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# STRENGTHENING PARTNERSHIPS

IN CRISIS AND OPPORTUNITY ALIKE

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The EBC Report on the  
Japanese Business Environment



**EBC**

EUROPEAN BUSINESS COUNCIL IN JAPAN



Strengthening partnerships in crisis and opportunity alike

The EBC Report on the Japanese Business Environment  
2020

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

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The European Business Council (EBC) is the trade policy arm of the 15 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 250 company executives participate directly in the EBC's 25 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.

For more information on the EBC and its activities, please contact the EBC secretariat at the following address:

Sanbancho POULA Bldg. 2F  
6-7 Sanbancho, Chiyoda-ku, Tokyo 102-0075  
Tel: 03-3263-6222  
Fax: 03-3263-6223  
E-mail: [ebc@ebc-jp.com](mailto:ebc@ebc-jp.com)  
Web: <https://www.ebc-jp.com>

## **Strengthening partnerships in crisis and opportunity alike The EBC Report on the Japanese Business Environment 2020**

Editor and Principal Author: Bjorn Kongstad

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Sanbancho POULA Bldg. 2F, 6-7 Sanbancho, Chiyoda-ku, Tokyo 102-0075  
Tel: 03-3263-6222 Fax: 03-3263-6223  
E-mail: [ebc@ebc-jp.com](mailto:ebc@ebc-jp.com) Web: <https://www.ebc-jp.com>



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# Messages

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## *Message from the EBC*

Welcome to “Strengthening partnerships in crisis and opportunity alike”, the 2020 Report of the European Business Council in Japan (EBC). Various changes were made in the EBC structure last year, including the issuance of the EBC Report in June rather than December, for it to be used as a direct channel to the Japanese Government officials and politicians so as to respond to sudden issues in a timely manner.

Similar to the EBC, 2019 and 2020 have, for better or for worse, been two years of change. While the long-awaited entry into force of both the EU-Japan Economic Partnership Agreement (EPA) and the Strategic Partnership Agreement helped improve trade between the EU and Japan, the recent COVID-19 pandemic has paralysed the global economy.

On February 1, 2019, the EU-Japan EPA entered into force, and the EU joined Switzerland in having a Free Trade Agreement with Japan. The process to reach this agreement has been a very long one. The EPA can be said to have started as early as 2006 for the EBC and its Committees. At the time, the term Economic Integration Agreement (EIA) was used. As this is the first EBC Report after the entry into force of the EPA, while it is impossible to mention all those who participated at various levels in the process, we are forever grateful for their contributions. This gratitude does not only extend to the EBC members, but also to the European Commission, Japanese Government officials, and, last but not least, the EU Delegation and its staff throughout the years. The importance of the EPA to both EU and Japanese businesses is enormous.

Yet the work of the EBC does not end with the EPA: this White Paper emphasizes a significant number of issues hindering European business in Japan that lie outside the scope of the agreement. Some of these issues are specific to European companies, but very many affect all companies, domestic and foreign, and serve only to delay new products, inflate costs, and restrict consumer choice. EBC expert Committees will, therefore, continue to highlight them and make practical recommendations for how they should be resolved. The EBC does want to underline that a great portion of our recommendations will benefit all companies and consumers, independent of nationality.

Unfortunately, it is not possible to talk about 2020 without mentioning the COVID-19 crisis. What started out small is now affecting us all. At the company level, supply chain problems, restrictions on travels and difficulties to meet customers face-to-face (some of our Committee Reports raise Covid-19 related issues); at the individual level, the obligation to observe social distancing or self-isolation and perhaps the impossibility to meet relatives. Only time will tell when this crisis will be over and what long-term effects we will see. However, it is now more important than ever for the EU-Japan relationship to remain strong and for their close collaboration to continue.

The EBC work is made possible by the continuing support of its stakeholders, especially the European national Chambers of Commerce, their corporate members that also join the EBC and other business organisations represented in Japan. Together with the Delegation of the European Union to Japan and the European national embassies in Tokyo, who keep offering their unique insights and guidance, we all work towards making European business more successful in Japan.

We also gratefully acknowledge all sponsors and supporters who have made this publication possible and whose names are listed at the end of the Report. The EBC is committed to helping Europe and Japan reach new levels of mutual trade and economic growth. We approach these challenging times with unwavering optimism as Europe and Japan continue to strengthen their relationship.

Michael Mroczek  
President, European Business Council in Japan  
European (EU) Chamber of Commerce in Japan  
(Partner, Okuno & Partners)

Valerie Moschetti  
Chief Operating Officer  
European Business Council in Japan  
European (EU) Chamber of Commerce in Japan

## *Message from H.E. Dr. Patricia Flor, the Ambassador of the European Union to Japan*

The EU-Japan Economic Partnership Agreement (EPA) entered into force on 1 February 2019 and already in the first ten months of its operation it has shown positive results: EU exports to Japan went up by 6.6% compared to the same period the year before. Japanese exports to Europe grew by 6.3% in the same period. Through this agreement, EU and Japan have also sent out a powerful signal that two of the world's biggest economies reject protectionism. As rightly pointed out by Commissioner for Trade Phil Hogan: "the EU-Japan trade agreement is benefitting citizens, workers, farmers and companies in Europe and in Japan. Openness, trust and a commitment to established rules help deliver sustainable growth in trade".

The EPA is an extremely ambitious agreement: it covers 37% of world's trade. It removes the vast majority of the €1 billion in custom duties that were charged annually on EU exports to Japan. Once the agreement is fully implemented, Japan will have scrapped customs duties on 97% of goods imported from the EU and annual trade between the EU and Japan could increase by nearly €36 billion. Thanks to the agreement, we will be able to remove not only custom duties but also other trade barriers between Europe and Japan; we will create a platform to cooperate in order to prevent future obstacles to trade and we will work together to shape global trade rules, in line with our high standards and shared values.

The agreement creates new opportunities for European companies to boost their exports and expand their business in Japan. In order to be effective and bring tangible benefits, however, the implementation of the EPA needs to be closely monitored, so that corrective measures can be put in place to ensure a correct interpretation of the provisions of the agreement, or the resurgence of new barriers, and maximise its utilization rate among European companies, large and small.

In this context, I am delighted to address the 2020 report of the European Business Council (EBC) on the Japanese business environment. In order for the EPA to be successful, we need to make sure that European companies are well aware of the EPA existence and know how to make use of it. The EBC report is therefore a crucial tool to disseminate awareness and information about the EPA among the European business community in Japan. Through it and by closely following the agreement's implementation, the EBC can play a key role in ensuring the EPA success.

As always, the EU Delegation to Japan will continue to look forward to a close cooperation with the EBC to support our industry in accessing the Japanese market and consolidate and expand the cooperation between the EU and Japan.

Patricia FLOR  
Ambassador of the European Union to Japan  
Head of the Delegation



# Introduction



**Mr. Bjorn Kongstad**

Policy Director,  
European Business Council in Japan  
Sanbancho POULA Bldg. 2F  
6-7 Sanbancho, Chiyoda-ku,  
Tokyo 102-0075  
Phone 03-3263-6222  
Fax 03-3263-6223

## INTRODUCTION

2019 and 2020 have seen quite some changes to the business environment as far as European industry in Japan is concerned. We have seen the entry into force of the Economic Partnership Agreement (EPA), and its implementation. We are now entering the second year of said agreement, and the EBC committees have seen quite some changes to their issues and recommendations as a direct result of the agreement. It should be stated though, that some committees are not directly affected by the agreement, and that there are still issues that have not been resolved. The EBC, nonetheless, look very positively at the developments post-EPA.

The European food sector is a prime example of where the EPA have been a very positive catalyst. Tariffs have gone down considerably. As a result, we have seen an influx of European food products, not only on the consumer market but also as ingredients to the Japanese food industry. The EBC believes that this trend will continue in the future with further reductions in tariffs and increases in quota volumes. It is also important to mention that it does take time to find new customers, as they need to be convinced of the new improved competitive advantage of European products.

Another example of the same, is from the materials segment, both metals and chemicals, where Japan has removed tariffs completely for products with EU origin. For what is partially a commodity market, even small tariff reductions play an important role. It is also important to mention the improved market access due to other parts of the agreement, such as improved access to the public procurement market. For the EBC, this is most visible in the railway sector where the removal of the operation safety clause in February 2020 will give access to the procurement market for railway related products. It is, however, important to mention that this will require monitoring to make certain that what has been offered and promised by the agreement is also properly implemented. This is true not only for the railway sector, but also for other sectors.

