

# WITHIN REACH

*The EBC Report on the  
Japanese Business Environment*

2016



EUROPEAN BUSINESS COUNCIL IN JAPAN  
THE EUROPEAN (EU) CHAMBER OF COMMERCE IN JAPAN

Within Reach

The EBC Report on the Japanese Business Environment  
2016

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

## European Business Council in Japan 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 26 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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## Within Reach The EBC Report on the Japanese Business Environment 2016

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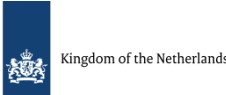
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# Messages





## *Message from the Chairman*

Welcome to “Within Reach”: the 2016 Report of the European Business Council in Japan (EBC).

Why “Within Reach?” Simply because, after nearly four years of negotiations, an EU-Japan Free Trade Agreement is finally looking not just theoretically possible, but genuinely achievable. The EBC has been calling for such an agreement for many years – ever since we realised that the traditional EU-Japan regulatory dialogue would never deliver even substantial reform, let alone the true potential of the trade relationship. The

lack of progress frustrated the efforts of European companies keen to grow and invest in Japan, to the detriment not only of those companies but also the Japanese market and the economy as a whole. We were not alone in wanting change: Japanese companies were also seeking solutions to the challenges they faced in their EU operations. Ultimately, neither Japan nor the EU could afford to pass up the economic boost that increased trade would bring – and so finally, in 2013, a decision was taken to launch negotiations towards an EU-Japan Free Trade Agreement.

Since then, there have been numerous meetings and rounds of negotiations. Yet even now, there is no guarantee that the negotiations will be successful. Significant hurdles remain across a range of issues highlighted in this report, and real determination is required to resolve them. We in the EBC are convinced that all issues on the table must be resolved to the satisfaction of both sides for a final agreement to deliver sustained benefits. We are also clear that an agreement that lacks such ambition, that lacks balance, will ultimately lack support. And we are realistic that the political momentum required to achieve consensus may not last forever. So we are urging the leaders of Japan and the European Union to focus now, before this crucial moment passes, on securing a truly comprehensive EU-Japan Free Trade Agreement.

At the same time, we are unrelenting in our quest for reform of the many issues that lie outside the scope of the Free Trade Agreement but nevertheless hold back business, domestic and foreign, in Japan. Such issues include a tax regime that too often discourages inward investment; a healthcare system that inflicts unpredictable price revisions on products vital to patient welfare; airport fees so excessive that they drive away business; labelling requirements of no consumer benefit that serve only to inflate costs; and labour legislation that still rewards long-service ahead of performance. The individual chapters of this report, written by the EBC’s expert Committees, give details of these and many other issues, and recommend changes that would set Japan on course for a more open, competitive and thriving economy. In many cases, the changes needed are straightforward and, with government support, easily implemented – so, once again, tantalisingly “Within Reach”.

The EBC has a strong commitment to Japan and the EU, and immense knowledge and experience of operating businesses in these and other markets. We stand ready to offer whatever further information and ideas we can to help the EU and Japan foster new levels of mutual trade and economic growth. As the EU-Japan FTA negotiations edge towards a conclusion, the benefits of a strong agreement - for business, for consumers, for the economy - are becoming clearer. Now is the time for the authorities on both sides to focus hard on those benefits and ensure they are achieved. So much trade, so much investment, so many jobs, so many companies depend on success. At last, it is “Within Reach” – don’t let it slip away!

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 “Within Reach”, its 2016 Report on the Japanese Business Environment.

Negotiations towards a Free Trade Agreement between the European Union and Japan have arrived at a crucial point: we understand that, while there are still numerous issues to be resolved, sufficient progress has been made for there to be a realistic prospect of success. This is excellent news for both the EU and Japan, whose economies stand to benefit from a significant boost in mutual trade and investment. It is also excellent news for companies. Here in Japan, European companies have for years wrestled with all manner of tariffs and measures that undermine their efforts to develop and grow: this agreement could finally remove many of them. Yet we remain cautious: there is still a risk of disappointment, of an agreement that fails to address key issues, or fails to balance the interests of both sides. Mindful of this, the EBC’s own expert Committees continue to work hard to support the negotiating process, providing detailed information on the barriers faced in each sector and area of business. Their top priorities for the negotiations are highlighted in the individual chapters of this report. It is essential that all these priorities are discussed and resolved to achieve an agreement that is truly comprehensive, ambitious – and a success.

At the same time, the EBC continues to urge the Japanese authorities to resolve the many important issues outside the scope of the FTA negotiations that hold back business development in Japan. Some of these issues are exclusive to foreign businesses operating here and illustrate their continuing struggle to achieve a fair and level playing field for all. Other issues are common to all business in Japan, domestic and foreign, and highlight the urgent need for regulatory reform to create a more globally integrated and competitive economy. The Committee chapters of this report give details of such issues alongside recommendations for how they should be resolved. We commend their proposals to all those committed to enabling the Japanese economy reach its full potential.

I would like to thank each of the EBC’s expert Committees for their valued contributions to this report and, indeed, to the work of the EBC. I would also like thank the EBC Policy Director, Bjorn Kongstad, for coordinating the inputs to this report and for providing a very helpful overview in his Introduction.

The EBC appreciates the support of our stakeholders, especially the European National Chambers of Commerce and other business organisations represented in Japan. We also thank the Delegation of the European Union to Japan and the European national embassies in Tokyo for their valuable insights and advice. Finally, we gratefully acknowledge all those EBC Members whose generosity has made this publication possible and who are listed in the sponsors and supporters sections of this report.

2016 has been another challenging year for business in Japan and the EBC remains committed to helping create an environment that fosters growth and long-term prosperity. This report highlights many of the key actions needed: if these are promptly and properly addressed, a brighter economic future is at last “Within Reach”.

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







# Introduction



## INTRODUCTION

Occasionally in life there is a moment when, after much hard work, the realisation dawns that a once distant goal is now within reach. It is a moment filled with optimism that success is near, and fear that a prize so evidently achievable could yet be lost. It is at precisely such a moment that this EBC Report on the Japanese Business Environment goes to press. Historic opportunities to boost the economy and enhance EU-Japan trade and investment are tantalisingly close to being realised, but could still so easily slip away. The EBC is in a unique position to understand what is at stake and has devoted this report to highlighting what must be done to make sure these opportunities, at last within reach, are finally and firmly grasped.

The first opportunity is the EU-Japan Free Trade Agreement / Economic Partnership Agreement (FTA/EPA). Many years of largely ineffectual Regulatory Reform Dialogue proved to both the EU and Japan that the huge untapped potential in their mutual trade relationship could only be realised through a properly negotiated and binding agreement. Work towards such an agreement was formally launched in April 2013, and now, some seventeen rounds of negotiations later, sufficient progress has been made to say that there is a real prospect of success. This prospect must not be squandered.

The FTA/EPA negotiations cover many crucial aspects of the EU-Japan trade relationship, including tariffs, non-tariff measures, services, investment, procurement, sanitary and phyto-sanitary measures, rules of origin, intellectual property and competition. As the EBC made clear from the beginning, any final agreement must be this comprehensive to achieve its economic potential and win the support of both sides. From an EU business perspective, we are therefore concerned that, as the final rounds of negotiations approach, every effort is made to ensure that the Agreement will deliver:

- Mutual recognition of standards, product certifications and marketing authorisations, and adoption of international standards - for example in terms of automobiles, household products, automotive components, medical diagnostics and telecommunications equipment.
- Removal of barriers, such as unnecessary costs and bureaucracy, that prevent or delay products from reaching the Japanese market – for example, tariffs on materials and foods, excessive regulation of imported vaccines, and Japan-only product labelling requirements.
- Fair competition and equal treatment of all companies in the Japanese market, domestic and foreign - for example, in the airline, express delivery and insurance sectors.
- Fair and open tenders for public contracts – for example, in Japan’s railway and construction sectors.
- Better conditions for Foreign Direct Investment (FDI) in Japan – for example, improvements in the tax treatment of R&D and in the rules for cross-border and triangular mergers.

This is not some fanciful wish-list drawn up by the EBC: it is a realistic assessment of what can and must be achieved if an EU-Japan FTA/EPA is to fulfil its potential in terms of higher levels of mutual trade and investment and much-needed growth in both the EU and Japanese economies. It is also the minimum necessary for an FTA/EPA to win the support of EU companies, whose efforts to grow in the Japanese market have for too long been thwarted by unnecessary and unreasonable barriers to trade. There are numerous examples of such barriers in this report, as well as concrete recommendations on how they should be addressed. We urge the authorities in both the EU and Japan to use the current momentum within the negotiations to seal an FTA/EPA that will lift these barriers and so bring a new level of prosperity within reach.



The second opportunity to boost the economy through enhanced trade and investment comes in the form of the Government's Growth Strategy, or so-called Abenomics. Having initially focused primarily on short-term fixes to keep the Japanese economy out of recession, through a combination of monetary policy and fiscal stimulus, last year the emphasis turned to structural reform, which offers the possibility of much longer-term improvements. Abenomics is now aiming to "boost productivity", "drive innovation and trade", and "energise corporate activities" through a range of measures that will, amongst others, enable Japan to maintain worldwide leadership in the technology industry, expand its healthcare market, reinforce tourism, promote quality infrastructure investment, strengthen investor confidence, attract more foreign companies, increase investment in energy and address global warming.

Among the various initiatives launched so far, the corporate tax rate has been reduced, making Japanese operations more internationally competitive; new Stewardship and Corporate Governance Codes have been introduced, encouraging more investment; measures to improve childcare benefits and provision have been developed, boosting female participation in the workforce; programmes have been created to increase inward tourism; and limitations on the recruitment of skilled professionals from overseas have been eased. These and other reforms should make Japan a more attractive location for foreign business and could help Japan to release its economic potential.

The EBC is concerned, however, that many reforms announced by the Government are undermined by other existing or even new policies that conflict with their aims. There is, as yet, almost no coordinated policy approach to ensure the reforms succeed. Among the many examples detailed in this report:

- Through various initiatives, the Government has highlighted the need for both increased FDI and the importance of attracting highly skilled workers. Despite these goals, Japan expanded the inheritance law to include both domestic and global assets of foreigners from the first day as a resident of Japan. This is clearly a disincentive for talented individuals to come to Japan, making it difficult for companies trying to secure the best possible human resources and impeding their efforts to invest.
- Long after its much-vaunted privatisation of Japan Post, the Government still retains a majority shareholding. As a result, the public continues to believe that the Government will underwrite the various Japan Post entities, giving them an unfair advantage in the market and so sapping the very competition the policy was meant to encourage.
- The Government is seeking to increase female participation in the workforce yet many metropolitan areas cannot provide adequate care facilities for children. The Government has furthermore also abandoned its target to fill 30% of all senior positions with women by 2020, and is now aiming for a mere 7% in the public sector and 15% in the private sector.
- Despite singling out Healthcare as a major growth industry for Japan, the Government persists in price reimbursements for medical equipment that are so unpredictable that they deter companies from developing or launching new products. Similarly, additional and irregular repricing exercises for pharmaceuticals are threatening to undermine growth in the overall market.
- Japan's Energy Policy is aimed at ensuring both a stable energy supply and environmental sustainability, yet the Government is failing to promote the development and use of renewables, such as wind and solar energy, which could contribute to both these goals.

- While the Government is keen to increase tourist travel to Japan, it is ignoring the problems airlines face at its main international airports, such as high fees and inadequate infrastructure, which undermine the development of profitable routes.
- Approvals for animal health products are still marred by long approval periods. Japan wants to limit the impact on the farm industry of both an increasing number of free trade agreements and an ongoing decline in the number of farmers, who are aging and not being replaced. Accordingly, the Government cannot afford to delay the introduction of innovative animal health products that could benefit farmers and make the agricultural sector more efficient.

All these factors are contributing to failure of the ambitious, fundamental structural reform component of Abenomics to materialise as promised. No doubt it faces resistance at times from the bureaucracy, vested interests, and a prevailing attitude of risk aversion. However, Prime Minister Abe is right now in a uniquely strong position to overcome this resistance. Abenomics has had some success in overcoming deflation and the economy is growing, if only slightly. The Coalition Government has a commanding majority in both houses of the Diet and enjoys high public approval ratings. There will not be a better time to push through reforms that are clearly needed and so nearly within reach. The EBC urges the Prime Minister and his Government to come together to seize this opportunity to transform the economic outlook of the nation for decades to come.

The EBC trusts that the ideas and recommendations in this report will prove 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.

### **How this report is organised**

Following this introduction, 29 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, the committees have also highlighted their top priorities for an EU-Japan FTA/EPA. The content of this report was compiled as of November, 2016.

# **Business**

# **Fundamentals**

**Human resources  
Intellectual property  
Legal services  
Retail & wholesale  
Tax**

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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. Given the low unemployment rate, already only limited sourcing is possible from within the group of active job seekers. Moreover, 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 workforce, increasing the birth rate and/or increasing the number of immigrants. The EBC believes that policies in all four areas are needed to secure a skilled and competitive workforce.

