

A stylized map of Japan, including all major islands (Hokkaido, Honshu, Shikoku, and Kyushu) and surrounding islands, colored in a solid yellow. The map is positioned in the background of the cover.

Golden Opportunity

The EBC Report on the Japanese Business Environment 2015

**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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CONTENTS

Message from the Chairman	4
Message from the Executive Director	5
Introduction	8
Business fundamentals	
Financial reporting	12
Human resources	14
Intellectual property	16
Legal services	18
Retail & wholesale	20
Sustainable development	22
Tax	24
Financial services	
Asset management	28
Banking	30
Insurance	32
Transportation and communications	
Airlines	36
Railways	38
Telecommunications carriers	40
Telecommunications equipment	42
Logistics & freight	44
Health science	
Animal health	48
Medical diagnostics	50
Medical equipment	52
Pharmaceuticals	54
Vaccines	56
Cosmetics & quasi-drugs	58
Consumer goods	
Liquor	62
Food & agriculture	64
Industry	
Automobiles	68
Automotive components	70
Aeronautics	72
Space	74
Defence & security	76
Construction	78
Materials	80
Energy	82
Appendices	
Pinnacle Sponsors	86
Blue Star Sponsors	87
Special Sponsors	89
Sponsors	90
Supporters	93
EBC Premier & Affiliate Members	94
Executive Operating Board	95
Board of Governors	96



Message from the Chairman

Welcome to the 2015 Report of the European Business Council in Japan (EBC). This year has seen developments in Government policy, regulation and international trade that could at last pave the way for a more open and competitive business environment in Japan. We are cautiously optimistic that, finally, some of the many barriers stifling growth and investment here might fall, benefitting not only individual companies but also the economy as a whole. However, none of these developments is yet sufficiently established or mature to guarantee a positive result: the events of the coming year will be crucial to determining the ultimate direction and outcome. So this Report aims to identify areas where further action is needed and makes clear recommendations for what precisely should be done. We believe this is a golden opportunity for Japan – let's make the most of it!

Structural reform of the economy has always been an integral part of Prime Minister Abe's Growth Strategy and is desperately needed if the country is to break from long years of economic stagnation and dependence on export demand. It is therefore a relief that finally, after prolonged discussion, the Growth Strategy is now being translated into policy and from policy into action. We have already seen changes to lower corporation taxation and improve corporate governance, and the Government has stated its intention to boost inward investment, foster innovation, increase female participation in the workforce, facilitate visas for highly qualified foreigners, extend use of IT and robotics, and upgrade healthcare and tourism facilities. It is too early to say whether these initiatives will succeed, and it is likely that many more will be needed to make a real difference, but there is real hope that, if this opportunity for internal restructuring is grasped, Japan can lift its economy to a new level.

Nevertheless, any policy initiative will founder if not accompanied by detailed reform of underlying regulation. Too often, regulation in Japan frustrates innovation and healthy competition, and spawns unnecessary bureaucracy that slows the introduction of new products, inflates costs and deters investment. Every year, EBC Committees recommend action that would change this, improving the situation for business and consumers. This year is no exception. While welcoming positive reforms in sectors ranging from medical diagnostics and animal health to retail and wholesale, this Report shows that even in sectors such as medical equipment, identified as key to the revitalisation of the Japanese economy, the pace of change remains slow and far more needs to be done, faster. Japan has plenty of opportunities to change its economic fortunes, if only it would seize them.

It seems that new trade agreements may provide the catalyst Japan so needs. Recognised in the Government's Growth Strategy as an important vehicle for progress, such agreements open up new markets, encourage adoption of international standards and stimulate flows of investment, goods, services, technology and expertise. Negotiations towards a Free Trade Agreement between the European Union and Japan are advancing and, with sufficient commitment from both sides, could reach a successful conclusion in 2016. An agreement could boost trade relations and set both economies on a path to greater prosperity. Yet none of this will happen if the agreement is too narrow, if tough issues are left unresolved, or if the final outcome fails to meet the needs of both sides. That is why we are highlighting in this Report the top issues that each EBC Committee insists must be resolved. While this list of issues is not exhaustive and many more will still need to be addressed, it provides a clear indication of the scope and depth required.

The EBC believes that the people and businesses of the European Union and Japan deserve a Free Trade Agreement that is ambitious, balanced and comprehensive. We believe that such an agreement, while challenging, is possible and increasingly within reach. 2016 presents a golden opportunity to bring negotiations to a successful conclusion: we urge the authorities on both sides to seize it.

Danny Risberg
Chairman, European Business Council in Japan
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 “Golden Opportunity”, its 2015 Report on the Japanese Business Environment.

A major theme this year is the continuing negotiations towards a Free Trade Agreement between the European Union and Japan. This agreement is much needed by both sides, offering not only to boost mutual trade, but also to increase the competitiveness of both economies and their ultimate prosperity. For European companies in Japan, the agreement should also finally remove many of the tariffs and non-tariff measures, which for so long have undermined their efforts to invest and build a business here. The EBC’s expert Committees have been working hard to support the negotiating process, providing detailed information on the barriers faced in each sector and area of business. An insight into their top priorities for the negotiations is included in the individual chapters of this Report.

The FTA negotiations are inevitably complex and time-consuming, but there is currently significant momentum and support for the process and, from the EBC’s perspective, a real chance to reach a successful outcome in 2016. So we are urging the EU and Japan to seize this golden opportunity to achieve an ambitious and comprehensive agreement that meets the needs of both sides.

Equally, the EBC is urging the Japanese authorities to resolve the many issues which may fall outside the scope of an FTA but, nevertheless, hold back business development in Japan. Some of these issues are already on the Government’s agenda, included amongst the structural and regulatory reforms that contribute to Prime Minister Abe’s Growth Strategy. Others remain unrecognised or ignored. Yet, as the Committee chapters of this report demonstrate, put together these issues limit consumer choice, deter innovation, frustrate competition and ultimately constrain the economic growth this country so needs. So we commend to the authorities the recommendations made by each EBC Committee on how best to eliminate these constraints and free the economy to achieve to its full potential.

Clearly, this Report could not exist without the input of the EBC’s expert Committees and I should like to thank them for contributing their valuable time, insights and ideas to the development of each chapter. I would also like to thank the EBC Policy Director, Bjorn Kongstad, who has worked tirelessly to bring together all the various contributions and has also provided a helpful overview in his Introduction.

The EBC remains indebted to our many stakeholders, including the European National Chambers of Commerce and other business organisations represented in Japan, for their continuing support for our work. We also greatly appreciate the advice and guidance received from the Delegation of the European Union to Japan and the European national embassies in Tokyo. Finally, we gratefully acknowledge all EBC Members whose generosity has made this publication possible and are listed in the sponsors and supporters sections at the end of the Report.

2015 has been another challenging year for business in Japan and the EBC remains determined to do all it can to help create an environment that truly fosters growth and long-term prosperity. The recommendations contained in this Report are a first step and we look forward to discussing them with the Government and others who share our goal. With sufficient effort and commitment, 2016 could be the year an EU-Japan FTA is agreed and the Japanese economy gets back on track – so let’s make the most of this golden opportunity!

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



Introduction



INTRODUCTION

“Abenomics is progressing!”: so claims the latest presentation on the Government’s Growth Strategy. But what about Japan? The economy is in the doldrums, the deficit is enormous and the country is facing a productivity crisis. As the population ages and the birth rate falls, workforce shortages are starting to emerge and the pressure on welfare services, especially healthcare, has intensified. These problems have been decades in the making and, in the coming years, will become more acute. Japan must act fast to avoid economic and social disaster. So is Abenomics the answer?

For the first two years, Abenomics - the Government’s Growth Strategy - focused primarily on short-term fixes to keep the economy out of recession. A combination of monetary policy and fiscal stimulus were reasonably effective. By the beginning of 2015, business conditions were improving, corporate profits increased, average wages rose by 2.2 per cent (the highest level for seventeen years!) and unemployment fell. However, by the end of the second quarter, the economy had started to contract again, not least because of weakening demand from China, and by the third quarter, the Bank of Japan was cutting its forecast for real GDP growth over the fiscal year from 1.7 to just 1.2 per cent. The problem is that monetary policy and fiscal stimulus alone do little to address underlying weaknesses in the business environment. Structural reform is needed.

Regrettably, it took two years for structural reform to come to the top of the Abenomics agenda: happily, it is now a major focus. A number of initiatives have been launched this year that should start to make a difference. A reduction in the corporate tax rate has brought the effective rate down from 35.6% to 33%, which will make Japanese companies slightly more competitive and give them that bit more to invest. New Stewardship and Corporate Governance Codes have been designed to promote the interests of investors and bring more independent directors onto company boards, which should help stimulate investment and risk-taking. Innovation will get a boost from stronger links between universities, research institutes, venture capital and industry. Action is also being taken to promote more extensive use of ICT and robotics, including in healthcare. Plans are being laid to boost inward tourism and make Narita Airport a regional hub. Finally, revised visa / residency rules aim to attract more skilled professionals from overseas; and measures to improve childcare benefits and provision should encourage more female participation in the workforce. All these reforms will help Japan to release its economic potential. But even they are still not enough.

As this Report makes clear, many of the Government’s reforms suffer from a piecemeal approach and are being more or less undermined by action (or inaction) in other areas. Moreover, companies, both domestic and foreign, are still wrestling with many other regulatory barriers that inhibit their development and yet have been left untouched by Abenomics. A significant number of these barriers even relate to activities and sectors which the Growth Strategy is intended to promote. For example:

- The Government wants healthcare to become a major growth industry for Japan, yet its own price reimbursement scheme is so unpredictable that it deters companies from developing and marketing new products.
- The Government wants to attract more inward investment and boost home-grown innovation, but only offers tax relief on R&D expenses incurred in Japan, if those expenses are borne locally. Most foreign firms take the cost of R&D at the level of their headquarters (wherever they may be) and so are not eligible for relief in Japan, making Japan less attractive as a destination for such activities.
- The Government wants to increase tourist travel to Japan but its main international airports are blighted by excessively high fees, and Haneda Airport in particular with inadequate infrastructure for the airlines, which inhibit the development of profitable routes.
- The Government wants Japan to be at the forefront of ICT development, yet the Japan Fair Trade Commission is proposing changes to its “Guidelines for the Use of Intellectual Property under the Antimonopoly Act”

which could reduce the value of cutting-edge proprietary technology used in open standards such as LTE and 5G, and consequently reduce incentives to invest in R&D.



Such shortcomings need to be swiftly addressed and a far more holistic and outward-looking approach adopted if the Government's Growth Strategy is to succeed. With this in mind, the EBC believes that new trade agreements, which form part of the Strategy, can play a transformative role. Such agreements open up new markets, stimulate competitiveness, and increase the flow of goods, services, talent and knowledge. Japan is a party to the recently concluded Trans-Pacific Partnership agreement that is now awaiting ratification in the twelve participating nations. Meanwhile, negotiations towards an EU-Japan Free Trade Agreement are advancing. These negotiations cover a wide range of topics, including tariffs, non-tariff measures, services, procurement and competition. Neither side can afford to miss the opportunity to boost mutual trade and investment and the EBC is doing all it can to make sure it is firmly grasped. In particular, EBC Committees are supporting the process, building on their own experience of operating in Japan and other markets to brief EU negotiators on the key issues. The EBC stresses that all these issues must be addressed in a final agreement: failure to do this would diminish the value of the agreement and risk bias. A shortlist of top Committee priorities for the FTA is included in the relevant chapters of this Report, as an indication of the scope and depth required. These cover areas such as:

- 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 materials and foods, and Japan-only product labelling requirements.
- Ensuring fair competition and equal treatment of all companies, domestic and foreign, for example in the airline, express delivery and insurance sectors.
- Ensuring fair and open tenders for public contracts in the railway and construction sectors.
- Improving conditions for foreign direct investment, including the removal of requirements unique to Japan in the banking and asset management sectors.

The EBC understands that the FTA negotiations, while complex, are moving forward and that, with sufficient commitment from both sides, it should be possible to reach a satisfactory conclusion during 2016. This would set both the EU and Japan on a path to boosting their mutual trade and lifting their economies to a higher level, and it would also usher in the concrete reforms needed to take Abenomics from progress to success. This is a unique, once-in-a-generation, golden opportunity – so let's strike gold in 2016!

How this report is organised

Following this introduction, 30 chapters, each written by an EBC sector / expert committee summarise the key issues and developments in the Japanese business environment over the past year, and are accompanied by concrete recommendations for reform. Where appropriate, Committees have also highlighted their top priorities for an EU-Japan FTA.

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, the European Union, and all others who genuinely wish to see the EU-Japan trade relationship reach its full potential.

Business

Fundamentals

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

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FINANCIAL REPORTING

Introduction

2015 saw continued momentum in Japan towards the adoption of a single set of accounting standards that would enhance the cross-border comparability of companies' consolidated financial statements, with many companies adopting International Financial Reporting Standards (IFRS). The Tokyo Stock Exchange (TSE) released data showing that 112 companies, representing a quarter of total market capitalisation, have adopted or plan to adopt IFRS and that nearly 200 additional companies are actively considering adoption. Despite a more unsettled and uncertain economic environment in the latter part of 2015, the EBC believes the use of IFRS by Japanese companies will spread further, as it is seen as a factor that facilitates cross-border investment. Adoption of a stricter corporate governance code and the introduction of the JPX-Nikkei 400, a new stock market index for companies holding themselves accountable to stricter corporate governance principles also supported the momentum towards comparable accounting standards, because the number of companies in the new index using IFRS is high. 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 taking a more gradual approach.

The EBC welcomes the efforts of the Accounting Standards Board of Japan (ASBJ) to enhance the use of IFRS in Japan and, in our view, the creation of Japan's Modified International Standards (JMIS) can be seen as supporting such efforts. The EBC was pleased that JMIS adopted only limited modifications to full IFRS; specifically, these modifications related to accounting for Goodwill and Other Comprehensive Income. The more JMIS deviates from full IFRS, the bigger is the danger that constituents outside Japan cannot easily analyse or understand differences between financial statements prepared under JMIS and those prepared under full IFRS. Therefore, the EBC would strongly support an approach by the ASBJ that ensures minimal modification in JMIS compared to full IFRS and advocates that the ASBJ should work with the International Accounting Standards Board (IASB) in order to reduce the differences between the two sets of standards. The EBC hopes that over the next few years the application of full IFRS in Japan will increase, which may mean it is not necessary for JMIS to be kept as a separate set of accounting standards.