Unfortunately, the other major external factor is the COVID-19. This has seen far-reaching consequences for not only the industry independent on whether it is European or domestic, but also society as a whole. Several EBC committees have brought up the issue of the COVID-19 and have offered recommendations specific to its area. Japan must continue to support and promote 'work from home'. While companies are implementing policies regarding this, some obstacles have been highlighted. Examples of these are the need for a *hanko* on many documents, the use of faxes for official correspondence or the need to physically be in the office for some activities, especially in the financial sector. While European companies are perhaps more advanced when it comes to working remotely since this has been previously implemented in European, it is apparent that some parts of the domestic industry are struggling. As EBC companies work very closely with Japanese companies this affects us as well.

The EBC trusts that the ideas and recommendations in this report will prove a positive contribution to the thinking of the Government of Japan, Europe and all others who genuinely wish to see Europe-Japan trade and investment reach its full potential.

### How this report is organised

Following this introduction, 25 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.



# ABOUT THE EUROPEAN BUSINESS COUNCIL

Founded in  
**1972**

The European Business Council in Japan (EBC) is the trade policy arm of 15 European national Chamber of Commerce and business associations in Japan and has been working to improve the trade and investment environment for European companies in Japan since 1972. The EBC was registered with the Ministry of Economy, Trade and Industry (METI) in 2008 as the European (EU) Chamber of Commerce in Japan.

**25**  
Industry  
committees

The EBC currently represents around 2,500 local European corporate and individual members through their respective national Chamber of Commerce. Some 350 executives of some 200 companies participate directly in one or more of the EBC's 25 industry committees, whose work covers a wide variety of economic sectors.

The EBC committees identify the issues keeping the companies from achieving their full potential in Japan and use the vast array of EBC's lobbying tools, including the annual EBC Report on the Business Environment, to bring change by eliminating the problems.

**200**  
companies

The EBC works closely with the Delegation of the European Commission in Japan, the national European Embassies, and other business organisations to co-ordinate policy proposals and make recommendations to the Japanese Government on how to create an open environment for trade and investment in Japan.

## Be Part of the Change - Join the EBC

The EBC is a key actor in bringing change for good to the Japanese economy. By participating in existing EBC committees, or by forming new committees, companies have the opportunity not only to learn about the important changes taking place in Japan, but also to play a critical role in influencing the change themselves.

Joining an EBC committee gives you:

- influence on issues addressed in political forums;
- access to key information in your sector (implementation of the EPA);
- valuable contacts with other European professionals;
- advice in formulating and resolving your regulatory concerns under the EBC umbrella;
- a direct channel to the Japanese Government officials and politicians.

## To reach out to the EBC, please contact:

Valerie Moschetti, Chief Operating Officer  
vmoschetti@ebc-jp.com  
03-3263-6225

Bjorn Kongstad, Chief Policy Director  
bkongstad@ebc-jp.com  
03-3263-6224



# **Business Fundamentals**

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

# HUMAN RESOURCES

## Introduction

As we write, the COVID-19 pandemic spreading around the world represents an extraordinary global event, challenging the resources of governments and businesses, and the need for swift and coordinated implementation of protective measures for workers and society at large. In Japan the unprecedented crisis also represents an opportunity for the acceleration of policies and technology use that facilitate new and flexible approaches to work and the workplace, including remote working from home.

Meanwhile, the EBC Human Resources Committee is encouraged by Prime Minister Abe's Government policy initiatives aimed at shortening the workday by reducing overtime, as a central pillar of the government's work-style reforms. At the same time, the EBC supports initiatives which encourage a focus on outcomes over time spent at work and promote greater work-life balance. Specifically, the enhancement of the flexitime system, through revisions to the Labor Standards Act from April 2019 allowing the extension of the period of adjustable working hours to 3 months, is seen as a positive step in the right direction by the EBC, as is the policy of ensuring use of annual paid leave of at least 5 days. Regarding the capping of overtime working hours to 45 hours per month and 360 hours per year, how this is implemented in practice particularly for SMEs will become clearer from April 2020. The EBC appreciates the initiatives of the Government, whilst at the same time encourages a broader dialogue in promoting productivity and flexible working, through measures that can be taken to improve the way work is done, including reducing less value adding practices, facilitating remote working from home, and embracing technology.

The labour market in Japan has continued to remain tight amid an ageing demographic and declining birth rate, representing a challenge for economic growth and competitiveness, but also an opportunity for labour market reform and deregulation. For businesses, this situation coupled with low unemployment rates has led to a limited pool of active job seekers in the labour market and shortage of skilled and unskilled workers.

The EBC applauds the Government's policy aims to promote women's active participation in the workforce, and by calling on companies to increase women in leadership positions. Its steps in improving support for working parents are clearly important initiatives requiring concrete follow-up for a successful outcome. The Government needs for instance to continue to find creative ways to offer more public child-care centres and private child-minding services, and to support and encourage men to take child-care leave. Towards this end, the EBC believes that further efforts to change attitudes and awareness in society about childcare and paternity leave should be actively promoted.

The Japanese Government has implemented measures to improve Japan's attractiveness to foreign professionals, which the EBC appreciates in bringing innovation to individual companies as well as positive roll-on effects to the economy as a whole. These measures have aimed at increasing the number of foreign professionals, including improving the benefits of the 'highly skilled foreign professional visa', and from July 2019 introducing online Japan visa renewals for highly skilled professionals, to simplify the application process when applied for by agents or employer organizations. On immigration law revisions for less skilled workers, the Japanese Government also introduced a new visa program from April 2019 to increase the quota of foreign workers, with a plan to allow 340,000 workers on 'specified skills visas' in 14 sectors to enter Japan over a five-year-period. The EBC commends the Government for these measures aimed at alleviating the acute labour shortage in factory operations, whilst encouraging further review of measures to increase the uptake of the visas. The EBC believes in the necessity of the program, and in the importance of overcoming various challenges in terms of cultural integration of these workers in the workplace and in daily life.

On the important topic of pensions, the Japanese government, since introducing the Defined Contribution Pension Law of 2001, has rolled out a series of revisions to enable 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, including further enhancing investment education programs and the ability for individuals to increase their contributions to the funds.

## Key Issues and Recommendations

### ■ Labour market regulations and flexibility

*Yearly status report: some progress.* The future prosperity of Japan in an increasingly globalised world hinges on ensuring a highly skilled, diverse and competitive workforce that can support its ageing population and drive its economy. Key to this are policies that allow more flexible approaches to working, greater female participation in the workforce, and new ways of sourcing foreign labour. The EBC strongly urges the Japanese Government to place focus on achieving greater productivity in the workplace and flexibility for both employees and employers.

#### **Recommendations:**

- Introduce employment legislation that encourages the creation of a competitive workforce based on merit and performance. Adequate protection of employees is required, but employers also need a legal framework within which to remove under-performing workers, and whose skills may be transferable. The same shall apply for corporate re-structuring with clear rules on how to compensate affected workers.
- Encourage companies to create policies to allow greater numbers of employees to take advantage of flexible ways of working, including remote working from home, by providing government guidelines to support this. Overcoming workplace cultures that place value on physical presence over outcomes gains is a key focus area.
- Actively promote the uptake of technology that contributes to boosting productivity in the workplace, including incorporating digitalisation and artificial intelligence into daily operations.
- Increase and improve the infrastructure necessary to support greater work-life balance, by ensuring sufficient child-care facilities 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.
- Remove the spouse special income tax credit (*haigusha-tokubetsu-kojo*).
- The Japanese Government and universities in Japan should promote the set-up of internship programmes for university students in incorporating work experience, reflecting the changing needs of businesses.
- Amend the employment legislation to expand the “highly skilled system” to include employees who earn less than the current system regulating highly skilled professionals, while keeping adequate protections of employees. People with high skills and high motivation want to work based on output instead of work hours.

### ■ Pensions

*Yearly status report: gradual progress.* The Defined Contribution (DC) Pension Law of 2001 has introduced a series of revisions to enable employers to offer more flexible and attractive pension schemes to employees. Further incentives are necessary though to encourage individuals to prepare financially for their own retirement. Meanwhile, 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. This is important not only with European countries but also with neighbouring countries.

#### **Recommendations:**

- Raise the DC plan contribution level limits to allow for further adoption of the corporate plans.
- Extend the payback period and expand pay-back to include the company contributions for leaving expats.

### ■ Immigration legislation and policies

*Yearly status report: good progress.* The Government needs to take an increasingly proactive approach to immigration policies and deregulation. Several sectors are currently restrained by the shortage of available labour. This holds true for both skilled labour and unskilled labour in the major urban centres and regional Japan.

#### **Recommendations:**

- Extend the scope of on-line visa applications and visa extensions.
- Lower the requirement for industry experience from ten to five years for those without a university degree.
- Formalise visa procedures for partners that are not married or are in same-sex partnerships.
- Continue to review concrete measures to increase the uptake of the ‘specified skills visas’ to non-high skilled workers, and their integration in the workplace and society.