The EBC was pleased by initial signals that Prime Minister Abe's Government was considering new ways to increase the participation of women in the labour market: currently, although about 65% are active, the majority only work part-time. The Government's plan included an overhaul of the current income tax break given to tax payers whose spouses do not work or work only limited hours, to remove the incentive for spouses to work part-time. The Government also called on companies to employ more women and increase the number of women in executive positions. The initial target was to fill 30% of senior positions with women in both the government and private sectors by 2020, but this has been revised down to 7% for the public sector and 15% for the private sector. Furthermore, Prime Minister Abe has talked of improving support for working parents, which is clearly a step in the right direction, but requires concrete follow-up. The Government needs, for instance, to offer more public child-care centres and private child-minding services, and to support and encourage men to take child-care leave.

On a positive note, the EBC commends the Government and the Ministry of Justice for improving Japan's attractiveness to foreign professionals through a new system covering re-entry permits and the extension of visa periods. This new system is complemented by efforts to admit greater numbers of highly skilled workers. Together these measures will benefit individual companies and the economy as a whole. There are indications that the Government is contemplating introducing online visa applications, which would be a welcome step as the processes, including for extensions and changes of visa status, are currently very time-consuming. In addition, a Government committee on labour has suggested that Japan should accept more foreign manual workers, going beyond the current limitation to those engaged in "specialised and technical fields": a necessary step as some industries are in grave need of manual labour.

On the negative side, expansion of the inheritance tax to include all registered foreigners in Japan is reducing Japan's attractiveness from an employment perspective, thus making it more difficult for companies to bring talent to Japan.

Regarding pensions, Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees. 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 per year and this needs to change. Discussions on lowering the minimum period of premium payments required in order to receive a pension should 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 pension 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 also provides 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;
- Lower 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;
- Automatically grant work permits to spouse visa holders so that multinational companies can attract the best talent to postings in Japan;
- Extend the benefits, such as permission to sponsor a foreign maid or nanny, given to “highly skilled professions” to permanent residency holders.
- Look into the possibility of granting short-term work visas for manual labour.

### ■ Labour market regulations and diversity

*Yearly status report: some progress.* Japan’s future prosperity depends greatly on maintaining an adequate workforce that can support its ageing population and drive its economy. By far the easiest way to increase the working population would be to increase female participation. The EBC strongly urges the Japanese Government to place more focus on workplace diversity and to support and encourage more female participation in the workforce and more male participation in household and child-rearing activities.

#### **Recommendations:**

- Remove the spouse special income tax credit (*haigusha-tokubetsu-kojo*).
- 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 on 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. Nevertheless, online marketing and sales of their products in the form of allegedly authentic “parallel imports”, mingled with counterfeits of both their brands and also 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 91.1% of all fake goods flowing into the country.

In 2015, some 690,000 fake items were stopped at the border by Japan Customs. Given that it is impossible for Customs to examine all imported goods, this number is probably only a fraction of the total volume of fakes. As the purchase of counterfeits for “personal use” is not forbidden in Japan, some fake items cannot be stopped even if detected.

Until recently, many Japanese consumers purchased fake items knowingly. However, the main issue today is how to help them avoid fraudulent websites (most of them managed overseas), which deceive them either into buying counterfeits despite their wish to purchase the genuine brand, or into buying products that will never be delivered after payment. Public awareness of intellectual property rights (IPR) is rising, and IPR has become integrated in Japan’s consumer protection strategy. The Government is now studying the feasibility of blocking access to websites fraudulently selling counterfeits.

Relevant ministries and agencies are making considerable efforts to protect IPR. For example, from 2007 onwards, the Customs Bureau gradually eased the obligation for rights holders to visit Customs offices to check items suspected of being counterfeits, and this requirement was removed completely in 2013. The Consumer Affairs Agency has set up a Cross-Border Consumer Center to help consumers who have unwittingly purchased counterfeits. The Center publicises on its website the names of online stores selling counterfeit items. Moreover, the National Police Agency protects consumers by providing the global Anti-Phishing Working Group with information about websites selling counterfeit products so that alerts can be displayed in web browsers.

Major online retailers Yahoo!, Rakuten and DeNA are also playing an important role in combating counterfeits. Yahoo!, for example, is endeavouring to clean up 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 cleaning up 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. However, problems still remain. Specifically, partnerships with internet service providers (ISPs) need to be developed to build a proper system to protect consumers and control the sale of counterfeit items “for personal use”. The definition of “for personal use” needs to be tightened and made legally binding. This should solve the issue of increasing sales of counterfeits on internet flea markets.

### 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, where counterfeits may account for as much as 99% of the total merchandise being sold. Overall, initiatives against counterfeit sales websites, fraudulent websites and spoof websites are progressing far 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 or browsers, but these have not yielded fundamental solutions to the problem. Given that public awareness of the need to protect IPR and consumer interest are undoubtedly rising, now is the time to take bold and swift action to combat the sale of counterfeit products.

#### **Recommendations:**

- Japan's 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 postal mail 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 if they are for “personal use”, 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, because no concrete changes have been made to date.

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

1. A Study Group was set up under the auspices of the Ministry of Justice to discuss the *gaiben* system. With the increase in demand for international legal services, in 2015 this Study Group devoted six months each to (1) reviewing the requirement for foreign-qualified lawyers to have specific work experience in order to register as a *gaiben*, (2) reviewing the current limitation on *gaiben* and *bengoshi* (Japanese lawyers) establishing a *hojin* (corporation) together.

The EBC, together with the American Chamber of Commerce in Japan and the Gaiben Association, was invited to present its views on 1(1) and 1(2) mentioned above in May 2015 (the third Group session) and September 2015 (the sixth Group session), respectively. In July 2016, the Study Group, together with the *Nichibenren* (Japan Federation of Bar Associations), issued its report, which makes the following recommendations.

- The current three-year work experience requirement (two years of which must be experience gained outside Japan) should be changed to either (i) three years (one year of which must be experience gained outside Japan) or (ii) two years (one year of which must be experience gained outside Japan).
  - It should be permissible in law for *gaiben* and *bengoshi* to establish a *hojin* (corporation) together.
2. Transparency of the *gaiben* registration system: The Ministry of Justice began to consider this topic in 2015. A forum has been set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary, with a view to making the registration process and timing more transparent and to improving user-friendliness for registrants.
  3. Making the *gaiben* registration process simpler: 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, with a view to making the registration process simpler and faster.

The EBC welcomes the recommendations made by the Study Group in July 2016 and eagerly awaits changes to the law to reflect them. Going forward, the EBC will continue to recommend that any requirement for work experience prior to registration as a *gaiben* should be abolished. The EBC will also take a close interest in the roll-out of the recommendations, not least because the Study Group's 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.

### Key FTA/EPA Issues

- **Japan should recognise foreign lawyers if they are recognised in their home jurisdiction, without the current requirement for prior professional work experience in their respective home law**

## Key Issues and Recommendations

### ■ Recognition and approval as a foreign lawyer in Japan

*Yearly status report: reasonable progress, pending enactment of the July 2016 Study Group recommendations.* 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, of which two must have been 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 recognised 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 practised. 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. An overhaul of the system could resolve 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 practised.
- Continuing focus is needed 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: reasonable progress, pending enactment of the July 2016 Study Group recommendations.* Legislation was finally 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.

#### **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 practise 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

Despite some signals of slowing down, 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 decade has 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. It also benefits the Japanese economy at large, by creating considerable employment and helping to revitalise cities that were previously in decline. Japanese retailers and wholesalers themselves gain from the presence of European competition as it provides incentives to further strengthen their global competitive edge.

Nevertheless, European wholesalers and retailers still face considerable barriers in the Japanese market that make it difficult to take advantage of global-scale logistics. This creates higher costs and therefore higher prices for Japanese consumers. Moreover, the process of developing and opening new retail outlets remains fraught with restrictions, inefficiencies and delays, added to which, there are related sales restrictions. The Government of Japan also continues to insist on applying unique national rules and regulations to products that have already met European standards. Japan's reluctance to accept EN (European) and ISO standards or CE (*conformité européenne*) markings, for example, delays the introduction of new products to the Japanese market and increases import costs. 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, and their mutual recognition would create a level playing field for all players. An example of the barriers encountered by European retailers and wholesalers is Japan's unique labelling rules, as specified by the Consumer Affairs Agency (CAA). Other examples include 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 and European approvals. Non-harmonised procedures for importing, certifying and labelling consumer products are unnecessarily costly and complex. The EBC hopes that the HACCP (Hazard Analysis and Critical Control Point) system, which the Japanese Government has finally decided to roll-out in Japan, will be duly and transparently implemented, without introducing requirements unique to Japan.

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 prohibited vertical restraints, without any accompanying bright-line rules. The result is that 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 in Japan 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 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 business**

## Key Issues and Recommendations

### ■ Prohibitive import, testing and certification procedures

*Yearly status report: no progress.* The Government of Japan continues to insist on applying unique national rules and regulations to products that have already met European / international standards to the detriment of 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. In particular, it should revise its legislation applying to products with food contact.
- Japan should accept inclusion of common non-SI units on measuring devices when SI units are also used.

### ■ Labelling

*Yearly status report: no progress.* Both the Regulatory Reform Council (RRC) in 2013 and the Prime Minister's Cabinet in 2014 decided on the need for reform of the Household Goods Quality Labelling Act.

**Recommendation:**

- The CAA should accelerate reform of the Labelling Act as indicated in EBC's recommendations to the RRC.

### ■ Shoe quotas

*Yearly status report: no progress.* Most shoe tariff lines are covered by quotas, enabling imported shoes to benefit from a lower tariff. Quotas are allocated partly on the basis of historical import figures, while a proportion is reserved for "newcomers". The current system lacks transparency and companies no longer involved in the shoe business retain quotas, which they unlawfully "sell" to others. This behaviour is illegal, but persists. The Japanese Government's position is, anachronistically, that such quotas are justified for "social reasons".

**Recommendation:**

- The quota system should be abolished and tariffs removed. In the interim, METI should monitor the situation to reject applications from entities not trading shoes, release their quotas, and implement stricter penalties.

### ■ Limitations on selling liquor via telecommunication channels

*Yearly status report: no progress.* The retail sale of liquor across prefectural borders via any telecommunication channel (including the internet) is restricted. However, old (grandfathered) liquor licences do not have this limitation, giving an unfair advantage to holders of old licences versus new entrants.

**Recommendations:**

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

### ■ Unclear implementation of HACCP (Hazard Analysis and Critical Control Point)

*Yearly status report: new issue.* HACCP has been implemented in many countries, including in the EU. It is now a Japanese policy target, but the timeline is unclear, creating uncertainty in the retail and wholesale industry.

**Recommendation:**

- Japan should clearly state the scope, timeline, and steps that will be taken toward complete implementation.

### ■ Competition law / Anti-trust legislation

*Yearly status report: no progress.* Striking differences exist between Japanese Competition Law and global business practices. Examples include the recognition of "market power" with minor share in vertical restraint, and "superior bargaining power" irrespective of dependence. The EBC believes that JFTC's "yellow card" system, where infringement notices can be issued without an explanation, 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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# TAX

## Introduction

The EBC welcomes the Japanese Government's aim to stimulate the economy and increase Japan's attractiveness to investors by reducing the corporate tax rate. Reforms to date have reduced the overall effective rate from 35.6% to 31% for large companies in metropolitan areas and to 35% for SMEs. The Government's mid- to long-term intention is to reduce the overall effective tax rate to 30% or just below. However, in contrast to this, the Government has postponed for a second time its plans to help restore the country's finances through an increase in the consumption tax rate from 8% to 10%. As a result, Japan still trails behind other countries, including EU Member States, in transitioning its tax profile from a focus on taxing income to a focus on taxing consumption.

Nevertheless, public statements made by Prime Minister Abe in the course of the G7 Summit, in Ise-Shima in May 2016, indicated that Japan aims to take the lead in contributing to the growth of the world economy and to reboot Abenomics to the greatest possible extent. Since none of its policies to date involve significant curbs on expenditure, the growing deficit in the Government budget will at some point 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 2016 and beyond include measures such as increasing the minimum taxable income before Net Operating Loss (NOL) utilisation from 20% to 50% by April 2017. Regrettably, 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.

This negative impact is reinforced by the Government's increased focus on taxation of wealthy individuals with above average income, imposing inheritance, gift and income tax rates as high as 55% or more. The EBC welcomes news in August and October 2016 indicating that, in the case of short-term foreign residents, the Government may apply inheritance tax only to their Japanese assets starting in fiscal year 2017. If this reform is enacted, foreign corporate investors should look more favourably on Japan, although the main Asian investment hubs of Hong Kong and Singapore would, overall, remain more attractive tax jurisdictions for individuals, particularly for those wishing to reside long-term in the region.

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 also enable employers' and employees' contributions to social security systems within the EU and Japan to be treated as tax deductible on a mutual basis. The EBC welcomes the conclusion and ratification of the long-awaited new tax treaty between Germany and Japan. However, Japan's treaties with 21 other European Union countries still have not been revised, leaving amongst others, Austria, the Czech Republic, Denmark, Finland, Hungary, Ireland, Italy, Luxembourg, Poland, Portugal, Spain and Sweden with decades-old treaties.

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 an EU Member State and Japan does not resolve double taxation**

## Key Issues and Recommendations

### ■ Research and Development (R&D) tax incentives

*Yearly status report: no progress.* Innovation-intensive industries are a key driver of growth and employment. R&D tax incentives are widely recognised as an effective instrument for encouraging R&D activities and related (foreign) investments. While Japanese rules give some tax consideration to R&D expenses incurred in Japan, the current tax credit is generally too restrictive in scope (both in terms of access and benefit) to be a deciding factor in a foreign company's choice between potential R&D locations. Japan should consider revising its current R&D tax policy in order to maintain and improve its international attractiveness as a location for R&D activities. In this respect, it should be noted that many other countries have in recent years introduced some form of "back-end" Intellectual Property (IP) regime that applies to income earned after the creation and exploitation of IP. Furthermore, the current R&D credit regime is not available to companies that are loss-making, and so is of little benefit to many start-up companies.