In the meantime, 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 ASBJ for statutory reporting purposes and to 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 JMIS 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. 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.

The issuance of new standards under IFRS poses significant challenges for 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.

Key Issues and Recommendations

■ Revenue Recognition

Yearly status report: new issue. The recognition of revenue is a significant accounting policy for any preparer of financial statements and one on which J-GAAP currently provides limited guidance. In a number of industries, products, services and/or projects may be delivered over a longer time period and/or in a manner that results in less transparency regarding the rights to receive the related cash flows at any stage, period or point in time. This can lead to misunderstanding in a preparer's financial statements about the performance and position or their comparability. To ensure appropriate and consistent treatment of revenue recognition, it is vital that accounting standard setters adopt clear and principled revenue standards and provide adequate guidance to preparers and auditors of financial statements. IFRS 15, "Revenue from contracts with customers", has recently been published and is due to become effective for reporting periods beginning on or after 1 January 2018. The EBC believes that Japan would benefit from trusted and comparable financial statements that adhere to a new comprehensive revenue recognition standard. Furthermore, any new standard should be accompanied by guidance that addresses some of the judgemental areas of revenue recognition. Finally, the standards should include a robust set of required disclosures to ensure that users of financial statements fully understand the assumptions, judgements, uncertainties and sensitivities of revenue recognised in relation to underlying products, services and projects.

Recommendation:

- The ASBJ should prioritise the adoption of a new revenue recognition standard aligned with the principle of the standards published by the IASB and FASB and should, as much as possible, seek full convergence with these standards. The new standard should include a robust set of disclosure requirements and be accompanied by guidance on problematic judgemental areas.

■ Financial instruments

Yearly status report: some progress. While the EBC notes many similarities between the accounting standards of financial instruments under IFRS and J-GAAP, there is one key 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. The EBC expects that aligning the accounting treatment under J-GAAP with IFRS will yield efficiency gains for issuers of financial statements who need to prepare financial statements under both regimes. The EBC notes that JMIS does not propose 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.

■ Property, Plant & Equipment (PPE)

Yearly status report: no progress. 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 to 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 shortage of skilled labour, an ageing population and a declining birth rate together present significant challenges for the long-term vitality of the economy in general and for business, both domestic and foreign, in particular. Several forecasts suggest that the population of Japan may reduce by as much as half by 2050. The EBC sees only four ways to combat the effects of 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 ensure a skilled and competitive workforce.

When Prime Minister Abe introduced the third arrow of his growth strategy, he stressed the importance of improving Japan's human resource capital. He talked, for example, about the need for more female participation in the labour market; however so far little has changed. 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*). Furthermore, it is still difficult in most metropolitan areas to find a day-care facility to look after children while their parents are at work. The situation calls for a far more radical, committed and creative approach from the Government and local Authorities, without which women, a key potential resource, will remain at home.

The EBC has therefore been encouraged by recent signals that the Government is considering new ways to increase the participation of women in the labour market, including an overhaul of the current income tax break given to tax payers whose spouses do not work or work only limited hours, which would remove the incentive for spouses to work only part-time. The EBC believes this is a clear step in the right direction but that still greater efforts should be made, for instance by offering more public child-care centres and private child-minding services, and by supporting and encouraging men to take child care leave.

On a more positive note, the EBC commends the Government and the Ministry of Justice on the changes they have introduced to improve Japan's attractiveness to foreign professionals, through a new system related to re-entry permits and the extension of visa periods. This new system is being complemented by efforts to admit greater numbers of highly skilled persons. Together these measures will benefit individual companies and the economy as a whole.

On the pension side, Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees. However, given the current demographic trend and the inevitable stress this will place on the Japanese social security system, it is imperative that further incentives are created to encourage individuals to prepare financially for their own retirement. Currently, it is only possible to claim a tax deduction for private pension contributions of up to 50,000 yen and this needs to change. Discussions on lowering the minimum period of premium payments required in order to receive a pension need to be brought to a successful conclusion. Meanwhile, Japan must ensure that its efforts to open up to more skilled foreign workers are not undermined by its pensions regulations. Amendments are still required to enable such workers to get a full refund of all mandatory Japanese pension fund contributions when they finally leave the country, rather than the current limit of the last three years of premium payments. The Government should also 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 seamless 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, for example, by lowering the requirement for industry experience from ten to five years for those who do not have a relevant university degree;
- 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;
- Extend the benefits given to “highly skilled professions” to permanent residency holders.

■ Labour market regulations

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.
- 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.
- Encourage companies to set up child-care facilities by offering them identical or similar financial contributions to those given to public day-care centres.
- 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.
- Allow longer periods during which over-time can be balanced.
- Allow for easier corporate restructuring, while setting up clear rules for compensation of regular employees whose jobs disappear.

■ Pensions

Yearly status report: gradual progress. Social security agreements have been concluded or are being negotiated with several European countries, to the benefit of their citizens, whose mandatory contributions to Japanese pension plans can now be refunded in full. For the nationals of countries without an agreement, however, refunds remain capped at a maximum of three years. Meanwhile, the EBC is encouraged by the discussions on lowering the number of years of pension premium payments required in order to receive a pension.

Recommendations:

- Lower the number of years required to pay pension premiums in order to receive a pension.
- Make contributions to foreign-based pension plans subject to the same tax relief as contributions to pension plans in Japan.
- Japan and EU Member States should swiftly conclude mutual social security agreements.

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INTELLECTUAL PROPERTY

Introduction

In Japan, luxury brand products reach consumers via one of two sales channels: either regular distributors or dealers in parallel imports. The sale of parallel imported goods is not illegal in Japan. While luxury brands strive to develop sales through regular shops or internet sites, the need to protect the image of their products makes them reluctant to engage in e-commerce using any other distributors. However, online marketing and sales of their products in the form of allegedly authentic “parallel imports”, mingled with counterfeits of both luxury brands and top brand electric appliances, are growing. As in many other countries, the top producer and exporter of counterfeit goods distributed in Japan is China, accounting for 92.9% of all fake goods flowing into the country.

In 2014, some 895,792 fake items were stopped at the border by Japan Customs. Given that it is impossible for Customs to examine all imported items, that number can be assumed to be a tiny fraction of the overall volume of fake imports. Moreover, as the purchase of counterfeit products for “personal use” is not forbidden in Japan, in many cases Customs cannot stop the entry of counterfeits even if detected.

In the past, many Japanese consumers seemed happy to purchase fake items knowing they were counterfeits. However, the main issue today is how to assist consumers tricked into buying counterfeits, despite their wish to purchase genuine brand products. Such consumers face disappointment and financial loss and also possible risks to their health or safety from the poor-quality counterfeits they receive. As a result, respect for intellectual property rights (IPR) has become an integral part of Japan’s consumer protection strategy. Encouraged by a rise in public awareness of the importance of IPR, the Government is studying the feasibility of blocking access to counterfeit sale and fraudulent websites.

Relevant ministries and agencies are making considerable efforts to protect IPR. Starting in 2007, the Customs Bureau gradually eased the obligation for rights holders to visit Customs offices to check items suspected of being counterfeits, and two years ago the requirement was removed completely. The Consumer Affairs Agency has launched initiatives, including setting up a Cross-Border Consumer Center to assist consumers who unwittingly purchased counterfeit items from abroad, and publicising a list of online counterfeit stores on its website. The Ministry of Economy, Trade and Industry is seeking to tighten controls on internet transactions through its Specified Commercial Transaction Act.

Yahoo!, Rakuten and DeNA are also playing an important role in combating counterfeits. Yahoo!, for example, is endeavouring to “purify” its auction service by regularly exchanging information with brands, via rights-holders’ associations, on counterfeits and criminal dealers. It has established its own information-gathering function and has a team of 200 staff members conducting continuous independent checks based on the information obtained. Such efforts allow Yahoo! to detect and, at the request of the concerned brand, eliminate a large proportion of posted fake products. Rakuten is also actively “purifying” its shopping website. When a product posted on Rakuten is suspected of being a counterfeit because, for instance, of a particularly low price or information received from a consumer, the operator makes a test purchase of the item to verify its authenticity with the cooperation of the relevant brand. If the item turns out to be counterfeit, the posting dealer is banned from the website with immediate effect.

Finally, concerted efforts are being made by different sectors in Japan to set up a framework to eliminate counterfeits. Some of their approaches are more advanced than those applied in Europe or the USA. Yet it is undeniable that a number of problems remain unsolved. Specifically, partnerships with internet service providers (ISPs) should be developed to build a proper system to protect consumers, and the possession of counterfeit items “for personal use” should be controlled and the definition of such use tightened and made legally binding.

Key FTA/EPA Issues

- **Ensure that IPR issues are taken up in the FTA/EPA negotiations in sufficient depth to improve the current situation**
- **Create common rules to provide solutions to the problems described above**

Key Issues and Recommendations

■ Strengthened and continuous actions to eliminate counterfeit products from online malls in Japan and abroad

Yearly status report: some progress: While major auction websites have succeeded in reducing the proportion of counterfeit products on their sites to less than 1%, some shopping websites are still failing to take the necessary measures and so the share of counterfeits of certain brands on their sites remains relatively high. The delay in taking action by shopping websites can be explained partly by the fact that most uploaded image data are not adequate for determining whether the items for sale are counterfeit or not, and it is often necessary to make test purchases to verify authenticity. Additionally, thorough countermeasures against counterfeit products are yet to be taken in respect of the internet flea markets launched recently by a number of emerging ISPs. Overall, initiatives against counterfeit sales websites, fraudulent websites and spoof websites are progressing much too slowly. Measures already put in place by the relevant Japanese ministries and agencies include the freezing of bank accounts used by the operators of such websites, publication of their URLs, and display of alerts via security software, but these have not yielded fundamental solutions to the problem. Given that public awareness of the need to protect IPR and consumer interests is undoubtedly rising, now is the time to take bold and swift action to combat the sale of counterfeit products.

Recommendations:

- The Specified Commercial Transaction Law should be amended to strengthen checks on branded goods sold on the internet, with a view to eliminating counterfeit goods from shopping websites. In addition, the Government should encourage ISPs, distributors and rights-holders to establish their own anti-counterfeit guidelines to promote private sector initiatives in this field.
- Radical measures should be taken against counterfeit sales websites, fraudulent websites, and spoof websites hosted by foreign servers, for example: blocking access to them or removing them from search engines.
- The Government should encourage emerging ISPs operating internet flea markets to implement measures against fake products.

■ Tighter definition of “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 for commercial purposes. As a result, the Customs Authorities waste manpower and time detecting counterfeits only to find they have no choice but to grant import permits. If this loophole cannot be closed, at the very least the definition of “personal use” should be tightened. Dealers importing numerous counterfeit watches by post several times a year, for example, could be stopped simply by defining the minimum period of possession (such as one year) and the maximum number of items that may be presumed to be “for personal use”. Given that the resale and transfer of fake products remain lawful, relevant laws and regulations must be improved to prevent such dealers from being able to claim that the goods are for their personal use.

Recommendations:

- The importation and purchase of counterfeits, even for “personal use”, should be controlled under the law.
- If the importation and purchase of counterfeits “for personal use” cannot be prohibited by law, the definition of such use should be tightened to address the current situation where importation of unlimited numbers of fake products is permitted so long as they are declared to be “for personal use”.

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LEGAL SERVICES

Introduction

The EBC's recommendations in respect of Legal Services in Japan remain the same as last year's, because nothing concrete has changed to date.

Further to the Cabinet's Regulatory Reform Plan, approved on 24 June 2014, the following deliberations took place in respect of the regulations applicable to *gaiben* (foreign-educated lawyers):

1. A study group was set up to discuss the *gaiben* system: this was set up under the responsibility of the Ministry of Justice. With the increase in demand for international legal services, in 2015 this study group has devoted six months to (1) review the requirement to have certain work experience (i.e. the 3-year requirement) in order to register as a *gaiben*, and a further six months to (2) review the current limitation on *gaiben* and *bengoshi* (Japanese lawyers) to establish a *hojin* (corporation) together.

The EBC together with the American Chamber of Commerce and the Gaiben Association was invited to present its views on points 1(1) and 1(2) mentioned above on 20 May 2015 (the third group session) and 18 September 2015 (the sixth group session), respectively.

2. Transparency of the *gaiben* registration system: Consideration of this topic started in 2015 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 has been set up for discussions between the Ministry of Justice and the *Nichibenren* (Japan Federation of Bar Associations) taking into account opinions from registrants as necessary.
3. Making the *gaiben* registration process simpler: Consideration of this topic started in 2015 under the responsibility of the Ministry of Justice. With a view to making the registration process simpler and faster, a separate forum has been set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary.

The recommendations from the study group and the forums are eagerly awaited by the EBC.

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 FTA/EPA Issues

- **Japan should recognise foreign lawyers if they are recognised in their home jurisdiction without the need for the additional qualification of three years of professional work experience in their respective home law, out of which two have to be obtained outside Japan.**

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 finally been passed, in 2014, 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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RETAIL & WHOLESALE

Introduction

The Japanese retail market remains 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 (for example Uniqlo and Nitori) and wholesalers gain from the presence of European competition as it provides incentives to further strengthen their global competitive edge.

Despite recent successes, European wholesalers and retailers still face considerable barriers in the Japanese market. Firstly, 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 which, there are related sales restrictions. Thirdly, the Government of Japan continues to insist on applying unique national rules and regulations to products that have already met European standards. While sharing the Government's concerns regarding consumer protection, the EBC believes that European rules more than adequately address these same concerns, ensuring safe and good-quality products. Examples of the barriers encountered by European retailers and wholesalers are Japan's unique labelling rules, non-acceptance of non-SI units (International System of Units), food sanitation rules that are not truly related to safety standards, and non-recognition of global standards or European approvals. These barriers are particularly damaging to companies with a global supply chain and create higher costs and therefore higher prices for Japanese consumers. 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. An example of this is the joint effort of the Consumer Affairs Agency (CAA) and the Ministry of Economy, Trade and Industry (METI) in implementing the ISO (International Organization for Standardization) washing instruction standard.

