as to create new industries. In June 2013, the Cabinet approved "the world's most advanced IT nation creation declaration" and with it intensified Japan's efforts to realise an IT-based society.

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. Although some additional products have been added to its scope, many products are still not covered by the SVC.

In the area of spectrum allocation, in 2012 Japan allocated both the 700 and 900 MHz bands for mobile telephony by a process requiring each applicant company to submit information on its planned use of the bands 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.

There are approximately 6.8 billion mobile subscriptions globally and 2.4 billion of these are connected to mobile broadband, with overall mobile data traffic doubling each year. In a mature market like Japan, with advanced data services and LTE introduction, smartphone penetration is about 50% and is driving mobile broadband growth and a projected traffic usage of 10 GB/month per user in 2020. There is a paradigm shift from a traditional telecom model to a networked society model, where applications and users can demand variable speeds and latencies. The various applications used on smartphones, such as video and social networks, and machine-to-machine communication, place different demands on the network. In order to address the strong traffic growth, Japan created an action plan and strategy in 2010 with the aim of securing an additional 300 MHz by 2015 and by 2020 to have secured another 1,500 Mhz worth of bandwidth for mobile communication.

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 in general and that the application has not been expanded to include other telecommunications equipment, except for 3G/LTE and WiFi functions in mobile terminals thus continuing to exclude radio base stations for mobile networks.

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.
- 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. Therefore, the EBC was pleased to note that in 2010, 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 has completed a study report on the technical requirements for IMT-advanced especially in the band between 3,400 MHz and 3,600 MHz. MIC is working towards partially awarding this band before the end of 2014.

Recommendations:

- The Government of Japan 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 spectrum for IMT systems.

■ Licensed shared access of spectrum

Yearly status report: new issue. The EBC acknowledges that the Government of Japan has begun studying the licensed shared access of spectrum between incumbent and prospective licensees, to address the increasing demand of spectrum for mobile broadband. The EBC supports this initiative, while noting that the sole use of spectrum by a single operator is prioritised as it ensures the Quality of Service (QoS) to end-users.

Recommendations:

- The Government of Japan should further study the concept of licensed shared access to find how this should be implemented in Japan.
- The Government of Japan should identify potential frequency bands and relevant incumbent radio systems, where licensed shared access can be used.

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LOGISTICS & FREIGHT

Introduction

European forwarding and express companies offer Japanese consumers the benefits of access to their worldwide logistics operations, but still face serious and significant regulatory challenges. Moreover, they struggle with Japan's high cost base, inadequate infrastructure, restricted aircraft operation time windows, heavily congested ports and rigid customs clearance procedures. They also have to deal with outdated restrictions on foreign-owned companies engaging in the domestic freight forwarding business, and unfair competition caused by differences in the rules and regulations applied to carriers even when providing exactly the same service, resulting in inefficiencies and higher prices for users. The EBC believes that Japan needs to put more emphasis on addressing these problems, which are becoming worse every year.

Currently, Japan has nine separate customs areas and no central customs authority. A company is only allowed to lodge customs declarations if its clearance operation is physically located within the jurisdiction of the responsible customs office. This makes it difficult for foreign logistics companies, which lack multiple regional offices in Japan, to expand their geographical coverage. Within the Tokyo region there are two different customs territories: Tokyo, covering the Tokyo area, Narita and Baraki port and Yokohama, responsible for the rest of the region. It is against this background that the EBC has welcomed various proposals tabled by the Ministry of Finance (MoF) on customs liberalisation and improved flexibility. Real change is not scheduled until 2017, but the EBC would like to see earlier implementation, perhaps through pilot projects.

Japan Post, which is currently restructuring, has plans 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. The EBC recognises the need for a universal service obligation to meet certain socio-economic goals. However Japan Post is benefitting from unfair competitive advantages in the express delivery market, where its Express Mail Service (EMS), a special value-added international express package, already accounts for 18% of the market. EMS is not subject to the strict regulations applied to private sector 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. It is important to note that EMS is not deemed part of the universal service in Europe or the US. In Europe it is explicitly referred to as different from the universal postal service, while in the US it belongs to the category of "Competitive Services". The EBC believes that there are no obstacles to moving EMS outside the scope of universal service in Japan, similar to the treatment applied to "yu-pak".

Companies expected the introduction of the Authorised Economic Operator (AEO) concept in Japan to lead to simplification of many of the transport and customs processes they need to undertake in order to provide their services. Unfortunately, the new system has missed this target: instead of streamlining these processes, it has burdened companies with an increase in administrative tasks and compliance requirements in order to achieve AEO status. The EBC believes that more simplifications should be introduced similar to those proposed when the AEO concept was first presented.

Reforms aimed at improving Japan's overall business infrastructure have not done much to remedy the challenges to shipping services. The Super Core Port initiative, announced by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) as far back as November 2002, has yet to yield tangible improvements to the high cost structure of Japan's ports. The development of Japanese container ports and terminals is being initiated by local authorities rather than by central Government, such that the anticipated economies of scale and efficiencies will remain difficult to achieve. Data show Japan's decline in port activity: Kobe Port, for instance, has now dropped in the Asian rankings from fourth place in 1980 to 53rd place in 2014. Tokyo too has shown a decrease in freight traffic compared to other Asian ports. Structural improvements are desperately needed if Japan wants to remain a vibrant shipping country.

Key Issues and Recommendations

■ Customs clearance and declaration

Yearly status report: some progress. Currently, Japan limits which customs procedures can be carried out in a region where a company is not physically present or if a customs related licence is not issued for that region. The current set-up makes it difficult for foreign logistics companies, and also small and medium-sized Japanese companies, to expand the reach and coverage of their customs clearance businesses. 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 EBC therefore welcomes recent proposals from the Ministry of Finance (MoF) to liberalise customs and introduce further improvements.

Recommendations:

The Government of Japan should:

- Commit to implementing the proposed policy on customs jurisdictions. The EBC also asks for early implementation, perhaps in the shape of pilot projects.
- 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 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.
- Introduce a single national customs area, or as a first step, merge Tokyo and Yokohama ports, as well as Osaka and Kobe ports.

■ Level playing field with Japan Post's EMS

Yearly status report: no progress. Currently, Japan Post is only required to declare EMS packages to customs when the goods they contain exceed 200,000 yen in value, substantially higher than the value applied to equivalent packages handled by private sector operators. Additionally, although the National Police Agency has declared that EMS is subject to the Parking Law, in practice the Law is not applied to EMS-carrying vehicles. 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 the first port of entry (usually an airport), 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) ensuring equal rules for submitting advance cargo information.
- The Government of Japan should allow private express delivery companies to use their own facilities to clear quarantine-related goods.

■ Authorised Economic Operator (AEO)

Yearly status report: some progress. 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 powers 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, provided 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 handled by AEOs, including but not limited to:
 - ◇ Deregulating customs clearance beyond the local customs jurisdiction territories;
 - ◇ Reducing the physical examination of shipments.

■ Port costs and development

Yearly status report: limited progress. Port costs in Japan are exceptionally high in comparison to other advanced economies. High costs not only hinder European companies from operating to their maximum potential in Japan, but also drive many Japanese companies to switch production overseas and ship lower volumes through Japanese ports. High port costs also undermine the competitive position of Japanese ports in Asia, for example in the provision of trans-shipping services, since South Korea and China offer far more competitive services. Furthermore foreign shipping lines are still not allowed to trans-ship their own overseas cargo on their own vessels in Japan, thus encouraging them to trans-ship such cargo in other countries, further reducing business at Japanese ports. While similar restrictions apply in Europe, it is nevertheless possible for a Japanese carrier to transport its cargo across borders within the EU, for example from Germany to France, thereby meeting business requirements.

Recommendations:

- The Government of Japan should address the high cost of the port operations structure within its Asia Gateway Strategy Council.
- Rules and regulations that prevent container lines from offering intermodal-through-transportation in Japan should be reviewed and brought in line with international standards. The same applies to coastal transportation of empty containers, where currently, special permits are required unless the country in which the pertinent vessel is registered has a bilateral agreement with Japan.

■ Promote competition in port operations

Yearly status report: limited progress. The Japan Harbour Transportation Association (JHTA) still wields enormous discretionary power on the waterfront. Shipping lines wishing to make changes to their operations require prior approval from the JHTA. The process lacks transparency and effectively prevents shipping lines from seeking alternative, competitive services on the waterfront. If shipping lines want to operate a terminal independently, they may apply for a licence. Whilst the MLIT has committed to process applications within two months of receipt, requirements such as minimum employment levels still prevent firms from developing true competition for port services in Japan. It is not yet possible for a foreign company to set up its own terminal handling operations in Japan.

Recommendations:

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

■ Competitive bidding for stevedore services

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

Recommendations:

- Competitive bidding for stevedore services through open tenders should be promoted and regulated.
- The prevailing “Grand Father Principle” that effectively prevents shipping lines from changing container terminal service providers should be reviewed and eliminated.

Health Science

Animal health
Medical diagnostics
Medical equipment
Pharmaceuticals
Vaccines
Cosmetics & quasi-drugs

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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 medicines. VICH aims to harmonise registration requirements for animal health products at the global level and this has helped to some extent in reducing the 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 unnecessary, since these products will have gone through a rigorous review process in Europe and the USA prior to registration, thus assuring their efficacy, safety and quality. 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. More rapid access to new animal vaccines and medicines is necessary for the Japanese livestock industry to remain competitive with foreign producers. This issue will become more acute in the future should Japan's participation in the EU-Japan FTA/EPA and the Trans-Pacific Partnership free trade zone (TPP) require the elimination or reduction of tariffs and subsidies for animal agriculture. If producers in Japan cannot maintain competitiveness, Japan will continue to become increasingly dependent on imported animal products.

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 while these are improving to some extent, 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: 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. In the case of the generic application of veterinary pharmaceutical products, bio-equivalency studies conducted overseas are not acceptable by MAFF for inclusion in the registration dossiers. 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, and part of the registration is not globally harmonised, the registration of food-producing animal products can take an extremely long time.

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 Japanese 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: limited 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 discriminatory 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, protozoa, and fish vaccines should also be eligible for inclusion in the seed-lot system.

■ MAFF/NVAL proposed action items

Yearly status report: progress. On December 3, 2012, MAFF and the NVAL (National Veterinary Assay Laboratory) presented to the Japan Veterinary Products Association Committee on Technical Issues and Regulatory Affairs a list of ten action items for policy change targeted as measures to improve marketing authorisation procedures. Five of the ten action items had been implemented by Aug. 2014.

Recommendation:

- Although, in the opinion of the EBC, this list does not comprehensively represent all of the required reform areas, we support this initiative and request the regulators to continue to identify additional reform opportunities. Furthermore, we request MAFF and the NVAL to consult closely with the industry before any detailed policy change occurs to ensure harmonisation with similar policy in other major countries.