#### **Recommendation:**

- Revise the current R&D tax policy to maintain and improve Japan's international attractiveness as a location for R&D activities (taking account also of the specific position of start-up companies).

### ■ 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, and this has a stifling effect on inward investment.

#### **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.

### ■ Income and Inheritance Taxes

*Yearly status report: some progress.* With top rates of 55% and higher, Japan's income, inheritance and gift taxes are the highest in Asia and, indeed, in the world. Foreign nationals are subject to Japan inheritance and gift tax from their first day of residence in Japan. The taxes apply even to property located outside of Japan. The 55% top inheritance tax rate applies also to inheritance between close family members and starts at much lower thresholds and allowances than in other countries. Japan's current inheritance tax and gift tax regime is negatively impacting Japan's ability to attract foreign intellectual capital and foreign investment from multinational companies. The EBC welcomes news in August and October 2016, indicating that, from 2017 onwards, in the case of short-term foreign residents, the Government may only apply inheritance tax to their Japanese assets.

#### **Recommendations:**

- Change the categories of foreign nationals who are subject to inheritance and gift tax laws to align with the categories of foreign nationals who are subject to exit tax, so that only foreign nationals who can reside permanently in Japan are subject to Japanese inheritance and gift tax.
- The plan to exclude overseas assets owned by foreigners residing short-term in Japan should be enacted in the 2017 tax reform as an interim measure.

### ■ 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. This means taxpayers are unable 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.



## ■ Extended tax return filing periods

*Yearly status report: no progress.* 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 continues 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 system should be more user-friendly.
- 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 and ratified a new tax treaty with Germany. However, its treaties with 21 other 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

In recent years, the Japanese authorities have been implementing a number of policies to encourage Japanese households to shift their financial assets from deposits to investments, including:

- Cultivating a sound environment within the investment community (investors, issuers and distributors) through introduction of a stewardship code, a corporate governance code, and a focus on fiduciary duty (customer-oriented business management).
- Creating incentives to encourage long-term investment and regular saving plans and to overcome risk aversion through introduction of the Nippon Individual Savings Account (NISA), Junior NISA, and long-term NISA, and expansion of the Defined Contribution (DC) pension scheme coverage.

Action to encourage a shift from deposits to investments and policies to support this shift remain essential to overcome the current situation where more than 50% of the financial assets of households are held in the form of bank deposits, compared to only 5% invested in funds. This raises concerns, firstly, because excess deposits of savings are unproductive for the Japanese economy. Even in the current situation where domestic banks are largely over-funded, excess savings deposits are not being used effectively to boost the national economy through lending or investing. Secondly, these excess deposits are also unproductive from the individual account holder's perspective. Even if safe, the deposits provide little or no return and cannot help households to prepare for the future. As Japan is facing demographic-related challenges, with issues of long-term imbalances in the retirement system and persistent low interest rates, long-term investing is more than ever a necessity.

The negative interest rate policy implemented by the Bank of Japan in February 2016 could have been seen as a trigger for retail distribution networks to accelerate the shift from deposits to off-balance-sheet saving products. However, this has not yet happened. Gross sales of retail funds (excluding Exchange-Traded Funds) dropped by more than 50% in 2016 compared to 2015, and restoring confidence in fund investing remains the top priority for asset management companies and distributors.

Indeed, volatility in the global market and the negative interest rate environment have created uncertainty, resulting in anxiety, among existing fund investors. They are also deterring potential new investors. In order to restore confidence in fund investment, several issues need to be tackled. These include the successful delivery by the asset management industry of moderate risk/moderate return products aimed at newcomers looking to invest. The EBC furthermore believes that improving operational structure is critical, as highlighted in the first recommendation on the next page. Another issue that should be improved is financial literacy. If the Japanese authorities decide to change the "default option" for DC pensions from cash to diversified investments (multi-asset/target year-type products), that would provide an important opportunity for financial education and increase familiarity with fund investing.

Finally, Japan's asset management industry needs to continue its efforts to compete successfully in the global arena. Attracting more talent from overseas and preparing well for the introduction of the Asian Regional Fund Passport (ARFP) are examples of areas to work on. The EBC remains committed to contributing to the sharing of best practice and to constructive discussions aimed at the development of the Asset Management industry in Japan.

## Key Issues and Recommendations

### ■ Globalisation and efficiency of the operational platform

*Yearly status report: progress.* In June 2016, the EBC submitted recommendations based on the 2015 EBC report on the business environment to the Financial Policies Monitor, a report vehicle set up by Japan's Financial Services Agency (FSA) and is encouraged by the proactive discussions that have resulted from this. However, the isolated and sometimes obsolete nature of the operational platform prevents Japan from becoming more globally competitive. Some of the issues are:

- Japanese trust banks separate Japanese yen and overseas assets for custody services;
- Japanese accounts have no overdraft facility;
- The rate of Straight Through Processing (STP) at trust banks is low, and there are other issues related to settlement instructions;
- It is practically impossible to merge funds.

Such operational isolation could be a major issue for successful participation in the ARFP. Moreover, the EBC is concerned about the amount of duplicate work required among stakeholders, especially between trust banks and asset managers, such as for Net Asset Value calculation or reporting functions. To improve operational cost efficiency, Japan might draw on best practices in Europe relating to the respective roles of the asset management company, the custodian and the fund administrator/valuation agent.

Lastly, all stakeholders in our industry now regard a review of the current fund governance as a key topic. For example, how to facilitate the decision-making process related to the evolution of products, while still respecting the primary interest of unit-holders, is a matter of concern. The EBC believes that discussions of such issues is important, including the possibility of broadening the utilisation of Company-type funds, like SICAV (*Société d'Investissement à Capital Variable*) in Europe, to mainstream retail products.

#### **Recommendations:**

- Japan should address and reform inefficient market practices that have become de facto standards.
- The EBC applauds the Japan Investment Trust Association for taking the lead in setting up a Committee to discuss some of the issues related to the operational platform. This Committee, with all stakeholders, including foreign-affiliated organisations, should proactively aim to produce tangible recommendations on how to improve the globalisation and effectiveness of the operational platform for the asset management industry in Japan.

### ■ Collective engagement

*Yearly status report: new issue.* Collective engagement is an effective way for minority shareholders to hold boards accountable and influence corporate behaviour when improvement is desired. Most stewardship codes, the Principles for Responsible Investment (PRI), and the ICGN (International Corporate Governance Network) encourage collective engagement, but it has been omitted from the Japan stewardship code. It has been pointed out that the Japanese Financial Instrument and Exchange Act makes collective engagement difficult in practice, as the law requires investors acting in concert to submit a report of their holdings if the aggregate exceeds 5%. While this issue is not exclusive to Japan, regulators in other parts of the world have tried to clarify which collaborative activities do or do not constitute "acting in concert", to avoid undermining their corporate governance frameworks. The latest Principles of Corporate Governance issued by the G20/OECD (the Organisation for Economic Co-operation and Development) have even introduced a specific paragraph on the issue, recognising cooperation, under certain limitations, as part of basic shareholders' rights.

#### **Recommendation:**

- Due to the importance of collective engagement as a tool for constructive dialogue between corporates and investors, the EBC recommends that the FSA takes the necessary measures to facilitate collective engagement and supports this approach in the next review of the Japanese stewardship code.

# 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 waning attractiveness as a financial centre, Tokyo has started to bounce back. For two years running, the Economist newspaper has listed Tokyo fifth in its Global Financial Centre Index (GFCI), which ranks the relative 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 that better reflects the real economic status of Japan. It is, furthermore, important to point out that Japan cannot rely on monetary policies only. The banking sector in particular needs to be able to recruit talented personnel, including from overseas, and to keep pace with changes in the global industry, which Japan’s current rigid immigration and labour laws make difficult to achieve.

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 the appointment process is made more transparent.

A new and pressing issue is fair disclosure. Fair disclosure lays the foundation for a market place where company-specific information is properly distributed at the same time to all categories of investors, thereby protecting consumer interests and helping to avoid insider trading. Unfortunately in Japan, disclosure of such information often occurs through media channels some days before any official public announcement, even though such practices are not officially sanctioned. The EBC, therefore, believes more effort is needed to clarify the responsibilities of all parties involved, which would be in line with the Japanese Government’s policy on improving corporate governance.

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

## Key Issues and Recommendations

### ■ Revitalisation of the financial market

*Yearly status report: no progress.* The introduction of the first two “arrows” of Abenomics (focused on fiscal stimulus and monetary easing) led to a flurry of activity in the financial market in Japan. Now, just a few 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. It is, meanwhile, important that Japan does more to attract talented human capital to Japan, especially since neighbouring markets are becoming more successful in this respect.

#### **Recommendations:**

- Japan should expand the mandate of the GPIF as announced and encourage the move in the GPIF from low-yield investments to investments with higher returns.
- Japan should do more to incentivise talented people to come to Japan.

### ■ Fair disclosure regime

*Yearly status report: new issue.* Fair disclosure regimes are in place in most mature markets to ensure an open and fair market. However, this is not the case in Japan. Information is sometimes made known to select audiences through so called “earnings previews”, weeks before it is made public through official channels. Japan needs to swiftly introduce a regime to deal with this situation. It is important that there is clarity regarding the responsibilities of all parties. It should also be pointed out that fair disclosure is a fundamental component of good corporate governance.

#### **Recommendations:**

- The Japanese authorities should address the problem of asymmetrical information and introduce a fair disclosure regime.
- The authorities should ensure that a robust sanction system is in place to disincentive the circulation of preview reports.

### ■ Banking agency system

*Yearly status report: good progress.* The banking agency system used to require Japanese branches of European banks to apply for a special business licence each time they introduced any new banking services provided by another banking entity, even if that entity was a branch of the same financial group located outside Japan. This had a negative impact on 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 the EBC appreciates the positive results achieved by the FSA in improving the system, by introducing group approvals, more information is needed on the administrative procedures required to obtain these approvals. It is of utmost importance that these procedures are easy to use and that the administrative burden imposed on the applicant does not negate the actual benefits.

#### **Recommendations:**

- The FSA should further clarify and streamline the application process for banking agency licences.
- The FSA should make certain that the group approval system is easy to use, and that it will not impose a heavy administrative burden on the applicant.

### ■ Information sharing

*Yearly status report: new issue.* While the firewall between different financial activities within the same financial group has been liberalised (for example, enabling increased double-hatting) there is still a ban on information sharing. The EBC believes this is unnecessary and 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 reserving and solvency regulations that are inconsistent with international norms; the lengthy, non-transparent product approval process; the Government's continuing majority ownership of Japan Post even beyond its privatisation; and the separate regulatory framework applied to mutual aid cooperatives (*kyosai*). 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 its life insurance business as part of Japan Post Holdings where, despite an Initial Public Offering (IPO), the Japanese Government continues to hold a majority stake. Nevertheless, JPI is being allowed to launch new life insurance products. 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 advocate 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 also propose 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 should adopt the appropriate proposed policy measures and additionally shift to a post-funded scheme for protecting policy holders.

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

In parallel, the FSA should accelerate de-regulation of distribution practices based on a risk-based approach, which is in alignment with the trend towards consumers wanting better access to more convenient distribution channels targeting their individual needs.

Overall, 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 economic growth. This would also benefit the domestic financial services industry, consumers and Japan's ability to retain foreign investment.

### Key FTA/EPA Issues

- The Government of Japan should swiftly carry out the IPO of Japan Post in accordance with its original commitments, and ensure a level playing field - 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

### ■ 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 FSB/IAIS proposed policy measures for the Japanese market, the Government 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 should clarify planned changes so that all parties concerned, including private insurers, can prepare for the new framework.
- The Government should also consider reforming the Policyholder Protection Corporation when introducing Japanese Solvency II.

### ■ Product approvals

*Yearly status report: some progress.* The EBC appreciates the FSA's initiatives to improve the product approval process, and the setting up of a regular dialogue between regulators and insurance companies. 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 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.

### ■ Fair competition in bank distribution

*Yearly status report: limited progress.* As the importance of bancassurance increases in providing benefits to Japanese consumers, the EBC is concerned about the strong influence that Japanese insurance companies have over Japanese banks as their major shareholders. For example, in the area of group credit life insurance and related products, the EBC member companies have brought a series of innovations to the Japanese market in past years, providing valuable protection for critical illness and disability to Japanese mortgage borrowers. This business is now being copied by Japanese insurers, and while the EBC welcomes healthy competition in the marketplace to further benefit Japanese consumers, we expect the FSA to carefully monitor the situation to ensure that competition is based on the quality of products and services and capacity to bring innovation and not merely on the shareholding relationship between insurers and banks, which is irrelevant to the Japanese consumer.



**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.
- The FSA should carefully ensure that competition is based on fair comparison of offers, and is not biased by pre-existing shareholding relationships.

**■ Japan Post reform**

*Yearly status report: some progress.* Even with the IPO implemented, the Government remains the majority shareholder in Japan Post, and so the public continues to believe that it guarantees the various Japan Post entities. The EBC considers this gives JPI an unfair competitive advantage, especially since JPI has indicated its intention to expand its product portfolio.