The EBC is also concerned about possible complications arising from the recent relaxation of Japan's Antimonopoly Law. This was done through the issuance of amended guidelines on vertical restraints prohibition. Without bright-line rules, this has unfortunately created a situation where the legal application of these guidelines has become very difficult. The EBC hopes that the Japan Fair Trade Commission (JFTC) will remedy this situation by issuing clearer guidance that will facilitate compliance.

The EBC calls on the EU and Japanese authorities to ensure that, in the process of negotiating an EU-Japan FTA/EPA, the barriers met by European retailers and wholesalers are 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 a wider mutual acceptance of standards and certification, which will benefit companies and consumers in both markets.

Key FTA/EPA issues

- **Harmonise or mutually recognise approvals, certifications and standards**
- **Remove shoe quotas and/or implement a better quota management system**
- **Harmonise and simplify competition law to better match the needs of the business**

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 accept inclusion of common non-SI units on measuring devices when SI units are also used.

■ Labelling

Yearly status report: progress. The EBC appreciates the work of the Regulatory Reform Office with the Cabinet Office and looks forward to working closely with the CAA to bring about meaningful reform. We commend the CAA for implementing the ISO washing instruction standard, and ask to be kept informed and involved in the revision of the Household Goods Quality Labelling Act.

Recommendation:

- The CAA should speed up reform of the Labelling Act.

■ 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 unlawfully "sell" to other companies. This behaviour is illegal, but still persists.

Recommendation:

- The quota system should be abolished. As an interim measure, 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.

■ Limitations on selling liquor via telecommunication channels

Yearly status report: some progress. Although improvements were made to the liquor wholesale licence scheme some years ago for in-store liquor sales only, the retail sale of liquor across prefectural borders via any telecommunication channel (including the internet) is still restricted. This leads to higher transaction costs for new entrants. Old licences do not have this limitation (grandfathered licences), creating an unfair imbalance between new and old licence holders.

Recommendations:

- Japan should abolish the telecommunication channel limitation within the liquor retail licence system.
- Japan should stop the practice of grandfathering archaic licenses.

■ Competition Law/Anti-trust legislation

Yearly status report: new issue. Some striking differences exist between Japanese Competition Law and international practices. Examples include the recognition of "market power" with minor share in vertical restraint, and "superior bargaining power" irrespective of dependence. Furthermore, the EBC believes that the JFTC's "yellow card" system entailing counts of infringements without the provision of explanations lacks both a legal basis and transparency.

Recommendations:

- The "yellow card" system should be abolished.
- Japanese Competition Law should be harmonised with global business practices with bright-line rules.
- The Japanese Government should further clarify the recent notification on vertical restraints.

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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, in a variety of industries, committed to contributing to sustainable development. These companies have developed products that have proven themselves in other markets. Japan shares with Europe the goal of promoting a sustainable future and the introduction of many European products would therefore benefit Japan's commitment to achieving that goal. To promote access to these products, Committee members recommend a two-pronged approach. First they have identified barriers that block the access of European sustainable products. These often take the form of a non-tariff barrier: lack of acceptance of European sustainable standards. Second, Committee members point out that local standards and regulations sometimes create perverse incentives that discourage the use of sustainable products, hence reducing demand for them, regardless of whether or not they are imported.

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 choices for sustainable goods and services 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. In addition to individual reform initiatives, the EU-Japan FTA/EPA offers an opportunity to promote sustainable development in a comprehensive fashion.

Sustainable Development Committee member companies come from a number of fields including energy, food, water, construction materials, and construction-related management services. 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 energy consumption of buildings will 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 they are acting on it.

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—insulation, spectrally selective glass, curtain wall systems that prevent thermal bridging.

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.

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 many energy-efficient technologies such as energy-conserving equipment. Nonetheless, there are very few incentives to encourage consumers to demand more 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 0.5% of all food sold in Japan. This is much lower than in Europe and possibly the lowest penetration 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. Japan should take measures to promote 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.
- 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 certain rating level under CASBEE (Comprehensive Assessment System for Built Environment Efficiency) before issuing a building permit.
- Recognise certain ratings under foreign green building rating systems such as LEED (Leadership in Energy and Environmental Design) (US), BREEAM (Building Research Establishment Environment Assessment Methodology) (UK), DGNB (German Sustainable Building Council) (Germany) and Green Star (Australia) as equivalent to certain CASBEE ratings in satisfaction 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 Japanese Government's aim to stimulate the economy and increase Japan's attractiveness to investors by continuing to reduce the corporate tax rate. Reforms to date have reduced the overall effective tax rate from 35.6% to 33% for the fiscal year beginning April 2015 and to 32.3% for the fiscal year beginning April 2016. The Government's mid- to long-term intention is to reduce the overall effective rate to 30% or just below. It is also pleasing to note that the Government has continued its plans to help restore the country's finances through an increase in the consumption tax rate from 8% to 10% from April 2017. This move - from a focus on taxing income to a focus on taxing consumption - mirrors the transition in tax profiles of the EU Member States over the past few decades.

Nevertheless, public statements made by Prime Minister Abe in June 2015, at the launch of the Basic Policies for Economic and Fiscal Management and Reform and the 2015 revision to the Japan Revitalization Strategy, indicate a continuing strong focus by the Government on reducing the fiscal deficit over time. Since none of its policies to date involve significant curbs on expenditure, the resulting gap in the Government budget will have to be made up from increased tax revenues. Consequently, the widening of the tax base that has occurred in recent years is set to continue. Tax Reforms for 2015 and beyond include measures such as increasing the minimum taxable income before Net Operating Loss (NOL) utilisation from 20% to 35% and finally to 50% by April 2017. Regrettably, therefore, despite specific policies such as the reduction in the corporate tax rate, the Government's overall approach will inevitably have a negative impact on the attractiveness of Japan to potential overseas investors.

The negative impact is reinforced by the Government's increased focus on taxation of wealthy individuals, imposing a very high tax rate at the top income bracket and aggressive inheritance taxes that now apply to any overseas assets. This, in addition to the new exit tax, will cause investors to look unfavourably on Japan, particularly relative to the main Asian investment hubs of Hong Kong and Singapore, which are very attractive tax jurisdictions for individuals.

On the administrative side, the Government has indicated its commitment to improved tax efficiency through the introduction of a personalised identity system, known as "My Number", from January 2016. While this is a welcome move towards greater transparency and efficiency of tax management, too many questions have been left unanswered during the short introduction phase. The EBC urges Japan to consider further ways of improving tax management through (i) the extension of corporate tax compliance filing deadlines, and (ii) an improved formal tax ruling system.

Moreover, bilateral trade and investment between the EU and Japan would benefit significantly from mutual elimination of double taxation and withholding tax on dividends, royalties and interest, as provided for in recent tax treaties between Japan and individual EU Member States. An EU-Japan 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 the tax treaty text itself does not avoid double taxation in effect. The FTA/EPA should 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 summary, while the EBC considers that some of the tax reforms undertaken so far by the Japanese Government are heading in the right direction towards encouraging and supporting inward investment, others are likely to work directly against those goals. Consequently, the growth anticipated by the Government may be difficult to achieve. This situation will persist as long as the significant fiscal deficit remains to be addressed and tax revenues are used as the supposed solution to this problem.

Key FTA/EPA Issues

- **The FTA/EPA should include an arbitration clause to ensure that double taxation will be effectively eliminated if the applicable tax treaty between the EU Member State and Japan does not resolve double taxation.**

Key Issues and Recommendations

■ 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. Elimination of this discrepancy could encourage Foreign Direct Investment.

Recommendation:

- Research and development conducted in Japan by foreign investors should be eligible for tax benefits, no matter where expensed.

■ Corporate restructuring

Yearly status report: no 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.

Recommendations:

- Tax deferral should be permitted in respect of share-for-share exchanges, including those involving foreign companies with no previous operations in Japan.
- Rules and regulations underpinning corporate restructuring laws should be further simplified and clarified to reduce costs and limit the tax authorities' discretion to define key concepts.

■ Individual income taxation

Yearly status report: new issue. Japan now uses three different definitions of “residency” to determine which taxes an individual must pay. A tax on worldwide income applies to all those who have been in Japan for five years or more. However, exit tax only applies to Japanese nationals, permanent residents or spouse visa holders. Meanwhile, inheritance tax applies to all residents of Japan, even if they have only been in the country for one day.

Recommendation:

- Align residency criteria for exit and inheritance taxes, so that both are only applicable to Japanese nationals, permanent residents, or spouse visa holders.

■ Transfer pricing

Yearly status report: no progress. The Japanese tax authorities continue to use domestic corporate tax rules relating to donations to make assessments in relation to transfer pricing matters. For taxpayers this results in an inability to access the mutual agreement procedures arising under Japan's tax treaty network.

Recommendation:

- All cross border transactions should be dealt with under transfer pricing legislation and not under domestic corporate tax rules relating to donations.

■ Consumption tax for provision of cross border digital content services

Yearly status report: new issue. As part of Japan's Base Erosion and Profit Shifting (“BEPS”) initiative and in order to capture e-commerce companies providing services to Japanese taxpayers that are currently outside the Government's tax jurisdiction, a reverse charge will be instituted for all e-commerce companies providing digital content services to Japanese businesses. Although this law is effective from October 2015, there is still limited guidance on what constitutes “digital content”. This makes it difficult for taxpayers to understand whether they are within the scope of this new law or not. Moreover, as a result of this new law, there are now two different consumption tax law treatments for services, depending on whether they contain digital content or not. This is likely to lead to confusion, which in turn will result in increased compliance costs for both taxpayers and the tax authorities. To avoid this problem, a simple solution would be to make all services subject to consumption tax based on the location of the service recipient (as for the new cross border digital content services), and not based

on the location of the service provider. As in the EU, only the portal - not each and every digital content provider going through one of the major portals or other e-commerce intermediaries - should file Consumption Tax.

Recommendations:

- The Government should convert the entire consumption tax law for services from one based on location of the service provider to one based on location of the service recipient.
- At the very minimum, the Government should publish detailed guidelines as to what constitutes “digital content” for the purposes of applying the new consumption tax law to cross border services.
- E-commerce intermediaries (not those contracting through them) should file Consumption Tax.

■ **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 and family lives of those preparing the returns, while driving up expenditure on overtime. 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.

■ **Accountability**

Yearly status report: no progress. The overall lack of transparency and systematic accountability in the domestic tax regime continue to impede the development of business in Japan.

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 consider the merits of introducing a system offering Horizontal Monitoring, Risk Rating, and Senior Accounting Officers, which have improved efficiency in the UK and The Netherlands.

■ **Tax treaties**

Yearly status report: progress. Japan recently concluded new tax treaties with Switzerland, The Netherlands and the UK. A new treaty with Germany has been announced. However, treaties with 22 EU Member States still need to be renegotiated. The EBC welcomes treaties that include the exemption of withholding tax on royalties and qualified dividends and interest, and that contain arbitration provisions.

Recommendations:

- The Government should review all current tax treaties with EU Member States.
- Any new or revised treaty should address the issue of withholding tax on royalties and qualified dividends and interest, and contain arbitration provisions.

Financial Services

**Asset management
Banking
Insurance**

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ASSET MANAGEMENT

Introduction

The asset management industry continues to be at the centre of significant developments in Japan's financial sector, particularly in the following areas:

- "From saving to investing": The Japanese authorities are encouraging households to move from keeping their money in general savings accounts to investing in financial products, including funds. NISA (the Nippon Investment Savings Account) has provided both a specific investment opportunity and an important vehicle for improving public awareness of and knowledge about funds.
- Stewardship Code and Corporate Governance Code: Asset managers have been playing a critical role in developing dialogue between investors and companies, and thereby contributing to better corporate governance and return on capital in Japan. The new JPX-Nikkei 400 index illustrates the desire of many Japanese companies to adopt new standards and to be valued accordingly.
- Major allocation shifts: Substantial shifts are being seen in the portfolios of large institutions, including public pension funds.

In this context, the retail fund market reached a historical high level of Assets Under Management (AUM) in 2015, exceeding 100 trillion yen for the first time, and many market participants believe there is still significant potential for growth. The future success of the asset management industry depends in part on development of products that can attract bank depositors who are new to or have little experience of investing, (for example, an expansion of NISA or revision of the pension system to incentivise private pension savings). Today, much of the accumulated capital in Japan is invested in low-interest government bonds or regular saving accounts. The EBC believes there is a need to re-balance the investment portfolio to achieve a more satisfactory return on capital.

In the institutional market segment, the EBC has seen a range of encouraging developments, including major asset reallocations and adoption of new strategies.

There are however still several areas requiring improvement, such as the promotion of fund mergers, which today are difficult to achieve and are viewed unfavourably by retail investors. Furthermore, Japan needs to increase its efforts to become a true international financial centre, against fierce competition from neighbouring countries.

The EBC Asset Management Committee continues to view the Japanese market as a major opportunity for successful expansion and development, benefitting clients and companies alike. The EBC furthermore recognises that sharing best practices from our member firms for the benefit of Japanese investors is one of our key missions.

Key Issues and Recommendations

■ Small funds

Yearly status report: new issue. As highlighted by the FSA Financial Monitoring Report, published in July 2015, one of the major problems faced by the Japanese asset management industry is the high number of funds, many of which are small. In fact Japan has more than 5,500 funds with an average AUM of only 17.5 billion yen. This situation is challenging not only for the asset management industry but also for investors needing to make a selection from such a huge variety of funds. It also creates problems for the funds themselves, which require a certain level of AUM to achieve more efficient portfolio management processes and hence obtain desirable outcomes for investors over a long period of time. This situation is in sharp contrast to the US and Europe. For example, in Europe the regulatory environment and operational processes associated with fund mergers have served as a major factor enabling asset managers to maintain an optimal product line-up for retail investors. In Japan, however, fund mergers do not happen. Closures of funds are rare and if they do occur, can generate a heavy administrative burden and a negative perception by retail investors.

Recommendation:

- All industry stakeholders should be encouraged to make a joint effort to introduce flexible fund consolidation processes. Stakeholders whose opinions should be sought include IT-system providers for fund administration, trustee banks and distributors, who are responsible for critical platforms as well as IT systems to accommodate fund mergers, and regulators who are in a position to consider less burdensome legal processes, such as introducing prior notification instead of advance consent procedures in respect of individual unit holders.