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MEDICAL DIAGNOSTICS

Introduction

Healthcare provision in Japan suffers as a result of the increasing pressure on the social security system from the effects of an ageing society, reduced birth rate, and burgeoning costs. To remedy this situation, the Japanese Government needs to reform the way the system operates while also re-evaluating its actual purpose. In particular, given the current move toward enhancing the quality of medical care, while at the same time optimising medical costs, a serious discussion is needed on the value and contribution of medical diagnostics. It is crucial that both medical care providers and medical system operators properly understand and evaluate the major role that medical diagnostics can play in medical care, so that their full contribution to medicine can be realised.

Since 2007, the problems, challenges and future direction of the reimbursement system for medical diagnostics have been under discussion. Research papers on the topic have been published, and proposals and recommendations have been made, both at study sessions on medical diagnostics and at periodic meetings on the medical reimbursement system conducted jointly by the Japanese Promotion Council for Laboratory Testing (JPCLT), the in vitro diagnostic (IVD) drug industry associations, and the Ministry of Health, Labour and Welfare (MHLW). The EBC appreciates the fact that, as a result of these activities, IVD fees improved continuously between 2008 and 2014, reflecting greater recognition of what is referred to in periodical medical reimbursement price revisions as the need for “quality enhancement of clinical diagnostics and faster examination”. While IVD fees fell by 1.4% in 2014 in real terms, thus wiping out the 0.4% increase in the 2012 revision, there has been a significant overall improvement compared with the revisions before 2008, when members of the EBC Medical Diagnostic Committee reported drastic cuts. Furthermore, category E3 qualification requirements for reimbursement were revised this year, as long advocated by industry groups, and the EBC welcomes this improvement. As a result, “Clinical meaning and enhanced convenience” has now been added to E3 (whereas previously only “New Items” and “Addition of Samples” were approved). Effective implementation of this new rule is expected to contribute to more appropriate evaluation of clinical diagnostics.

Medical diagnostics provide 70% of the information required for deciding on a treatment strategy, yet account for only about 4% of total healthcare costs. These facts demonstrate both the significant role and the extraordinary value of medical diagnostics in providing the necessary information for medical care to progress from prediction to accurate diagnosis, treatment and monitoring. If new applications for medical diagnostics are to be discovered, it is vital to understand the relationship between the value they can add and the medical reimbursement system, as well as to create an environment where appropriate diagnostics are available at the right time and place, and at an appropriate price. Both the public and private sectors need to start in-depth discussions on this important issue, to enable the quality of healthcare and patients’ quality of life to be improved.

It is obvious that medical technology and related environments are becoming increasingly advanced and complex, as seen in the examples of personalised treatment using companion diagnostics. The development of personalised treatment depends not only on the development of the primary drug itself, but also on the development from an early stage of companion diagnostics to predict the effectiveness and side effects of the drug. The development of companion diagnostics, the associated approval process and relevant reimbursement system are all currently under discussion, in response to requests from industry organisations. The EBC believes a system should be set up promptly to enable widespread personalised treatment in Japan.

The EBC Medical Diagnostics Committee continues to advocate the value of medical diagnostics in cooperation with the JPCLT and other IVD industry groups, such as the Japan Association of Clinical Reagents Industries (JACRI) and The American Medical Devices and Diagnostics Manufacturers’ Association (AMDD). We believe that streamlining and reform of the current reimbursement system will be essential for maintaining and improving the quality of medical diagnostics and therefore also the quality of medical care.

Key Issues and Recommendations

■ Quick access to new IVDs

Yearly status report: progress. To improve healthcare in Japan it is important to ensure prompt access by the medical sector to effective IVDs. Examiners and applicants have agreed to cooperate and jointly study measures to shorten the time period required for regulatory approval of new products. As a result, the Action Plan for Speedy Examination of IVDs was announced by the MHLW in March 2014, confirming the following actions:

1. Establishing a scheme to enhance quality in the approval and examination process
2. Setting a standard examination period
3. Increasing the number of examiners
4. Conducting a study on ways to improve management of the process and achievement of objectives.

Recommendations:

- The MHLW should promptly start concrete actions such as increasing the number of examiners.
- The MHLW should enhance the quality of applications by setting up a consultation system that is easy for applicants to use.
- The MHLW should enhance the quality of examinations by upgrading the examiner training system.
- The MHLW should hold periodical working-level meetings with participants from both the public and private sectors; verify the progress of the scheme; and monitor the timely achievement of term objectives.

■ Reimbursement system based on clinical value

Yearly status report: slight progress. The EBC Medical Diagnostics Committee has jointly produced a Position Paper on IVD reimbursement with JACRI and the IVD Committee of the AMDD. The paper, entitled “Reimbursement System Based on Clinical Value – Meeting the Diversifying Medical Needs” was submitted to the MHLW on 20 June 2014. The paper argues that clinical reagents should be classified into categories reflecting recent advanced inspection technology and diversified clinical needs, with clear-cut operational rules set for each respective category. Furthermore, to accommodate the needs of future patients and lessen the strain on the healthcare budget, Japan needs to be more active in promoting IVDs in non-hospital environments. Japan has already moved in this direction by approving sample measuring rooms where patients can conduct a blood test by themselves with a fingertip puncture, which is now possible thanks to technological innovations. Quantitative inspection techniques using simple medical equipment have also been developed. However Japan needs still to make certain that such self-checks meet the necessary quality levels.

Recommendations:

- Japan should set up a new category in the reimbursement system called Investigational Use Only (IUO) (provisional name) for situations where a reagent’s clinical validity is not yet confirmed, but analytical adequacy is recognised. Once classified into this category, the relevant reagents should be approved officially to enable their use in clinical practice.
- Guidelines for conducting clinical performance tests should be established to standardise the use of IVDs at medical institutions. The development time could be greatly shortened by introducing a system that ensures fair and rapid clinical performance tests.
- Japan should, furthermore, promote the use of IVDs in home care, nursing care, community healthcare, and self-care. A fair reimbursement price must be set, both to support diagnostic quality and to help foster better *point-of-care testing* coordinators.
- Japan should also increase the range of equipment and reagents used in self-checks.
- Recent technological innovation allows patients to undertake safe blood sampling with a fingertip puncture. The EBC requests that such tests be included in the scope of over-the-counter clinical reagents.

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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. In 2012, the national cost of medical care reached 39.2 trillion yen, up by 0.6 trillion yen from the previous year, reflecting a society that is rapidly ageing and placing increasing demands on health services. In addition to solving the resulting problem of healthcare financing, Japan must build a healthcare system that extends as much as possible healthy life expectancy or “life with no restrictions in daily life” by offering high-quality medical care (providing for disease prevention, early diagnosis and early treatment). Investing in innovative, efficient medical equipment can help Japan reach this goal, by presenting individual patients with the opportunity of enjoying a substantially higher quality of life for longer, and so also reducing total expenditure on medical care over time.

Many Japanese regulations and processes relating to healthcare differ from international standards. European manufacturers hoping to introduce their medical equipment to the Japanese market must find extra resources, time and money for the additional tests required to satisfy Japan’s unique regulations and requirements. At the same time, Japan’s current reimbursement system neither recognises nor fully evaluates innovations in medical equipment. It offers no predictability in regard to the reimbursement price and thus hinders assessment of marketability. Quite a number of European manufacturers are discouraged from launching their products on the Japanese market and back away from investment in innovation because of these non-tariff barriers, depriving patients of access to innovative medical equipment.

Nevertheless, there has been some positive progress from 2013, including:

- Enactment of a Law on Quality, Effectiveness and Safety of Pharmaceuticals and Medical Equipment (Pharmaceuticals and Medical Equipment Law), effective from November 2014.
- Improvement of the approval and examination process in terms of speed.
- Partial easing of duplicated regulation in respect of PSE (the Electrical Appliance and Material Safety Law) for medical equipment.
- Improvement in the Quality Management System (QMS) for medical equipment and increased alignment of clinical evaluation (Good Clinical Practice / GCP) with international standards.

Furthermore, negotiations towards an EU-Japan Free Trade Agreement / Economic Partnership Agreement (FTA/EPA), which started in April 2013, are moving forward. The EBC continues to request that the EU and Japan take this opportunity to agree improvements in the medical equipment approval process and alignment with international standards.

The Japanese Government considers health and medical care as a priority area in its growth strategy, and is allocating budget accordingly. The EBC believes that European businesses can, if allowed, make a major contribution to this strategy and so hopes that any financial incentives will not be exclusively directed to Japanese businesses. Many excellent medical equipment and technologies are developed outside Japan. Collaboration between foreign companies with advanced technologies and Japanese enterprises promises to spur growth, and help Japanese companies to reach their strategic goal of true globalisation.

The EBC Medical Equipment Committee will continue to work closely with the Japanese Government, the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Device Agency (PMDA) as well as related industry associations to establish an environment that allows excellent European medical equipment to be delivered smoothly to patients in Japan.

EBC Medical Equipment Committee Member Companies

B.Braun Aesculap Japan	Japan Lifeline	Otto Bock Japan
Baxter	Japan MDC	Philips Electronics Japan
Biotronik Japan	JIMRO	Radiometer
Coloplast	Laerdal Medical Japan	Siemens Japan
Dentsply IH	Lima Japan	Smith & Nephew Wound Management
Dornier MedTech Japan	Maquet Japan	Sorin Group Japan
Draeger Medical Japan	Medis medical imaging systems	Teijin Pharma
Edaptechnomed	Molnlycke Health Care	TKB
Elekta	Nippon Becton Dickinson	VitalAire Japan
Hollister	Nippon BXI	Wako Shoji
Intuitive Surgical	Nobel Biocare Japan	

Key Issues and Recommendations

■ Speedier medical equipment examination

Yearly status report: some improvements. The Japanese Government's action plan implemented between April 2009 and March 2014 to improve medical equipment examination processes was largely successful, but the lack of predictability in approval times remains a problem. The EBC will collaborate with the government to achieve targets advocated in the new 5-year plan, "Collaboration Plan for Speedy Examination of Medical Equipment."

Recommendation:

- The Government should implement structural reform of the PMDA in a timely manner to achieve the new targets. Furthermore, the technical expertise of PMDA examiners should be increased.

■ Clinical evaluation

Yearly status report: slight progress. Alignment of Japan's GCP with ISO14155 has advanced the process of clinical evaluation considerably. However, further improvements are required in actual implementation.

Recommendations:

- The Government should clarify the notification on clinical evaluation (Notification 0804001, August 4, 2008) specifically as regards judging whether clinical evaluation is necessary.
- The Government should publish guidelines as soon as possible for creating clinical evaluation reports.

■ Mutual recognition and alignment of QMS

Yearly status report: slight progress. When Japan's Pharmaceuticals and Medical Equipment Law was enacted, rationalisation of the QMS survey was mutually agreed and differences between the QMS Ministry Ordinance and ISO13485 were identified. However, detailed rules for implementation based on ISO13485 have not yet been disclosed and relevant information has not been disseminated to overseas interested parties.