**Mr. Laurent Dubois**

Chair, Intellectual Property Rights Committee  
(Representative, Union des Fabricants)  
c/o Union des Fabricants  
SK Bldg. 3F, 1-5-5 Hirakawacho  
Chiyoda-ku, Tokyo 102-0093  
Phone 03-3239-3110  
Fax 03-3239-3224

# INTELLECTUAL PROPERTY

## Introduction

In Japan, luxury brand products reach consumers via one of the following two sales channels, regular distributors or dealers in parallel imports. (Please note that 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 product seems to hinder them from being active to further engage in e-commerce by using any other actors for distribution. As in many other countries, the top producer and exporter of counterfeit goods distributed in Japan is China, accounting for 92.2% of all fake goods flowing into the country.

In 2019, more than 1.000.000 fake items were stopped at the border by Japan Customs. Given that it is impossible for Customs to examine all imported goods, this figure is probably only the tip of the iceberg of fake items imported in Japan. As buying counterfeit products “for personal use” is not forbidden in Japan, the flow of fake items cannot be fully stopped by Customs even if items appear to be obviously fake.

Until recently, many Japanese consumers purchased fake items knowingly. However, the main efforts today are focussed on how to prevent consumers from accessing fraudulent websites (mostly operated abroad) which are deceitfully selling counterfeit products to consumers who are deceived either into buying counterfeits despite their wish to purchase authentic products, or into buying products that will never be delivered, or which intend to collect buyers’ information such as credit card information. The Consumer Affairs Agency (CAA) has set up the Cross-border Consumer Center to support consumers who have inadvertently bought counterfeit goods. The CAA also publishes on its website the names of online stores that sell counterfeit goods. Furthermore, the National Police Agency protects consumers by providing information on websites selling counterfeit products to the security software distributors and the international organisation APWG (Anti-Phishing Working Group) so that alerts can be displayed on web browsers.

Major online retailers Yahoo! and Rakuten are also playing an important role in combating counterfeit products. For example, these online retailers are endeavouring to clean up websites by regularly exchanging information on counterfeits and criminal dealers with brands, via IP rights-holders’ associations. Further, in order to “clean up” their shopping websites, site operators make a test purchase to verify the authenticity of the products, with the cooperation of the relevant brand, when an item posted for sale is suspected of being a counterfeit product because of, *inter alia*, its extremely low sale price or information given by a consumer. If the said item turns out to be counterfeit, the shop who has put the counterfeit product for sale may be banned from the shopping website with immediate effect. As for the fast-growing Flea market, some websites, who have been focusing on the eradication of counterfeit goods, have obtained satisfactory results similar to those of existing auction services. On the other hand, some websites are still being left far behind in the efforts to fight against counterfeit products which continue to flood the market.

Finally, concerted efforts are being made by different sectors in Japan to set up a framework to eliminate counterfeit products. Some of their approaches are more advanced than those implemented in Europe or the USA. However, problems still remain. Specifically, it is necessary to consider how to prevent counterfeit products “for personal use” from penetrating into the market. This should solve the issue of increasing sale of counterfeits on the internet.

## Key Issues and Recommendations

### ■ **Strengthening and continuation of actions to eliminate counterfeit products from online malls in Japan and abroad**

*Yearly status report: no progress.* While major Consumer to Consumer websites have succeeded in reducing the percentage of counterfeit products to around 1%, some Business to Consumer (B2C) websites have not taken appropriate measures with the cooperation of relevant IP right-holders yet. This despite the approval in principle of such measures against counterfeit products. The delay in taking action by shopping websites can be explained partly by the fact that most uploaded image data are showing authentic products exclusively and that it is often necessary to make an actual test purchase to determine the authenticity of the product. Additionally, countermeasures against counterfeit products have not yet been taken in respect to some internet flea markets, being targeted as counterfeit-selling market from China. It is well known that some B2C market conditions became unfavourable due to repetitive negative coverage by major media. In the future, in addition to the measures already implemented, a further strengthening of the measures, such as tightening of regulations under the Specified Commercial Transactions Law is required.

#### **Recommendations:**

- Japan's Specified Commercial Transaction Law should be amended to strengthen checks on brand goods sold online and verification of the identity of the sellers, with a view to eliminating counterfeit goods from Business to Consumer websites. In addition, the Government should encourage internet service providers, distributors and IP 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: removing them from search engines.
- Although the government has already endeavoured to call for the joining of non-participants ISP companies to the dialogue forum where SP companies and right-holders discuss countermeasures against counterfeit products, this policy should continue in the future.

### ■ **Legislation to prohibit the importation of counterfeits or change of statutory interpretation of “for personal use”**

*Yearly status report: sign of 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, after having wasted manpower and time to detect counterfeit products, have no choice but to grant importation. According to the “2019 Intellectual Property Strategy Program”, the Government has already decided to continue to consider how to restrict the importation of counterfeit products “for personal use”. In order to get an effective result, the importation must be restricted, by revising the Trademark Act or by changing statutory interpretation of the property right of the counterfeit products so that it will be deemed to belong to the sellers at the time of clearance procedure.

#### **Recommendations:**

- The importation of counterfeit products, even “for personal use”, should be restricted by applicable laws and regulations.
- The revision of the Trademark Act or change of statutory interpretation will enable to restrict the importation and to improve the current situation”.



**Ms. Rika Beppu**

Chair, Legal Services Committee

(Partner, Squire Gaikokuho Kyodo Jigyo Horitsu Jimusho)

c/o Squire Gaikokuho Kyodo Jigyo Horitsu Jimusho

Ebisu Prime Square Tower 16F.

1-1-39 Hiroo, Shibuya-ku, Tokyo 150-0012

Phone 03-5774-1885

Fax 03-5774-1818

# LEGAL SERVICES

## Introduction

The EBC is delighted to hear of prospective changes in the laws of Japan in respect of the work experience requirement for foreign-qualified lawyers to register as *gaikokuho-jimu-bengoshi* (foreign-qualified lawyers or “*gaiben*”). Currently three years of work experience is required, out of which two years have to come from experience gained overseas. The Ministry of Justice's Review Committee for the Registered Foreign Lawyers System proposed that the overseas experience element is reduced from two years to one year, as well as the ability of *gaiben* and *bengoshi* to establish a corporation together, subject to the implementation of the change in the law.

1. Further to deliberations by the above mentioned Committee which took place throughout 2015 and culminating in a Report being issued on 5 July 2016, we understand that the following changes to the Act on Special Measures concerning the Handling of Legal Services by Foreign Lawyers (Act No. 66 of 23 May 1986) (the “Act”) were firmly on the agenda for the Diet parliamentary session in the Spring of 2020. We understand that the Upper House approved the draft changes to the Act, and that deliberations have taken place in the Lower House, after which time the Upper House formally approved the changes on 22 May 2020 and thereby the changes are now enacted into law. Once enacted, we understand that it will be a matter of a few months before the changes to the Act are implemented. We await confirmation that the changes to the Act have been implemented by no later than September 2020.

1.1 The current three-year work experience requirement (two years of which must be experience gained outside Japan) will be changed to three years (one year of which must be experience gained outside Japan).

1.2 It will become permissible under law for *gaiben* and *bengoshi* to establish a *hojin* (corporation) together.

1.3 The scope of “international arbitration cases” under the Act will be clarified so that *gaiben* will be able to be involved in such cases. For example, (1) the condition that an “international arbitration case” must have Japan as its chosen arbitration venue, as well as (2) the condition that the case must involve at least one party whose main business location or head office is overseas is due to be changed to (1) the chosen venue of arbitration does not need to be Japan, and (2) the majority of the shares or voting rights of at least one of the parties are held by an entity or individual whose address is overseas.

2. Transparency of the *gaiben* registration system and making the registration process simpler: We would welcome any updates from the forum which has been set up for discussions between the Ministry of Justice and the *Nichibenren*, taking into account opinions from registrants as necessary. This with a view to making the registration process and timing more transparent, simpler and faster.

The EBC welcomes the prospective changes to the law and implementation thereof to reflect the items in paragraphs 1.1, 1.2 and 1.3 above. Going forward, the EBC will continue to recommend that any requirement for work experience prior to registration as a *gaiben* should be abolished in their entirety. The EBC will continue to take a close interest in the roll-out of the recommendations as a whole, not least because the 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 Issues and Recommendations

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

*Yearly status report: reasonable progress, pending implementation of the prospective changes in the law.* 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 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 30 years of operation, the *gaiben* system needs 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.
- 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 implementation of the prospective changes in the law.* 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 2014 legislation did not permit *gaiben* and *bengoshi* together to establish a *hojin*. The effect is to severely limit the usefulness of the 2014 legislation. We understand that the changes in the Act to permit *gaiben* and *bengoshi* to establish a *hojin* together have been enacted and we await confirmation that the changes have been implemented by no later than September 2020.