**Recommendations:**

- Until 100% of Japan Post's shares are held privately, JPI's product portfolio should not be expanded and its issue limit should remain the same. Hence the Japanese Government should ensure a level playing field.
- 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 should adhere to its commitments made under the WTO GATS.

**■ Kyosai**

*Yearly status report: no progress.* Currently *kyosai* are not subject to Japan's Insurance Business Law. Instead, different ministries regulate the various *kyosai* depending on the sector in which the *kyosai* is active. For example, JA *Kyosai* is regulated by the Ministry of Agriculture, Forestry and Fisheries.

**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, as originally intended, to a well-defined group, such as a certain profession.

**■ Distribution practices**

*Yearly status report: some progress.* Insurance sales by an incorporated insurance agency to members of its parent and affiliated companies are restricted to so-called "third sector" products (Insurance Business Law Enforcement article 234, 1998 MoF Notification No. 238). The EBC fully acknowledges the reasons for this restriction as discussed at the Administrative Reform Committee (1997) and the Insurance Council (1992). The EBC, however, considers that the current rule could be a barrier for new entrants and may not be beneficial to Japanese consumers.

**Recommendation:**

- Taking into account emerging new technology and evolving insurance distribution, the FSA should review the said notification and related regulations, and present a roadmap for further deregulation for the benefit of Japanese consumers.

# **Transportation & Communications**

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

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# AIRLINES

## Introduction

The volume of inbound air travellers to Japan continued to grow in 2016. As in previous years, the growth was led by passengers from Asian countries. An increase in visitors from Europe was also evident, driven by a general rise in interest in Japan as a tourist destination and a more favourable exchange rate, which makes land portions, such as the cost of accommodation, food, sightseeing, and so on, of leisure trips more affordable. Despite a stagnant economy, business travel, both inbound and outbound, also rose consistently.

However, the increase in overall inbound travel has not compensated for a severe decline in outbound leisure travel from Japan to Europe. This decline is due primarily to the recent terrorist attacks and to a general drop in consumption by the Japanese. It has led to a reduction in scheduled frequencies, deployment of smaller aircraft and even total withdrawal from the market.

If Japan is to reach the ambitious targets set by the Government for inbound tourism over the next few years, the total number of airline seats will need to increase. Capacities will also have to be ramped up for the Tokyo Olympics in 2020. The EBC urges the Government to take a two-pronged approach to reverse the current decline on European routes. The first step should be to promote outbound leisure travel. The EBC appreciates the initiative to subsidise passport costs for young people to encourage them to travel. Stronger demand for outbound travel from Japan to Europe will benefit both domestic and foreign businesses, including travel agencies and tour operators in Japan that earn commission on sales, since their commission for European destinations tends to be higher than for other destinations.

The second step should be to reduce fees at Japanese international gateway airports. During prolonged periods of low demand, airlines adjust capacity downwards, in order to reduce costs and achieve commercial objectives. It is in the long-term interest of airports to ensure that airlines can continue operating at such times without incurring significant losses. Lower fees would help significantly and allow them to maintain higher capacities for longer, facilitating an easier capacity ramp up when demand returns. The EBC recommends re-evaluating and reducing the current high landing fees, navigation charges, airport terminal rent, airport terminal common usage fees, and parking fees. Other regional airport hubs in Asia have reduced such fees to ensure that airlines do not decrease or eliminate flights in the short term.

The EBC continues to support the further opening of Haneda Airport (HND), with additional slots distributed fairly in order for airlines to add new flights. The EBC also encourages the Japanese Government to expand the infrastructure for catering and cargo facilities at HND. The current lack of proper infrastructure creates logistical impediments resulting in higher costs for operating airlines. Moreover, the EBC requests the Japanese Government to further clarify the application of the so-called *Shibari* rule, which is the unofficial requirement for airlines to remain at Narita (NRT) despite the expansion of flights at HND. This undermines the ability of European airlines to operate efficiently to and from Tokyo. It may even prevent the expansion of seat capacity and flights in total.

The EBC regrets that several other issues raised in previous EBC Annual Reports remain unresolved. One such issue is the subsidising of the new low cost carrier (LCC) terminal at NRT. The EBC has yet to receive information on the cost structure of this building or proof that the cost was borne by the LCCs rather than by the existing tenants. Another related issue is the effect of competitive distortions in the market caused by one carrier being given more favourable financial conditions than others. When this happens, for whatever reason, the EBC believes the playing field should be levelled by compensating all other carriers, domestic and foreign.

European airlines have taken numerous measures to lessen their impact on the environment, including the purchase of new fuel- and noise-efficient aircraft, more efficient navigation technology, and bio-fuel testing. The EBC fully supports the opening of new approach and departure patterns at HND in order to reduce fuel consumption and increase cost efficiency. In addition, the EBC recommends abolishing the early “gear down” policy at NRT, which unnecessarily increases not only fuel usage, but also noise for local residents.

## Key Issues and Recommendations

### ■ Revitalisation of outbound tourism

*Yearly status report: limited progress.* The Government continues to allocate substantial funds to promote Japan as a destination, yet the EBC believes the expected inbound travel volumes, including for the 2020 Olympics, cannot be met by sustainable supply if outbound tourism is not also encouraged.

**Recommendations:**

- The Japanese Government should continue to promote “exploring the world” initiatives with PR campaigns and should work together with tour operators and travel agencies with a focus on Europe.
- The Government should continue its subsidisation of passport costs for young people in order to encourage travel abroad.

### ■ High costs at Japanese airports

*Yearly status report: no progress.* Operating costs at Japanese airports continue to be high, with no real relief in sight. As demand for outbound travel to Europe declines, airlines are struggling to sustain flight capacities. Inbound travel volume can in no way compensate for the resulting deficit. The situation may get worse if the yen rises against the euro and travel costs in Japan (including for hotel accommodation) increase, causing a negative impact on inbound numbers. The risk is that airlines will continue to reduce capacity to/from Europe, making a sudden capacity increase for the 2020 Tokyo Olympics difficult. Added to such cost issues, the Government continues to require airlines to file their published fares and surcharges for approval, prior to sale - a time-consuming and costly exercise which other major markets do not require.

**Recommendations:**

- The EBC recommends that all airport fees be lowered. This will encourage airlines to maintain and grow capacity and frequencies, which will enable growth in traffic to and from Japan. The current airport fees are too high, particularly in comparison with other airports in the region, which have in some cases lowered fees to ensure that airlines retain capacity even in an uncertain market environment.
- The recent decision by the Japanese Government to reduce specific fees at domestic airports in Japan to further encourage travel should be used as a template to lower fees at international airports.
- The EBC urges the Government to reconsider the value to consumers of insisting that airlines file published fares and surcharge for approval prior to sale.

### ■ Airport infrastructure

*Yearly status report: limited progress.* The EBC encourages the continued opening up of HND airport slots. In addition, improved “on or near airport” facilities for catering and cargo are needed.

**Recommendations:**

- The “early landing gear down” policy at NRT should be re-evaluated in consultation with local communities, on environmental as well as cost grounds, as it results in higher fuel consumption and increases noise.
- HND should be fully opened up to all international traffic, including flights to and from Europe, on a non-discriminatory basis.
- Immigration staff should be increased at international airports as waiting times continue to be high.
- The new air corridors over Tokyo currently being studied should be approved and quickly introduced to enable an increase in slots and therefore passenger traffic. The reduction in fuel consumption through more direct approaches would have a positive impact on the environment.
- More space for catering and cargo suppliers should be allocated at HND, in order to increase efficiency and reduce costs for operators.
- Additional car park facilities should be added at HND to alleviate waiting times for parking spaces. This would improve quick access to the airport.

# RAILWAYS

## Introduction

Japan has long been a nation with an extensive railway network, connecting Kyushu in the south with Hokkaido in the north. These two islands, separated by the main island of Honshu, are now also connected via high-speed rail after the extension of the Tohoku Shinkansen to join the Hokkaido Shinkansen. The Japanese railway sector has always been and continues to be dominated by domestic suppliers. Relatively few foreign players are present, a situation that is at its most extreme in the rolling stock market, in which none of the major foreign players has any significant activities. According to the Japan Association of Rolling Stock Industries, the value of rolling stock produced in Japan, including for export, in fiscal year 2015 was 181.6 billion yen. The EBC considers that Japan represents a large market with good potential for European manufacturers and service providers, and would welcome more openness to imports.

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

In Japan, even if products have already been tested and certified according to international standards, they will not even be considered by Japanese railway operators without further extensive, yet unnecessary, testing. (The only exception to this is products the operators have sourced themselves from specific manufacturers.) The EBC strongly requests the Japanese Government to combat this waste of time and resources by improving the legal environment to facilitate smoother imports and exports. It is of the utmost importance that when considering harmonisation in the railway sector, the Japanese and EU authorities ensure that the Japanese standards and specifications examined are those actually used by the Japanese operators. It is, furthermore, important that standards and specifications are made publically available so that European manufacturers have a genuine opportunity to meet and exceed these requirements. We believe that the technical working group set up in the framework of the EU-Japan FTA/EPA negotiations is a good start towards achieving this goal, but more information from the working group needs to be shared with industry, and industry should be more closely involved in this exercise.

The EBC welcomes the FTA/EPA negotiations and the progress achieved to date as regards railways. However, the EBC does not understand why the Japanese Government believes that safety concerns can be grounds for not using public calls for tenders, as the Government and the railway operators would still be allowed to set their own safety-related standards. We therefore 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 Operational Safety Clause
- As a party to the WTO Agreement on Government Procurement, the Government of Japan should make certain that public procurement is carried out in accordance with its provisions

## 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 (OSC) 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 swiftly remove the OSC without any phase-out periods.
- The Government of Japan should ensure that when planning new railway projects (such as LRT), local cities abide by or use the GPA as guidance to set up a proper public procurement scheme, and do 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 calls for tenders for 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 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 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.* 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. With the Tokyo 2020 Olympics just around the corner, Japan is looking to showcase its latest technology to the world. The Government has already announced its intention to have 5G up and running in time for the Olympics and is currently investigating how it can support the growing need for more bandwidth for cellular applications. This is not limited to more obvious telecommunication areas such as big data and the Internet of Things, but also to areas such as healthcare and transportation related to both ground-based vehicles and drones.

The EBC appreciates the opportunity to contribute to the Ministry of Internal Affairs and Communications’ (MIC) policy committees as an official participant and applauds the Government’s overall commitment to an industry-led, global approach to standards and platform development. Important steps have already 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 mainly 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.

There are approximately 7.4 billion mobile phone subscriptions globally and 3.7 billion of these are connected to mobile broadband, with overall mobile data traffic doubling each year. Even in a mature market like Japan, with advanced data services and the introduction of Long-Term Evolution (LTE), smartphone penetration is already about 50% and is driving mobile broadband growth - projected traffic usage in 2020 is 10GB/month per user. The various applications used on smartphones, such as video and social networks, and machine-to-machine communication place different demands on the network. After having successfully allocated the 700, 900 and 3,400MHz band to mobile telephony, the Government is now contemplating further allocations. The EBC very much supports this further expansion and hopes that Japan will continue to implement spectrum bands that are harmonised with other markets.

In January 2016, the Japan Fair Trade Commission (JFTC) issued a revised set of Guidelines on IP (Intellectual Property) and Competition analysis (“Guidelines for the Use of Intellectual Property under the Antimonopoly Act”). The EBC is pleased to see that the revised final guidelines were modified and improved to bring them in line with international best practices for antitrust. This was achieved by employing a more flexible effects-based approach, similar to the recommendation made by the EBC in 2015. We commend the JFTC for seeking public comments on the draft guidelines, and for working with industry stakeholders to bring them in line with international best practices. Striking the right balance between technology contributors and technology users is key to ensuring a healthy pro-competitive standardisation ecosystem that benefits consumers. A case in point is the recent deviation by one standard-setting body, the IEEE, from a balanced approach, such that a number of technology contributors are now no longer willing to make licensing commitments under its new policy.

### 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 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 "Specified Radio Equipment".

### ■ Harmonisation of spectrum for IMT (IMT-2000, IMT-Advanced, and IMT-2020)

*Yearly status report: some progress.* The EBC acknowledges that 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 3,600MHz to IMT-Advanced systems and that MIC is working to ensure allocation of the 1,700MHz, 2,300MHz, 2,600MHz and 3,400MHz bands to address the increasing demand for mobile broadband, in accordance with the 2015 harmonised frequency plan and the report from the MIC Study Group on Radio Policy toward 2020. The EBC is also pleased to see that candidate ranges for IMT-2020 (5G) have been identified.

#### **Recommendations:**

- The Government of Japan should work jointly with other governments to achieve a globally harmonised spectrum allocation on the bands of, for example, 700MHz, 1,700MHz, 2,300MHz, 2,600MHz, 3,400-3,600MHz, 3,600-4,200 MHz, 4,400-4,900MHz, and 27.5 GHz-29.5GHz, as well as ranges mentioned in agenda item 1.13 of the World Radio Communication Conference in 2019 (WRC-19). For the 2,300MHz band, consideration should be given to the concept of licensed shared access to the spectrum for incumbent and prospective licensees.
- The Government of Japan should engage actively in relation to agenda item 1.13 of WRC-19, in order to identify new harmonised spectrum for IMT systems above 6GHz.