Recommendations:

- Japan should rationalise the QMS implementation rules between overseas headquarters of foreign companies and Japanese sellers and send relevant information to overseas interested parties.
- Japan should set up a system conforming exactly to the QMS concept (ISO13485).

■ Reimbursement prices

Yearly status report: no progress. The reimbursement price of some new medical equipment is lower in Japan than the average corresponding price in foreign countries, which discourages manufacturers from investing in the Japanese market. The current reimbursement scheme should be reviewed to increase incentives for manufacturers to develop and market new products and to ensure a stable supply.

Recommendations:

- The Government should provide a more detailed division of functions into subcategories, introduce multiple prices for medical materials in the same category, and abolish the repricing system.
- The Government should ensure predictability of reimbursement price applications for Category 2 products.
- Japan should properly recognise and value innovation and the cost of home-use medical equipment.

■ Designation of construction supervisor

Yearly status report: no progress. A company selling medical equipment requiring construction of facilities to house it must have a licenced *construction supervisor* on its board. This rule applies even if the construction is outsourced.

Recommendation:

- Appointment at board level of a *construction supervisor* should not be required if a medical equipment company outsources construction.

■ Patient registration system

Yearly status report: new issue. The Patient Registration System concept is currently the subject of a study by a government-appointed panel that has no representatives from the medical equipment industry.

Recommendation:

- Interested parties from the medical equipment industry should be represented in the expert panel.

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PHARMACEUTICALS

Introduction

Japan's national expenditure on medical care in fiscal year 2013 was an estimated 39.3 trillion yen, up 0.8 trillion yen (2.2%) from the previous year. Overall medical expenditure relative to GDP stood at 10.3%, exceeding the OECD average (9.3%) for the first time, and approaching levels in countries with similar medical insurance systems, such as France and Germany. The proportion of total medical care expenses accounted for by drug expenditure has remained relatively stable over the last 10 years at about 20%. Relative growth in drug expenditure has been kept in check, in spite of an ageing population and progress in medical technologies. In April 2013, the Government of Japan announced a "Roadmap to Promote the Use of Generics", and intends to increase the share of generics among replaceable drugs from approximately 45% in March 2013 to 60% in March 2018. This target is expected to be achievable. Meanwhile the Government is suggesting that the drug pricing system should be revised every year, which is something that EFPIA and the EBC oppose on the grounds that it risks undermining the stability of the overall healthcare pricing system as well as investment in Japan's pharmaceutical industry, which has been identified as a key area in the current administration's growth strategy.

A new system was introduced on a trial basis in 2010 to promote the development of new drugs and eliminate unapproved off-label use. Although there have been discussions on whether the new system should be made permanent, it remains only a trial. Early data from European R&D-based pharmaceutical companies indicate that, since the trial started, the number of new drug development projects and investments in Japan has increased significantly. Given that trial implementation over the first four years has been effective, and the new system properly recognises the value of innovation, we believe it should be made permanent. While introducing this new system, consideration should also be given to eliminating arbitrary re-pricing measures that cut the prices of drugs whose sales significantly exceed initial expectations (as well as the prices of comparable drugs), and thereby undermine efforts to promote innovation.

Despite government policies to promote new drug development, patient access to innovative drugs is hindered by the blanket restriction of prescription lengths to a maximum of 14 days for all new drugs in the first year after their launch. Until this restriction is lifted, physicians will, in many cases, continue to put off prescribing new drugs. In practical terms, this usually means a delay of one year in patient access to drugs that are already in extensive use abroad. Although the period in Japan between the approval of drugs and their reimbursement is the shortest in the world, and the drug lag is gradually decreasing due to recent improvements in the approval and examination process, a review of the restriction on the prescription period is not even on the Government's agenda. However, the safety of new drugs in Japan is now underpinned by the post-marketing surveillance system, and by the introduction of a Risk Management Plan (RMP) in fiscal year 2013. Accordingly, EFPIA and the EBC believe that the time has come to revise the blanket restriction of prescription lengths for all new drugs.

Following a revision in December 2012, Japanese Good Clinical Practice (GCP) in clinical trials is now steadily aligning with global standards. However, action is still needed to address differences between Japanese medical institutions in terms of the efficiency of the clinical trials they conduct, impacting the capacity to optimise trial costs and expand the number of cases. At the same time, there has been no progress in extending the scope of the existing Mutual Recognition Agreement (MRA) for EU and Japanese Good Manufacturing Practice (GMP). The current limitation of the MRA to solid oral preparations leads to duplicate trials and inspections for all other products, incurring additional costs for the industry and ultimately the healthcare system. EFPIA and the EBC call on the EU and Japan to work together to eliminate such unnecessary costs.

Finally, as the consumption tax rate was raised in Japan to 8% in April 2014, and a further increase to 10% in 2015 is being considered, the Government should now move the focus of debate from the pricing of individual drugs to the funding of the entire healthcare system, as part of its "Comprehensive Reform of Social Security and Tax". EFPIA and EBC members are ready and willing to contribute to this debate through meetings with the Government.

EFPIA Japan Member Companies

Abbott Japan	Guerbet Japan
Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Baxter	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	Sanofi
GE Healthcare Japan	Shire Japan
GlaxoSmithKline	UCB Japan

Key Issues and Recommendations

■ National Health Insurance drug pricing system

Yearly status report: slight progress. In 2010, a new National Health Insurance (NHI) drug pricing system was introduced on a trial basis to promote the development of new drugs and eliminate unapproved off-label use. This has succeeded in stimulating drug development activities, as exemplified by a recent remarkable increase in the number of new drug development projects and investment in Japan. However, there has been no change to the contradictory policy of reducing the prices of drugs that have exceeded initial sales forecasts, making the result of investments highly unpredictable.

Recommendations:

- The Government of Japan should make the new drug pricing system permanent so that innovation is rewarded. The new system helps stimulate more continuous investment in drug development in Japan, and enables the provision of innovative new drugs, which are much needed if the Japanese pharmaceutical industry is to survive in the face of fierce global competition.
- The policy of reducing the prices of drugs that exceed initial sales predictions hinders innovation and increases uncertainty for business, and should be eliminated. In particular, drugs that have been priced based on comparable drugs should be excluded from the scope of the pricing system.

■ Access to new drugs

Yearly status report: no progress. A blanket maximum prescription length of 14 days is imposed on new drugs in the first year after their launch onto the market. This restriction causes excessive caution among doctors and delays patient access to the latest drug therapies. Once new drugs are on the market in Japan, their safety is upheld by the post-marketing surveillance system, combined with the introduction of a Risk Management Plan (RMP), which together constitute one of the most advanced safety monitoring systems in the world.

Recommendation:

- The prescription of new drugs is limited to 14 days in accordance with the stipulations of the Rules for Professionals in Charge of Healthcare Services under Health Insurance Programs (*Ryotan-kisoku*). These stipulations are unique to Japan and should be revised to improve patient access to new drugs, taking account of the introduction of new and enhanced safety monitoring systems.

■ Clinical trial environment / MRA

Yearly status report: limited progress. Japanese Good Clinical Practice (GCP) in clinical trials has been gradually internationally aligned, not least through revisions made in December 2012. However, action is still needed to address differences between Japanese medical institutions in terms of the efficiency of the clinical trials they conduct, impacting the capacity to optimise trial costs and expand the number of cases. At the same time, the scope of the existing Mutual Recognition Agreement (MRA) for EU and Japanese Good Manufacturing Practice (GMP) still covers only 15 of the 28 EU Member States. Furthermore, limiting the MRA to solid oral preparations leads to duplicate trials and inspections for other products, incurring additional costs for the industry and delaying market introductions.

Recommendations:

- Japan should carry out specific actions to further promote enhanced efficiency in clinical trials, in accordance with the Government's own "Report concerning Enhancement of Efficiency in Clinical Trials (2011)" and the "2012 Action Plan for the Five-Year Program toward the Revitalization of Clinical Studies and Trials (2012)".
- The existing EU-Japan MRA for EU and Japanese Good Manufacturing Practice (GMP) should be extended to cover all 28 EU Member States and expanded to include non-solid oral preparations. This will eliminate the potential for a drug lag due to duplicate inspections and examinations, and will reduce GMP costs.

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VACCINES

Introduction

In 2014, the Ebola outbreak in West Africa prompted Japan's Ministry of Health, Labour and Welfare (MHLW) to issue alerts to overseas travellers and to prepare for possible suspected infections in Japan. Furthermore, domestic cases of dengue fever have been reported for the first time in about 70 years, causing the MHLW to hold an emergency meeting and exterminate mosquitoes spreading the infection. The vaccines against these infections are still under development and the EBC and EFPIA hope for progress in this endeavour. Meanwhile the domestic situation has improved rapidly as regards existing infectious disease vaccines in the past several years, after sequential introduction of new vaccines. In July 2014, the meningococcal vaccine was approved, and from October 2014, varicella vaccine and adult pneumococcal vaccine were included in the routine immunisation system. Whether or not to include the mumps vaccine, hepatitis B vaccine and rotavirus vaccine in the routine immunisation system is currently under discussion.

Improvements in the routine immunisation system indicate that Japan is catching up with the EU and US in the number of approved antigen types. On the other hand, protection by vaccines remains insufficient in Japan. In 2013, it was reported that a rubella epidemic had caused a temporary vaccine shortage. Japan stopped recommending the papillomavirus vaccine in June 2013, and this decision remained in effect as of September 2014. In addition, many of the pediatric combination vaccines necessary to protect Japanese infants from infections remain unapproved and are not in use, even though infants represent the future of Japan. In other countries, the congested immunisation schedule for infants has been alleviated thanks to the approval of a variety of such combination vaccines that have now been in use for more than 10 years. Japan is indisputedly lagging behind in this area. The DTaP-IPV (Diphtheria, Tetanus and Pertussis – Inactivated Polio Vaccine) combination vaccine was approved in Japan only in 2012, 15 years behind Europe. The MMR vaccine (Mumps/Measles/Rubella) and the 5- or 6-in-1 combination vaccines, produced by adding hepatitis B and/or polio vaccines to the DTaP-IPV 4-in-1 combination vaccine, which are already widely used overseas, were still not in use in Japan as of September 2014.

The Immunization/Vaccine Subcommittee of the Health Science Council was established in 2013, and underneath it three additional subcommittees were formed for basic immunisation policy; research, development and manufacturing/logistics; and adverse reactions. The Subcommittee was set up to handle the above combination vaccines as vaccines of high development priority, and the situation is described in the "Basic Plan Related to Vaccination" announced by the MHLW in March 2014. In addition, in the subcommittee for adverse reactions, adverse reactions to human papillomavirus vaccine were discussed, and in June 2013, the MHLW made a decision "to suspend recommending human papillomavirus vaccination, while keeping it in the routine immunisation" which sends an ambiguous message to healthcare professionals and vaccine recipients. This measure is still in effect today, although such long-term suspension of a recommendation for this vaccine is extremely rare throughout the world. Furthermore, as of September 2014, it was not clear how long the suspension would last. We believe that one of the main reasons behind the suspension is a lack of understanding and insufficient awareness of the benefits of vaccines, not only among the population and the mass media, but also within the regulatory authorities and the Government.