**Recommendation:**

- Implement the changes to 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.

### ■ Scope of International Arbitration Cases which *gaiben* can be involved in

*Yearly status report: reasonable progress, pending implementation of the prospective changes in the law.* We await confirmation that changes in the Act have been implemented by no later than September 2020. We understand that changes have been enacted to clarify the scope of “international arbitration cases” under the Act so that *gaiben* will be able to be involved in such cases.

**Recommendation:**

- Japan shall pass and implement the changes to the Act so that *gaiben* can take a more active role in international arbitration cases in Japan.

### ■ 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.

**Mr. Karl Hahne**

Chair, Retail &amp; Wholesale Committee

(President &amp; Representative Director, Häfele Japan K.K.)

c/o Häfele Japan K.K.

14-17 Kami-shinano

Totsuka-ku, Yokohama 244-0806

Phone 045-828-3117

Fax 045-828-3119

# RETAIL & WHOLESALE

## Introduction

The Japanese retail market remains one of the largest and most vibrant in the world. After many years during which the presence of European retailers was more or less limited to the luxury sector, the last decade has seen the rapid establishment of new European retailers 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.

With the implementation of the EU-Japan EPA, the market access for European products and services has improved. Tariffs has been reduced. In most cases it has gone down to zero already on the day of entry into force. The EBC is also hoping for a more harmonisation of standards and regulations between the two economies. Where harmonisation is difficult or requires time to implement mutual recognition of standards, approvals and test result shall be established to improve the situations. The EBC would like to point out that the protection of the consumer will not be reduced as both economies have robust systems in place to achieve this. We are hoping that EU and Japan will work closely in this respect and make use of the regulatory cooperation mechanism in the EPA.

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. The Government of Japan still 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 delays the introduction of new products to the 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. Mutual recognition of rules and regulations therefore makes sense and would create a level playing field for all players. Just one example of the barriers encountered by European retailers and wholesalers is the unique labelling rules, specified by Japan's Consumer Affairs Agency (CAA). Other examples include non-acceptance of non-SI units (International System of Units), importing process for food contact products (UCP) regulated by Food Sanitation Law, and non-recognition of global standards and European approvals. Furthermore, non-harmonised procedures for importing, certifying and labelling consumer products are unnecessarily costly and complex.

The Japanese Electrical Appliance and Materials Safety Act, known as the *Denan* Law, is a further source of unnecessary cost and complexity for retailers and wholesalers. The Ministry for Economy, Trade and Industry (METI) lists various groups of products that fall within the scope of this Law. However, it is often difficult to decipher whether a specific product is covered or not, resulting in uncertainty about test requirements. In addition, there has been a lack of harmonisation in this field, and where the Japanese equivalent to the IEC (International Electrotechnical Commission) standards is used, it is not always based on the most recently updated IEC standard.

Finally, the EBC is also concerned about Japan's Antimonopoly Law, following an apparent relaxation of prohibited vertical restraints with no safe harbour, and enforcement of the Subcontractor Law, without bright-line rules, against retailers and wholesalers. As a result, application of the Law has become more unpredictable and non-transparent, thereby increasing the difficulty of compliance. There is a real risk that this situation could be exploited and the market manipulated, so we urge the Japan Fair Trade Commission (JFTC) to issue as soon as possible clear written guidance that facilitates compliance.

## Key Issues and Recommendations

### ■ Prohibitive import, testing and certification procedures

*Yearly status report: some progress.* To the detriment of trade, the Government of Japan continues to insist on applying unique national rules and regulations to many products that have already met European / international standards. The EBC requests that the MHLW harmonises positive list for utensils, container and packaging (UCP) in the Food Sanitation Act with other countries.

**Recommendations:**

- MHLW should make certain that the current draft positive list for food contact products is harmonised with other countries. It is furthermore of important that the list is also offered in English.
- Japan should accept inclusion of common non-SI units on measuring devices when SI units are also used.
- Japan should simplify its *Denan* Law, avoid introducing further unique Japanese requirements and make certain that detailed information on standards and their application are readily available in English.

### ■ Regulatory cooperation

*Yearly status report: new issue.* The EPA provides for regulatory cooperation between the EU and Japan. The EBC has long called for the two economies to work together to make certain that double testing is eliminated or that products do not have to be developed specifically due to differences in regulations or standards in the two markets.

**Recommendation:**

- The EU and Japan should work together to achieve better harmonisation between the two regions with the aim of avoiding re-testing when marketing the products on either market.

### ■ Labelling

*Yearly status report: slight progress.* The revised Household Goods Quality Labelling Act introduced some improvements, however requirements remain too detailed and inflexible for retailers and labels too complex for consumers.

**Recommendation:**

- The Labelling Act should be reformed to aid the consumer in understanding the product and to introduce flexibility for the retailer.

### ■ 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. Furthermore, grandfathering old licences is unfair to new entrants.

**Recommendations:**

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

### ■ Competition law/Anti-trust legislation

*Yearly status report: no progress.* Japanese Competition Law includes recognition of “market power” with minor shares in vertical restraint, and “superior bargaining power” irrespective of dependence, which differs from global practice. The Subcontractor Law lacks bright-line rules, and “yellow card” infringement notices lack explanation.

**Recommendations:**

- Japanese Competition Law/Subcontractor Law should be harmonised with global practices.
- The “yellow card” system, not transparent and lacks both a legal basis and bright-line rules, should be abolished.

**Mr. Hans-Peter Musahl**

Chair, Tax Committee

(Partner, Ernst & Young Tax Co.)

c/o Ernst & Young Tax Co.

Hibiya Mitsui Tower, Midtown Hibiya, 1-1-2 Yurakucho

Chiyoda-ku, Tokyo 100-0006, Japan

Phone +81-90-9848-6525

# TAX

## Introduction

The EBC welcomes the Japanese Government's continued efforts to increase Japan's attractiveness to investors. The unprecedented challenges caused by the corona crisis, affecting the world and the Japanese economy, have led to two record supplement budgets in April and June 2020 with far reaching consequences also for the tax environment under which European companies are active in Japan.

Further to the tax reform 2020, Japan aims to take a lead amongst global economies in contributing to autonomous, self-led and sustainable growth of the economy to the greatest possible extent. Almost by definition, the COVID-19 economic stimulus measures are financed through growing deficits, which at some point will have to be made up from increased tax revenues. Consequently, the widening of the tax base that has occurred in recent years is set to continue. 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.

The EBC appreciates recent inheritance tax reforms that benefit short and mid-term residents. However, the Asian investment hubs of Hong Kong and Singapore will, overall, remain more attractive tax jurisdictions for individuals, particularly for those wishing to reside long-term in the region, also as the exit tax will drive away international entrepreneurs by a June 30, 2020 deadline.

Bilateral trade and investment between Europe and Japan benefits significantly from mutual elimination of double taxation, as provided for in recent tax treaties between Japan and individual EU Member States and in the arbitration provisions of the multilateral instrument developed under the OECD's Base Erosion and Profit Sharing (BEPS) Action Plan. However, Japan's treaties with the majority of Member States (i.e. Bulgaria, Czech Republic, Hungary, Ireland, Italy, Luxembourg, Poland, Portugal, Romania and Slovakia) still lack exemptions in respect of areas beyond the scope of the multilateral instrument, such as elimination of withholding tax on dividends, royalties and interest. No treaties have been agreed with Greece, Cyprus and Malta, while a treaty with Croatia has been concluded and negotiations with Greece have commenced in the meantime.

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 Issues and Recommendations

### ■ Tax policies to promote innovation, open innovation

*Yearly status report: little progress.* Innovation-intensive industries are a key driver of growth and employment. R&D and innovation promotion 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 and (open) innovation 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. Having said that, the decision to award higher credit rates to increased R&D expenses or newly started activities is welcome and foreign companies reviewing their R&D policy in Japan could benefit from this, provided that R&D cost are not borne centrally by the headquarter but locally by a Japanese entity. In general, however, Japan still needs to revise its current R&D tax policy if it wishes to maintain and improve its international attractiveness as a location for R&D activities. Furthermore, the current R&D credit regime is not available to companies that are not locally expensing R&D cost or are loss-making, and so is of little benefit to many foreign and 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, paying particular attention to the specific position of foreign and start-up companies.

### ■ Directors' compensation

*Yearly status report: new issue.* Recent tax reform has provided some degree of relief from unfavourable directors' compensation tax rules that limit the deductibility of performance-based directors' compensation. However, in practice the relief only applies to listed companies issuing securities reports. In particular, small and medium-sized enterprises and foreign affiliated companies are unable to take advantage of the reforms, with the result that these companies have to pay performance-based directors' compensation from their after-tax income.