### ■ Future-proof radio regulation for mobile equipment

*Yearly status report: new issue.* Japan is promoting new wireless technologies for the Internet of Things (IoT), the Intelligent Transfer System (ITS) and 5G. Advanced wireless technologies can facilitate innovative use of ICT, and contribute to emerging industries and economic growth. The EBC believes that Japanese radio regulation is insufficiently flexible and, by stipulating technical requirements based on specific technology on each frequency band, may delay the launch of new wireless technologies. Japanese radio regulation creates an additional burden by enforcing measurement of radio equipment on a regular basis to see that it meets requirements.

#### **Recommendations:**

- Japan should adopt a future-proof and flexible radio regulation for mobile equipment so that emerging technologies, such as LTE-M and NB-IoT, can be swiftly deployed in Japan.
- Japan should review the current radio regulation to avoid imposing undue requirements on radio base stations, especially AAS for Massive MIMO (Multiple Input – Multiple Output), which is used in relatively small products. In particular, radio performance checks of equipment at antenna or equivalent monitor ports, which are required on a regular basis (once per 5 years), should be carefully reviewed.

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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 despite providing the same service, resulting in inefficiencies and higher prices for users. The EBC believes that the Government should take a holistic view on what is needed to make Japan a viable logistics hub for regional trade.

Japan has nine separate customs areas and no central customs authority. Currently 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. 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. The EBC would also like to point out the limited possibility of using English when working with NACCS.

Japan Post, currently restructuring, has plans to aggressively expand while still enjoying preferential regulatory treatment. The EBC recognises the need for a universal service obligation to meet certain socio-economic goals. However Japan Post is benefitting from unfair competitive advantages in the express delivery market, where its Express Mail Service (EMS), a special value-added international express package, already accounts for 18% of the market. EMS is not subject to the strict regulations applied to private sector express services (as detailed on the following page), hence its expansion threatens further to distort competition and will negatively affect not only foreign private operators but also Japanese companies and individuals. It is important to note that EMS is not deemed part of the universal service in Europe or the US. In Europe it is explicitly referred to as different from the universal postal service, while in the US it belongs to the category of "Competitive Services". The EBC believes that there are no obstacles to moving EMS outside the scope of universal service in Japan, similar to the removal of *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 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, dropped in the Asian rankings from fourth place in 1980 to 59th place in 2015. Tokyo and Yokohama ports combined only ranked in 20<sup>th</sup> place globally in 2015 based on containers moved. 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: 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, especially on remote filing.
- 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.

### ■ 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 200,999 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 anticipated simplifications. 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:
  - ◇ Enabling access to NACCS from servers outside of Japan
  - ◇ Reducing the physical examination of shipments
  - ◇ Allowing the use of digital archives
  - ◇ Removing individual customs brokerage license and introducing company-based licences

## ■ 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 (MA) of veterinary medicinal products (VMPs) are granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF) and registration dossiers are 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, establishing acceptable daily intakes and maximum residue limits, respectively. According to industry research specialist, Fuji Keizai (2016), the Japanese animal health market (excluding pet food and prescription diets in the veterinary channel) was worth 114.1 billion yen on the basis of ex-wholesalers in 2015. The market saw only marginal growth in the period 2011-2015, with a compound annual growth rate of just 1.9%. More than 60 companies in Japan manufacture and/or import VMPs to supply to customers. The market share of products derived from multinational animal health companies is steadily increasing, reaching almost 50%, due to their continuous investment in innovations for both veterinary pharmaceuticals and biological development. Meanwhile, over the last two decades, the majority of Japanese human pharmaceutical companies have divested their animal health divisions to multinational animal health companies, and nearly all domestic Japanese animal health companies operate only locally, with just a minor level of exports. In particular, for veterinary pharmaceutical products, multinational companies are the main source of innovative products containing new chemical entities, whereas domestic companies tend to be reactive in the area of generic developments, albeit adding some unique features in innovative formulations.

Japan's participation in the Trans-Pacific Partnership (TPP) requires the elimination or reduction of tariffs and subsidies for animal agricultural products (for example, pork, beef) imported from overseas, threatening the businesses of local livestock producers. To ensure the sustainability of the livestock sector 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 helped to some extent in reducing the registration costs for globally developed products. There are, however, still some requirements unique to Japan that prevent or delay access to innovative and useful VMPs for animal owners, veterinarians and consumers. In the case of biological products, some specification items are unique to Japan, including the requirement for a serological potency test on live vaccines. Product specifications have to be established purely for the Japanese market and each batch of vaccine has to be released based on these unique specifications, often requiring duplicate testing at the manufacturing site. While studies conducted overseas under Good Laboratory Practice (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 any overseas production facilities involved in the manufacture of VMPs for importation into Japan, regardless of whether the products are active pharmaceutical ingredients or final products, have to be accredited by MAFF, even though their GMP status has been approved by European authorities. The process involves a large amount of redundant administrative paperwork despite the fact that MAFF recently revised the regulations and now issues accreditation licences in Japanese and English, a move welcomed by the animal health industry.

For the last few years, MAFF has been making efforts to implement measures that will improve the predictability, quality, and speed of the registration process. The EBC particularly welcomed the initiative announced on September 30<sup>th</sup>, 2016, allowing MAFF, MHLW and the FSC to simultaneously review MA applications for food-producing animals, which is expected to shorten the overall MA review period. While review periods are improving significantly, there are still delays in the review process for some product segments. Accordingly, customer access to innovative and cost-effective VMPs in Japan suffers relative to the speed at which they are available overseas. For example, the long review process required before granting permission for use of Genetically Modified Organisms (GMOs) in the laboratory and in the field results in serious delays to the availability of innovative VMPs in Japan.

## 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 MAFF's 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 testing requirements, such as in-process testing, that do not exist in the internationally recognised seed-lot system. One example is the requirement for a serological potency test, using target or laboratory animals, on live vaccines produced in accordance with the seed-lot system. Despite the fact that the safety of vaccines for dogs and cats is tested in the target animals, an additional Abnormal Toxicity Test using laboratory animals is required, which creates not only animal welfare concerns but also an increased cost burden 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.

### ■ Restrictions on Genetically Modified Organisms (GMOs)

*Yearly status report: limited progress.* Japan enacted the Cartagena Act in 2003, implementing the Cartagena Protocol on Biosafety to the Convention on Biological Diversity. This also applies to veterinary live vaccines that utilise GMOs. Unlike conventional inactivated or modified live vaccines, two specific permits are required when using GMOs as the basis for vaccines: type 2 and type 1. Type 2 is granted for GMOs to be used in a laboratory setting to ensure that proper containment measures are taken, whereas Type 1 is intended for GMOs to be used or investigated in a field or other open space (such as in clinical trials), once the relevant GMOs are confirmed to have no adverse effects on biological diversity. Currently, it is not possible to apply for both permits at the same time. Instead, this must be done sequentially—first type 2 and then type 1. It is not possible to commence the clinical trial until Type 1 permission is granted, and it is not uncommon for companies to spend more than three years just completing the review by MAFF and satisfying the external expert panel for GMOs, as required to obtain the two permissions. Unsurprisingly, as a result, compared to the EU and the USA the number of GMO live vaccines for animals in Japan is very limited, thus restricting the access of Japanese customers (farms, pet owners) to innovative technologies.

#### **Recommendation:**

- For veterinary live vaccines utilising GMOs that have already been approved in the EU or USA, the review for Type 1 and Type 2 permissions should either be conducted in parallel or combined, in order to shorten the period before companies can start clinical trials in Japan.



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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 consideration of 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 the related discussion.

Discussion about the role of medical diagnostics is not new. Since 2007, research papers have been published, and proposals and recommendations have been made both 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). 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” led to IVD fees rising continuously between 2008 and 2014. In the 2016 medical reimbursement price revision, Global Standard Examination Management Additions were introduced. Whether a facility qualifies for these additions depends on its ability to demonstrate “Approved technological competence based on global standards” and on the quality of examination. This has had a positive effect on the medical diagnostics sector.

Cooperation between the medical diagnostics industry and the pharmaceutical industry, and consultation with the Government are progressing on the increasingly important topics of personalised health care and companion diagnostics. The end objective is the introduction of relevant approval processes and the establishment of an insurance reimbursement system linked to drugs. 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 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, such as the American Medical Devices and Diagnostics Manufacturers’ Association (AMDD) and the Japan Association of Clinical Reagents Industries (JACRI).

### 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 accelerate the introduction of these products to Japan

## Key Issues and Recommendations

### ■ Quick access to new IVDs

*Yearly status report: slight progress.* The Action Plan for Speedy Examination of IVDs, announced by MHLW in March 2014, confirmed the following actions, which are currently being implemented:

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 the management of processes and facilitate achievement of objectives.

**Recommendations:**

- MHLW should set year-by-year milestones and concrete actions for its 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 to enhance the quality of the approval and examination process; and monitor the timely achievement of term objectives.

### ■ Approval examination and safety measures

*Yearly status report: progress.* The EBC, jointly with JACRI and the IVD Committee of the AMDD, presented the following recommendations in a periodical opinion exchange meeting (28 July 2016) with MHLW's Pharmaceutical and Food Safety Bureau, to discuss the approval examination and safety measures.

**Recommendations:**

- MHLW should improve the operation of the current control system and promptly issue notifications on generic names. This should remedy delays in practical applications.
- Delays in starting pre-approval tests are lengthening examination periods and creating bottlenecks. MHLW should shorten the examination period by reviewing its contents and improving the process.
- The Government should work with the EBC and other industry organisations until guidelines for clinical performance testing have been established. For example, the industry has been endeavouring to establish a "specimen bank" for the stable supply of specimens used in clinical performance tests. During this process, the Japan Agency for Medical Research and Development proposed the use of specimens maintained by public bio banks in Japan. The Japanese Government's cooperation in establishing and realising the envisaged system has been much appreciated.

### ■ Medical reimbursement of IVDs

*Yearly status report: progress.* Since April 2016, the EBC has been given the opportunity to express its opinion in the Central Social Insurance Medical Council (Chuikyo) on insurance coverage for IVDs (E2 and E3). Building on this, the EBC together with JACRI and the IVD Committee of the AMDD have set up a "Joint Task Force to Negotiate with Chuikyo", for the purpose of discussing IVD medical reimbursement and sending requests to the Special Committee of Chuikyo.

**Recommendation:**

- MHLW should create a scheme for new innovation in IVDs to be correctly and promptly covered by national health insurance. This scheme should be thoroughly discussed in the Chuikyo.

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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 the 2015/2016 fiscal year, the national cost of medical care reached 41.5 trillion yen, up by 1.5 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 a swift introduction, Japan should align its regulations and processes with international standards, allow for the use of European approvals and data, and improve the predictability of the reimbursement system. 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 should continue to introduce measures to improve the Foreign Direct Investment (FDI) environment as this has proved to be a real driver for investments in the domestic market.

In 2015, progress was made in a number of areas, including:

- Establishment of 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.
- Improvement in the speed of the approval and examination process, and progress in the promotion of research and development activities.
- Introduction of concrete measures, improving the environment for FDI.

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

### Key FTA/EPA Issues

- **Work toward speedier medical equipment examination**
- **Improve clinical evaluation**
- **Mutually approve and internationally align QMS (the Quality Management System)**
- **Treat software programmes as medical equipment in new legislation and align with global standards**
- **Revise the need for a construction licence**

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Intuitive Surgical	Nobel Biocare Japan	Wako Shoji
Japan Lifeline	Novocure	
Japan MDC	Otto Bock Japan	

## Key Issues and Recommendations

### ■ Speedier medical equipment examination

*Yearly status report: some progress.* The Government's new 5-year plan has started and the main theme still remains enhancement of the technical expertise of applicants and examiners.

#### **Recommendation:**

- Further cooperation is needed between Government and industry, as well as an increased budget for PMDA.

### ■ Clinical evaluation

*Yearly status report: progress.* The guidelines for creating clinical evaluation reports and clinical evaluation consulting materials have been published.

#### **Recommendation:**

- 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 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 product group, and rationalise the QMS investigation prescribed in Chapter 3, Production and Marketing of the QMS ministerial ordinance.
- MHLW should disseminate the QMS ordinance (contents and methods) in English with the Medical Device Single Audit Program (MDSAP) rationalisation in mind.

### ■ Reimbursement prices

*Yearly status report: some progress.* Progress has been seen in the evaluation of materials innovation and in a more detailed classification of functions. While some progress is also noted in the inclusion of improved technology in C2, the C2 application process needs further discussion in respect of the evaluation of diagnostic and therapeutic devices.

#### **Recommendations:**

- Japan should not introduce yearly revisions of reimbursement prices.
- Regarding the proposed cost effectiveness evaluation system, the Government should clearly define the scope of application and proceed with the plan very carefully.
- As for medical materials, functions should be classified in more detail, and innovation should be rewarded. The EBC continues to oppose the repricing system and the introduction of repricing for market expansion.
- Regarding medical technology, Japan should clarify the contents of the C2 application and the relevant process. The EBC also recommends a new medical reimbursement system for this category.
- Home medical equipment, including improvement thereof, should be adequately evaluated.

### ■ Construction licences

*Yearly status report: no progress.* Currently, a company selling medical equipment that needs to be physically constructed must have a construction business licence, even if outsourcing the construction work. Recent slight easing of this requirement has had no real effect.

#### **Recommendation:**

- The requirement for a construction licence should be further eased.

### ■ Improvement of environment for IT medicine

*Yearly status report: slight progress.* Globally, discussions on health data handling are increasing.