The EBC and EFPIA request the Japanese Government to promote dialogue at an early stage and implement the reform necessary to encourage Japanese and foreign vaccine manufacturers to invest in developing and producing vaccines (especially paediatric combination vaccines) that contribute to improving preventive medicine in Japan. For this purpose, the EBC and EFPIA request the competent authorities to include in the routine immunisation those vaccines still outside its scope and which, therefore, are more expensive for the vaccinee (mumps vaccine, hepatitis B vaccine and rotavirus vaccine), to promote further vaccine combinations, to revise clinical and nonclinical guidelines for infection-preventing vaccines in Japan and to implement vaccination policy based on scientific rationales and reflecting the benefits to vaccine recipients.

Key Issues and Recommendations

■ **Periodic review of MRBP (Minimum Requirements for Biological Products)**

Yearly status report: no progress. A revised MRBP, including major changes to the sections on test items and methods, was issued in September 2013. However, since then, there has been no move to review its contents, other than the addition of new vaccine products. The MRBP is unclear in regards to predefined timing, procedures for revision and criteria for listing. Furthermore, neither the administrative process nor the necessary periodic revision has been completed.

Recommendation:

- The MHLW should regularly revise the quality requirements for vaccines to reflect state-of-the-art science and technology and to harmonise Japan's approach with other regions. Accordingly, the current MRBP should be abolished, and its contents consolidated and integrated into the Japanese Pharmacopeia.

■ **Elimination of redundant quality testing for imported vaccines**

Yearly status report: no progress. A Summary Lot Protocol (SLP) was introduced in 2012 to ensure rigorous control of vaccine quality. Thus, from a scientific point of view, the continuing requirement to subject imported vaccines to all the quality test items and national testing after import is questionable.

Recommendation:

- The Government should provide a scientific and technical rationale to justify mandatory retesting and omit retesting where no such rationale can be demonstrated.

■ **Expansion of target countries and scope of items in EU-Japan Mutual Recognition Agreement (MRA)**

Yearly status report: no progress. The top priority for the EU-Japan MRA negotiations should be its expansion to include the remaining EU Member States currently not covered by the agreement. The MRA should also be expanded to include biopharmaceuticals and vaccines, which currently, are not even being discussed. By thus shortening import times, Japanese preventive medicine will improve.

Recommendation:

- Japan and the EU should work together to expand the MRA or add an MOU (Memorandum Of Understanding) to cover all EU Member States and include biopharmaceuticals and vaccines.

■ **Incorporate WHO-recommended vaccines into routine immunisation and promote development of combination vaccines**

Yearly status report: progress. The Immunization Law was revised on 1 October 2014, and both the varicella and adult pneumococcal vaccines were included in the routine immunisation system. Also mumps vaccine, hepatitis B vaccine and rotavirus vaccine were positively discussed in the Immunization Vaccine Subcommittee of the Health Science Council with the aim of including them in the routine immunisation system. In addition, prompt development of combination vaccines was proposed as an issue of high priority.

Recommendation:

- The MHLW should ensure that the remaining mumps vaccine, hepatitis B vaccine and rotavirus vaccine are included in the routine immunisation system without further delay. In addition, combination vaccines should be promptly developed.

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COSMETICS & QUASI-DRUGS

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 their products by investing in the research and development of new ingredients and technology, conducting clinical studies, 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 2,290 billion yen in 2012. Japan imported cosmetics valued at about 214 billion yen in 2013, of which cosmetics from the EU accounted for about 81 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 that 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 ingredients or excipients 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 as it does in Japan, 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 faster registration of quasi-drugs, expanding efficacy claims and aligning their respective positive and negative lists for cosmetics and quasi-drugs. 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. ICCR meets 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: progress. The Ministry of Health, Labour and Welfare (MHLW) released a model template for ordinary quasi-drug application documents in 2013, and a Q&A notice for quasi-drug applications in 2014 to clarify their evaluation policy. In addition, the Ministry also published 25 raw material specifications on already approved excipients. These actions helped to improve the transparency of the quasi-drug review system. The MHLW also released a new pricing policy to charge higher evaluation fees for quasi-drugs which contain new active ingredients to enable the hiring of more evaluators. Thanks to these improvements, a shortening of the evaluation period can be expected.

Recommendations:

- The MHLW should establish clear processes for the periodical updating of lists of approved active and excipient ingredients and for expansion of raw material specifications on excipients, in order to increase the transparency of the quasi-drug review system.
- The MHLW should allow the use of excipients in cosmetics without restrictions or limits, as long as there are no special notes regarding safety or usage restrictions for each ingredient.
- The MHLW should establish approval standards for all quasi-drug categories to expand the number of quasi-drugs evaluated by the prefectural authorities. This would help shorten the new product evaluation period. We also recommend that the MHLW establish a system to review the standards periodically.

■ Harmonise quasi-drug & cosmetic ingredients

Yearly status report: New issue. The fluoride concentration levels permitted in oral care products in Japan are not aligned with the higher levels permitted in other developed countries. Japan permits a maximum of 1,000 parts per million (ppm) of fluoride in toothpaste sold as a quasi-drug, while concentrations of fluoride of up to 1,500 ppm are permitted in Europe. Japan does not accept fluoride in mouthwash products although mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States. The use of fluoride to prevent dental cavities has been shown to be effective and safe in scientific studies conducted around the world. Moreover, the EU and Japan maintain different rules governing which ingredients are allowed in cosmetics, expressed respectively in terms of negative and positive lists.

Recommendations:

- Japan should revise the Medicated Dentifrice Approval Standard by raising the fluoride concentration allowed in toothpaste sold as a quasi-drug to 1,500 ppm and in mouthwash sold as a quasi-drug to 226 ppm.
- Japan should resolve the inconsistency between Japan and the EU in the maintenance of positive and negative lists for all quasi-drug and cosmetic ingredients.

■ Promotion of self-medication advisory role of pharmacists and general practitioners

Yearly status update: New issue. Self-medication is the selection and use of medicines by individuals to treat recognised illnesses or symptoms. It includes the use of non-prescription medicines sold over the counter (OTC) and as quasi-drugs. If more people were to visit general practitioner doctors and pharmacists for advice and use OTC and quasi-drugs to manage minor health problems on their own, then specialist doctors at major hospitals would have more time to focus on other patients with more serious conditions. This would improve health and help reduce total healthcare spending.

Recommendation:

- Japan should promote self-medication where it is safe and appropriate to do so by creating financial incentives for patients and pharmacists.

■ Expansion of efficacy claims for cosmetics and quasi-drugs

Yearly status report: No progress. A scheme for specifying the efficacy of cosmetics was presented in the “Notification on Enforcement of Pharmaceutical Affairs Law” in 1961. Subsequently, 55 efficacy claims were defined for cosmetics in the “Notification on Revision of the Scope of Efficacy Claims for Cosmetics” issued in 2000. In 2011, the efficacy claim of “making fine wrinkles due to dryness less noticeable” was added to the list. Yet the scope of efficacy claims approved in Japan is still narrower than in other countries, which hinders the entry of foreign-made cosmetics based on the latest research and technology to the market.

Recommendations:

- Japan should expand and harmonise the scope of positive efficacy claims for cosmetics and quasi-drugs with the EU, including the claim of “preventing photo-ageing caused by exposure to ultra violet light.”
- To align with EU regulation, the MHLW should abolish the efficacy claim list and allow companies to communicate product efficacy within the definition of cosmetic based on verifiable data.

■ Electronic notification for cosmetics and quasi-drugs

Yearly status report: New issue. Foreign cosmetic companies seeking to import cosmetics and quasi-drugs into Japan must submit two different notifications with significant duplicate information. The MHLW requires paper-form submission of an Import Notification for all cosmetics to be imported for sale in Japan, prior to any of the import-designated products proceeding through Japan Customs. The reviewed notification must also be submitted to Japan Customs at the time of the customs clearance processing. This procedure is time-consuming and duplicative. In many other countries in the world companies are allowed to use an electronic notification system.

Recommendation:

- The MHLW should simplify the Import Notification procedures for importing foreign-manufactured cosmetics and quasi-drugs by establishing an electronic system for the import notification process. It should be designed in such a way that not only will the current burdensome paper-based notification process be eliminated, but the number of necessary supporting documents can be reduced.

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

Yearly status report: No progress. Once a *partial change request* has been approved for a cosmetic or quasi-drug, no previously approved versions are allowed through the customs quality check and onto the market. Given the difficulty in predicting approval timing and shipping time, sea freight importers expecting a *partial change request* approval must hold large amounts of current stock in Japan to guarantee a stable supply. To avoid these extra costs, many importers avoid *partial change requests*. They instead apply for approval of partial changes as if relating to completely separate products. This forces companies to maintain multiple approvals for products that appear identical to the end-customer.

Recommendation:

- After *partial change* approvals are granted, there should be a grace period during which the previous version of imported products can continue to undergo customs quality checks and be sold.

■ Establishing of alternatives to animal testing

Yearly status report: No progress. Cosmetic and quasi drug manufacturers are still expected to submit safety data based on animal testing in Japan and validated alternatives are limited. The use of alternatives to animal testing was officially recommended in a February 2011 MHLW Administrative Circular. MHLW guidance on replacing the skin sensitisation test took effect in May 2013, corresponding to Organisation for Economic Co-operation and Development (OECD) guidelines 442A and 442B. Japan participates in activities of the International Cooperation on Alternative Test Methods in the International Cooperation on Cosmetic Regulation.

Recommendations:

- Japan should accelerate the establishment of validated alternatives for animal testing of ingredients and products based on safety endpoints that are harmonised with those used in the EU.
- Japan should abide by its international commitment to protect humans, animals and the environment.

Consumer Goods

Liquor
Food & agriculture

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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 2013, at 251 billion yen (according to Japan Customs), accounted for a mere 4% 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 applying international standards for product definition and in eliminating non-tariff barriers to market access.

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. Despite this, Japan still does not comply with all relevant WTO rulings and international standards. The Ministry of Finance (MOF) has made clear its long-term goal of classifying 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. The EBC cannot understand the grounds for such high tariffs nor 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.

Japan's tax system for beer is equally baffling. Instead of taxing beer based on alcohol content or as a heterogeneous liquor group, beer in Japan is taxed on malt content, divided into basically three categories, with "real beer", which has a malt content of more than 67%, attracting the highest rate. All European beer, apart from a few exceptions, is classified as real beer. The tax system thus has the unfortunate effect of making arguably lower quality beer cheaper and so more accessible. As a result, low malt beer, or *happoshu*, and 0% malt-based beer make up almost 40% of the Japanese beer market. The EBC believes that the tax system should be made independent of malt content so that high quality beer is not taxed more heavily than low malt or 0% malt based beer.