**Recommendation:**

- Remove barriers to relief for small and medium-sized companies, as well as foreign affiliated companies, to enable the deduction of reasonable performance-based directors' compensation.

### ■ Extended tax return filing periods

*Yearly status report: some progress.* The filing period for Consumption Tax has been extended by one month and a waiver for late filing penalties has been introduced for companies affected by the COVID-19 crisis. Japanese rules require companies and individuals to file tax returns no later than two to three months after the end of the calendar or fiscal year. The extremely short deadlines 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. Except for the COVID-19 struck March 2020, no relief is granted to individuals. Corporate measures in theory allowing for an extension of filing periods have proven impractical and have yet to be adopted by many Japanese taxpayers.

**Recommendation:**

- Extension of tax return filing periods for individual income taxes should be granted until May 30 as in other European countries. Where professional service providers are involved, a further extension by six months should be allowed. Also, the law should allow individuals to apply for extensions in exceptional cases.



## ■ Income and Inheritance Taxes

*Yearly status report: progress with drawbacks for long-term residents.* With top rates of more than 55%, Japan's income, inheritance and gift taxes are the highest in Asia and, indeed, in the world. Foreign nationals are exempt from Gift and Inheritance Tax for the first ten years of their stay in Japan. However, anyone who becomes a long-term resident is fully subject to Gift and Inheritance Tax. Moreover, Japan's top inheritance tax rate applies to inheritance between close family members, and starts at much lower thresholds and allowances than in other countries. Japan's Gift and Inheritance Tax is negatively impacting the ability to retain long-term residents, potentially triggering a loss in foreign intellectual capital and foreign investment.

### **Recommendation:**

- Align the categories of foreign nationals who are subject to Gift and Inheritance Tax 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 taxation on global assets.

## ■ 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 enshrine the right to request and obtain tax rulings. The system should be more user-friendly.
- Consider the merits of introducing a system offering Horizontal Monitoring, Risk Rating and Senior Accounting Officers, which have each helped to improve efficiency in the UK and The Netherlands.
- Transparency would be enhanced, if the tax authorities allowed for communication in English.

## ■ Tax treaties

*Yearly status report: progress.* Japan recently concluded new tax treaties respectively tax treaties in principle with Croatia and Serbia which have or will come into force soon. The EBC welcomes treaties that include the exemption of withholding tax on royalties, qualified dividends and interest. However, its treaties with 10 other EU Member States still need to be renegotiated and no treaties have been concluded with three countries, among them Greece. Furthermore, employees' contributions to social security systems within the EU and Japan should be treated as tax deductible on a mutual basis.

### **Recommendations:**

- Any new or revised treaty should address the issue of withholding tax on royalties and qualified dividends and interest, and contain arbitration provisions if not already covered by the multilateral instrument.
- Treaties should be agreed with those countries having no agreement with Japan at present.

## ■ Centralise local tax

*Yearly status report: new issue.* Taxpayers who operate throughout Japan have to file local tax returns in numerous municipalities and have to make dozens, sometimes hundreds of tax payments three times a year, and to apply for tax refunds where applicable.

### **Recommendation:**

- The EBC recommends to centralise the administration of local taxes by the national Government or, as similar to Consumption Tax, centralise tax payment by the local Government where the head office of the tax payer is located.

## ■ Abolishment of stamp tax

*Yearly status report: new issue.* Stamp duties as low as 200 JPY require significant additional administrative efforts for internal processes and payment. The cost of administration is not in proportion to the tax revenues. An abolition of the tax is also requested by numerous domestic business associations and publicly debated in the tax reform discussion.

### **Recommendation:**

- The Government should consider to abolish the imposition of stamp tax.

# **Financial Services**

**Asset management  
Insurance**

**Mr. Nicolas Sauvage**

Chair, Asset Management Committee  
(Representative Director, Amundi Japan Ltd.)  
c/o Amundi Japan Ltd.  
Hibiya Dai Bldg. 20F, 1-2-2 Uchisaiwai-Cho  
Chiyoda-ku, Tokyo 100-0011  
Phone 03-3593-5900  
Fax 03-3593-5932

# ASSET MANAGEMENT

## Introduction

Times are challenging for the asset management industry and for its clients. This is due not only to the COVID-19 virus, but also to some specific issues related to the development of long-term investing.

In early June 2019, the Japanese Financial Services Agency (FSA) released a report on the future financial security of senior citizens (we have to be prepared to live for 100 years!). In this report, some simulation suggested that the “average” retired couple would need an additional 20 million yen to bridge the gap between their combined savings and pension benefits on one hand and their actual needs on the other hand. Due to the highly politically-sensitive nature of this simulation result, the full report was ultimately rejected by the Japanese Ministry of Finance (MOF). However, the “20 million yen” gap generated a lot of media coverage and therefore interest from the general public on the importance of building financial savings with a long-term perspective.

Meanwhile the Japanese retail fund market did shrink in 2019. The shift from deposits to higher-return instruments is not happening, deposits continue to balloon in banks, and banks have been losing market share against securities firms on mutual fund sales to individuals.

The revision of the Foreign Exchange and Foreign Trade Law was announced mid-2019, regarding prior notification for foreign investments in business sectors related to national security. It initially created serious concerns in the financial community. The first draft of the revision could be seen as discriminatory against foreign-affiliated financial firms, including asset management companies, and from an operational point of view was unpractical as the scope of the law would be expanded dramatically with the threshold being lowered from 10% to 1%. Welcomed clarification and exemptions were provided in October 2019, and detailed implementation is still being debated (public comments being called until April 2020). The EBC Asset Management Committee continues to follow this issue very closely. At the same time, we do want to express our gratitude to the MOF for its willingness to communicate and listen to the views of the EBC. Recent drafts have been received far more positively by the industry.

Geopolitics, natural disasters and now early 2020 the Coronavirus pandemic further contribute to darken the landscape. While we are fully aware of the challenges, both current and future, we believe that it is important that the authorities provide guidance in particular to the continued move for a higher degree of digitalisation, and the possibility for remote work.

Still, it should not be time for capitulation, it should be time for action: even more than before, the asset management industry needs to achieve its mission of bridging the need of the real economy with a pool of savings, by delivering appropriate solutions to meet the diverse needs of all segments of the investment community. This in particular, including individuals who are new to fund investing.

In that regard, Environmental, Social and Governance (ESG) and Sustainable Development Goals (SDGs) remain a highly discussed topic in Japan. More public and private initiatives are expected to demonstrate that the investment community can contribute to develop a sustainable economy and that such approach can have positive impact on financial returns. European leadership is well recognised and EBC members are keen to contribute to those developments in Japan.



## Key Issues and Recommendations

### ■ Global competitiveness of Tokyo in regard to the operational platform

*Yearly status report: some progress.* Even if some progress can be noted, trust banks still remain behind the curve in operational efficiency, as illustrated by lack of CSA (Credit Support Annex attached to ISDA (International Swaps and Derivative Association) contracts), only partial adoption of SWIFT and of CLS (Continuous Linked Settlement), especially for pension mandates.

In September 2019, Japan Investment Trusts Association (JITA) released its report on single NAV (Net Asset Value) which is a very important first step towards the modernisation of the industry. It opens the door to further discussions about the establishment of fund administrators and transfer agents in Japan, similar to the European business model. EBC Asset Management Committee had participated to the public comments organised by JITA on single NAV in May 2018.

**Recommendation:**

- System developments to facilitate fund mergers should be encouraged to facilitate the simplification of product line-ups.

### ■ Anti-Money Laundering (AML) – Countering the Finance of Terrorism (CFT)

*Yearly status report: new issue.* Japanese FSA has issued several guidelines over the past 18 months to ensure the local asset management industry reaches global standard immediately, even before the change of law, on AML-CFT (including due diligence to distributors, to external managers, screening of securities portfolios). The EBC Asset Management committee issued a statement to JITA in April 2019 to ensure AML questionnaires (such as Wolfsberg questionnaires) could be posted on the website of each financial institution (such as fund distributors) or in a digital library managed by the respective industry associations to facilitate the process of due diligence.

**Recommendation:**

- There are still on-going discussions about what should be the format of Due Diligence Questionnaires (DDQs) for fund distributors; leadership on this topic is expected from Japan Securities Dealers Association (JSDA) and banking industry associations.

### ■ Encouraging Japanese households to invest for the long term

*Yearly status report: some progress.* Distributors have been changing their business model under the pressure of the “Customer oriented business”, tax incentive must follow to enable the new business model to generate positive flows towards financial products and specifically mutual funds. This is especially important after the sharp market decline across all asset classes generated by the Coronavirus turmoil, to bring back attention towards fund investing especially for new investors. In this context, boosting financial literacy will be key, at all levels and for all generations, including through the websites of Corporate Defined Contribution (DC) and iDeCo (individual Defined Contributions) platforms.