■ Globalisation of the operational platform

Yearly status report: new issue. The EBC considers that, for Japan-based investors, operational platforms for the asset management industry are relatively isolated from the global environment. To give a few examples, there is no “global custody” function per se in Japan, as domestic assets are in the custody of Japanese trustee banks, whereas non-Japan assets are segregated in the custody of global sub-custodians. Usage of SWIFT messages for domestic assets is still limited to a few trustee banks. One encouraging sign, however, is that Japan signed on to the Statement of Understanding related to the Asia Region Funds Passport (ARFP) in September 2015. This means that Japan’s operational platform would need to become globalised to comply with the ARFP.

Recommendation:

- Working groups should be set up by stakeholders, including foreign organisations, with the aim of producing tangible recommendations on how to better set up global platforms.

■ Solicitation for off-shore funds

Yearly status report: new issue. Under the current regulatory regime, active introduction of global expertise to Japanese institutional investors through “off-shore funds” could be regarded as solicitation of overseas securities and, therefore, require a Type I (or Type II, depending on the type of securities) licence. The EBC believes this type of activity will become more important in future as Japanese institutional investors (e.g. asset owners and asset managers) continue to diversify their portfolios internationally. When introducing an offshore fund under the Type 1 licence (even if the scope is restricted to asset management products), asset management companies must meet various requirements, including capital ratio requirements. However, the asset management company does not handle customer assets including cash nor participate in any critical process of individual order placement procedures, such as wiring of subscription and/or redemption proceeds. Furthermore, unlike typical activities performed by investment banks with a Type I license, the asset management company does not require its own capital or balance sheet for the above-mentioned activities. In such cases, the capital ratio requirement for a Type 1 licence whose scope is restricted to asset management products is an unnecessary administrative burden.

Recommendation:

- The competent Japanese authorities should consider how other countries have dealt with solicitation of off-shore fund vehicles, with a focus on the existence (or not) of capital requirements, and with a view to developing regulations that better support and promote the industry in Japan.

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 fifth 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. Furthermore, the introduction of a new corporate governance code and the stewardship code should make Japan more attractive to investors. Early signs indicate that corporations are now thinking more about return on equity and that consequently, yields have improved. However, it is of the utmost importance that real changes be implemented so that external directors are indeed truly independent and that their appointments are made more transparent.

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.

While the firewall between different financial activities within the same financial group has been liberalised (e.g. increased double-hatting) there is still a ban on information sharing. The EBC believes that a conflict management regime combined with appropriate inspection/supervision practices should suffice. This would be in alignment with other principle-based regulations, something that the Financial Services Agency (FSA) has introduced for other regulatory frameworks.

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.

Recommendation:

- 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.

■ Transparency and regulatory efficiency

Yearly status report: good 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 in the past imposed an excessive administrative burden on regulated firms. The EBC is encouraged by the efforts of 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:

- 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.

■ 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. The EBC recognises that consumer or client protection is indeed important but still believes that there are frameworks in other market that fulfil this goal without an additional layer of registration.

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 look at other markets to see how this issue of consumer or client protection is solved.

■ Information sharing

Yearly status report: new issue. While the firewall between different financial activities within the same financial group has been liberalised (e.g. increased double-hatting) there is still a ban on information sharing. The EBC believes that a conflict management regime combined with appropriate inspection/supervision practices should suffice.

Recommendation:

- Remove the ban on information sharing within a financial group.

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INSURANCE

Introduction

The Japanese insurance market is the second largest in the world after the USA. The market share of foreign affiliates in Japan is increasing, but they continue to encounter obstacles that can limit efficient development of their businesses. Examples include the competitive advantages handed to Japan Post on privatisation and similarly enjoyed by mutual aid cooperatives (*kyosai*), as well as reserving and solvency regulations that are inconsistent with international norms, and the lengthy, non-transparent product approval process. Future growth of the insurance market 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. 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 reports, repeatedly drawn attention to issues concerning Japan Post. Japan Post Insurance (JPI) is currently conducting life insurance business as part of Japan Post Holdings. While Japan Post is private in the sense that it is incorporated, it is still owned by the Government, which plans to retain a 50% shareholding when the planned IPO (Initial Public Offering) is implemented. Nevertheless, JPI is already being allowed to launch new life insurance products, subject to regulatory approval under the amended Postal Service Privatization Act. The EBC is following with interest recent developments regarding business alliances between JPI and private insurers, as well as the IPO of Japan Post Holdings, Japan Post Bank and JPI. Clearly, however, these developments will not completely resolve the issue; as long as the Japanese Government continues to hold a majority shareholding, Japan Post will continue to enjoy advantages in the market and competition will remain distorted. It is therefore 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) was tasked by the G20 and the Financial Stability Board (FSB) to designate nine insurers as global systemically important insurers (G-SIIs). The FSB/IAIS advocates 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. They are also 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.

In addition to these reforms, we believe a permanent, post-funded scheme should be established for the Policyholder Protection Corporation (PPC). Moreover, 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 applying clear and consistent rules and regulations, would assist Japan's recovery from the financial crisis. This would also benefit the domestic financial services industry, consumers and Japan's ability to retain foreign investment.

While the FSA has indeed made efforts to speed up the approval process through both a more efficient procedure as well as increased staffing, the EBC still believes that a "file-and-use" system should be introduced for quicker approval of standard products. This will free up resources for the FSA to be able to better focus on more advanced products.

Key FTA/EPA Issues

- The Government of Japan should swiftly carry out the IPO process in respect of Japan Post in accordance with its original commitments, and ensure that a level playing field is established. Until 100% of the shares are held privately, JPI's product portfolio should not be expanded and its issue limit should remain the same.
- *Kyosai* should be brought under FSA supervision, be covered by the Insurance Business Law, and not be allowed to expand their businesses until such provisions are in place. Until this is achieved, *kyosai* and their competent authorities should apply the same standards and regulations as the FSA.

Key Issues and Recommendations

■ Japan Post reform

Yearly status report: some progress. Along with other entities, such as the Life Insurance Association of Japan, the EBC welcomed Japan's original IPO plan in which 100% of JPI shares would have been released. However, while Japan Post is private in the sense that it is incorporated it is still owned by the Government, which plans to retain a 50% shareholding when the IPO is implemented. For as long as the Government remains a shareholder, the public perception will be that it guarantees the various Japan Post entities. The EBC believes this will give JPI an unfair competitive advantage, especially since JPI has indicated its intention to expand its product portfolio.

Recommendations:

- The Government of Japan should swiftly carry out the IPO process in accordance with its original commitments, and ensure that a level playing field is established. Until 100% of the shares are held privately, JPI's product portfolio should not be expanded and its issue limit should remain the same.
- The Government should publish a roadmap for its divestiture of each publically traded entity.
- The Government should clarify how and in which area JP group companies work together and how they select business partners to provide financial services, and ensure that good corporate governance is in place for Japan Post Holdings, Japan Post Insurance and Japan Post Banks.
- The Government of Japan should adhere to its commitments made under the GATS.

■ *Kyosai*

Yearly status report: no progress. Under commitments made by the Government of Japan, these organisations should be governed by the same rules and regulations as private insurance companies. Currently, however, *kyosai* are not subject to the Insurance Business Law. Instead, different ministries regulate the various *kyosai* depending on the sector in which the *kyosai* is active. While the EBC appreciates that the FSA and local Finance Bureaus supervise Small and Short-Term Insurance, larger *kyosai* remain under the supervision of other ministries and as such these ministries are responsible for much of the market: JA *Kyosai* has, for instance, more than 13 million policies with an annual premium income of 5 trillion yen.

Recommendations:

- *Kyosai* should be brought under FSA supervision, be covered by the Insurance Business Law, and not be allowed to expand their businesses until such provisions are in place.
- Until this is achieved, *kyosai* and their respective competent authorities should apply the same standards and regulations as the FSA.
- The membership of *kyosai* should be further clarified and restricted to a well-defined group as originally intended, such as a certain profession.

■ 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 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.
- 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.
- The Government of Japan should clarify planned changes so that all parties concerned, including private insurers, can prepare for the new framework.

■ Product approvals

Yearly status report: some progress. The EBC appreciates the FSA's initiatives to improve the product approval process. In 2014, the FSA publically explained the product approval process, and in July 2015 indicated its areas of interest and the data and information required for new product examinations. These actions help insurance companies to prepare for product examination. However, the product approval process is still sometimes lengthy in comparison with foreign markets, causing product development delays and making effective business strategy planning difficult. The EBC believes that faster product approval will be beneficial to not only insurers but also consumers. Furthermore, while ensuring customer protection, the EBC encourages the FSA to introduce a "file-and-use" system and to present a plan for its implementation.

Recommendations:

- The FSA should continue the effort to improve and clarify its product approval process. One way forward is to set up a regular dialogue between the regulator and insurance companies, both foreign and domestic.
- The FSA should commence studying how product approvals are conducted overseas. The EBC would be pleased to contribute expertise in order to make the research effort more efficient and effective.
- The FSA should introduce a system allowing insurers to register products, instead of having to obtain pre-approval. The FSA could retain the authority to conduct post-checks and issue withdrawal orders.

■ Bancassurance or bank sales channel

Yearly status report: limited progress. It is common practice for insurance companies to use banks and their physical networks to better market and sell various insurance policies. Although this market has been liberalised, there are still areas to be further examined and deregulated - notably the regulations preventing insurance sales by loan managers, insurance sales to employees of companies with no more than 50 employees, and the use of customer information obtained from the banking business to identify potential customers for insurance products. The EBC understands that the rationale behind the current approach is to prevent banks from using their superior bargaining power to force clients to buy unnecessary or inappropriate insurance policies, but also notes that such behaviour is already prohibited by anti-trust law and bank codes-of-conduct. New regulations to be enforced in May 2016 will require confirmation of a customer's needs and intentions before concluding insurance contracts. The EBC is unaware of any major complaints from consumers about banks mis-selling insurance policies.

Recommendations:

- The FSA should further liberalise bancassurance.
- As a first step, the FSA should allow banks to sell insurance to any company employee, regardless of the relationship between the bank and the company, and to use bank data.

■ Policyholder Protection Corporation (PPC)

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

Recommendations:

- The FSA should amend the PPC into a post-funded system and simultaneously introduce provisions for the system to better mirror the current market situation regarding total funding and annual assessment.
- The Japanese authorities should take into consideration the situation of the G-SIIs when amending the PPC system.

Transportation & Communications

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Railways
Telecommunications carriers
Telecommunications equipment
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AIRLINES

Introduction

2015 has seen a dramatic increase in the volume of inbound air travel to Japan, especially from Asian countries, but also from Europe. However, this increase in inbound traffic has not compensated for lower levels of outbound traffic from the relatively larger Japan market. Substantial weakening of the yen and an increase in consumption tax, combined with terror attacks abroad have had a substantial negative impact on Japanese demand for leisure travel. Significant effort is now needed to revitalise this demand, especially for leisure travel to Europe, as this market is of great importance to domestic agents and tour operators. Currently most resources and initiatives are aimed at increasing the volume of visitors to Japan, building towards the Olympics, which will be held in Tokyo in 2020. However the airline seat capacities envisaged by Japan for the Olympics can only be met if there is sufficient outbound demand to support the maintaining and developing of such capacities on Japan-Europe routes.

The EBC urges the Government of Japan to reduce fees at Japanese airports - especially those offering vital links to and from international markets - in order to reach its ambitious growth targets. To date, the scope and pace of change have been disappointing. Mainline airlines have long been required to pay exorbitantly high 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. A new plan from the Japan Civil Aeronautics Bureau to install 56 automated body scanners at Japanese airports over the next few years has no obvious public funding and there is a risk that, yet again, airlines and their passengers will be burdened with the cost. Tellingly, the revised fee structure at Narita Airport (NRT), introduced in 2013, has not succeeded in producing any substantial cost reductions for users. Although landing fees were lowered, costs such as rent and baggage handling were increased. Cost savings from the abolition of physical checks on cars/buses at the airport have not been passed on to airlines. As a consequence, NRT's profits have grown ever healthier.

User charges at Haneda Airport (HND) exceed even those at NRT, although the infrastructure is far from adequate. There are insufficient catering and cargo facilities, leading to additional costs for the airlines. In view of the envisaged increase in capacity at HND for international flights, the EBC urges the Government to earmark the necessary space to accommodate production/storage facilities for vital airline suppliers such as catering companies and cargo forwarders.

Meanwhile, a new terminal for low cost carriers (LCCs) has been opened at NRT airport. The EBC has yet to receive a transparent explanation of the cost structure for this terminal, but expects the complete cost to be borne by the LCCs. No cross subsidy should take place between existing terminals financed by incumbent airlines and the new terminal used by LCCs. This will be especially important as the share of LCCs among NRT users is anticipated to increase.

Healthy competition is a pre-requisite for establishing a functioning market driven by an economic rather than political rationale. The EBC greatly appreciates that the Government no longer requires carriers serving HND to maintain the same number of flights at NRT. We urge the Government to ensure that, in future, access to airports is provided on equal terms to all carriers. We also request that the Government carefully considers the competition implications of the government-supported bail-out and recapitalisation of Japan Airlines (JAL). Long-lasting tax breaks (9 years) and access to valuable slots at HND have 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. We urge the Government to ensure that Japanese and European airlines can enjoy the same fair and level playing field.

Key FTA/EPA Issues

- **The EU and Japan should work together to ensure that neither European nor Japanese airlines are negatively affected in the case of a bail-out. Furthermore, if compensation is given to domestic companies, the same compensation should be given to Japanese or European airlines (whichever is applicable).**

Key Issues and Recommendations

■ Revitalisation of outbound tourism

Yearly status report: limited progress. Currently the Government is allocating substantial efforts and funds to promote Japan as a destination for foreign air travellers. However, the capacities envisaged for travel from Europe to Japan for the 2020 Olympics can only be provided if the volume of Japanese customers travelling to Europe is similarly increased. Overseas travel should be encouraged, particularly among the younger generation.

Recommendation:

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

■ High costs

Yearly status report: no progress. The revised NRT fee structure did not produce the expected substantial cost reduction for users – the lowering of landing fees was accompanied by increases in rental and baggage handling system costs. Meanwhile, NRT has announced discounts to airlines serving the airport for the first time or increasing capacity. This approach will disadvantage incumbent carriers, which have for years paid high prices. If NRT is to remain competitive with other hubs in Asia, substantial reductions in airport costs are necessary.