In Japan, the use of lot codes (traceability information) is not compulsory under the Food Sanitation Law, although it is recommended in the administrative guidelines of the Ministry of Health, Labour and Welfare (MHLW). By contrast, the EU makes it obligatory to display lot codes on food and beverage products as such codes fulfil an important role in any effective and efficient product recall or withdrawal process. Despite the fact that most importers of EU liquor products ensure that lot codes are in good order when the products are marketed and put into distribution in Japan, it is common practice for some opportunistic traders, prioritising business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up. While the EBC appreciates the notice issued by the National Tax Agency (NTA) in September 2014 stating the NTA's concern regarding the presence of liquor products with erased lot codes in the market, the EBC continues to urge the Japanese Government to take proactive measures to protect the health and safety of Japanese consumers.

Finally, the lack of accurate Geographical Indicator (GI) definitions in Japan's Liquor Tax Law is of great concern to the EBC. In the long term, this lack may hinder the ability of European businesses to compete in the Japanese market. The EBC therefore calls on the EU and Japan to adopt common definitions within the context of the EU-Japan FTA/EPA.

Key Issues and Recommendations

■ Traceability

Yearly status report: minimum 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. The National Tax Agency has finally issued an industry notice outlining concerns regarding erasing, tampering with and covering up lot codes, a practice that prioritises business profit over consumer safety. However, the notice has no binding force to halt the import and sales of any such products with lot codes that have been erased, tampered with or covered up.

Recommendation:

- The Government of Japan should issue legislation, reinforced by penalties, that forbids the wholesale or retail of liquor bottles whose lot codes have been erased, tampered with or covered up, if the National Tax Agency notice has an insufficient effect.

■ Tariff on wine and white spirits

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). The temporary zero tariff on white spirits, rum, gin, vodka and liqueurs should be made permanent.

Recommendations:

- The EBC urges Japan to completely remove all tariffs on wine.
- The EBC urges Japan to change the applicable tariff lines for white spirits to become permanently zero.

■ Liquor tax on beer

Yearly status report: new issue. The liquor tax on beer in Japan is based on malt content. This unfortunately puts real beer with a malt content of over 67% at a disadvantage and has created a situation where arguably lower quality beer is more favourably priced. This is very clear when looking at the market share of low malt beer, or *happoshu*, and 0%-malt based beer, which together account for almost 40% of the Japanese beer market.

Recommendation:

- Japan should revise its liquor tax system for beer to make it independent of malt content.

■ 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 other 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 and threatens to undermine European products in the Japanese market.

Recommendation:

- The Government of Japan should reconsider the GI rules in its Liquor Tax Law and introduce amendments in line with widely accepted EU definitions.

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FOOD & AGRICULTURE

Introduction

In general, Japan's regulatory environment favours the import of raw materials for use by the domestic food 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 supermarkets in 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 specialist 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.

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, in that the majority of food additives and enzymes declared safe by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO) are still not approved in Japan. The fact that some 46 such additives have now been approved, as requested by the EU, US and Australia in 2002, is therefore particularly welcome. Meanwhile, Japan has still given only limited acceptance to scientific evaluations by international bodies, such as JECFA (FAO/WHO Joint Expert Committee on Food Additives) and the Codex Alimentarius Commission (CODEX), resulting in additional approval procedures in Japan that are both unnecessarily time-consuming and overly costly. The issues surrounding food enzymes are more or less the same as for food additives.

The EBC is encouraged by improvements in the regulatory approach to *Listeria monocytogenes*, introducing a distinction between foods in which listeria can and cannot grow. The efforts of the Ministry for Health, Labour and Welfare (MHLW) in this respect should be applauded and the EBC expects the new standard to be introduced as planned by the end of 2014.

One area that has not been discussed previously in the EBC's annual report is Maximum Residue Levels (MRLs). Some EU products cannot be imported into Japan due to the non-harmonisation of MRLs between the EU and Japan. In addition to this, Japan uses a positive list of products and levels, and any product not on the list must have a residue level of 0.01 ppm or less - an unsubstantiated low level - even if the base input material has a higher level.

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, the market share of organic food in Japan lags far behind that in other developed markets.

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. Under the EU-Japan FTA/EPA, tariffs should be abolished, standards harmonised and market authorisations of both regions mutually recognised. The EBC Food Committee believes this can be achieved without compromising food safety. Furthermore, such an agreement will lead to more choice in supermarkets, stimulating healthy competition in the food and agricultural sectors of both zones, and to European food becoming more accessible, something we know Japanese consumers would appreciate.

Beltrade	Nestle Japan
Bresse Bleu Japon	Norwegian Seafood Export Council
CSM Japan	Perfetti Van Melle Japan Services
Danisco Japan	Pick
Danone Japan	PinguinLutosa Japan
DSM Nutrition Japan	Puratos Japan
Hiestand Japan	Roquette Japan
IKEA Japan	SKW East Asia
Japan Europe Trading	TÜV Rheinland Japan
MIE PROJECT	Valrhona Japon

Key Issues and Recommendations

■ Tariffs & quotas

Yearly status report: no progress. Japan continues to impose high import duty rates on many foods and food ingredients. 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 the quota management system adds complexity 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 management system should be improved.

■ Food additives and enzymes

Yearly status report: slow progress. Differences in the lists of approved additives and enzymes are still common between Japan and other major markets. While the EBC has seen progress in Japan's approval of additives, the approval process still remains an obstacle, with long application periods and difficulties in determining exactly what supporting documents are required. Currently the process is both time- and money-consuming as well as being highly non-transparent and lacking deadlines set in the legislation. Both foreign and domestic companies would benefit from a system where each step of the approval process has clear deadlines to be followed by the authorities.

Recommendations:

- MHLW together with the Food Safety Commission (FSC) should introduce legally binding deadlines for each part of the approval process. Furthermore, repeated requests for additional information should be avoided.
- MHLW and the FSC should ensure that standards of use in Japan are not in conflict with international standards of use. Current examples where conflict exists are sulphur dioxide and sorbic acid (potassium sorbate).
- The EU-Japan FTA/EPA should guarantee that food enzymes in wide use in the EU and accepted as safe by JECFA will be approved for immediate use in Japan.
- MHLW should put the same focus on enzymes as it has on food additives and actively approve enzymes that are well established in other major markets.

■ Maximum Residue Levels

Yearly status report: new issue. While a large number of pesticides approved and in common use in Europe are approved in Japan, Japanese regulation on MRLs is far stricter. Japan uses a positive list. The main difference between the EU and Japan can be found in how they treat pesticide MRLs in processed products that are not explicitly listed. When a derived product is not explicitly mentioned in Europe the pesticide MRL for the input (raw) material would be used (for instance the MRL for deltamethrin in maize is 2ppm, hence the MRL in maize starch-derived products would also be 2 ppm). In Japan, however, derived products that are not in the positive list would have a default MRL of 0.01 ppm even if the original product has a higher MRL (for instance the MRL of deltamethrin in maize is 0.05 ppm, but that in a maize starch-derived product not listed would also be 0.01 ppm)

Recommendations:

- The EU and Japan should work together to harmonise MRL levels and, in cases not regulated, follow the CODEX levels.
- Japan should introduce the concept of using the level set for the base product for derived products that are not on its positive list.

■ Beef and processed food including beef and by-products (casings, gelatines)

Yearly status report: progress. During 2013-2014, France, The Netherlands, Ireland and Poland were granted approval to export beef to Japan. Several other EU Member States have started the approval process, but progress is very slow. The EBC would like to point out that several Member States are designated as having “negligible BSE (Bovine Spongiform Encephalopathy) risk”. This is the same status applying to Japan.

Recommendations:

- The Ministry of Agriculture, Forestry and Fisheries (MAFF) and MHLW should speed up the approval process for EU Member States that have already submitted data.
- 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: progress. The EBC has long called for the introduction of the so called double standard approach, distinguishing between foods that support the growth of *L. monocytogenes* and foods that do not. During 2014, Japan finally announced a regulation that will hopefully take care of this problem. EBC welcomes the new regulation and hopes for its swift implementation.

Recommendation:

- Japan should implement the new standard on listeria as announced.

■ Yearly analysis (additives, bacteriological) at Customs

Yearly status report: no progress. At present, certain foods and all drinks imported into Japan require analysis on an annual basis. Yet, 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 often also carried out on a random basis. This is an area of great concern to food importers as it results in unnecessary costs and delays, which can lead to wasteful disposals. In cases where testing of imported foods at Customs is justified, such as products that are new to the market, the EBC recommends that a swift appeal system be established before disposal of a product that is declared “unsafe”.

Recommendations:

- Japan should eliminate the need for a yearly analysis at Customs of EU foods (additives, microbiological).
- Japan should introduce a swift appeal system whereby independent official analyses, including those from the producer, that indicate a product is safe can be used as justification for a retest.
- Japan’s various Customs offices and quarantine stations should share information on what products have passed the tests in order to avoid duplicate inspections.

■ Organic food – Full equivalence between the EU and Japan

Yearly status report: slow progress. The market for organic food is still very small in Japan, estimated at a mere 0.4% of the total food market. Part of the reason for this is the regulatory environment where the scope of Organic-JAS still does not include meat or animal-based products or honey, although these are covered by organic labelling both in the EU and the US. This means that, for instance, chocolate with a content of more than 5% of organic honey or milk cannot be labelled Organic-JAS. Furthermore, although supplementary certificates from EU embassies are no longer needed, the requirement for an individual organic certificate to accompany every shipment is an unnecessary administrative burden for both importers and exporters.

Recommendations:

- MAFF should declare full equivalence between Organic-JAS and Organic-EU.
- Japan should expand the scope of Organic-JAS to include meat, animal-based products and honey.
- Japan should abolish the need for individual organic certificates for every shipment. An annual certificate should suffice.

Industry

Automobiles

Automotive components

Aeronautics

Space

Defence & security

Construction

Materials

Energy

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AUTOMOBILES

Introduction

European automobile importers have ridden a rollercoaster in 2014. Sales have fluctuated wildly. In anticipation of the increase in consumption tax from 5 to 8% from 1 April, sales of European cars in the first quarter swept upwards by 35%. In the second quarter, the pattern was reversed and sales plummeted by 16%, as GDP contracted by 7.1% and demand for consumer durables slumped. Sales began to recover in the third quarter, but are still below the 2013 level. Notwithstanding these gyrations, European imports at 204,000 units in the first nine months of 2014 took 5.6% of the domestic passenger car market, slightly down on their 2013 market share.

Non-tariff barriers continue to hold back European sales in Japan by adding to the cost of doing business for European importers of both passenger cars and commercial vehicles. The EBC Automobile Committee therefore welcomes the progress in the first year of the EU-Japan FTA negotiations to eliminate the non-tariff barriers identified in the Scoping Exercise, which preceded the launch of the negotiations. Further efforts are, however, needed to achieve the objective that a vehicle type approved in Europe can be sold in Japan without the need for modification of its specifications or further testing and/or certification.