**Recommendations:**

- Increase the maximum yen amount that can be saved tax free in NISA, Junior NISA and DC platforms, especially if those amounts are funded by conversion of deposits.
- Change the default options for DC schemes to long-term financial investment products.
- The Japanese Government should foster and publicise the provision of IFA (Independent Financial Adviser) services – with services provided in-person or online – to help boost household investments.

**Mr. Kazutaka Matsuda**

Chair, Insurance Committee  
(Executive Officer, General Counsel,  
Legal & Compliance, AXA Life Insurance Co., Ltd.)  
c/o AXA Life Insurance Co., Ltd.  
NBF Platinum Tower, 1-17-3 Shirokane  
Minato-ku, Tokyo 108-8020  
Phone 03-6737-7734; Fax 03-6737-5874

# INSURANCE

## Introduction

In recent years, the Japanese authorities have been gradually harmonising laws and regulations relating to the domestic insurance market with global standards. However, foreign insurance company affiliates in Japan still encounter obstacles that limit efficient development of their businesses. Examples include reserving and solvency regulations that are inconsistent with international norms; the improving, but still lengthy 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 healthcare. The EBC urges the FSA (Financial Services Agency) to facilitate a truly open and competitive insurance market capable of meeting consumers' needs.

In the development of Insurance Capital Standard (ICS) Version 1.0 for extended field testing and the years of field testing preceding it, the IAIS has had appreciated both commonalities and differences in solvency regimes across the jurisdictions. There are many practical implementation issues to consider for the ICS to be implemented as a Prescribed Capital Requirement (PCR). The International Association of Insurance Supervisors (IAIS) is aware that stakeholders have been calling for greater clarity on what the implementation of the ICS, following the completion of field testing in 2019, will mean in practice.

The IAIS has agreed that implementation of ICS Version 2.0 will be conducted in two phases. The first phase is "monitoring period", during which ICS Version 2.0 will be used for confidential reporting to group-wide supervisors and discussion in supervisory colleges, but not be used as a PCR triggering supervisory action. After five year monitoring period, the second phase will start for "implementation of the ICS as a group-wide PCR". They also propose that national insurance regulatory bodies in each country increase information sharing with other regulators across borders.

The FSA has recently abolished the Inspection Manual. In promoting principle-based regulation, the EBC appreciates the more flexible approach by the authorities putting emphasis on the needs of consumers and progress of technologies, and is looking forward to working in close collaboration with the FSA on this topic.

The EBC, moreover, appreciates that the FSA supports and directs that insurers promote their products and services under the fiduciary duties among which the practices of fees and commissions paid to brokers are carefully monitored.

In line with the changes of international regulatory environment, the EBC believes that 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 focus its attention on more advanced products.

In parallel, the EBC believes that the FSA should accelerate de-regulation of distribution practices based on a risk-based approach, to cater to the growing demand from consumers for better access to more convenient distribution channels targeting their individual needs. This would also benefit the domestic financial services industry, Japanese consumers and Japan's ability to retain foreign investment.

As for Japan Post, the Government should carefully consider the timing of the public offering partly because of the compliance problems of Japan Post. The EBC furthermore believes the Government ownership in Japan Post has a negative impact on the private sector.

## Key Issues and Recommendations

### ■ Harmonisation with global solvency and other regulatory standards

*Yearly status report: some progress.* The EBC appreciates the FSA's willingness to take a leadership role among international regulators. However, 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. The EBC is in a position to provide the relevant information to the FSA on these issues.

#### **Recommendations:**

- Japan should accelerate reforms to achieve convergence between Japanese and global solvency standards.
- Japan should consider the approval process of an internal model for risk calculation on new solvency regulation to evaluate the risk characteristics of each insurer correctly.
- The market-based Solvency Margin calculation methodology should be further aligned with Solvency II.
- In adopting FSB/IAIS-proposed policy measures for the Japanese market, the Government should consider the burden that risk management reporting and capital adequacy requirements could impose on businesses and minimise any conflicting cross-border jurisdictional requirements.
- The scopes of the Policyholder Protection Corporation should be reformed to align with introducing a new solvency regulation.

### ■ Product approvals

*Yearly status report: some progress.* The advantages of simplicity in the approval process have been articulated in our previous submissions. Incremental progress has been made however we continue to seek real enhancement in the form of a file and use system. Not only does it enhance efficiency, but it also enables the FSA to allocate resources to complex products that require more attention. Moreover, real product innovation requires insurers to offer truly new proposition to customers. At this dynamic era where our customers' needs are constantly changing due to lifestyles, ageing and technology, the insurance industry needs to catch up in offering better coverage in new diseases/illnesses as well as play a more active role in improving our customers' health. These initiatives often require global insights without necessarily locally proven experience. The current FSA product approval philosophy is to focus on proven local data and experience, this significantly hampers product innovation progress, and not in line with practices by overseas regulators, ultimately disadvantaging Japanese consumers. The EBC believes this recommendation to broaden the philosophy will also benefit also Japanese insurers.

#### **Recommendations:**

- 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.
- The FSA should relax the requirement for new innovation to include global expertise and experience.

### ■ Fair competition in providing group insurance program to banks

*Yearly status report: some progress.* The EBC continues to be concerned by the strong influence of Japanese insurers over Japanese banks as their major shareholders. The EBC appreciates the monitoring actions taken by the FSA on this topic and wishes for the FSA to continue its attention as the concerned influence still exists. The EBC firmly believes that the competition in this area should be based on the quality of products and services rather than on the shareholding relationship which is irrelevant to the interest of Japanese consumers.

#### **Recommendation:**

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

### ■ Distribution practices under fiduciary duties

*Yearly status report: new issue.* We recognise that the FSA encourages insurers including brokers to conduct its fiduciary duties. Along with promoting fiduciary duties, the FSA has been investigating the brokers' fee system. The EBC, furthermore, appreciates the focus on the benefit of the customers, and also the possibility for industry,

including European insurers, to leave comments. On the other hand, we believe that the current rule could be a barrier for new entrants and may not be beneficial to Japanese consumers, unbalancing with the potential risk of mis-selling. For example, insurance sales by an incorporated insurance agency to members of its parent and affiliated companies are restricted to so-called “third sector” products (“koseiin-kisei”)

**Recommendations:**

- The EBC recommends that the FSA continue to work closely with industry without drastic changes that may badly affect consumers.
- The FSA should carefully make certain that sales of innovative products are not hampered, for instance under a low-interest rate environment, while ensuring that fiduciary duties are fulfilled.
- Taking into account emerging new technology and evolving insurance distribution, the FSA should review the related regulations, and present a roadmap for further deregulation for the benefit of Japanese consumers.
- When looking into distribution practices, the FSA should put more emphasis on enabling the customer to choose from a wider product portfolio.

## ■ Digitalisation/Personal data

*Yearly status report: new issue.* In line with the EU’s GDPR, the regulation of the personal information protection is to be more restricted. The EBC recognizes that the FSA will put in place the new regulatory requirements with the Personal Information Protection Commission (PPC). The EBC recommends that the new regulatory requirements should strike a balance between protecting consumers’ data privacy and leveraging innovation and digitalisation by means of use of data for the better life of consumers.

**Recommendations:**

- The FSA should make certain that any standard introduced does not hamper insurers from continuing to develop innovative products and services that will benefit consumers.
- The FSA should make sure that the required procedures are not complicated and burdensome for the industry.

## ■ Japan Post reform

*Yearly status report: some progress.* 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 believes the Government should accelerate the speed of the privatisation even though JPI needs to tackle with its compliance problems first.

**Recommendations:**

- Until 100% of Japan Post’s shares are held privately, JPI’s product portfolio should not expand and its issue limit should be capped at the current level. Japan should accelerate the speed of privatisation while ensuring a level playing field.
- The Government should publish a clearer road map on how it intends to sell its shares.

## ■ Liberalisation of sales through bank channel

*Yearly status report: no progress.* There are continued restrictions on the sale of insurance through bank channel, which should be liberalised in the interest of Japanese consumers. Our concerns include the restriction related to lending relationships as well as the use of personal financial data held by banks.

**Recommendation:**

- The FSA should allow banks to sell insurance to employees of companies where banks have a lending relationship, as the current restriction deemed excessive and redundant. At the same time, certain financial information should be allowed to be use, just as is allowed in the asset management sector.

## ■ 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.

**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.
- The membership of *kyosai* should be further clarified and restricted, as originally intended, to a well-defined group, such as a certain profession.