Recommendations:

- Fees should be lowered drastically if Japan is to become a true tourist destination in Asia.
- The competent authorities should ensure that no differentiation is made between new and incumbent airlines, and that the announced lower fee for LCCs is not subsidised by mainline carriers.
- The Government should share cost savings resulting from abolition of perimeter security control at NRT with the airlines that hitherto covered this cost through the airport fee. The cost for the planned installation and maintaining of body scanners should be borne by the Government.
- The Government should abolish Airport Development Special Accounts to pave the way for lowering fees.
- While the EBC supports the privatisation of Japanese airports, there is a risk that unrealistically high bids, if accepted, lead to higher fees for airport users, as the winning consortium seeks to recover its costs - as has happened in Osaka. A more successful example is Sendai Airport's privatisation, which is on track for 2016.

■ Airport infrastructure

Yearly status report: limited progress. As of summer 2014, 30,000 new daytime slots had been assigned at HND for international routes.

Recommendations:

- HND should be fully opened up to all international traffic, including flights to/from Europe, on a non-discriminatory basis. More space for catering and cargo suppliers should be assigned to reduce additional costs for airport users. An increase in operating hours at NRT should be considered due to the much lower noise levels of modern airplanes and their reduced environmental impact.
- The unique and historic “early landing gear down” policy for NRT airport should be revised in cooperation with local communities to reduce noise levels and increase fuel efficiency.
- Immigration staff should be increased at international airports: current waiting times are not acceptable.
- Japan should introduce new efficient air corridors over Tokyo.

■ Competition issues – bail-outs and compensation

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 ensure that the long-term tax breaks and guaranteed loans enjoyed by Japan Airlines do not have a negative effect on competition.
- During the next round of slot allocations at HND, European airlines should be treated favourably in order to balance out the long lasting effects of the bailout on their market position.

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RAILWAYS

Introduction

Japan, being an island nation, is not connected to neighboring countries by rail. The EBC Railways Committee believes that the industry of a country will prosper if air, sea and land transportation are available without limitation to reach neighboring countries directly. In Europe, for example, the island nation of the U.K. is connected to France via a tunnel. Between France and Germany, the TGV and ICE mutually operate just as the airline companies do. In Istanbul, Turkey, railways link Asia and Europe under the Bosphorus, which were built by the Marmaray Project. Connecting Japan to neighboring countries by rail is indispensable for Japan to become truly international. This view of the EBC Railways Committee was expressed in the 2014 EBC White Paper and remains unchanged in 2015.

The Space Elevator, a concept aimed at connecting a structure in space to the surface of the earth with an elevator, has been under consideration for many years. Railway technology, which has a long history of development, has the potential to contribute to such space development in the future. The EBC Railways Committee has a vision that by the time a space elevator comes into practical use, railway infrastructure connecting Japan with Russia and Japan with Korea will also have been realised by railway manufacturers, thus revolutionising global transport.

More than four years have passed since the Tohoku Earthquake, yet many railways remain damaged. Some communities are planning provisional restoration with Bus Rapid Transit (BRT), while others are still undecided on how to restore the railways. 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 in place of BRT. The development of LRTs would definitely contribute to the well-being of people in an ageing and depopulated society. It would also revitalise commerce in the region.

The total value of rolling stock produced in Japan in 2014 was 175 billion yen, down 11.4% from the previous year. The figure includes new production, remodeling and repairs. In comparison, the value of rolling stock imported from abroad was very low, amounting to only 7.5 billion yen. The value of railway-related parts production in Japan in 2014 was 279 billion yen, up 10.5% from last year, whereas the value of imported parts was just 17.7 billion yen. The EBC still considers 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 FTA/EPA negotiations and the progress achieved to date. The EBC does not understand why the Government believes that safety concerns can be grounds for not using public calls for tenders as the Government and the operators would still be allowed to set their own safety-related standards. We urge Japan to recognise that the EU and Japan have comparable safety standards and to agree on elimination of the Operational Safety Clause (OSC).

Key FTA/EPA Issues

- **Japan should recognise European approvals and test results.**
- **Japan should remove the operation safety clause.**
- **The Government of Japan should make certain that public procurement is carried out in accordance with the World Trade Organisation (WTO) Agreement on Government Procurement.**

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 healthcare 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 the SVC’s scope, many products are still not covered.

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 Long-Term Evolution (LTE) introduction, smartphone penetration is already about 50% and is driving mobile broadband growth and a projected traffic usage of 10 GB/month per user in 2020. The country is shifting 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 associated traffic growth, Japan created an action plan and strategy in 2014 with the aim of securing 2700-MHz worth of bandwidth in total for mobile and Wireless Local Area Network (WLAN) communications by 2020.

Key FTA/EPA Issues

- Introduce true mutual recognition of product certifications so that EU approvals can be used on the Japanese market and vice versa
- Increase the scope of products that are covered by SVCs in Japan

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 in 2004 by the Government of Japan of SVC, 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.
- The application of SVC should be expanded to all equipment in the category of "Specified Radio Equipment".

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

Yearly status report: some progress. The EBC acknowledges that the Government of Japan has been active in trying to identify a globally harmonised spectrum for International Mobile Telecommunications (IMT) systems. This approach would bring enormous benefits to the industry and consumers by eliminating the need to develop local variations of new telecommunications equipment. The EBC is pleased that MIC has awarded the band between 3,480 and 3,600 MHz to IMT-Advanced systems in accordance with the 2014 harmonised frequency plan and that the Ministry is working to ensure harmonised spectrum on the 1,700 MHz and 2,300 MHz bands in order to address the increasing demand for mobile broadband.

Recommendations:

- The Government of Japan should work jointly with other governments to achieve a globally harmonised spectrum allocation for IMT systems on the bands of, for example, 700 MHz, 1,700 MHz, 2,300 MHz and 3,400-3,600 MHz. For the 2,300 MHz band, consideration should be given to the concept of licensed shared access to the spectrum for incumbent and prospective licensees, noting that the exclusive use of spectrum is prioritised as it can ensure Quality of Service (QoS) to end-users.
- The Government of Japan should engage actively in relation to agenda item 1.1 of the World Radio Communication Conference in 2015, in order to identify new harmonised spectrum for IMT systems.
- The Government of Japan should participate actively in the World Radio Communication Conference in 2015 to establish a new agenda item of studying and identifying new harmonised spectrum for IMT to facilitate the deployment of 5G systems.

■ JFTC Guidelines on IPR and Competition Law

Yearly status report: new issue. In July 2015, the Japan Fair Trade Commission (JFTC) issued a draft update of its "Guidelines for the Use of Intellectual Property under the Antimonopoly Act". The document introduces changes that could be used to significantly reduce the value of cutting-edge proprietary technology used in open standards such as LTE and 5G. Consequently, such changes may reduce incentives to invest in R&D and to add innovative technology to open standards.

Recommendations:

- Japan should carefully consider any such change in order to address both hold-out and hold-up scenarios in a balanced manner.
- The Government of Japan should consider these issues through a broad inter-agency approach to ensure full consideration of all potential ramifications, including the potential effect on 5G.

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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 these problems, which are worsening every year.

Japan has nine separate customs areas and no central customs authority. A company is only allowed to lodge customs declarations at a clearance operation physically located within the jurisdiction of the responsible customs office. This makes it difficult for foreign logistics companies that lack multiple regional offices in Japan to expand their geographical coverage. Within the Tokyo region there are two customs areas: Tokyo, including Narita and Baraki, and Yokohama, responsible for the rest of the region. It is against this background that the EBC welcomed various proposals tabled by the Ministry of Finance (MoF) on improved flexibility. Real change, however, is not scheduled until 2017 when amendments to the NACCS (Nippon Automated Cargo and Port Consolidated System) will be implemented.

Japan Post, 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 removing “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. 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 FTA/EPA Issues

- **Ensure a level playing field between Japan Post and private express delivery companies**
- **Ensure that the Japanese maritime related legislation does not discriminate between foreign and domestic companies**

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 the proposals from the MoF to liberalise customs and introduce further improvements.

Recommendations:

The Government of Japan should:

- Commit to implementing the proposed policy on customs jurisdictions.
- 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.
- Create a single customs area, or as a second best option, merge the Tokyo and Yokohama ports, and also the 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 through the NACCS system when the goods they contain exceed 201,000 yen in value, while private sector operators are required to declare all packages through NACCS (as de minimis up to 10,000 yen and Low Value Dutiable up to 201,999 yen). 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, may be checked in postal facilities, whereas such packages transported by private sector operators must be inspected at the first port of entry (usually an airport).

Recommendations:

- The Government of Japan should ensure a level playing field by (1) applying the same NACCS declaration method 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 transport all shipments directly to their off-airport bonded warehouses in the first instance, and ideally allow inspections of quarantine-related goods in those facilities.

■ Authorised Economic Operator (AEO)

Yearly status report: some progress. The current system of AEO has not led to the simplifications hoped for. On the contrary, in many cases the administrative burden has increased. The EBC seeks a system giving companies a simplified process and extended powers to handle matters without involvement of the authorities in every single case, provided operators can demonstrate sufficient control over the flow, and that traceability is ensured.

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 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;
 - ◇ Allowing the use of digital archives

■ 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 to 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.
- Japan should remedy the problem of fixed operating hours of the ports, which today are limiting.
- The Government of Japan should remedy the situation with congested traffic in and around the port of Oi. Without prompt action the situation will probably worsen with the Olympics in 2020.

■ 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

As with human medicines, the Japanese animal health market is highly regulated. Marketing Authorisations (MAs) for veterinary medicinal products (VMPs) are granted by the Japanese Ministry of Agriculture, Forestry and Fisheries (MAFF) and each associated registration dossier is reviewed by the National Veterinary Assay Laboratory (NVAL). Moreover, for any 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. According to Fuji Keizai, a market research company, the Japanese animal health market, including not only VMPs but also pet foods sold via the veterinary clinic channel, was worth 104.9 billion Japanese yen on the basis of ex-wholesalers in 2014. The market had declined slightly at the compound annual growth rate of -0.1% for 2010-2014. More than 60 companies manufacture VMPs to supply to customers in Japan. Foreign multinational animal health companies account for almost half of the market and their share is steadily increasing due to due to continuous investment in innovative veterinary pharmaceuticals and in biological development. In the last two decades, the majority of Japanese human pharmaceutical companies have divested their animal health divisions, selling them to foreign multinational animal health companies. Meanwhile, nearly all Japanese animal health companies have focused on the domestic market, with only minor levels of exports. Foreign multinational companies are the main source of innovative veterinary pharmaceutical products containing new chemical entities, while domestic companies tend to be reactive and to specialise in developing generics featuring unique formulation innovations. However, when it comes to veterinary biological products, domestic companies are still competitive, both in terms of innovation and commercial excellence, even though Japanese vaccines are seldom sold overseas. The Consortium of Japanese Veterinary Medicinal Products Manufacturers (CJVM) was established by eleven domestic animal health companies in order to reach out to the Asian markets in particular.

Japan's participation in the Trans-Pacific Partnership (TPP) will require the elimination or reduction of tariffs for animal agricultural products, such as pork and beef, which poses a threat to the economic viability of local livestock producers. To ensure the sustainability of the livestock sectors in Japan, prompt access to innovative VMPs at competitive costs is critical. Japan belongs to the trilateral (EU-Japan-USA) programme of VICH (International Cooperation on Harmonization of Technical Requirements for Registration of VMPs), a veterinary equivalent of the International Conference on Harmonisation (ICH) for human medicines. VICH aims to harmonise registration requirements for VMPs at the global level and this has to some extent helped reduce registration costs for globally developed products. There are, however, still some requirements that are unique to Japan and that often prevent or delay access to innovative and useful VMPs for animal owners, veterinarians and other consumers. In the case of biological products, some of the specification items are unique to Japan, including the requirement for a serological potency test on live vaccines. As a result, 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 (GLP) or Good Clinical Practice (GCP) are accepted by MAFF for inclusion in the registration dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for VMPs. This means that overseas production facilities involved in the manufacture of VMPs (whether active pharmaceutical ingredients or final products), have to be accredited by MAFF, even if the EU authorities have approved their GMP status. This process involves a large amount of redundant administrative paperwork, despite MAFF having recently revised the regulations to issue accreditation licenses written in Japanese and English, a move welcomed by the animal health industry.

For the last few years, MAFF has been making a tremendous effort to implement measures to improve the predictability, quality and speed of the registration process. While significant improvements have been made, there are still delays in the review process for some product segments. Accordingly, customer access to innovative and cost-effective VMPs suffers relative to the speed at which counterparts overseas can make use of them. For example, the long review process applied to laboratory and field use permissions for Genetically Modified Organisms (GMO) in Japan is a cause of serious drug lag for innovative VMPs.

Key Issues and Recommendations

■ 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 in 2008, some animal vaccines no longer require a national assay for batch release. The EBC appreciates the on-going efforts made by MAFF to include eligible protozoa, fish and genetically engineered vaccines in the seed-lot system. However, some European vaccines cannot enjoy this benefit due to additional unique Japanese testing requirements, such as in-process testing that does not exist in the internationally recognised seed-lot system. The requirement for a serological potency test using target animals or laboratory animals on live vaccines produced in accordance with the seed-lot system is one such example. 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 additionally required, which raises not only animal welfare concerns but also leads to increased costs for customers.

Recommendations:

- The requirement for a serological potency test on live vaccines in the seed-lot system should be eliminated.
- The requirement for an Abnormal Toxicity Test on vaccines for dogs and cats should be eliminated.

■ MAFF/NVAL proposed action items

Yearly status report: progress. On December 3, 2012, MAFF and NVAL presented a list of ten action items for policy change, targeted as measures to improve market authorisation procedures, to the Japan Veterinary Products Association's committee on Technical Issues and Regulatory Affairs. By August 2015, seven out of the ten action items had been implemented, and the rest were undergoing a final review prior to implementation. The EBC particularly welcomes the current proposal by MAFF to shorten the overall review period for veterinary medicinal products for food-producing animals, by allowing MAFF, MHLW and FSC to conduct reviews in parallel to some extent.

Recommendation:

- Although, in the opinion of the EBC, the MAFF/NVAL 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 NVAL to consult closely with the animal health industry before any detailed policy change occurs to ensure harmonisation with similar policies in other major countries.