This can be achieved by:

1. The harmonisation of the technical requirements between Japan and the EU on the basis of internationally agreed UN Regulations.
Both Japan and the EU are signatories of the UN-ECE (United Nations Economic Committee for Europe) 1958 Agreement on the harmonisation of technical requirements and certification procedures. However, there are still nine areas covered by a UN Regulation where Japan does not accept a UN certificate as demonstrating compliance with Japan's type approval requirements.
2. The elimination of other unique Japanese requirements for both passenger cars and commercial vehicles in areas not covered by UN Regulations

Technical harmonisation alone will not be sufficient. Currently, the unique Japanese system of classifying vehicles shuts European compact cars out of 39% of the passenger car market. As noted in previous annual reports, Japan's specifications for mini-cars, known as kei-cars, reduces the market opportunities for foreign compact cars. Furthermore, kei-cars receive preferential tax treatment and other regulatory privileges, making uncompetitive imported cars with a similar performance and pre-tax price.

The EBC Automobile Committee welcomes the tax changes for FY 2014 and beyond as a first, tentative step towards the correction of this anomaly. But even when these changes are implemented, the basic tax levied on a kei-car will still be some 60% lower than that paid by a comparable compact car.

The EBC Automobile Committee therefore hopes that in the FTA negotiations, Japan and the EU will:

- Complete the harmonisation of technical requirements on the basis of UN Regulations
- Eliminate other unique Japanese requirements for passenger cars and commercial vehicles not covered by UN Regulations
- Take further measures to make it possible for European compact and subcompact cars to compete on a level footing with kei-cars

Key Issues and Recommendations

■ Harmonisation of technical standards and certification procedures

Yearly status report: some progress. The EBC Automobile Committee welcomes Japan's adoption of additional UN Regulations and the cooperation between Japan and the EU to introduce in 2016 an International Whole Vehicle Type Approval (IWVTA) system. Its implementation would mark an important step towards the mutual recognition of vehicle certification between Japan and the EU.

Recommendations:

The Government of Japan should:

- Complete the adoption of existing UN Regulations in areas where Japan retains unique national requirements.
- Work closely with EU Member States and the European Commission to implement the International Whole Vehicle Type Approval system and to adapt the Japanese type approval system accordingly.

■ 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 Automobile Acquisition Tax and Tonnage Tax when the consumption tax is increased to 10%.
- Simplify the structure of the taxation of automobiles and reduce the overall tax burden on motorists in line with international best practice.
- Conduct a comprehensive review of the taxation on fuels from the perspective of environmental policy.
- Adopt and implement in line with the EU internationally harmonised standards to measure fuel efficiency and exhaust emissions used to assess tax incentives for environmentally friendly vehicles.

■ Kei cars

Yearly status report: little 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: some progress. The High Pressure Gas Safety Act impedes the introduction into the Japanese market of new environmentally friendly technologies, such as fuel cell and CNG (Compressed Natural Gas) vehicles, already in use in the EU and elsewhere.

Recommendation:

- The Government of Japan should take the necessary steps to harmonise with the EU the technical requirements for the use of these technologies with the minimum administrative burden.

■ Commercial vehicles

Yearly status report: new issue. Japan's regulations concerning the maximum width, length and axle load for buses, the method of calculating vehicle weight and the endurance testing requirements for emission control devices for heavy-duty vehicles and other unique technical requirements restrict the business opportunities for European commercial vehicle exporters.

Recommendation:

- The Government of Japan should harmonise its requirements with the EU.

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AUTOMOTIVE COMPONENTS

Introduction

Japanese vehicle manufacturers are today more open to doing business with foreign companies, both from a monetary perspective and for spreading their 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 an increasing number of companies 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, many 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 have, however, been a number of slight discrepancies between Japan's regulations and those of UNECE, one of which being Japan's regulation corresponding to UNECE Regulation No. 54, which was stricter in the scope of its application. The Ministry of Land, Infrastructure, Transport and Tourism (MLIT) resolved this issue by widening the *Jishin* 1533 (2013) scope of new vehicle tyre approval to include not only tyres that conform to the Japan Automobile Tire Manufacturers Association's (JATMA) Year Book, but to Regulation No. 54 standards as well. The EBC greatly welcomed this action. It is vital that Japan continues to address such discrepancies and supports further regulatory harmonisation at the global level. In addition to the above mentioned regulations EBC would also like to point out that Japan has not implemented UNECE Regulation number 106 on tyres for agricultural vehicles.

Finally, the EBC notes the almost oligopolistic situation in the Japanese tyre market, in particular for commercial vehicles. Brand-exclusive networks make it very difficult for outsiders to penetrate the market, leading to less competition, higher prices and less consumer choice. In particular, this is the case for light trucks and the segment called truck & bus. EBC strongly recommends that the Japan Fair Trade Commission (JFTC) monitors this sector.

Key Issues and Recommendations

■ Globalisation of the automobile industry

Yearly status report: progress. The EBC welcomes the opportunity that globalisation 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 and consumers. 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 improve 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 27 – 29 May, 2015 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 future to include Japanese venues.

■ Tyres

Yearly status report: progress. The EBC appreciated the action taken by MLIT to improve market access in Japan for European tyres, especially with the issuance of *Jishin 1533* (2013). Despite this positive change and even though the Japanese authorities deem European tyres to be safe, some differences still exist between UNECE and Japanese regulations for tyres of commercial vehicles, which can lead to uncertainties about what is really allowed. EBC also notes the difficulties in gaining access to sales channels in this sector.

Recommendations:

- The EBC urges Japan to further accelerate worldwide harmonisation of technical standards and regulations.
- The EBC recommends that JFTC monitors the tyre sector to improve access to sales channels.

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AERONAUTICS

Introduction

In recent years, Japan's cooperation strategy has been evolving steadily. A preferred US partner since the post-war days, the country is opening up to more balanced political and economic ties with other regions, among them, the EU. Even though it may take some years, the ongoing FTA/EPA and TPP negotiations are indicating a shift to more worldwide cooperation in the future.

Politics have long influenced the aeronautical industry in Japan, sometimes favouring the long-term relationship with the US over business realities. The Airbus A350 selection by Japan Airlines (JAL), and selection of the A320 neo by ANA are signs that traditional Japanese corporations may now be thinking differently. The private sector is expected to make business decisions based on economic grounds rather than politics, creating opportunities for Europe and Japan to develop new commercial and industrial ties. The military sector also seems increasingly open to consider cooperation with European manufacturers. The EBC will actively support this evolution.

Historically dominated by US manufacturers since the beginning of the 1950s, the Japanese commercial aircraft and helicopter market is among the largest in the world. The EBC welcomes the decision by the two Japanese major airlines to choose European products. This is clear evidence that Europe can lead the way when it comes to high technology, quality, customer services, and cost-effectiveness.

There are several examples of successful cooperation between our industries. Kawasaki Heavy Industries (KHI) and Airbus Helicopters on the BK117 helicopter co-development programme, and the collaboration between KHI/Mitsubishi Heavy Industries (MHI)/IHI and Rolls-Royce on the Trent engines are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. The Ministry of Economy, Trade and Industry (METI) and the Directorate General for Civil Aviation of France (DGAC), after having signed a Memorandum of Understanding, are now targeting a concrete program/project. Thanks to this encouraging development both governmental organisations arranged several workshops during the year. The EBC expects positive results deriving from concrete programmes of EU-Japan co-development.

EBC strongly believes that shifting from a policy of sole domestic development to one of international co-development will create superiority in the technological field, and expand Japan's market in both volume and range of products. Proactive collaboration with successful European companies would enable Japanese corporations to strengthen their positions 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 are considerable opportunities for large-scale joint development programmes between Japanese and European industries, especially in the field of transport aircraft, and urges Japan's Government and aerospace players to support such initiatives.

Key Issues and Recommendations

■ Promoting partnerships with the EU

Yearly status report: progress. The aeronautics market is becoming more and more global, and Europe has strong competitive advantages. For example, European companies have experience in the area of high-end technologies that are environmentally friendly. Procurement decisions should be made not only on a competitive basis, but also with future technological advantages in mind. European manufacturers of commercial aircraft, engines, components, and navigational equipment offer state-of-the-art technology at internationally competitive prices. However, even with the decision of JAL to use European products in the future, the European share in the Japanese market for commercial aircraft and related equipment is still considerably smaller than its average share worldwide.

EBC consistently requests Japan to modernise 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.

Recommendations:

- 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, the general public, and shareholders.
- The EBC also urges 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 biased in favour of North America. However, METI has supported international co-development of aircraft with Europe. European companies also need METI to support similar cooperation as in the case of the Boeing 787 programme. The EBC is 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 aeronautics cooperation. Furthermore, the scale of Japanese financial support for such activities with European companies remains significantly lower than for activities with US companies.

The EBC expects further agreements or Memoranda of Understanding (MOU) between the EU and Japan, similar to the MOU between METI-DGAC. 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 the civil aviation sector. 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.
- 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.
- EBC strongly recommends Japanese heavy industries to consider international joint development programmes for building aircraft or helicopters from scratch.

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SPACE

Introduction

After a decade of reforms, the Space Policy Commission and the Office of National Space Policy (ONSP) established within the Cabinet office now set Japan's space policies across all ministries and agencies. A "Basic Plan on Space Policy" was adopted in January 2013. Space is now regarded as an important industrial and commercial sector, also critical for national security. Japan's high sovereign debt contributes to making an effective unification of space policies a necessity. In an attempt to maintain a healthy domestic space industry, Japan's administration actively seeks growth in export markets, although the Japanese industry is still mostly geared towards domestic government contracts.

The Ministry of Economy, Trade and Industry (METI) has been pro-actively helping all-Japanese industry consortia to supply satellite systems to emerging countries through Official Development Assistance (ODA) funding. The packages often include satellites, launch services, operations, data analysis, maintenance, training, technology transfers, and other services. Contrary to EU policy, Japan's ODA is tied, which means that contracts must be awarded to its domestic industry, resulting in a distorted market that excludes foreign manufacturers and service providers.

The private satellite market (roughly one commercial satellite per year) is ostensibly open. 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) and broadcasting satellite (BSAT) series.

Bidding for government tenders is generally not possible for foreign companies. No-tender government programmes include the science and technology satellites of the Japan Aerospace Exploration Agency (JAXA), some programmes under METI, and the defence-purpose remote-sensing Information Gathering Satellites (IGS). The ONSP's priority is the Quasi-Zenith Satellite System (QZSS), a Japanese positioning, navigation and timing satellite system. A defence communications satellite programme is also underway. Japan's willingness to cooperate in satellite development programmes still rarely extends to European companies.

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 possible technical mishaps. However, talks between the Japanese and European space authorities towards a mutual back-up of government launch missions have been stalled for years.