# **Transportation & Communications**

**Airlines  
Railways  
Telecommunications equipment  
Logistics & freight**

**Mr. Donald Bunkenburg**

Chair, Airlines Committee

(General Manager for Japan, Lufthansa German Airlines)

c/o Lufthansa German Airlines

3-1-13 Shibakoen, Minato-ku, Tokyo 105-0011

Phone 03-5402-5201

Fax 03-5402-5209

# AIRLINES

## Introduction

The current situation for the world and particularly for the airline industry has changed dramatically due to the COVID-19 pandemic. From a very positive outlook with the Olympics, the pandemic has now resulted in an overall reduction in demand for travel of up to 90% and up to 98% in certain areas. Airlines are faced with severe liquidity challenges with enormous pressure to reduce costs. In addition, new passenger and crew safety measures have been adopted to protect health. Many airlines have turned to their governments for financial support in order to weather the crisis.

Therefore, radical measures are required. Governments, including the Japanese Government, must do its utmost to provide a framework for the airline industry to survive the current situation. Actions could be, while not limited to: changing or interpreting the regulations so that airlines do not lose slots due to not being temporarily able to use them, facilitate the change from passenger traffic to freight traffic, improving the situation for freight transportation at Haneda Airport, work together with the airline industry to come up with good and practical guidelines how to deal with airplane crews that arrive in Japan. These measures must be presented and implemented promptly. The EBC is committed to work together with the other industry organisations and the Japanese authorities to make the best of the situation.

New health screening for arriving passengers, while understandable, has been implemented which lengthens the arrival processing times. In addition, airlines have been given restrictions of passenger loads for inbound flights alleviate bottlenecks at arrivals. Continued restrictions of this nature will reduce the economic viability of flights and could slow down the re-introduction of capacity. This will slow access to Japan by business people and other segments of passengers.

Looking beyond the Coronavirus situation, the EBC recognises and appreciated that MLIT (Ministry of Land, Infrastructure, Transport and Tourism) and Ministry of Justice have implemented to facilitate the increased passenger traffic to Japan. With allocated slots to European airlines through better access to Haneda (HND), and through increases passport control officials at the airports. We also appreciate the engaging approach by the Narita Airport officials who are listening to and working closely with the airline industry. The EBC hopes that this can serve as a blueprint for all airports.

Airport fees, particularly in Tokyo continue to be high in comparison to regional competitors in Asia which is also an issue when airlines evaluate expansion. Higher fees were recently introduced for HND. The recent agreement concluded between IATA (International Air Transport Association) and Narita Airport (NRT) is satisfactory in that fees remain status quo, but there continues to be unusual charges such as a parking fee structure which does not conform to international norms. The EBC recommends refraining from any increase in airport related fees. In addition, the cost of the continued improvement of security needs to continue to be borne by airport operators and government.

The EBC has continued concerns about the implementation of the Tourism Tax. The collection process burdens airlines. In addition, there is no transparency as to the usage of the resulting funds. EBC advocates the use of the funds to benefit the transportation infrastructure. In addition, the current data requirements set up by the Japanese authorities and how to deliver the data are unclear and European airlines may not be in the position to deliver this requested data due to strict EU data protection law. This needs to be urgently reviewed.

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. It follows that 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 line with this, the EBC recommends abolishing the early “gear down” policy at NRT, which unnecessarily increases not only fuel usage, but also noise for local residents.

To end on a positive note, Japan has shown that it has the potential for increase passenger traffic, especially with more tourism, and increased trade leading to more business passengers. We believe that once the Coronavirus situation has improved that there is no reason that Japan will not return to the pre-Coronavirus status. However, it is important that the Japanese Government works together with the airline industry to make this possible.



## Key Issues and Recommendations

### ■ Coronavirus

*Yearly status report: new issue.* The Government must facilitate and support airlines in the short-term so that it can change from activities focusing on passenger traffic to freight traffic. It is also imperative that whatever aid is offered to domestic operators if also offered to the domestic activities of foreign airlines.

**Recommendations:**

- The Japanese Government should improve the situation for freight transport, especially at Haneda. At the same time, it should be possible for airlines to, in a flexible manner, to increase its freight transport capacity in place of its passenger traffic capacity.
- Airlines should be able to retain its slots even if temporarily due to the Coronavirus, they reduce their traffic.
- The Government should include foreign airlines domestic activities when and if offering monetary support to the airline industry.
- Sufficient resources need to be dedicated to new screening procedures at airports for arriving international travellers in order to alleviate long waiting times and passenger load restrictions for inbound flights. Further restriction on inbound passenger loads will reduce the airlines abilities to ramp up operations and meet expected demand.

### ■ High costs at Japanese airports and new Tourism Tax proposal

*Yearly status report: some progress.* Operating costs at Japanese airports continue to be high in comparison similar airports. While demand for outbound travel to Europe is strong, it is the commercial viability of flights that determines the addition of capacity. Recent negotiations with NRT held the line on prices. Added to such cost issues, the Government continues to require airlines to file published fares and surcharges for approval prior to sale – a time-consuming and costly exercise not required in other major markets.

**Recommendations:**

- The EBC recommends that airport fees be temporarily reduced to support short term cost reduction for airlines. This will encourage airlines to ramp-up capacity and frequencies at a faster pace. Current airport fees are too high, particularly in comparison with other airports in the region.
- The 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 surcharges for approval prior to sale.
- The EBC was against the implementation of the new Tourism Promotion Tax as it burdens the airlines to collect it and raises costs for the consumers. In the implementation phase, the EBC requests clarification of data requirements which may be in conflict with EU data protection laws and prohibit EU airlines from delivering it. Also needed is a transparency of usage for the collected revenue.

### ■ 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, including for catering and cargo are needed. We welcome the opening of the new air corridor at HND with its positive business and environmental impacts.

**Recommendations:**

- HND should continue opening up to international traffic, including flights to and from Europe
- 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.
- Numbers of immigration staff should be increased at all international airports as waiting times are high.
- 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.

**Mr. Shigetoshi Kawahara**

Corporate Adviser

c/o European Business Council in Japan

Sanbancho POULA Bldg. 2F.

6-7 Sanbancho, Chiyoda-ku, Tokyo 102-0075

Phone 03-3263-6222

Fax 03-3263-6223

# RAILWAYS

## Introduction

Japan has long benefitted from an extensive railway network, connecting Kyushu in the south with Hokkaido in the north. 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. Nevertheless, Japan represents a large market that would benefit enormously from the technological expertise and international competitiveness that European manufacturers and service providers offer.

The value of railway rolling stock produced in Japan in FY2018 was 247.4 billion yen, up 13.1% from the previous year. The corresponding import figure was a mere 10 million yen. The production value of railway rolling stock parts was 368 billion yen, 1.1% up compared to the previous year, while the value of imported parts was 5.69 billion yen. This imbalance is further reinforced when looking at other market where Europe has a much higher share. At the same time, there are a number of successes where European companies together with Japanese companies are successfully executing projects on third markets.

Just as Japanese manufacturers need European expertise in a global competitive market, the EBC believes that the domestic market would also benefit from higher penetration of advanced European products and services. The previously mentioned global expertise and references are a good base to continue to deepen the cooperation between EU Rail technology companies and Japanese rail companies looking for a win-win situation.

In October 2019, the typhoon No. 19 affected the railway infrastructure over an extensive area, and the Nagano Shinkansen vehicle centre of the Hokuriku Shinkansen was hit by the collapse of the Chikuma River causing damage to electrical equipment. Parked vehicles were submerged and damaged. Thankfully, the operators seemed to suffer little human damage due to the planned suspension of operations. As global warming progresses, the suspension of railway infrastructure due to extreme weather phenomena is not only a problem in Japan but also a global problem including the EU. In particular, the railway business, and its knowledge and expertise that can reduce CO<sub>2</sub> emissions should be shared between Japan and the EU. Involved parties should aim for coexistence and prosperity.

The EBC appreciates the work of both the European Commission and Japanese ministries in concluding the EU-Japan EPA, both in terms of the technical work in harmonising standards and test methods, and in recognising overseas approvals, but also regarding the expansion of local entities that will be covered by the regulations on public procurement. Not to forget is of course also the removal of the Operation Safety Clause (OSC). It is however important to state that the success of the agreement will depend on the actual result of its implementation. So the EBC takes for granted that the removal of the OSC will be implemented as stated in EPA within one (1) year after the entry into force of the EPA. Furthermore, the Ministry of Land, Infrastructure, Transport and Tourism shall support and make certain that cities and entities covered by the agreement do take the necessary preparations to inform and include European companies in the railway related procurement.

We believe, however, that efforts should not stop with the agreement. It will be vital to further harmonise regulations and standards, and to eliminate double testing to make it easier for European companies to do business and invest in Japan, and vice versa. The EBC furthermore hopes that the committee on technical rules set up during the EPA negotiations will continue its work to harmonise and achieve mutual recognition of standards and approvals.