■ Post marketing surveillance

Yearly status report: new issue. The cost of regulatory maintenance for pioneer VMPs in Japan has increased when compared to that in the EU and US. As with human medicines, Japan requires veterinary pioneer products to undergo studies with the efficacy of GMP, GCP, GLP and safety tests not only at the point of initial market authorisation but also at the subsequent life cycle management stage (e.g. new indications, new species) under post marketing surveillance during the regulatory data protection period (i.e. not applicable to generics). For VMPs whose large-scale clinical trial fully complied with VICH GL9 (guideline 9) and for which market authorisation has been granted, reconfirmation of substantial effectiveness during the regulatory data protection period appears to be redundant, since sample size and endpoint(s) have already been statistically justified. However, this does not disregard the importance of pharmacovigilance, which has to be implemented compliantly, not only during the development phase but also beyond the regulatory data protection period.

Recommendation:

- For pioneer VMPs whose clinical trial complied with VICH GL9, post marketing surveillance during the regulatory data protection period should be waived.

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MEDICAL DIAGNOSTICS

Introduction

Healthcare in Japan is suffering as the social security system comes under increasing pressure from the effects of an ageing society, declining birth rate, and burgeoning national healthcare costs. To remedy this situation, the Japanese Government needs to initiate reforms to the way the system operates while also re-evaluating its purpose. The urgent need to enhance the quality of medical care and optimise medical costs calls for serious discussion on the value and contribution of medical diagnostics. It is crucial that both medical care providers and medical system operators are fully informed and engaged in this discussion.

Medical diagnostics is not a new subject. Since 2007, research papers have been published, and proposals and recommendations have been made at study sessions on medical diagnostics and at periodical 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). As a result, 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”. Although IVD fees then 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. Furthermore, category E3 qualification requirements for reimbursement have been revised, as long advocated by the EBC and other industry groups. 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.

The development of personalised treatment, which has attracted increased attention in Japan in recent years, depends not only on the development of a primary drug but also on the development of companion diagnostics to predict the effectiveness and side effects of that drug. Hence, it is essential that, from an early stage of drug development, concurrent efforts are made to develop effective companion diagnostics. Discussions are now underway on the development of companion diagnostics and an associated approval process, plus a reimbursement system linked to the relevant primary drug, as requested by industry organisations. The EBC believes a system should be set up promptly based on the results of these discussions.

Together with increasingly personalised treatment, clinical application of advanced technologies, such as next-generation sequencing, is rapidly advancing. A system to evaluate the accuracy and quality of tests made available with these emerging technologies is required. Against this background, streamlining and reform of the current medical system is essential for expanding personalised treatment, maintaining and improving the quality of medical diagnostics and medical care, and ensuring that clinical diagnostics continue to play their value-added role. Other major improvements needed to enhance the quality of medicine and deliver the latest medical care to patients include providing prompt access to new IVDs and basing reimbursement fees for IVDs on their latest clinical value.

The EBC Medical Diagnostics Committee continues to advocate the value of medical diagnostics in cooperation with the JPCLT and other IVD industry groups.

Key FTA/EPA Issues

- As far as possible, Japan should align the unique regulations that it applies to medical diagnostics with global rules. Alternatively, Japan should accept the results of IVD examinations conducted overseas.
- Create guidelines for diagnostic pharmaceuticals that use next-generation sequencing or other advanced technologies, to enable the introduction of these products to Japan.

Key Issues and Recommendations

■ Quick access to new IVDs

Yearly status report: progress. The Action Plan for Speedy Examination of IVDs, announced by MHLW in March 2014, confirmed the following actions:

1. Establishing a scheme to enhance the quality of 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:

- MHLW should set year-by-year milestones and concrete actions for the 5-year plan.
- MHLW should enhance the quality of examinations by enriching the examiner training system.
- 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.

■ Updating pharmaceutical regulations

Yearly status report: slight progress. When the Pharmaceuticals and Medical Equipment Law came into force in November 2014, the EBC took the opportunity to reaffirm its commitment to cooperating with the Government on the creation of workable rules and improvement of processes. We would like to deepen mutual understanding between examiners and applicants throughout the application and examination process, as well as promote further rationalisation and effectiveness to speed up examinations. The EBC Medical Diagnostics Committee, jointly with the Japan Association of Clinical Reagents Industries (JACRI) and the IVD Committee of The American Medical Devices and Diagnostics Manufacturers' Association (AMDD), presented specific proposals in a periodical opinion exchange meeting with the Pharmaceutical and Food Safety Bureau, MHLW, and the Pharmaceuticals and Medical Devices Agency (PMDA) to discuss pharmaceutical regulations (July 2015) and these are summarised below.

Recommendations:

- Japan should introduce adequate classification of clinical reagents using categories that reflect recent advances in inspection technology and diversified clinical needs, with clear-cut operational rules set for each category. The EBC proposes a new category called "Investigational Use Only" (provisional name) for reagents whose clinical validity is not yet confirmed but whose analytical adequacy is recognised. Once classified into this category, the relevant reagents could be officially approved and used in clinical practice.
- MHLW should set up a research system to promote and accelerate IVD development. Guidelines for conducting clinical performance tests taking into account the characteristics and risks of IVDs should be established to ensure fair and rapid tests.

■ Medical reimbursement

Yearly status report: slight progress. In the periodical meeting with the Economic Affairs Division of MHLW's Health Policy Bureau and the Medical Economics Division of MHLW's Health Insurance Bureau on medical reimbursement, the EBC presented the following recommendations jointly with JACRI and the AMDD IVD Committee (August 2015):

Recommendations:

- Introduce healthcare services to be assessed before the provision of insurance (the so-called 240-day rule for medical equipment).
- Establish a new process to determine whether stable supply of diagnostics products and services is possible or not by showing inspection fees before deciding on insurance coverage.
- Conduct a comprehensive study into an efficient and effective insurance coverage process for companion diagnostics.
- Provide an opportunity for the EBC to participate in the discussion on insured medical treatment at the meeting of the Central Social Insurance Medical Council (*Chuikyo*) to present the expert opinion of European industry.

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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 2014/2015 fiscal year, the national cost of medical care reached 40.0 trillion yen, up by 0.7 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, as far as possible, extends 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 achieve this goal, creating opportunities for patients to enjoy a substantially higher quality of life for longer, and so also reducing total expenditure on medical care over time.

Innovative European medical equipment, materials and services can help Japan to meet its healthcare challenges. In particular, effective accident and emergency care, telemedicine and nursing care using IT medical technology should be introduced as soon as possible. In order to achieve swift introduction, Japanese regulations and processes need to be aligned with international standards and the predictability of the reimbursement system must be improved. Moreover, information on the Japanese medical care system should be provided internationally in multiple languages to encourage more European businesses to participate in the Japanese market.

Japan has already made positive progress in some areas. Since 2014, these include:

- Enforcement of the Law on Quality, Effectiveness and Safety of Pharmaceuticals and Medical Equipment in November 2014.
- Establishment of various plans and measures to develop the medical equipment industry. Thanks to the action plans implemented, the Government and industry can now exchange constructive opinions, resulting in the setting up and execution of concrete measures.
- Progress in international alignment; specifically official participation in the Medical Device Single Audit Program (MDSAP) Pilot and introduction of regulatory science initiatives.
- Improvement in the speed of the approval and examination process.
- Issuance of a notification and relevant action in respect of PSE (the Electrical Appliance and Material Safety Law) for medical equipment.
- Engagement of European businesses in processes for the consideration and setting up of medical care industry-related measures by the Government.

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

Key FTA/EPA Issues

- Shorten the time required for medical equipment examination
- Harmonise clinical evaluations in Japan with ISO14155
- Aim for mutual approval and international alignment of the Quality Management System (QMS)
- Treat software programmes as medical equipment and align with global standards
- Ease requirements for obtaining a construction business licence

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

Key Issues and Recommendations

■ Speedier medical equipment examination

Yearly status report: some progress. The major theme in the Government's new 5-year plan is enhancement of the technical expertise of applicants and examiners, which should speed up the examination process.

Recommendation:

- Cooperation between Government and industry should be increased to enhance the predictability of approval times and technical expertise of PMDA examiners and applicants, thus speeding up the examination process.

■ Clinical evaluation

Yearly status report: progress. Alignment of Japan's GCP (Good Clinical Practice) with ISO14155 is advancing.

Recommendations:

- MHLW should publish guidelines for creating clinical evaluation reports as soon as possible.
- MHLW should clarify the standard for deciding whether or not clinical trials are needed.

■ Mutual approval and alignment of QMS

Yearly status report: progress. As a result of the new QMS (Quality Management System) Law, rationalisation of QMS has begun. Although some problems remain, the EBC expects that progress will be made toward the final goal of globalisation of standards, through close cooperation between Government and industry.

Recommendations:

- MHLW should reconfirm the role of the periodical survey by item, and rationalize the QMS investigation prescribed in Chapter 3, Production and Marketing of the QMS ministerial ordinance.
- MHLW should disseminate the QMS ordinance (content and methods) in English with the MDSAP rationalisation in mind.

■ Reimbursement prices

Yearly status report: no progress. A review of the reimbursement scheme is needed to improve predictability and increase incentives for businesses to develop and market new products and ensure stable supplies.

Recommendations:

- Japan should not introduce yearly revisions of reimbursement prices.
- The Government should carefully evaluate the cost effectiveness of its intended introduction of the Health Technology Assessment (HTA) system.
- The Government should make provision for a more detailed division of functions into subcategories, introduce multiple prices for medical materials in the same category, and abolish the repricing system.
- Japan should ensure the predictability of C2 applications, and disclose the prices of other applicants. We also recommend a new medical reimbursement system for assessing innovation and safety management.
- The Government should appropriately evaluate improvements made to home medical equipment and expand the range covered by the "twice every 2 months" materials price-adding system.

■ Construction licence

Yearly status report: no progress. Currently, under Japanese law, a company selling medical equipment requiring the construction of facilities to house that equipment must have a construction business licence. This is true even when outsourcing the construction.

Recommendation:

- Requirements for obtaining a construction business licence should be eased in these circumstances.

■ Improvement of environment for IT medicine

Yearly status report: new issue. The regulations on IT medicine have so far not kept up with technical advances.

Recommendation:

- Set up rules for telemedicine, home healthcare, and utilisation of medical information; improve infrastructure; and introduce a reimbursement scheme designed to promote IT medicine.

PHARMACEUTICALS

Introduction

Although overall healthcare costs in Japan are rising as the population ages, pharmaceutical spending is already well controlled. Increased use of generics is creating the financial headroom to continue to fund the pro-innovation parts of the system.

Japan's total spending on healthcare in the 2014/15 fiscal year increased 1.8% on the previous year, rising by 0.7 trillion yen to 40.0 trillion yen. It accounted for 10.3% of GDP, exceeding the OECD average of 9.3%. Yet, despite the recent increase in overall healthcare spending, a study by EFPIA Japan forecasts that the Japanese pharmaceutical market will be broadly flat over the next decade, growing at an average annual rate of 0.13% to 2025. The current pricing system for pharmaceuticals in Japan and measures such as the encouragement of greater generic prescribing are expected to continue to prove sufficient in controlling the drugs bill. Furthermore, the new target for generic penetration of 80% by 2020 will provide even greater savings to the Government.

An innovation premium known as the "premium to promote the development of new drugs and eliminate off-label use" was launched formally on a trial basis in 2010 to promote the development of new drugs in Japan. In both 2012 and 2014, the premium was extended for further two-year trial periods. According to a survey of EFPIA member companies, the effect of the introduction of the premium has been a sharp increase in the number of new drug development projects in Japan – precisely the desired result.

The level of consumption tax in Japan is expected to rise from 8% to 10% in 2017, and there is talk of an additional market survey and drug repricing exercise taking place at the same time ("additional" to the scheduled 2016 and 2018 exercises). The idea of adopting annual repricing exercises is not new. However, EFPIA would caution that additional repricing exercises would lead to negative growth in the overall pharmaceutical market, thereby contradicting the Government's designation of healthcare as a strategic growth industry and reducing the incentive to invest in Japan from overseas. Great care is needed to avoid such an unintended but chilling effect. Already, drugs that significantly exceed the sales forecasts made at the time of their launch are liable to subsequent downward price revisions, acting as a penalty for success and a disincentive for innovation.

Furthermore, for the first 12 months after a drug is launched, it can only be prescribed for a maximum of 14 days, after which a further prescription is required. In effect, this means that in many cases, physicians will not prescribe a drug until the product has been on the market for at least a year. Given that Japan already has adequate safety measures, such as the Drug Risk Management Plan introduced in 2013, this 14-day rule is outdated and acts only as a barrier, preventing patients from accessing the treatments they need.

The Government has indicated that a form of cost-effectiveness health technology assessment (HTA) will be introduced in Japan from April 2016 on a trial basis. Unfortunately, the European experience shows that HTA can become yet another barrier preventing patient access to medicines and can create a major administrative burden for government and industry. EFPIA hopes that Japan learns from this experience.

Japanese Good Clinical Practice (GCP) in clinical trials is now steadily aligning with global standards, although action is still needed to reduce differences between Japanese medical institutions in the efficiency of the clinical trials they conduct. 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 Japan Member Companies

Abbott Japan	Ipsen Pharma Japan
Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Baxalta	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
Guerbet Japan	

Key Issues and Recommendations

■ Pricing system

Yearly status report: some progress. Japan currently enjoys a pro-innovation environment for new medicines, as a result of measures such as the 2010 launch of the innovation premium. However, there still exist some barriers to innovation that deter investment.

Recommendations:

- The innovation premium, which provides appropriate reward for innovative new medicines, needs to be continued. With international competition intensifying, the premium is necessary to ensure continued investment in Japan and the early delivery of new medicines to Japanese patients.
- There should be no price survey and no full repricing of pharmaceuticals at the time of the increase in the consumption tax from 8% to 10% in 2017. Any change should be restricted to a simple readjustment of prices, to account for the new tax rate. Price revisions once every two years should be continued in order to maintain consistency with the medical fee system.
- The 14-day rule should be abolished or revised. The safety environment has changed substantially since the introduction of the rule many years ago, and it serves now only as a barrier preventing patient access to drugs.
- The market expansion rule should be abolished as this penalises success and acts as a disincentive towards investment in innovation. In particular, products whose prices were set using the comparator method should be made exempt from this rule as a matter of priority.

■ Cost-Effectiveness Health Technology Assessment (HTA)

Yearly status report: some progress. Some form of cost-effectiveness health technology assessment (HTA) will be introduced in Japan from April 2016 on a trial basis.