#### **Recommendation:**

- The Japanese Government should set up a discussion forum, including all stakeholders, to work out a reimbursement scheme designed to promote the effective use of telemedicine and big data.

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# PHARMACEUTICALS

## Introduction

Although overall healthcare costs in Japan are rising as the population ages, and use of innovative pharmaceuticals is growing significantly, total pharmaceutical spending is well under control. This is because 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 2015/16 fiscal year increased 3.8% on the previous year, rising by 1.5 trillion yen to 41.5 trillion yen. 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 just 0.13% to 2025. The current pricing system for pharmaceuticals, and measures such as the encouragement of greater generic prescribing, are together expected to continue to prove sufficient in controlling the drugs bill. Furthermore, the new target for generic penetration of 80% by earliest timing between 2018 and 2020 will provide even greater savings to the Government.

The innovation premium, known officially 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 the regular reform of the drug pricing system every two years, 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.

Drug price revisions are conducted in two-year cycles, linked to the revision of medical service fees. Where an increase in consumption tax necessitates an interim drug price revision, EFPIA believes that revision should be confined to an adjustment to reflect the tax increase. Other additional and irregular repricing exercises, such as the market expansion repricing rule or the special repricing implemented in late 2015, will lead to negative growth in the overall pharmaceutical market. This would conflict with the Government's designation of healthcare as a strategic growth industry and reduce the incentive to invest in Japan from overseas.

Another issue is that, 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. As a result, many physicians will not prescribe a drug until the product has been on the market for at least a year. Given that Japan has robust safety measures, including the Drug Risk Management Plan introduced in 2013, this 14-day rule for new drugs is outdated and acts only as a barrier, preventing patients from accessing the treatments they need.

The Government introduced a form of cost-effectiveness health technology assessment (HTA) 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. EPFIA 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.

## Key Issues and Recommendations

### ■ Pricing system

*Yearly status report: negative progress.* It is still possible to say that Japan enjoys an environment that is broadly supportive of innovative new medicines, given measures such as the 2010 launch of the innovation premium. However, not only do barriers to innovation still exist, deterring investment, but changes in the past 12 months, such as the special repricing and the launch of HTA, have reduced the attractiveness of the Japanese market.

#### **Recommendations:**

- The innovation premium, which provides appropriate reward for innovative new medicines, should be continued without any additional conditions. With international competition intensifying, the premium is necessary to ensure continued investment in Japan and the early delivery of new medicines to Japanese patients.
- Although there has been some discussion of annual repricing or irregular price revisions for relatively expensive drugs, drug price revisions should be conducted no more frequently than every two years, linked to the revision of medical services fees.
- The market expansion rule, including the huge sales repricing introduced in 2016, should be abolished because it 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.
- The 14-day rule should be abolished or revised. The safety environment has changed substantially since its introduction many years ago, and it serves now only as a barrier, preventing patient access to drugs.

### ■ Cost-Effectiveness Health Technology Assessment (HTA)

*Yearly status report: no progress.* Health Technology Assessment (HTA) was introduced in Japan from April 2016 on a trial basis. The European experience has been that HTA can become yet another barrier preventing patient access to medicines and create a major administrative burden for government and industry.

#### **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 administrative 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

Access to vaccines in Japan started to improve rapidly from 2008 onwards, following the sequential introduction of several new vaccines. (Before then, Japan had suffered from a significant vaccine gap.) By October 2016, many vaccines had been designated an integral part of “routine immunisation”, i.e. among the suite of vaccines strongly recommended, as well as funded, by the Government, making the rotavirus and mumps vaccines the only remaining WHO-recommended (World Health Organization) vaccines excluded from Japan’s routine immunisation programme. The only other gap remaining derives from shortcomings in the development of combination vaccines, which would alleviate the congested immunisation schedule for infants. For example, the combined MMR vaccine (mumps, measles and rubella), and the 5- or 6-in-1 combination vaccine (where hepatitis B and/or Hib vaccines are added to the 4-in-1 DTaP-IPV -diphtheria, tetanus, pertussis and inactivated polio) are still not available in Japan.

At the end of 2015, Japan experienced vaccine supply issues, due to a mix of Good Manufacturing Practice (GMP) violations and natural disasters, and these had a major impact on both the medical front and on the manufacturers concerned. Vaccines with limited supply sources were the most affected, serving as a reminder that vaccine supply is an important topic on the risk management agenda. It should be noted that regulatory requirements in Japan create a bottleneck in the secure supply of vaccines: for example, it takes more than 6 months for vaccines to reach the market after import, which in effect cuts down their shelf life.

A further challenge is that in recent years there have been procedural issues with the introduction and development of vaccines. The process for recommending inclusion of vaccines in the routine immunisation programme is not clear and the outcome can be difficult to predict, thus increasing the risk for manufacturers considering the development of vaccines in Japan. Uncertainty is further increased by recommendations such as that first made in June 2013 and still in force as of September 2016, that use of the human papillomavirus vaccination should be suspended, even though it has been medically and scientifically proven that there is no causal relationship between various symptoms and the vaccination. If companies are to develop vaccines smoothly in Japan, an infrastructure must be created that will allow the regulatory authorities to make decisions based on scientific judgements. More specifically and importantly, women in Japan should not be deprived of the opportunity to prevent cervical cancer, and so the current situation should be promptly rectified.

As shown above, while the vaccine gap in terms of the vaccine product portfolio is moving towards closure, it has become more evident that the “structural vaccine gap” still needs attention from a procedural and a policy perspective. In short, scope remains 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

- **Securing a stable supply of vaccines**
  - Vaccine suppliers should be diversified to include multiple domestic and global manufacturers, securing stable supply routes
  - Long-term supply purchase agreements and stockpiling by the government should also be considered
- **Promotion of international harmonisation of regulatory requirements**
  - The Mutual Recognition Agreement (MRA)/ Memorandum of Understanding (MOU) should be expanded to include vaccines, and national testing procedures should be streamlined to greatly reduce the time it takes to supply vaccines
  - Quality requirements should be harmonised and the introduction of vaccines accelerated

## Key Issues and Recommendations

### ■ Incorporation of WHO-recommended vaccines into routine immunisation and promotion of development of combination vaccines

*Yearly status report: some progress.* As from October 2016, hepatitis B vaccine has been included in Japan's routine immunisation programme, and the Immunisation Vaccine Subcommittee of the Health Science Council is considering recommending that the remaining rotavirus and mumps vaccines be included as well. They have also proposed that the early development of combination vaccines should be treated as an issue of high priority.

#### **Recommendation:**

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

### ■ Securing a stable supply of vaccines

*Yearly status report: new issue.* Concerns have arisen that Japanese public health could be adversely impacted by issues such as problems with manufacturing processes or the occurrence of natural disasters that lead to an unstable supply of vaccines. Such an outcome was only narrowly avoided in 2015. Sporadic epidemics can also be a trigger for a disruption of supply. For important vaccines like those in the routine immunisation programme, diversifying supply sources to multiple manufacturers, both domestic and global, would allow a stable vaccine supply in Japan. Also, long-term supply purchase agreements and stockpiling should be considered.

#### **Recommendations:**

- Diversify vaccine suppliers to multiple domestic and global manufacturers, securing stable supply routes.
- Investigate long-term supply purchase agreements and stockpiling by the Government.

### ■ Elimination of the “structural vaccine gap”

*Yearly status report: no progress.* At a time when effective vaccines from overseas are being introduced and the number of vaccines included in routine immunisation is increasing, the relative inadequacy of Japan's vaccine policies is increasingly apparent and leading to the emergence of a new “structural vaccine gap”. An infrastructure should be established to enable the regulatory authorities to evaluate and recommend vaccination from a safety perspective based on scientific judgments, so that people will not be left unprotected from preventable infectious diseases. Also, it is difficult to predict whether the regulatory authorities will recommend that a particular vaccine should become part of the routine immunisation programme or not, and companies are hesitant to develop vaccines in Japan because of this uncertainty. As a result, there is a risk that the product portfolio vaccine gap will reappear.

#### **Recommendation:**

- The routine immunisation process should be streamlined and an environment created where clear policy decisions can be made based on sound medical and scientific evidence.

### ■ Promotion of international harmonisation of regulatory requirements including Mutual Recognition Agreement (MRA) and Minimum Requirements for Biological Products (MRBP)

*Yearly status report: no progress.* The number of EU Member States covered by the EU-Japan MRA on GMP was expanded in April 2016, but vaccines remain outside its scope. A great deal of time and effort is needed to introduce and supply vaccines due to excessive pharmaceutical regulations. For example, because of the procedures for conducting national testing, or the lack of clarity in MRBP related to timing of reviews, revision procedures, and criteria for listing, it can take more than 6 months before a vaccine is released onto the market after importation.

#### **Recommendation:**

- The MRA should be expanded to include biopharmaceuticals and vaccines, thereby reducing redundant quality testing items and accelerating the time from import to release.
- Quality requirements for vaccines should be revised based on state-of-the-art science and technology, harmonised with other regions. The current MRBP should be abolished and its contents consolidated and integrated into the Japanese Pharmacopoeia.



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# COSMETICS & QUASI-DRUGS

## Introduction

The EU Cosmetic and Quasi-Drugs sector works to ensure the quality, efficacy, safety, and environmental sustainability of its products in the market by investing in the research and development of new ingredients, monitoring global developments in science, 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). The sector produces a wide variety of innovative and safe cosmetic and quasi-drug products that contribute to consumers' quality of life (QOL), for example by helping them stay clean and healthy, protecting them against the damaging effects of extreme weather, preventing dental cavities, and improving their appearance. These outcomes fit well with the efforts being made by the Japanese Government to promote self-care and, where appropriate, self-medication, so that people in Japan can enjoy the best possible health and avoid placing unnecessary strain on the national healthcare budget. There are many cosmetic and quasi-drug products that can assist in these efforts.

Shipments of cosmetics in Japan were worth a total of 1,507 billion yen in 2015. In the same year, Japan imported cosmetics valued at about 244 billion yen, of which some 82 billion yen related to cosmetics from the EU. European cosmetic and quasi-drug products account for such a large share of imports because Japanese consumers recognise their value. The import process was made somewhat easier in 2016, when the Ministry of Health, Labour and Welfare (MHLW) abolished import notifications, and eased the rules relating to Partial Change Approval for prescription drugs, so that it is now possible for the applicant to decide the timing of a product change. The EBC applauds MHLW for these actions.

However, European companies still face challenges in bringing cosmetic and quasi-drug products to Japanese consumers 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 when the same products are already in global use and have clinically proven efficacy. Some quasi-drugs even need to be reformulated because their global version uses new active ingredients or excipients for which approval is too time-consuming or difficult to obtain in Japan. Moreover, information on which active and inactive ingredients and excipients have already been approved is very limited. The EU and Japan also maintain different rules governing which ingredients are allowed in cosmetics. 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.

The EBC believes that the EU and Japan have an opportunity to lead the way in the cosmetics and quasi-drugs market, by bilaterally negotiating faster registration of quasi-drugs, expanding efficacy claims, and harmonising ingredients that are allowed for cosmetics and quasi-drugs. The EU-Japan FTA/EPA is an important vehicle for this process. In addition, the EBC would welcome greater leadership by the EU and Japan in the International Cooperation on Cosmetic Regulation (ICCR), which 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

- In addition to abolishing import notifications, MHLW should accept electronic submission of applications and notifications and fully introduce electronic import procedures
- In order to promote the use of fluoride in oral care products, approval standards for medicated toothpastes should be revised and international harmonisation of toothpastes and mouthwashes should be realised as soon as possible

## Key Issues and Recommendations

### ■ Reform of the quasi-drug approval system

*Yearly status report: slight progress.* Having created examination guidelines for medicated shampoos and conditioners in 2014, MHLW asked the Japan Cosmetic Industry Association (JCIA) to draft an industry standard with a view to creating examination guidelines for medicated soap. In response, the JCIA has started to study examples of approved medicated soap. At the same time, in August 2015, the Director of MHLW's Evaluation and Licensing Division issued a notification concerning an "Investigation on Review of the List of Excipients for Quasi-drugs (Request)". Based on the notification, for the first time ever since the list was created in 2008, the upper values of existing ingredients and ingredients additionally listed in the Japanese Standards of Quasi-Drug Ingredients are now being reviewed. The Pharmaceuticals and Medical Devices Agency (PMDA) collected information from businesses on the raw material specifications of already approved excipients and published the results in a book entitled "Standards of Excipients for Quasi-drugs" in 2014. Additional information was solicited from businesses in 2015 and again in 2016, but so far, responses have been limited. Consequently, the book still covers only the small number of 27 ingredients. Furthermore, since April 2016 the PMDA has been provisionally asking applicants to attach a check list confirming the contents of their application documents and this procedure will be formally adopted in 2017, placing an additional burden on applicants. Although the quasi-drug review system has been improved, there is unfortunately no commitment in the above-mentioned notification to shorten the review period.

#### **Recommendations:**

- MHLW should shorten the review period for the quasi-drugs for which review guidelines have been created and which are believed to be identical to already-approved quasi-drugs.
- A code should be assigned to standards for ingredients used in already-approved quasi-drugs, and this code should then be used in applications for approval of other quasi-drugs that share the same ingredients, to obviate the need for repeatedly reviewing the standards for those same ingredients. This would enhance efficiency and shorten the review period.