A new domestic space law now under study would require Japanese satellite operators to seek government approval for each new satellite project. There is a risk that this law may be abused to discourage the procurement of foreign satellites and/or launch services. Indeed, even the simple fact of having to apply and wait for an approval that is not assured would mean a significant business risk for the satellite operators in this time-sensitive business.

In addition, a continuing risk for Public-Private Partnership (PPP) projects is that satellites with both government and commercial payloads could be declared "governmental" as far as building and launching them is concerned. Foreign satellite makers and launchers could thus be excluded from Japan's commercial market in a piecemeal fashion.

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.

The EBC generally supports Japan's reform as it has made its jurisdiction more consistent and intelligible. While respecting Japan's space policies, however, the EBC believes that fewer all-Japanese consortia, less tied ODA and more work with Europe would bring gains in terms of budgetary savings, national security, research and development, and commercial success. We hope that the current FTA negotiations will induce Japan to prove that its claims of an open market are credible. As of now, however, what we can see is a growing risk of new protectionism.

Key Issues and Recommendations

■ General environment

Yearly status report: growing protectionist risk. The approval system for new satellite projects now under study and the handling of future PPP projects bring with them new risks of protectionism. The EBC advocates increasing, not reducing, mutually beneficial trade and cooperation. More openness to European industry would benefit Japan. In addition, Europe provides many technologies free from “black-box” technology concealment policies.

Recommendations:

- The EBC hopes that the domestic space law now under study will not subject Japan's satellite operators to regulatory risks, burdens, difficulties or delays when acquiring foreign satellites or launch services.
- Satellite projects with both government and commercial aspects should not be declared “governmental” and therefore exclude the participation of foreign companies.
- The EBC urges more Japanese cooperation with European space agencies. Space agencies on both sides should compare their projects at an early stage and take greater advantage of cooperation opportunities.
- Japan should also encourage more cooperation between the Japanese and European space industries.
- The EBC recommends Europe-Japan coordination and cooperation in space-related ODA worldwide.

■ Satellites

Yearly status report: no progress. Japan mostly ignores Europe’s satellite technology. The space agencies of both sides cooperate and share data in science and research, but have almost no 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 put European makers at a disadvantage.

■ Launchers

Yearly status report: no progress. Although Europe and Japan now almost simultaneously start the development of their respective next generation launchers, they have very little significant cooperation in that area. A plan for a balanced mutual backup agreement to reduce delays in launching government satellites was evaluated positively by Japan’s space authorities in 2002, but no agreement is in sight as political leadership is missing on this issue.

Recommendations:

- New government satellite programmes will require more timely launches. The EBC urges Japan and Europe to bring about effective, formal back-up cooperation between Japanese and European satellite launchers.
- Europe and Japan should also consider cooperating on the development of non-critical components for their respective new generation launchers.

■ 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

Japan is the world's third largest economy and an important ally for the EU, US and NATO (North Atlantic Treaty Organization), sharing common values and interests in the Asia Pacific region and globally.

The security environment surrounding Japan remains complex. China continues to actively assert its claims on the Senkaku Islands and this combined with North Korea's missile development and ability to launch such weapons constitute an uncertain environment. In addition, political tensions remain with the Republic of Korea (Takeshima islands) and Russia (Northern Island chain). Because of these circumstances, Japan realises that it must reach beyond the US if it is to play a greater role on the global stage and has started to broaden cooperation with other maritime powers, such as Australia and India. Significantly, the Liberal Democratic Party (LDP) has followed through on the goal of the previous ruling party, the Democratic Party of Japan (DPJ), to form stronger defence and security ties with Europe.

Perhaps the biggest change in 2014 was the Cabinet decision on re-interpretation of article 9 of the constitution. The decision opens the possibility for Japanese participation in collective defence, which means that Japan could come to the aid of an ally under certain circumstances. While armed Japanese forces have been deployed before under a United Nations mandate, weapons could only be used in self-defence. With the new policy, weapons could also be used to carry out the task. Due to this change, strains will be placed on the Japanese Self-Defence Forces to upgrade their equipment and further steps will be required to ensure that the equipment is interoperable with that of allied countries. EBC believes that the European defence material manufacturers are perfectly placed to meet this demand.

In addition to the above mentioned changes, in December 2011, the former Government led by the DPJ announced revised guidelines for Overseas Transfer of Defence Equipment. These guidelines permit the overseas transfer of defence equipment under certain conditions, by allowing comprehensive exemption measures under the Three Principles on Arms Exports. The announcement of the revised guidelines was followed in April 2012 by a Joint Statement on the UK-Japan Defence relationship, agreed between Prime Minister Cameron and then Prime Minister Noda in an attempt to forge closer links between Japan and the UK. The UK-Japan relationship was formalised in July 2013 with the signing of a bilateral agreement for defence cooperation.

The agreement between the UK and Japan was followed by an agreement between France and Japan in July 2014. The EBC welcomed this development and hopes the agreement can be put to use without delays. Germany is also moving forward to promote cooperation ties in defence research and technology, and equipment. Throughout 2014, the Japanese government has released a series of clear messages that Japan cannot afford to develop all the defence capability it desires through its own defence budget.

The EBC has welcomed these changes and the opportunity to meet representatives from the Ministry of Defence (MoD), Ministry of Foreign Affairs (MOFA), Ministry of Economy, Trade and Industry (METI) and the Defence Production Committee of the Japan Business Federation (*Nippon Keidanren*) to discuss the guidelines and explore the implications for EU-Japan industrial partnerships. A series of forums has continued through 2014, organised between METI and various European bodies, including the EBC, GIFAS (Groupement des industries françaises aéronautiques et spatiales and ADS (Aerospace Defence Security) to push forward the industrial dialogue.

Key Issues and Recommendations

■ Procurement

Yearly status report: some progress. The EBC anticipates that the Japanese government's desire to move towards collaborative defence programmes with Europe and the progress in bilateral agreements with individual European nations will result in amendments to the defence equipment acquisition process and improvements in transparency of the decision-making. The EBC believes that the recommendations listed below will also benefit the Japanese industry as it prepares itself to enter the world of defence exports.

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 life cycle costs (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: progress. During the last couple of years, a series of Japan-Europe Defence Forums, organised with the support of METI, European bodies (EBC, GIFAS and ADS) and the *Nippon Keidanren*, have encouraged a closer dialogue between the Japanese and European defence industries. The Japan-UK bilateral agreement, the agreement with France, and hopefully, future agreements with other European countries will provide the vehicles to encourage collaboration between the industries. For example, pilot joint projects were implemented in 2013 and 2014 following the agreement with the UK. Revitalisation of the Japanese defence industry may depend on the diversification of its alliances as well as on joining new development programmes for dual use technology. In this respect, the European defence and aerospace industry is offering a number of new opportunities for joint development.

Recommendations:

- Japan and the EU Member States should move forward promptly with more substantial, collaborative industrial defence programmes and avoid running the risk of under-utilisation of the existing agreements.
- Intellectual property rights must at all times be respected if partnerships are to be successful.
- For Japanese authorities in charge of industrial policy, public funding should be provided to support those technologies that address both civil as well as military markets.

■ Defence exports

Yearly status report: some 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 that have a broader market application and are capable of export by the partnership. However there is a need for further relaxation in the Three Principles on Arms Export in order to define a 'white list' of countries to which Japan may agree to export.

Recommendation:

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

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CONSTRUCTION

Introduction

The Abe Cabinet's policy with the most direct impact on the construction market was the fiscal stimulus. This has generated the expected expansion in investment in construction. Construction spending in Japan peaked in 1992 at 82 trillion yen and then dropped to its historical low in 2010 at 41 trillion. By April 2013, just four months after the election of the new cabinet, construction spending shot up to 48.7 trillion yen, a year-on-year increase of 10.2%. In the current fiscal year 2014 ending in March 2015, 48.5 trillion in construction spending is expected, essentially the same as in fiscal 2013.

The fact that the increase in construction spending has levelled off so soon despite the massive amount of fiscal stimulus suggests that the construction industry is unable to meet the sudden increase in demand from public investment. Lack of sufficient construction labour is often cited as the cause of the capacity limitation, but increased demand for and rising prices of construction materials also play a role. Current procurement and implementation methods may be exacerbating the problem on large public projects with tight schedules.

In the earthquake-stricken Tohoku region, certain municipalities found they were unable to use their available budget to award reconstruction projects. In response, procurement methods were reconsidered in some instances. In August 2013, for the first time in Japan, a public construction contract was awarded using the construction management (CM) system with a Guaranteed Maximum Price (GMP) using the open-book system. This gave the general contractor the freedom to select specialist vendors without a call for tenders. Doing so greatly shortened the overall construction schedule. If the project is successful, a wider application of this type of contract can be expected for public works projects in future.

Fiscal stimulus and new procurement methods aside, ultimately the key to unlocking new growth potential will be new technologies. One such area is sustainability. Given that over 30% of energy in Japan is consumed by buildings, a proportion that continues to increase, the activities of the construction and property industry will fall under close scrutiny. Energy consumption remains a long-term problem because the Tohoku earthquake and the Fukushima nuclear plant accident have given rise to an environment in which energy supplies are tight and their prices rising. In response, suppliers, authorities, businesses and 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 local authorities in a difficult position when required to make fair and technically informed decisions on compliance. In some cases, decisions are made even though the local authorities lack the necessary knowledge to interpret the legislation correctly and sometimes do so without reference to international standards. This makes it difficult for companies, both domestic and especially foreign, to keep track of all the relevant guidelines. Much of the documentation is available only in Japanese. 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 prioritise policies that promote sustainable practices and advocates standardisation of regulations and application of global equivalencies and internationally recognised assessment techniques as alternatives to the current mix of local and proprietary incentives or quasi-mandatory administrative guidance.

The EU-Japan FTA/EPA should include mutual acceptance of standards and certifications to enable construction product convergence, so that EN standards (European Standards) and CE-marking (*Conformité Européenne*) can be used interchangeably with JIS/JAS (Japan Industrial Standards/Japan Agricultural Standards) standards. The FTA/EPA should also promote improved transparency, ensure that rules for government procurement are strictly enforced, and recognise the important role construction plays in promoting a sustainable society.

Key Issues and Recommendations

■ Harmonisation of building material standards and contractor qualifications

Yearly status report: no progress. Reform of overly prescriptive regulations and rationalisation of unnecessarily complicated procedures for obtaining mandatory approvals is needed so that the innovative designs, technology, materials and methods of European firms can be more readily applied in Japan. Little progress has been made in aligning standards and testing methods, so re-testing and re-certification are still required, raising the cost of imports and making them less competitive than domestic supplies.