Recommendations:

EFPIA published its views on HTA in July 2015, recommending that the Government should:

- Involve all stakeholders in meaningful discussions at all stages of the process;
- Set priorities for the initial trial introduction of HTA;
- Focus on achieving better outcomes, not solely on costs;
- Ensure no negative impact on patient access to pharmaceuticals nor on the physician's freedom to prescribe;
- Reward innovation and minimise the burden for both Government and industry.

■ International harmonisation (clinical trial environment / MRA)

Yearly status report: some progress. There is scope to improve the efficiency of clinical trials in Japan. In addition, limitations in the GMP mutual recognition agreement between the EU and Japan have led to an increase in delays and costs due to duplication of inspections and tests.

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 GMP should be extended to cover all 28 EU Member States and expanded to include non-solid oral preparations. This will eliminate duplicate inspections and examinations and hence reduce costs.

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VACCINES

Introduction

The constant battle against infectious diseases has in recent years focused on the H5N1 and H7N9 avian influenza outbreaks, mainly in mainland China; the Ebola epidemic in West Africa; cases of dengue fever in Japan in 2014; and most recently outbreaks of Middle East Respiratory Syndrome (MERS) in South Korea in 2015. Development of vaccines for these emerging infectious diseases is a global priority.

In Japan, access to vaccines has improved rapidly over the past few years after the sequential introduction of several new vaccines. In 2014, the meningococcal vaccine was approved, followed by the inclusion of varicella vaccine and adult pneumococcal vaccine in routine immunisation (i.e. the suite of vaccines strongly recommended by the Government and, in general, publicly funded). General improvements have been made in influenza vaccines, with those produced from 2015 onwards changing from the trivalent to the quadrivalent form, where one more antigen from the B-type strain is added. The question of including the mumps, hepatitis B and rotavirus vaccines in Japan's routine immunisation is also currently being discussed, giving hope of further improvement in the situation.

Hence, although the “vaccine gap” in Japan remains, the picture has somewhat altered. In terms of the number of approved antigen types, Japan is catching up with Europe and the US, and the number of vaccines in Japan's routine immunisation has increased. However, some vaccines used overseas are still not available in Japan, primarily paediatric combination vaccines. These alleviate the congested immunisation schedule for infants, and include the combination of mumps, measles and rubella and the 5- or 6-in-1 combination vaccines, where hepatitis B and/or Hib vaccines are added to 4-in-1 DTaP-IPV (diphtheria, tetanus, pertussis and polio vaccine).

A further concern is the decision to suspend recommending human papillomavirus vaccination from June 2013 onwards. To “suspend recommendation, while keeping it in the routine immunisation” sends an ambiguous message to healthcare professionals and vaccine recipients, and is an extremely rare measure, unseen in other developed countries. It remains unclear when this suspension will end.

In addition, the process for including vaccines in the routine immunisation is not clear. The “Basic Plan Related to Vaccination” announced by the Ministry of Health, Labour and Welfare (MHLW) in March 2014 states that the Immunisation/Vaccine Subcommittee should act as an advisory board to the Government. This body began discussion of the methodology in 2015. However, because the policy on vaccines is not clearly defined it seems that decisions are still being made in a way that is scientifically difficult to justify. If unresolved this could be a major issue, negatively influencing the incentives for research and development for manufacturers both within and outside Japan. Part of the problem may be a shortage of experts involved in the vaccines area in Japan.

There remains scope to improve vaccination policies and eliminate unnecessary regulations in order to greater incentivise manufacturers both within and outside Japan to invest in the development and manufacture of better vaccines that will contribute to the well-being of the Japanese public.

Key FTA/EPA Issues

- **Expansion of target countries and inclusion of vaccines in the EU-Japan Mutual Recognition Agreement (MRA) and elimination of redundant quality testing. By doing so, time from import to distribution will shorten and allow faster supply of vaccines to users.**
- **Incorporation of WHO (World Health Organisation)-recommended vaccines into routine immunisation and promotion of development of combination vaccines**
 - **Inclusion of mumps, hepatitis B and rotavirus vaccines in the routine immunisation**
 - **Prompt introduction or development of combination vaccines not available in Japan**

Key Issues and Recommendations

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

Yearly status report: slight progress. Since the revision of the Immunisation Law on October 1, 2014 leading to inclusion of varicella and adult pneumococcal vaccines in routine immunisation, a recommendation has been made to include hepatitis B vaccine as well. This will likely be realised after fiscal 2016. The Immunisation Vaccine Subcommittee of the Health Science Council has positively discussed including the mumps and rotavirus vaccines in routine immunisation, and also proposed development of combination vaccines as an issue of high priority.

Recommendation:

- The remaining approved and WHO-recommended mumps, hepatitis B and rotavirus vaccines should be included in routine immunisation without further delay. In addition, combination vaccines that are not available in Japan should be promptly introduced or developed.

■ Eliminate the “Structural Vaccine Gap”

Yearly status report: new issue. At a time when effective vaccines from overseas are being introduced into Japan and the number of vaccines in routine immunisation is increasing, the relative inadequacy of vaccine policies in Japan is becoming increasingly apparent. The result is the emergence of a new vaccine gap. Examples include the long-term suspension of recommendations to use human papilloma virus vaccines, and the lack of clarity in the process for including vaccines in routine immunisation.

Recommendations:

- Short term: the routine immunisation process should be clarified, and an environment created where clear policy decisions can be made based on scientific evidence.
- Mid to long term: the number of vaccine experts in both the public and private sectors should be increased. EFPIA is willing to support this, for example by providing leading examples from the EU.

■ Expansion of target countries and scope of items in EU-Japan MRA, and elimination of redundant quality testing

Yearly status report: no progress. The Regulatory Strategy Initiative announced by MHLW on June 26, 2015 states that it will target the expansion of both the number of EU Member States as well as product categories covered by the EU-Japan MRA related to Good Medical Practice (GMP) inspection results. However, this is almost the same position as stated in the Cabinet decision on “Policies on Regulatory Reform”, dated July 10, 2012, and indicates no progress has been made for three years.

Recommendation:

- The MRA should be expanded to include biopharmaceuticals and vaccines, thereby reducing redundant quality testing items and accelerating time to import. Signing of individual MOUs (Memorandums of Understanding) could be another approach.

■ Integration of Minimum Requirements for Biological Products (MRBP) into the Japanese Pharmacopoeia (JP)

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. MHLW’s Regulatory Strategy Initiative of June 26, 2015 states: “Further promote harmonisation of JP, as well as to make progress on state-of-the-art quality assurance methods”. Nevertheless, the timing of any review of the MRBP, procedures for its revision and criteria for listing remain completely unclear.

Recommendation:

- Quality requirements of vaccines should be revised based on state-of-the-art science and technology, harmonised with other regions. The current MRBP should therefore be abolished, and its contents consolidated and integrated into the Japanese Pharmacopoeia.

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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).

Shipments of cosmetics in Japan totaled 1,487 billion yen in 2014. In the same year, Japan imported cosmetics valued at about 226 billion yen, 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 recognize 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, even though the same products are 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, where the product approval process deviates from international standards and practices as it does in Japan, there is a significant increase in the complexity of that process and associated cost. Increasing transparency, streamlining the approval process, and promoting greater regulatory harmonisation with the EU would make allow more high-value-added products to reach Japanese consumers in a timely manner.

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 is an important vehicle for this process. The EBC 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 to minimise barriers to trade, while maintaining the highest level of global consumer protection.

Key FTA/EPA Issues

- **Harmonise quasi-drugs and cosmetics ingredients. Specifically, 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.**
- **In addition to abolishing import notification as planned, MHLW should also accept electronic customs clearance procedures.**

Key Issues and Recommendations

■ Reform of the quasi-drug approval system

Yearly status report: slight progress. In 2014, the Ministry of Health, Labour and Welfare (MHLW) released a ministerial notification called Examination Guidance on Medicated Shampoos and Conditioners. This improved the transparency of the quasi-drug review system. The notification was originally intended to speed up the review process, but unfortunately, there is no commitment in this notification to shorten the review period. In addition, the Pharmaceuticals and Medical Devices Agency (PMDA) collected information from businesses on raw material specifications of already approved excipients and published a book entitled, “Standards of Excipients for Quasi-drugs” in 2014. However, the information obtained from businesses was sparse and the book covers only a very limited number of raw materials.

Recommendations:

- MHLW should create review guidance covering all quasi-drugs and eventually use it as an approval standard to shorten the review period for those items that are believed to be identical to already approved quasi-drugs.
- MHLW should consider the introduction of a master file system for ingredients used in quasi-drugs in order to improve the transparency of the quasi-drug review system while protecting proprietary information on the ingredients (intellectual property) of the respective companies.
- 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.

■ Harmonisation of quasi-drug & cosmetic ingredients

Yearly status report: slight progress. The EU and Japan maintain different rules governing which ingredients are allowed in cosmetics, expressed respectively in terms of negative and positive lists. 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 allowed in Europe. Mouthwash with fluoride concentrations of 226 ppm is sold at drugstores and supermarkets throughout Europe and the United States. In 2015, Japan approved the use of fluoride in mouthwash for general consumption, but only as a drug requiring guidance.

Recommendations:

- MHLW should resolve the inconsistency between Japan and the EU in the maintenance of positive and negative lists for all quasi-drug and cosmetic ingredients.
- MHLW should revise the medicated dentifrice approval standard by raising the upper limit of fluoride concentration allowed in medicated toothpaste (a quasi-drug), and allow the use of fluoride in mouthwash and liquid toothpaste (quasi-drugs) at an early date.

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

Yearly status report: no progress. Self-medication is the selection and use of medicines by individuals to treat recognized illnesses or symptoms. It includes products sold as quasi-drugs. If more people were to visit general practitioner doctors and pharmacists for advice and use Over-The-Counter (OTC) and quasi-drugs to manage minor health problems, 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, pharmacists and medical institutions.

■ Expansion of efficacy claims for cosmetics and quasi-drugs

Yearly status report: no progress. Fifty-five 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 that of the EU.
- To align with the EU regulations, the MHLW should abolish the efficacy claim list and allow companies to communicate product efficacy within the definition of cosmetics based on verifiable data.

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

Yearly status report: great progress. The MHLW announced the abolishment of import notifications effective from 2016. This will significantly simplify import procedures. However, during customs clearance, paper-form submission of the Notification on Manufacture and Sale of Cosmetics and other documents may be required, and it is highly possible that the currently available electronic NACCS procedures will no longer be used.

The MHLW also eased the rules of the Partial Change Approval for prescription drugs and it is now possible to sell both the old and the new changed product during a 6-month-period (grace period). This enables the applicant to confidently perform product stock control, procure materials related to product marking, and change the quality control operation as required.

Recommendations:

- In addition to abolishing import notification as planned, MHLW should also accept electronic customs clearance procedures.
- MHLW should expand the revision of the rules on Partial Change Approvals to cover quasi-drugs as well.

■ Electronic notification of cosmetics and quasi-drugs

Yearly status report: no progress. In many other countries, the Government and businesses have jointly established and operate an online electronic notification system. In Japan, with the exception of import notifications, notifications and applications are submitted using floppy discs and paper documents.

Recommendation:

- An online notification and application system should be established for issuing Notifications on Manufacture and Sale of Cosmetics and Application for Approval of Quasi-drugs. This system should also be accepted in customs clearance procedures.

■ Establishment 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 MHLW guidance on replacing the skin sensitisation test took effect in May 2013, corresponding to Organization for Economic Co-operation and Development (OECD) guidelines 442A and 442B. Further, the MHLW guidance on replacing the eye irritation test with the bovine corneal opacity and permeability test (BCOP) came into effect in February 2014. In Europe, the human cell line activation test (h-CLAT), which is validated by the European Centre for the Validation of Alternative Methods (ECVAM), is recommended in the OECD test guideline. In Japan, this is still at the stage of third-party evaluation.

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 accelerate 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 2014, at 276 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.

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 display of producer 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. The EBC urges the Japanese Government to take more proactive measures to protect the health and safety of Japanese consumers. 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 FTA/EPA Issues

- Japan should permanently and swiftly eliminate tariffs on all liquor related products.
- Japan should recognise European GIs without further need for an application process.
- Japan should swiftly approve additives that are in common use among other industrialised countries.
- 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.

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 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, first requested by the EU, US and Australia in 2002, have now been approved is therefore particularly welcome. Meanwhile, Japan still accepts only a limited number of scientific evaluations made by international bodies such as JECFA (the 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 costly. The issues surrounding food enzymes are more or less the same as for food additives.

Another key non-tariff barrier 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. Moreover, 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.

The EBC is very keen to work closely with all relevant 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. Under the EU-Japan FTA/EPA, tariffs should be abolished, standards harmonised and the market authorisations of both regions mutually recognised. The EBC Food & Agriculture Committee firmly believes this can be achieved without compromising food safety. Furthermore, it 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.

Key FTA/EPA Issues

- **Tariffs including quotas and tariff quotas**
 - All products of interest to European companies, even if sensitive, should be included in the negotiations
 - Dismantling periods should be as short as possible
 - Any tariff quota system should be easy to use
- **Additives and enzymes**
 - Japan should approve additives and enzymes that are recognised internationally
 - The approval system in Japan should be swifter and more transparent
 - Legally binding deadlines for each part of the approval process should be introduced

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

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 simplified.

■ 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 lacking any deadlines, difficulties in determining exactly what supporting documents are required, and an overall lack of transparency. Both foreign and domestic companies would benefit from a system where each step of the approval process has clear deadlines set out in legislation to be followed by the authorities.

Recommendations:

- The Ministry of Health, Labour and Welfare (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. However, 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 is used (for instance the MRL for deltamethrine in maize is 2 ppm, hence the MRL in maize starch-derived products would also be 2 ppm). In Japan, however, derived products that are not on the positive list have a default MRL of 0.01 ppm, even if the original product has a higher MRL (for instance the MRL of deltamethrine in maize is 0.05 ppm, but that in a maize starch-derived product not listed would 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 the 2013-2014 period, 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” - the same status as 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 in Japan of the so-called double standard approach, distinguishing between foods that support the growth of *L. monocytogenes* and foods that do not. It therefore warmly welcomed the introduction of this approach during the 2014-2015 period, and applauds the MHLW for taking action. There is, however, a need for further clarification and guidance on the administration and testing of products that can be susceptible to listeria, especially on how to deal with products that have permissible traces of listeria but do not support growth.