### ■ Harmonisation of quasi-drug and cosmetic ingredients

*Yearly status report: slight progress.* The EU and Japan maintain different rules governing which ingredients are allowed in cosmetics. Furthermore, the fluoride concentration levels permitted in oral care products in Japan are not aligned with the higher levels permitted in other developed countries. The effectiveness of fluoride in preventing tooth decay is scientifically verified: it is important for the health of the mouth and the entire body and is therefore key to self-care. 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, whereas Japan approved the use of fluoride in mouthwash for general consumption in 2015, but only as a drug requiring guidance.

#### **Recommendation:**

- MHLW should revise the medicated dentifrice approval standard in line with international norms, raising the upper limit of fluoride concentration allowed in medicated toothpaste (a quasi-drug), and allowing the use of fluoride in mouthwash (another quasi-drug) as soon as possible.

### ■ Expansion of efficacy claims for cosmetics

*Yearly status report: no progress.* Fifty-five efficacy claims were defined as permissible for cosmetics in Japan in the "Notification on Revision of the Scope of Efficacy Claims for Cosmetics" issued in 2000. In 2011, a further efficacy claim of "making fine wrinkles due to dryness less noticeable" was added to the list. The Japanese Cosmetic Science Society and Japan Cosmetic Industry Association are now studying the efficacy claim of "prevention of ultraviolet ray-derived photoaging" which may lead to a further expansion. Yet the scope of efficacy claims approved in Japan is still narrower than in other countries, which hinders entry to the Japanese market of foreign-made cosmetics based on the latest research and technology. There is also a need, as part of the

Government's efforts to encourage self-care, to develop a proper method of distributing information to consumers on scientifically-proved efficacy, such as the effectiveness of warmth in improving atopic skin and the efficacy of sunscreen products in preventing skin cancer.

**Recommendation:**

- Japan should expand the scope of its positive efficacy claims for cosmetics to harmonise with that of the EU.

## ■ Simplified procedures for cosmetic and quasi-drug imports

*Yearly status report: significant progress.* MHLW announced the abolishment of import notifications effective from January 2016. This has significantly simplified import procedures. At the same time, however, the Nippon Automated Cargo and Port Consolidated System (NACCS)-based online procedures were abolished, and customs clearance now depends on presentation of a Production (Production and Sale) Permit and paper copies of the Notification on Manufacture and Sale of Cosmetics and other documents. This is a step backwards in terms of accelerating online procedures.

**Recommendation:**

- A system of online (rather than paper-based) procedures, involving for example the effective use of NACCS, should be established for handling documentation to support customs clearance of imported cosmetics and quasi-drugs.

## ■ Online notifications and applications for approval of cosmetics and quasi-drugs

*Yearly status report: no progress.* In its Basic Policy on IT Utilisation, the Japanese Government declared its intention to handle administrative procedures, such as applications, online rather than face-to-face or by document processing. For prescription drugs, applications for approval, along with supporting clinical investigation reports and other materials, will soon be accepted in electronic form via the Internet. However, for cosmetics and quasi-drugs, notifications and applications must still be submitted on floppy discs or in paper form, which are outdated methods compared to those used by many other countries. The systems used by prefectural authorities, the PMDA, and Customs are not linked, and separate procedures are required for notifications and applications for the manufacture and sale of cosmetics and quasi-drugs, notifications of export goods, and presentation of materials for import customs clearance.

**Recommendation:**

- An online notification and application system should be established for submitting Notifications on the Manufacture and Sale of Cosmetics and Applications for Approval of Quasi-Drugs. This system should be linked to the customs clearance system to provide a one-stop service for application procedures.

## ■ Establishment of alternatives to animal testing

*Yearly status report: no progress.* Animal testing for the purpose of studying the safety and efficacy of cosmetics is completely banned in the EU and the trend towards a ban is spreading to other countries and areas. However, in Japan, cosmetics manufacturers are still expected to submit safety data based on animal testing when applying for approval of quasi-drugs using new raw materials. Social pressure to abolish animal testing and shift to alternative methods is increasing. A notification issued by MHLW in 2011 supports the active use of alternative methods replacing animal testing when preparing applications for approval of quasi-drugs, but available alternative methods are limited in regard to phototoxicity, skin sensitisation, and eye irritation tests.

**Recommendation:**

- Japan should as soon as possible formally approve the proposed alternative methods, based on the Organisation for Economic Cooperation and Development (OECD)'s test guidelines, by issuing relevant MHLW Guidelines, so that these alternative methods are available when preparing applications for approval of quasi-drugs.

# **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 2015, at 291 billion yen (according to Japan Customs), accounted for a mere 5% 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 Indication (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: minimal 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.

### ■ 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: no progress.* 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: minimal 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: minimum 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 Indications

*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. EBC puts high emphasis on this issue and expects radical changes so that the Japanese market becomes more accessible for European products.

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. In addition, there are no timelines or deadlines specified in Japan's process for approving food additives making it difficult to know how long it will take for approval to be obtained. There are also cases where applicants have to submit test results that were not initially requested, further prolonging the approval process. 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	Norwegian Seafood Export Council
Corbion Japan	Perfetti Van Melle Japan Services
Danisco Japan	Pick
Danone Japan	PinguinLutosa Japan
DSM Japan	Puratos Japan
IKEA Japan	Roquette Japan
Japan Europe Trading	SAVENCIA FROMAGE & DAIRY JAPON
MIE PROJECT	SKW East Asia
Nestle Japan	Valrhona Japon

## Key Issues and Recommendations

### ■ Tariffs & quotas

*Yearly status report: no progress.* Japan continues to impose high import duty rates on many foods and food ingredients. Severe inflation in the cost of ingredients and transport, coupled with high import duties, make some imported foods prohibitively expensive. Examples include butter (with an import duty rate of 35% plus 1,159 yen/kg), cheese (26-40%), chocolate for professional use (29.8%), confectionery (25%), syrup (24% plus sugar tax related to quota), fruit juice and fruit puree for babies (21.3%), and herbal tea (15%). Quotas also exist, for example for dairy products and sugar, and the quota management system adds complexity when importing food containing such ingredients.

#### **Recommendations:**

- The Government of Japan and the EU should abolish tariffs on food products as part of the EU-Japan FTA/EPA.
- The quota management system should be 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.
- The EU-Japan FTA/EPA should guarantee that food enzymes in wide use in the EU and accepted as safe by FAO/WHO Joint Expert Committee on Food Additives 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 agro-chemicals 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 2ppm, hence the MRL in maize starch-derived products would also be 2ppm). In Japan, however, derived products that are not on the positive list have a default MRL of 0.01ppm, even if the original product has a higher MRL (for instance the MRL of deltamethrine in maize is 1.0ppm, but that in a maize starch-derived product not listed would be 0.01ppm).

#### **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.
- The EU and Japan should harmonise their respective lists of approved agro-chemicals.



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

*Yearly status report: progress.* While the approval process for many years was slow, in the last few years, the number of EU Member States approved for export of beef to Japan has increased. There are however still Member States waiting to gain such approval. 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:**

- 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.
- 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.

## ■ Malt and quota management system

*Yearly status report: no progress.* 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: no progress.* 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**

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# AUTOMOBILES

## Introduction

The Japanese passenger car market remains sluggish. In the first eight months of 2016, the overall market, including kei-cars, declined by 3.8% over the same period in 2015. Foreign brands, mainly from Europe, have however held their own in difficult market conditions, rising by 1% up till the end of August. The European share of the domestic passenger car market remains constant at just below 6%.

Non-tariff measures (NTMs) 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. However, much work remains to be done to reach agreement in principle before the end of 2016, yet there has been little recent progress. Some 70% of the NTMs affecting EU automotive exports to Japan are still being addressed. Additional 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, CO<sub>2</sub> emissions, and fuel consumption.
2. The elimination of other unique Japanese requirements for both passenger cars and commercial vehicles in areas not covered by UN Regulations. The FTA should include an annex that will commit the EU and Japan to cooperate so as to prevent future regulatory action by the two sides creating new barriers to trade.

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 urges the Japanese government to take further steps, as recommended by Ministry of Economy, Trade and Industry (METI), to narrow the discrepancy between the level of taxation of *kei*-cars and compact cars.

### 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 an International Whole Vehicle Type Approval (IWVTA) system. Its full 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 extend the scope of the International Whole Vehicle Type Approval system so that it covers all the requirements of the Japanese type approval system.

### ■ Tax reform

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

**Recommendations:**

The Government of Japan should:

- Abolish 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: little progress.* The operation of the High-Pressure Gas Safety Act impedes the introduction into the Japanese market of imported vehicles using 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: little progress.* 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 because it makes financial sense and spreads 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 were seldom 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 stronger.

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, defying the global trend towards single platform development and volume production. Japan still has some way to go to become a truly global market.

The EBC recognises that the Japanese authorities have been making efforts toward regulatory harmonisation related to tyres. For new vehicles, one example was the decision taken by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) in October 2015 to implement the UN/ECE (United Nations Economic Committee for Europe) R117-02 regulation (rolling sound emission, wet traction, and rolling resistance) for the Japanese market. This regulation will enter into force for passenger tyres in 2018, light truck tyres in 2019 and truck/bus tyres in 2023. The EBC welcomes this decision.

However, it should be noted that the tyre market consists of both new vehicle (original equipment) and replacement markets. For the replacement market, the timeline for the implementation of the above-mentioned UN/ECE R117-02 regulation remains undecided. There are, furthermore, roadblocks to market access in the replacement market because of the peculiarities of the Japanese distribution environment, which is fragmented, only partially integrated, and difficult for foreign companies to access.

Accessing consumers via garages, repair shops, and tyre shops is a critical factor for success in the Japanese replacement market. A recent survey of market concentration by the Japan Fair Trade Commission (JFTC) shows that domestic brands still account for most of the market: around 90% in all tyre segments (truck/bus, light truck and passenger tyres). The EBC would welcome any action aimed at limiting exclusive distribution and facilitating access to the fragmented distribution market.

### Key FTA/EPA Issues

- Continue to implement UN regulations, without exempting commercial vehicles

## 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:**

- Encourage 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.
- Foster free and open competition and avoid excessive reliance on affiliated companies.
- 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 24-26 May, 2017 in Yokohama.

#### **Recommendation:**

- Continue face-to-face meetings between leading representatives of European suppliers and the Japanese automobile industry. Such meetings have led to greater understanding between European component manufacturers and Japanese car manufacturers. The EBC also recommends that the scope of these meetings is expanded in future to include Japanese venues.

### ■ Tyres

*Yearly status report: progress.* The EBC appreciated the action taken by MLIT to implement the UN/ECE R117-02 regulation in Japan, which for new vehicle applications (original equipment) will be completed, step-by-step, by 2023. However, the EBC notes that there are still difficulties in gaining access to replacement market sales channels in this sector.

#### **Recommendations:**

- Further accelerate regulatory harmonisation for not only new vehicles but also the replacement market.
- Limit exclusive distribution and facilitate access to the fragmented distribution market.

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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 negotiations and conclusion of the Trans-Pacific Partnership Agreement (TPP) negotiations indicate 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 and the A380 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 is actively supporting 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, collaboration between various Japanese industries and Rolls-Royce on the Trent engines, and other cooperations between Safran and Leonardo with their respective Japanese partners, are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. The Government of Japan and European Governments have signed various bilateral agreements that have led to increased engagement and project discussions. 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.

As part of the Aviation Strategy adopted on December 7<sup>th</sup> 2015, the European Commission "recommended that the EU negotiates further bilateral aviation safety agreements with important aeronautical manufacturing nations such as Japan". In March 2016, the 28 EU Member States authorised the Commission to do so on behalf of the entire European Union. The Commission will be supported by the European Aviation Safety Agency, which is recognised throughout the world as the EU's aviation safety and aircraft certification body, to negotiate with its Japanese counterpart, the Japan Civil Aviation Bureau. The EBC is encouraging this initiative which will remove the duplication of oversight activities and support mutual safety recognition between the EU and Japan.

## 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 technological advantages. For example, European companies have experience in the area of high-end technologies that are environmentally friendly. Procurement decisions should be made taking into consideration both competitive and technological advantages. European manufacturers of commercial aircraft, engines, components, and navigational equipment offer state-of-the-art technology at internationally competitive prices. The EBC consistently requests Japan to modernise its air traffic management system. Some of the 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 such as for the air traffic management system. The EBC deplors 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 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.

### ■ Supporting BASA negotiation between EU and Japan

*Yearly status report: progress.* In March 2016, the European Commission was authorised by the 28 member states to open negotiations with a view to concluding a Bilateral Air Safety Agreement (BASA) between the European Aviation Safety Agency and its Japanese counterpart, the Japan Civil Aviation Bureau. Such an agreement will enhance air safety worldwide and enable cooperation in the aviation safety domain, including certification, testing and maintenance of aeronautical components, air operations, flight crew licensing, air traffic management and airports. It will also reduce the transaction cost of exporting aircrafts, while ensuring high levels of safety in partner countries and helping to harmonise product standards worldwide.

#### **Recommendation:**

- The EBC encourages the EU and Japan to start negotiations with the goal of finalising a Bilateral Air Safety Agreement as soon as possible in order to develop business opportunities between the EU and Japan by removing administrative hurdles.