Recommendations:

- Japan and the EU should work towards mutual recognition of JAS/JIS and EN standards for building materials and ensure that this is covered in negotiations towards a comprehensive FTA/EPA. CE marking of construction products should suffice as a guarantee of their high quality and safety when sold in Japan.
- The Japanese authorities should recognise relevant foreign experience 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 CO₂ emissions. The energy efficiency of most Japanese buildings is far below international standards and best practices. Improved insulation also reduces operating costs, thus improving returns on investment. Japan has introduced regulations requiring higher performance from new buildings, thus the natural next step will be to improve the energy efficiency of the existing building stock. Incentives geared to stimulating building renovations should be considered. Renovation opportunities range from simple component replacements (double-glazed windows; high-efficiency air conditioners; better insulated walls, floors and ceilings; windows with lower thermal transmission values) to the application of new technologies for on-site energy recovery, water treatment, and other conservation measures.

Recommendations:

- The Government of Japan should continue to strengthen regulations aimed at promoting energy efficiency in buildings as a way to fulfil its international commitment to cut carbon emissions. The best available technologies and transparent methods for measuring performance should be applied.
- The Government of Japan should mandate much stricter insulation standards for buildings. 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 a step in the right direction.

■ Transparency and accessibility of information and regulations

Yearly status report: no progress. Currently much of the interpretation of national construction-related legislation and guidelines is left to the discretion of local authorities. This creates great uncertainty. Moreover, the decisions of many local authorities may be questionable due to the lack of knowledge needed to interpret the legislation correctly.

Recommendation:

- The national authorities responsible for regulating the construction market should take appropriate action to rationalise the patchwork of local regulations that exists today and to further educate local authorities by clarifying the legal framework.

■ Immigration regulation

Yearly status report: some progress. Both the continuing reconstruction of the Tohoku region and anticipated demand from building projects for the Olympics will further strain the already tight construction labour market. Japan should swiftly amend its immigration policy so that construction companies can recruit skilled labour from abroad.

Recommendation:

- The Japanese Government should liberalise its immigration policy so that construction companies can use overseas skilled labour on fixed-term contracts.

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MATERIALS

Introduction

Japan has developed vast knowledge and expertise in processing and recycling 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. 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. The same is true for manganous manganic oxide as Japan's level of production is below 10% of the demand. Manganous manganic oxide is essential for the battery industry.

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.

During manufacturing processes, waste products are generated and at the end of a product's life, a recycling process is usually initiated. The by-products from the metallurgical, smelting and refining industries as well as end-of-life products, whether from industrial or end-user origin, are stockpiled, dumped or recycled. Japan's Waste Management and Public Cleansing Law, enacted in 1970, addressed the importance of preserving and recycling materials to the maximum amount possible for the sake of protecting the living environment and saving resources. Japan took the lead in recycling and many countries have in the meantime followed its example. A global industry has developed and companies in Japan and Europe are now world leaders in this field. The law in Japan has, however, been very restrictive with respect to importing and exporting waste for recycling. While this may be understandable to prevent any "waste" from being exported or imported for unethical or environmentally unfriendly processing, it has also hindered Japanese companies seeking the environmentally sound recycling schemes offered by European recycling companies. The EBC advocates that free movement be allowed as long as it complies with international laws (such as the Basel convention) and that best available technology is applied, even if this means that goods are exported with a negative value. Under current legislation, the conditions for export are too restrictive.

The EBC believes that the EU-Japan FTA/EPA should 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. Currently, Japan retains tariffs on some metals. These metals are in many cases essential for Japan's core industries including the vehicle, battery and more traditional steel industry. The tariffs constrain the competitiveness of Japanese manufacturing, a sector already under pressure from low-cost countries. Removal of import tariffs is, therefore, imperative for Japan to retain its competitive edge. For the stainless steel industry, where 40% of the production cost lies in the cost of nickel, the tariff plays a major role. The same can be said for the battery and photovoltaic sectors, where it makes little sense to penalise companies with an additional cost added through a tariff. The EBC believes that further investment could be made in these sectors if input materials could be imported duty-free. This is of particular concern for silicon carbide and manganous manganic oxide as domestic production of these goods accounts for only 10% of the demand. 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.

Recommendations:

- Under the EU-Japan FTA/EPA, 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.
- 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: some progress. With both the EU and Japan now having introduced chemical substance registration systems, producers, exporters and importers are faced with re-testing, double submissions and an increased administrative burden to fulfil the 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:

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

■ Waste Management and Public Cleansing Law

Yearly status report: new issue. The EBC believes the very stringent restrictions of the Waste Management and Public Cleansing Law that limit import and export of waste products for recycling purposes (by-products, industrial waste and end-of-life products) should be abolished to allow for free movement and trade of these products. This should be allowed irrespective of their value on the condition that international trans-border conventions are respected and good practices (environmental and ethical) are applied. In order to ensure proper handling, the EBC envisages an efficient and non-time consuming approval process.

Recommendation:

- Japan should apply international conventions to the import and export of waste products for recycling purposes and abolish its current restrictions on this trade.

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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 Ministry of Economy, Trade and Industry (METI), 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 has been in use since well before the partial liberalisation, and has been reviewed various times, but remains unchanged.

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 and power. However, after the March 2011 Tohoku disaster and related Fukushima nuclear accident, most of Japan’s nuclear plants were shut down with only Kansai’s Ohi No. 3 and No. 4 reactors online until September 2013. Accordingly, nuclear power accounted for less than 1% of Japan’s total electricity generation in FY2013 and, as of 2014 none are operating with the result that Japan’s dependence on imported fossil energy resources has increased again.

Japan’s Basic Act on Energy Policy 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 METI committee on industry reform proposed splitting off power generation from transmission operations and creating 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. In contrast, European and US grids are based on the mesh concept with extensive plans for use of High Voltage Direct Current (HVDC), which offers more flexibility in energy flows from one region to another and easier integration of non-conventional energy sources into the overall energy supply.

Besides the overall model, the energy mix was also placed under review, a process which is still ongoing. The current LDP Government has decided that “the former DPJ administration’s policy of abandoning nuclear power had to be reconsidered to help revive the economy”. It has said, in particular, that it plans to spend up to 10 years in determining the most appropriate future energy mix. In April 2014, the Government adopted a new Basic Energy Plan, confirming:

- Nuclear power is an important source of base load electricity, "which will be reduced as much as possible" but "a certain amount will be preserved with regards to security of supply, and costs".
- No specific targets for each source of energy; the target for renewables is “to go beyond previous targets set in past plans”.
- The closed-fuel cycle policy will continue.

In July 2012, a new Feed-In Tariff (FIT) scheme for renewable energy sources came into effect. This requires the utilities to buy power derived from solar, wind, geothermal, hydropower and biomass sources at a fixed tariff and allows them to pass on the 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.

The EBC calls on the EU and Japan to include energy in the framework of discussions towards a mutual FTA/EPA in order to further strengthen the ties between Japan and the EU in this area.

Key Issues and Recommendations

■ Stability of supply versus cost

Yearly status update: some progress. 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 the cost of imports is currently very high and exacerbated by the yen exchange rate, a situation which threatens the competitiveness of Japanese industry 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 a reliable approach to all safety issues and a clear confirmation of the closed fuel cycle policy (waste volume reduction, storage and re-use). It will, however, 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.

■ Deregulation and unbundling

Yearly status update: some progress. The current regulatory situation does not provide the transparency and cost efficiency required. Security of supply is also not guaranteed given the limited interconnections between utility companies as well as between the 50Hz and 60Hz networks. However, the EBC commends Japan for passing the bills necessary to establish the OCCTO (Organization for Cross-regional Coordination of Transmission Operators) and commence “full retail competition”. The EBC believes that fair and transparent processes will enable healthy competition in the electricity market.

Recommendations:

- Separate the ownership of generation from that of transmission to allow the required investments in the transmission grid, while providing transparency and efficiency in terms of cost.
- Give enough authority to the OCCTO to realise increased interconnection capacity between TDSOs (Transmission and Distribution System Operators).
- Utilise more generation options based on different technologies, such as the Integrated Coal Gasification Combined Cycle (IGCC), Carbon Capture and Storage (CCS) and renewable energy.
- Ensure that the redevelopment of nationwide electricity interconnections is based on High Voltage Direct Current (HVDC), Frequency Converters (50-60 Hz), Flexible Alternate Current Transmission System (FACTS) and Battery Energy Storage Solution (BESS) for transmission and distribution to support centralised and decentralised energy sources.

■ Nuclear energy & nuclear safety

Yearly status update: some progress. In the wake of the Fukushima nuclear accident, Japan has reformed its nuclear safety regulator, which is now an entity with enhanced independence. Since it was established in September 2012, the NRA (Nuclear Regulatory Authority) has worked on new nuclear safety standards and nuclear safety regulations, which were published and enforced for nuclear power plants in July 2013 and for other nuclear facilities in December 2013. The new safety standards introduce major changes and new rules, and will be used by the NRA to check the safety of all Japanese power plants, and confirm whether they can be restarted or not. As of September 2014, ten electric power companies had applied to the NRA for safety evaluations of a total of 20 reactors. The EBC believes it is of the utmost importance for the new safety rules to be properly implemented by the Japanese power utilities.

Recommendations:

- Continuously increase the level of safety of nuclear energy under supervision of the NRA.
- Further develop the nuclear expertise of the regulator and utilisation of independent technical expert support in technical reviews.
- Conduct detailed safety reviews at all individual plants with support from international nuclear experts and inspectors and implement all recommendations before any restart.
- Use international standards and procedures as minimum safety requirements, such as the nuclear asset and operation safety management system used in Germany and France.
- Share best practices and establish common safety requirements through international cooperation.
- Start-up the Rokkasho Reprocessing Plant as soon as the safety review is concluded and develop a practical working system to deal with final disposal of waste, which is still a pending issue.

■ Wind energy

Yearly status update: no progress. 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 could 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 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 transmission systems or isolated local grids. The EBC recommends that the Japanese Government takes note of the work on technical standards for wind energy being carried out by the International Electro-technical 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 and accept international accreditation for wind turbines and their componentry as technical requirements rather than existing local certification laws/regulations. This is vital both to facilitate increased investment and improve the potential for Japanese technology exports.

■ Solar energy

Yearly status update: some progress. The 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; and difficulties in obtaining reasonable interconnection commitments from regional electric utilities, and project financing for utility-scale PV (photovoltaic) projects. Additional challenges that Japanese utility companies may soon encounter are managing cost effective solutions to integrate de-centralised and intermittent renewable generations into the existing power grid.

Recommendations:

- Streamline the process to re-classify farm land so that it can be used for renewable power generation.
- Adopt internationally accepted certification standards for solar modules, system components and design qualifications rather than enforcing existing “Japan-only” components and certification standards.
- Adopt an accreditation scheme to support the acceptance of test results, reports and certificates from any accredited certification body, whether domestic or foreign, based on available international standards.
- Increase Government support for the adoption by national and regional banks of transparent standard criteria for debt financing.
- Create incentive and standardisation programmes for the power utilities to contract PV project construction to an emerging class of engineering and design companies, with the aim of reducing grid connection costs and lead times.

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