Recommendation:

- The competent authorities should clarify the specific documentation and testing that are needed for food products in regards to listeria.

■ Malt and quota management system

Yearly status report: new issue. Japan has a tariff quota system for brewing-malt to balance the demand from domestic beer manufacturers for cheap malt and the perceived need to protect domestic barley farmers and malt manufacturers. To make use of the quota, a company must manufacture beer or import malt exclusively for the use of a particular brewery. In addition, a company can only apply for the quota twice a year, meaning that any imports using the quota must be based on forecasts and not on actual short-term demand.

Recommendations:

- Japan should, as part of the FTA, abolish the tariff on malt so that the need for European suppliers to use the quota would cease.
- If this is not achieved, Japan should amend the system to allow importers to make use of the system throughout the year, and to be able to store the malt without the requirement for use in brewing at a specified brewery.

■ Cured meat and single needle injection requirement

Yearly status report: new issue. Meat can be cured in several ways. One method is to inject a saline solution into the meat using a needle. In Europe and in most other countries, this curing method uses multi-needle injection, where the meat is “stamped”. This approach is much more efficient and limits the time the meat is exposed. However, the approach is not allowed in Japan for meat that is unheated or for meat that will be consumed without further preparation: in such circumstances, only a single-needle method can be used. The EBC is not aware of any sanitary reasons for not approving multi-needle injections and, in contrast, considers the multi-needle process to be more sanitary as it is faster, thereby reducing the time of meat exposure before packing.

Recommendation:

- Japan should, without delay, allow multi-needle injections for cured unheated meat.

Industry

Automobiles

Automotive components

Aeronautics

Space

Defence & security

Construction

Materials

Energy

AUTOMOBILES

Introduction

The Japanese passenger car market has still not fully recovered from the impact on consumer spending of the increase in consumption tax from 5% to 8% from 1 April 2014. In the first seven months of 2015, passenger car sales were down 12% on the previous year. European automobile imports have however outperformed the market, rising by 1% up till the end of July. At 155,000 units in the first seven months of 2015, European imports took 6% of the domestic passenger car market.

Non-tariff measures continue to add to the cost of doing business for European importers of both passenger cars and commercial vehicles. The EBC Automobile Committee, therefore, welcomes the importance given to the elimination of non-tariff measures in the automobile sector in the EU-Japan FTA negotiations. Some progress has been made, but further efforts are needed so 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 areas of the Japanese type approval process covered by a UN Regulation where Japan does not accept a UN certificate as demonstrating compliance with Japan's national requirements. These include such key areas as the emission of pollutants, CO2 emissions and fuel consumption and noise.
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 some 40% 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 that undermine the competitiveness of imported cars with similar performance and pre-tax price.

The EBC Automobile Committee regrets that the Japanese government did not take advantage of the review of the taxation of automobiles that went into force in April this year to take further steps, as recommended by METI, to narrow the discrepancy between the level of taxation of *kei*-cars and compact cars. The Committee will continue to urge the Japanese government to remove this anomaly.

Key FTA/EPA Issues

- 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 the 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 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.
- Adopt and implement in step 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 with compact cars.

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 operation of the High-Pressure Gas Safety Act impedes the introduction into the Japanese market of imported vehicles using new environmentally friendly technologies, such as fuel cell and CNG (Compressed Natural Gas) vehicles.

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 gross 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. This trend is very much welcomed by the EBC.

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. 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. With the recent international mergers and other changes in the automotive components sector, the EBC believes that this trend will become even more amplified.

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. This reflects their lack of transparency and reluctance to consider new inputs, thus defying the global trend towards single platform development and volume production. 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 UN 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 for Japan to continue addressing such discrepancies and supports further regulatory harmonisation at the global level. In addition to the above-mentioned regulations, the EBC would also like to point out that Japan has not implemented UN 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) monitor this sector.

Key FTA/EPA Issues

- Continue to implement UN regulations

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 a highly 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 25 – 27 May, 2016 in Yokohama.

Recommendation:

- The EBC recommends 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 UN Regulations and Japanese regulations for tyres of commercial vehicles, which can lead to uncertainties about what is really allowed. The 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. With the US as its preferred 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 major Japanese 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 in recent years. 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.

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.

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.

■ Promoting the use of large aircraft at Haneda Airport

Yearly status report: limited progress. The Tokyo 2020 Olympics are less than five years away, and the number of foreign visitors to Japan is likely to exceed 20 million in that year, a target set by the Japanese Government. Accordingly, it is crucial for Haneda Airport, now the preferred airport in Tokyo, to accommodate the increase in traffic. The EBC welcomes the decision to allow Lufthansa to operate the 747-8i at Haneda, but the airlines should also be allowed to operate the A380. Such a decision will increase the number of passengers using Haneda without having to provide many additional landing and take-off slots. An added advantage is that the A380 has the lowest noise footprint among the new generation aircraft.

Recommendation:

- The EBC urges the Japanese authorities to engage potential A380 operators in a discussion on the use of Haneda by the A380 aircraft as soon as possible.

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SPACE

Introduction

After a decade of reforms, the Space Policy Commission and the Office of National Space Policy (ONSP) established in the Cabinet office set Japan's space policies across all ministries and agencies. A new "Basic Plan on Space Policy" was adopted in January 2015. Space is treated as an important industrial and commercial sector, and now officially as a national security asset. 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 industry is still mostly geared towards domestic government contracts.

The Ministry of Economy, Trade and Industry (METI) actively helps 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 basically excludes foreign manufacturers and service providers. In September this year, the Cabinet Office launched a joint government-industry task force on the export of space-related products.

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.

Direct bids in government tenders are 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 can play a broader role in cooperation. Arianespace and Mitsubishi Heavy Industries have made it possible for 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 a decade.

A new domestic space law planned for a Diet vote next year will 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 in 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 space-related administrative reforms as they have made the 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, technology, 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, what we can see is a growing risk of new protectionism.

Key Issues and Recommendations

■ General environment

Yearly status report: protectionist risk. The upcoming approval system for new satellite projects 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 next year’s domestic space law 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” for the purpose of excluding the participation of foreign industry.
- 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: status quo. 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: status quo. Although Europe and Japan almost simultaneously started the development of their respective next generation launchers, they have very little 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:

- Government satellite programmes increasingly require timely launches. The EBC urges Japan and Europe to bring about an 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.

In September 2015, Parliament passed legislation on re-interpretation of article 9 of the constitution. The legislation now allows 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. Under the legislation, weapons could also be used to carry out the task. Due to this change, strains will be placed on the Japanese Self-Defense 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.

The signing of a bilateral agreement for defence cooperation between UK and Japan took place in July 2013, and between France and Japan in March 2014. A similar agreement between Germany and Japan is now being finalised. The EBC is pleased by these developments and hopes the respective agreements can be put to use without delays. Throughout 2014, the Japanese government clearly indicated that Japan cannot afford to develop all the defence capability it desires through its own defence budget and expects the domestic defence industry to participate in international co-development projects, notably with European counterparts.

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 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.

Although in all of its communications, the Government of Japan has been positively in favour of cooperation with Europe in defence industrial projects, the EBC is extremely concerned by recent decisions taken by the Japanese Ministry of Defense. The first was elimination of the bid submitted by Kawasaki Heavy Industries and Airbus Helicopters in response to the call for tenders for the Ground Self Defense Force's UH-X helicopter. Even though KHI and Airbus Helicopters proposed a clean sheet co-development scheme for a new-generation helicopter for civil and military applications, the Ministry of Defence once again selected licenced production of an older-generation US-made helicopter. The second example was the Air Self Defense Force's Tanker tender, for which a decision was taken to not allow a fair price comparison between its A330-based multi-role tanker transport and similar offerings based on US products from rival firms. For this reason, Airbus Defense and Space announced its intention not to bid.

The EBC was very surprised by these decisions as they seem to indicate that in contradiction with the official communication, there has been no progress in opening the access of the Japan defence markets to European technologies or to partnerships with European companies.

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 and civil latest 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 fiscal stimulus implemented by Prime Minister Abe's Government shortly after winning the 2012 election has had a direct and significant impact on Japan's construction market. Previously, construction spending had peaked in 1992 at 82 trillion yen but then fallen away to an historical low in 2010 of just 41 trillion yen. The new fiscal stimulus so revived construction investment that, by April 2013, just four months after the election, spending had shot up to 48.7 trillion yen, a year-on-year increase of 10.2%. However, the corresponding figure for fiscal year 2014 dropped to 47.1 trillion yen and for 2015 is expected to be no more than 46.2 trillion.

The fact that 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 construction materials, leading to higher prices also plays a role. Moreover, 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 have found themselves unable to use their available budget to award reconstruction projects. As a result, in some instances procurement methods have been reconsidered. In August 2013, for the first time in Japan, a public construction contract was awarded under 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 issuing 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.

Ultimately, the key to unlocking new growth potential will be new regulations and technologies related to sustainability and energy efficiency. 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 industries are coming under close scrutiny. Energy remains a long-term challenge in the aftermath of the Tohoku earthquake and the Fukushima nuclear plant accident, resulting in an environment in which supplies are tight and more expensive. In response, authorities, businesses, and consumers have shown a renewed interest in sustainability and energy efficiency. Tighter regulation is now needed to drive change and yield measurable results.

Many regulatory initiatives are made at municipal level via the administrative guidance process. This places local authorities in a difficult position when required to make fair and technically informed decisions on compliance. In some cases, the local authorities make decisions without the knowledge necessary to interpret legislation correctly and sometimes without reference to international standards. This hampers the efforts of companies, both domestic and especially foreign, to keep track of all the relevant guidelines. Furthermore, much of the documentation is available only in Japanese, which reduces transparency and makes it difficult for foreign companies to recognise opportunities or ensure compliance, even when 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.

Key FTA/EPA issues

- **Harmonisation and mutual acceptance of building material standards 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**
- **Mutual acceptance of contractor qualifications**
- **Transparency and strict enforcement of rules for construction procurement**

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 complex procedures for obtaining mandatory approvals is needed so that innovative designs, technology, materials and methods, like those offered by European firms, can be more readily applied in Japan. Little progress has been made in aligning EU and Japanese 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. Improved insulation also reduces operating costs, thus increasing returns on investment. The energy efficiency of most Japanese buildings is far below international standards and best practices. Japan has introduced regulations requiring higher performance from new buildings, thus the natural next step is to improve the energy efficiency of the existing building stock. Long-term 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 an easy way to set a more ambitious target for cutting carbon emissions (the current target is to cut greenhouse gas emissions by just 26% by 2030). 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 (the 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, creating scope for unnecessary variation between authorities and uncertainty for potential suppliers. 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 who regulate the construction market should take appropriate action to rationalise the current patchwork of local regulations and support 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 put further strain on the already tight construction labour market. Under the Japan Revitalization Strategy, foreign trainees are now allowed to stay an extra 2 years in Japan (bringing the total to 5 years) and women are being encouraged to enter the work force.

Recommendation:

- Japan should continue efforts to increase women's participation in the labour market and liberalise 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.

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.

Key FTA/EPA Issues

- **Japan should remove all tariffs on industrial raw materials.**
- **The EU and Japan should work together to harmonise and mutually recognise the EU REACH and the Japanese Chemical Substance Control System.**

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.

Following the oil crisis of the 1970s, Japan set out to reduce its dependency on imports of gas, oil and coal through increased use of nuclear energy such that by 2010, nuclear energy accounted for 26% of the power generation energy mix. However, after the March 2011 Tohoku disaster and related Fukushima nuclear accident, all of Japan’s nuclear plants were shut down and a programme of safety reviews and upgrades was initiated, which is ongoing. The first reactor of Sendai 1 NPP has been back on grid since August 2015 and further reactors are expected to come on grid within the year. However, the largest plant, TEPCO’s Kashiwazaki-Kariwa nuclear plant is not expected to restart this year. Complete upgrades and reviews will require more time, so it will take until end 2016 for all the remaining nuclear power plants that are not being decommissioned to be completely restarted.

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 accident, 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 on the production sites, with the main transmission at 500 kV. Three convertor stations connect the 50 Hz and 60 Hz 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. 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 2015, METI approved a new energy mix target for 2030, meeting goals in terms of safety, energy security, economic efficiency and environment. The target mix consists of 20-22% Nuclear, 27% Liquid Natural Gas, 26% Coal, 8.8-9.2% Hydro and 13.4-14.4% Other Renewables. In July 2012, a new Feed-In Tariff scheme for renewable energy sources came into effect. Tariffs have been gradually reduced, but grid connections are overloaded and future development of renewables is difficult to assess.

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, however, on a reliable approach to all safety issues and clarification of how to deal with the issue of interim and final storage of spent fuel and other radioactive waste. It will 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, aimed at increasing the safety and reliability of energy supply.

■ Deregulation and unbundling

Yearly status update: some progress. The current regulatory situation fails to provide transparency and cost efficiency. Security of supply is also not guaranteed, given the limited interconnections between utility companies as well as between the 50 Hz and 60 Hz networks. The OCCTO (Organization for Cross-regional Coordination of Transmission Operators) was formed in April 2015 as a first step to addressing these issues. Subsequently, the Electricity Market Surveillance Commission (EMSC) was established under METI in September 2015 to monitor and regulate the market. The EBC is pleased to note that the bills covering “full retail competition” in 2016 and “legal unbundling of transmission & distribution sector” in 2020 have passed. The EBC believes that fair and transparent processes will enable healthy competition in the electricity market.

Recommendations:

- Japan should recognise legal unbundling is only a first step, which needs to be followed by separation of 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.
- Japan should strengthen the authority of the OCCTO and EMSC to deliver increased interconnection capacity between TDSOs (Transmission and Distribution System Operators) and fair electricity transactions.
- Japan should ensure electricity interconnections are developed both at a national and international level 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.
- Japan should introduce Micro-grids as an alternative solution to large nationwide interconnections as a “Grid-Mix”, to achieve resilience in the overall grid system.

■ 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 May 2015, ten electric power companies had applied to the NRA for safety evaluations of a total of 24 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 the 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.
- Develop complete interim and final waste repositories for spent fuel and radioactive waste, which remains 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, ranging from large transmission systems to 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 for re-classifying 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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