### ■ Promoting the use of large aircraft at Haneda Airport

*Yearly status report: limited progress.* After the successful Rio 2016 Olympics, the Tokyo 2020 Olympics is less than four years away, and with the number of foreign visitors to Japan already close to 20 million for 2015, the new target set by the Japanese Government is up to 40 million visitors in 2020. Accordingly, it is crucial for Haneda Airport, now the preferred airport in Tokyo, to be able to accommodate the increase in traffic. The EBC welcomes the decision to allow Lufthansa to operate the Boeing 747-8i at Haneda, but the airlines should also be allowed to operate the Airbus A380. With ANA planning to use the A380 aircraft between Tokyo and Honolulu from 2019, Haneda must be available for such an operation. The decision to allow day-time A380 operations at Haneda will increase the number of passengers using Haneda without having to provide 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

The Space Policy Commission and the National Space Policy Secretariat (NSPS) established in the Cabinet office now 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 August 2015, 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 NSPS'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 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.

## 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:**

- 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 on satellite platforms and ground systems.
- The EBC recommends Europe-Japan coordination and cooperation in space-related ODA worldwide.

### ■ Satellites

*Yearly status report: no progress.* Japan mostly ignores Europe’s satellite technology. The space agencies of both sides cooperate and share data in science and research, but have almost no industrially meaningful cooperation.

**Recommendations:**

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

### ■ Launchers

*Yearly status report: no progress.* Although Europe and Japan 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. The creation of Airbus Safran Launchers (ASL) and a new launcher development organization in Europe make it easier to realise industry-led cooperation on development.

### ■ 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.

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 will be finalized before the end of 2016. 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. In 2016, numerous bilateral events between EU and Japanese defense organisations have been conducted demonstrating renewed interest by Japanese defense organisations in developing cooperation with their EU 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 2016, organised between METI and various European bodies, including the EBC, GIFAS (Groupement des industries françaises aéronautiques et spatiales) and ADS (Aerospace Defence Security) to push forward the industrial dialogue.

## Key Issues and Recommendations

### ■ Procurement

*Yearly status report: some progress.* The EBC anticipates that the Japanese government's desire to move towards collaborative defence programmes with Europe and the progress in bilateral agreements with individual European nations will result in amendments to the defence equipment acquisition process and improvements in transparency of the decision-making. The EBC believes that the recommendations listed below will also benefit the Japanese industry as it prepares 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 the latest NATO and civil 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.
- The Japanese Government should present and explain the organisation and functioning of the new ATLA (Acquisition, Technology & Logistics Agency) to the European industry.

### ■ 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. 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.
- Defence agreements with EU member countries are crucial for future defence collaboration and the EBC strongly recommends finalising and concluding all on-going discussions in order to foster industrial partnerships.
- 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 finalise a 'white list' of countries to which Japan may agree to export.

#### **Recommendation:**

- The Japanese Government should continue to define its defence export policy.

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# CONSTRUCTION

## Introduction

Ongoing fiscal stimulus measures, continuing reconstruction efforts following the 2011 earthquake and the more recent April 2016 earthquake, and anticipated demand from building projects for the Olympics will ensure continued demand for residential and non-residential construction. Furthermore, Japan's housing market has received a boost from government measures, including the negative interest rate, and the Residential Property Price Index was up 2.3% in May 2016 according to figures from the Ministry of Land, Infrastructure, Transport and Tourism.

However, various challenges continue to inhibit Japan's construction sector and only minimal year-on-year growth to a total of 51.8 trillion yen is expected in construction spending for fiscal year 2016 and thereafter. In fact, construction spending has levelled off during the past few years suggesting that the construction industry is and will continue to be unable to meet the growing demand. 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.

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 CO<sub>2</sub> 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 technologies, such as those used to produce rechargeable batteries for hybrid vehicles, nanotechnologies for manufacturing semiconductors, and various products related to environmental technology. 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, essential for the battery industry, as Japan's level of production is below 10% of demand.

Tariffs are a barrier to increasing trade between Europe and Japan. So are non-tariff barriers, in the form of administrative burdens, regional differences in registration procedures and inconsistent use of classifications, which all make doing business in Japan unnecessarily costly and difficult for foreign companies. The benefits of eliminating tariffs and of harmonising and simplifying classifications and procedures would be felt not only by European suppliers, but even more by Japanese industry, making it more competitive.

Chemicals normally fall within the competency of the Ministry of Economy, Trade and Industry (METI), which is involved in the task of harmonising the rules regulating chemicals. However, some years ago, the Ministry of Health, Labour and Welfare (MHLW) initiated a discussion on how to label chemical products that could be harmful to people handling them. Unfortunately, MHLW's work seems to have been conducted in isolation and its new system, which entered into force on 1 July 2016, lacks logic. As an example, products that are not registered in Japan, despite having a CAS (Chemical Abstract Service) number, could now be labelled as harmful since MHLW's warning labels are based either on the product's chemical components (rather than on the final substance), or on the most similar substance already registered in Japan. Additionally, it remains unclear whether or not the results of testing conducted in Europe under REACH (Registration, Evaluation, Authorisation, and Restriction of Chemicals) can be used. There is furthermore very little information in English to help European companies to understand and follow MHLW's rules.

### 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 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 industries. 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 in determining competitiveness. 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 materials accounts for only 10% of demand. Moreover, 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 arbitrary 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 order for a European product to be tested and approved for sale in Japan, commercially sensitive information has to be handed over to Japanese competitors. This gives the competitors an undeserved advantage, and creates unfair 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.

### ■ Workers' safety labelling for chemicals

*Yearly status report: new issue.* When products are not registered in Japan despite having a CAS number, MHLW does not consider the actual nature of the substance but applies a warning label based either on the individual components or on the most similar substance that is already registered in Japan. This can lead to compounds being unnecessarily labelled as dangerous. There is, furthermore, a lack of information in English on this legislation.

#### **Recommendations:**

- MHLW should give due consideration to compounds not currently registered in Japan that nevertheless have an international CAS number.
- MHLW should provide proper information on how importing companies should comply with its regulations, including in English.



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# ENERGY

## Introduction

Japan's utility industry used to be run by ten regional Electrical Power Companies (EPCOs) that had a virtual monopoly on power generation, transmission and distribution in each area. In March 2000, partial liberalisation was introduced in respect of retail power supply for extra high voltage users. The Ministry of Economy, Trade and Industry (METI) opted for a limited model of liberalisation, where vertical integration of electricity generation, transmission and distribution was maintained in order to secure a stable supply. In 2011, the consequences of the Great East Japan Earthquake and the subsequent Fukushima nuclear accident revealed weaknesses in this model, due to limited grid interconnection between the EPCOs, low competition and strong price control, and a lack of flexibility to integrate renewable energy.

As the first step to address these issues, the Organization for Cross-regional Coordination of Transmission Operators (OCCTO) was formed in April 2015, and subsequently, in September that year, an Electricity Market Surveillance Commission (EMSC) was established under METI to monitor and regulate the market. A second step was taken in April 2016, when full retail liberalisation was introduced as part of the Electricity Market Reform planned by METI's Agency for Natural Resources and Energy (ANRE). The third step, legal unbundling of the transmission and distribution sector from the EPCOs, is scheduled for 2020. The EBC believes that fair and transparent processes will enable healthy competition in the electricity market.

Following the 1970s oil crisis, 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 May 2012, all of Japan's nuclear plants were shut down and a programme of safety reviews and upgrades was initiated, which is still ongoing. Two reactors, Sendai 1 and 2, were the first to be back on grid in August 2015, followed by Takahama 3 and 4 (now idle due to an injunction by Otsu District Court), and Ikata 3 in August 2016.

Japan's Basic Act on Energy Policy sets the following goals:

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

In April 2014, the Government completed a review of the energy mix and 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".
- 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, designed to meet goals in terms of safety, energy security, economic efficiency and the 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. Subsequently, in June 2016, the Feed-In Tariff (FIT) Rule changed. Moreover, an amendment to the Act on Special Measures Concerning Procurement of Electricity from Renewable Energy Sources by Electricity Utilities (the "FIT Amendment Act") was promulgated and will have a significant impact on projects that did not have a grid connection agreement by 31 July 2016, as new projects after that date will be subject to a three-year development deadline.

The EBC believes that the ties between the EU and Japan in this area should be further strengthened to facilitate commercial exchange, achieve consensus on common standards, support reaching the CO<sub>2</sub> emissions targets of COP21, and facilitate access to energy at the lowest possible cost. The Government's energy mix target for 2030 will be reviewed to check if the reduction target in greenhouse gas (GHG) of 26% in 2030 is feasible, from the base year 2013. However, the current investment plan to add new coal-fired power plants might lead to stranded assets.

## Key Issues and Recommendations

### ■ Stability of supply versus cost

*Yearly status update: some progress.* Stability of supply will remain the Japanese Government's top priority for the economy. Fossil fuels are and will most likely remain the key pillars of the energy mix, even if the cost of imports threatens the competitiveness of Japanese industry in the global market.

#### **Recommendations:**

- Accept international standard products and solutions, to reduce EPCO Capital Expenditure (CAPEX) and Operational Expenditure (OPEX).
- Increase the transparency of EPCO procurement in line with the World Trade Organisation's guidelines.
- Encourage development of renewable energy, which must be carried out ambitiously with realistic targets, aimed at increasing the safety and reliability of the energy supply.
- Since nuclear energy will remain a core constituent of the Japanese energy mix, ensure that its long-term sustainability is based on a reliable approach to all safety issues, and the smooth implementation of a back-end policy for recycling of spent fuel and final disposal of radioactive waste. It will also be necessary to address the issue of the ageing of existing plants (including considering plant lifetime extension and/or replacement of ageing reactors, and decommissioning).
- Since fossil fuels will remain the most significant source of electricity in the energy mix and in order to reduce greenhouse gases, favour the use of natural gas over coal for future investments in power generation.

### ■ Transmission and Distribution

*Yearly status update: progress.* Japan's transmission network is centred on the production sites, with the main transmission at 500kV. Only three convertor stations connect the 50Hz and 60Hz networks. The limited interconnections between EPCOs and between the 50Hz and 60Hz networks represent a real risk to security of supply. In contrast, European and US grids have 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.

#### **Recommendations:**

- While preparing for legal unbundling in 2020, implement regulations that will ensure security of supply and fair market mechanisms.
- Strengthen the authority of the OCCTO and EMSC to deliver increased interconnection capacity between Transmission and Distribution System Operators (TDSOs), achieving fair electricity transactions and encouraging mergers between TDSOs.
- Ensure electricity interconnections are developed at national and international levels based on HVDC, Frequency Converters (50-60Hz), Flexible Alternate Current Transmission Systems (FACTS), and Battery Energy Storage Solutions (BESS) to achieve resilience throughout the grid.

### ■ Nuclear energy and nuclear safety

*Yearly status update: some progress.* In the wake of the Fukushima nuclear accident, Japan reformed its nuclear safety regulator. The Nuclear Regulatory Authority (NRA) was established in September 2012 and, in July 2013, it introduced new nuclear safety standards and nuclear safety regulations for nuclear power plants. These were extended to other nuclear facilities in December 2013. The NRA is currently checking the safety of all Japanese power plants, to determine whether they conform to the new regulations and if they can be authorised to restart or not. As of May 2016, ten electric power companies had applied to the NRA for safety evaluations of a total of 25 reactors.

#### **Recommendations:**

- Increase cooperation and transparent exchange with international organisations such as the International Atomic Energy Agency (IAEA) and World Association of Nuclear Operators (WANO) to improve worldwide nuclear safety levels.
- Develop complete interim and final waste repositories for spent fuel and radioactive waste.
- Adapt the legal framework to clarify the process for nuclear reactor restarts.

## ■ Wind energy

*Yearly status update: no progress.* Wind energy could help Japan to reduce its reliance on imported fossil fuels and reach its CO<sub>2</sub> emissions targets. 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.

### **Recommendations:**

- Facilitate the development of on-shore as well as off-shore wind farms by reducing unnecessary regulations that add to their cost. This can be achieved by revising environmental impact assessment requirements that unreasonably extend the time frame for wind farm development.
- Learn and benefit from the technical standards activities for wind energy being carried out by the International Electro-technical Commission (IEC). 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 would both facilitate increased investment and 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 use, and the difficulties in obtaining reasonable interconnection commitments from regional electric utilities and project financing for utility-scale photovoltaic (PV) 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:**

- 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.
- Create incentive and standardisation programmes for the EPCOs 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.
- Encourage further grid interconnections, utilise existing pump storage power generation plants, battery storage, and consider new technologies, such as conversion to hydro for further PV integration.

## ■ Energy efficient lighting

*Yearly status update: progress.* The increasing global demand for light, in a world beset by resource constraints and climate change, has created a need for increased energy efficiency in lighting products. Lighting currently represents approximately 20% of global electricity consumption and the lighting industry will need to adapt to changing environmental regulations and the requirement for reductions in CO<sub>2</sub> emissions. The key benefits of LED over conventional lighting technologies are lower consumption and a longer lifespan. In addition, the integration of LED technology, lighting controls and software allows for new functionalities and services, which create a new market. Attractive and innovative lighting has become available as a result of the shift from conventional to LED lighting, as well as the expansion from individual products to connected lighting systems and services. Progress in extending the Internet of Things into lighting, and its innovation-driven strategy provide quality energy-efficient lighting and enable people to enjoy new lighting experiences and benefits through apps and cloud-based services for smart cities, smart retailing, smart offices and smart homes.

### **Recommendations:**

- Accelerate the introduction of digital lighting.
- Encourage connectivity in lighting.

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