On the same note, the EBC believes that the Japanese market would benefit from a national testing scheme which is used by all operators. The goal of the conformity assessment scheme should not be to limit differences in performance requirements where operators might have different requests and demands. The scheme would rather focus on safety which should be the same all operators in Japan. This would remove the need for testing to be repeated and would be beneficial to all suppliers in Japan, whether they are foreign or domestic. The EBC believes that the MLIT together with Japanese operators should take a greater role to achieve this.



## 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. This makes the Japanese market unique in comparison to other markets, where “buying off the shelf” is far more common.

**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 Japanese Government, research institutes, railway operators and industry should continue their dialogue on this theme.

### ■ Conformity assessment and mutual recognition of testing and certification

*Yearly status report: slight progress.* Japan is an active participant in various international standardisation bodies, but there is very little movement towards applying common standards across its domestic railway market. Moreover, Japan lacks a common conformity assessment scheme for this industry. The EBC believes that it will be mutually beneficial for Japanese operators to work together with the EBC Railways Committee to define common requirements. This issue has been discussed in the negotiations towards an EPA and the EBC is looking forward to improvement in this area.

**Recommendations:**

- Japan should establish a working group to identify minimum common requirements acceptable to all operators.
- EU and Japan shall continue the work in the technical committee set up by the EPA to further harmonise standards and regulations.
- The Japanese authorities should take a more active role in setting up a conformity assessment scheme.

### ■ Operational Safety Clause (OSC) and public procurement

*Yearly status report: progress.* At the time of the production of this report a year has passed since the entry in to force of the EU-Japan EPA. Therefore, the OSC is not applicable in relation to EU suppliers. The EBC is therefore looking forward to public procurement being conducted in accordance with the WTO GPA (World Trade Organization’s Agreement on Government Procurement) by those entities that are covered by said agreement. It should be stated though that it is at this time difficult to say exactly what actual changes and opportunities will be presented.

**Recommendation:**

- The Government of Japan should ensure that when planning new railway projects (such as LRT systems), local governments and entities covered by the WTO GPA abide by or use the GPA as guidance to set up a proper public procurement scheme, and do not apply the OSC.

### ■ Tenders by companies not covered by the GPA

*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 recently issuing calls for tenders for rolling stock. The EBC believes there is a clear business case for tendering and so urges that Japanese operators 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 will result in more transparency and better access to technical specifications, as well as information on how to meet and exceed any set requirements.

**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.

**Mr. Yoshio Honda**

Chair, Telecommunications Equipment Committee  
(General Manager, Standardization & Regulation,  
Technology & Research, Ericsson Japan K.K.)  
c/o Ericsson Japan K.K.  
MOMENTO SHIODOME, 2-3-17 Higashi-Shimbashi  
Minato-ku, Tokyo 105-0021  
Phone 03-6721-3300; Fax 03-5408-9744

# 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 approaching, 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 Games and is investigating how best to meet 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 (IoT), but also includes areas such as healthcare and transportation for 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, similar to the Suppliers' Declaration of Conformity (SDoC) introduced in Europe. 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 7.9 billion mobile phone subscriptions globally and 6.5 billion of these are connected to mobile broadband, with overall mobile data traffic doubling each year. In Japan, which is considered a mature market characterised by advanced data services and the introduction of Long-Term Evolution (LTE), smartphone penetration is already at about 70% and is driving mobile broadband growth - traffic usage is projected to rise to 10GB/month per user by 2020. Japan is promoting new wireless technologies for IoT, Intelligent Transportation Systems (ITS) and 5G. Advanced wireless technologies can facilitate innovative use of ICT, and contribute to emerging industries and economic growth.

Applications used on smartphones, such as video and social networks, and machine-to-machine communication place different demands on the network. Japan has played an active role in efforts to harmonise the spectrums used for International Mobile Telecommunications (IMT) systems at the global level. It is important to note that MIC took on an important role for this goal at the World Radiocommunication Conference 2019 (WRC-19), especially in relation to the identification of new harmonised spectrums for IMT above 24GHz (Conference agenda item 1.13). This would bring enormous benefits to the IMT industry and its customers by eliminating the need to develop local variations of new telecommunications equipment. The EBC strongly supports this work and hopes that Japan will continue to implement new spectrum bands according to the outcomes of WRC-19 that are harmonised with other markets.

The telecommunications industry is based on technical standards covered by so-called Standard Essential Patents (SEP), which commit the patent holder to licensing on Fair and Reasonable, And Non-Discriminatory (FRAND) terms. The Japan Patent Office (JPO) introduced in 2018 guidance for SEP licensing negotiations and a process for essentiality evaluation. The impact of these measures are closely monitored and extended to cover also Japan Fair Trade Commission's (JFTC) planned update on their SEP Licensing Guidelines.

## 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 and, although the differences are not substantial, they lead to double testing and certification for manufacturers. The current EU-Japan MRA provides only for recognised certification organisations to test for both markets. The EBC is disappointed that the SVC system in Japan is limited to wired telecommunications terminals in general and that it has not been expanded to other telecommunications equipment (except for 3G/LTE and WiFi functions in mobile terminals), thus excluding radio base stations for mobile networks.

#### **Recommendations:**

- The EU and Japan should mutually accept each other's technical standards and certifications for telecommunications equipment.
- SDoCs issued by European producers should be accepted in Japan without further testing or administrative requirements, not only in respect of wired terminals, but also in respect of 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-2020/5G)

*Yearly status report: some progress.* The EBC is pleased that MIC has been working to ensure additional spectrum allocation bands to address the increasing demand for mobile broadband and emerging new use cases of the vertical industries. The EBC recognises that MIC has allocated spectrum bands (3.7 GHz, 4.5 GHz and 28 GHz bands) for IMT-2020 in April 2019, and the plan for allocating additional bands (26 GHz and 40 GHz).

#### **Recommendations:**

- Japan should continue working for globally or regionally harmonised spectrum allocations for mobile use.
- Japan should engage actively in agenda item 1.2 of WRC-23.
- Japan should continue the process for allocating 5G spectrum, to facilitate the development of 5G equipment for its planned commercial service, considering the outcomes of the agenda item 1.13 of WRC-19.

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

*Yearly status report: some progress.* The EBC believes that Japanese radio regulation is not sufficiently flexible and, by stipulating technical requirements based on specific technology on each frequency band, risks delaying the launch of new wireless technologies. The EBC notes that an MIC's report for 5G issued in March 2020 mentions that the periodical inspection of mobile radio base stations should be studied further.

#### **Recommendations:**

- Japan should adopt future-proof radio regulation for mobile equipment so that emerging technologies can be swiftly deployed. It is worth studying the technology-neutral approach, especially for unlicensed bands such as 5GHz.
- Japan should review its radio regulation to ensure it avoids imposing undue requirements on radio base stations, especially in respect of AAS (Active Antenna Systems). In particular, the periodical inspection of radio performance at antenna or equivalent monitor ports should be reviewed for potential exemption.

### ■ IP (Intellectual Property) policy for SEP (Standard Essential Patents)

*Yearly status report: progress.* Japan Patent Office's "Guide to Licensing Negotiations involving Standard Essential Patents" released in June 2018 has not created issues during 2019. The "Essentiality Determination of Standard Essential Patents" process, which received less attention, established in April 2018 by JPO, was updated 2019, but still waits for its first case before its effectiveness and fairness can be verified. JFTC has launched a process to update their own SEP Licensing Guidelines. EBC will monitor the impact and fairness of these the newly established principle sand processes in regards to the European telecommunication industry.

#### **Recommendation:**

- Japan should continue the communication with European Commission, European Patent Office, and other European organisations to harmonise the regulations related to Standard Essential Patent licensing.

## Vacant

c/o Bjorn Kongstad, Chief Policy Director  
European Business Council in Japan  
Sanbancho POULA Bldg. 2F  
6-7 Sanbancho, Chiyoda-ku  
Tokyo 102-0075  
Phone 03-3263-6222  
Fax 03-3263-6223

# LOGISTICS & FREIGHT

## Introduction

The Coronavirus has created a very volatile situation for the logistics sector. Borders between countries have been closed, manufacturing plants have closed and an overall decrease in movement has taken its toll. Trade figures are unfortunately all pointing in the same direction, and there is currently little to indicating that this will change in the near future. At the same time we are seeing more demand for Business to Consumer (C2B) delivery as consumer patterns are changing to deal with the new realities. All this puts the logistic and freight industry under immense strain.

Under these circumstances it is important that the Japanese Government does its utmost to facilitate the smooth flow of goods, Goods that are vital for the functioning of our society, whether we are talking about the access to medical products or parts to the automobile industry. What is needed are clear guidelines and better alignment with other countries. There is also a need to continue to keep harbours and airports open while taking all the necessary precautions.

European logistics and freight companies offer consumers the benefits of access to their worldwide logistics operations. This has been even more evident in the last couple of years as e-commerce and home deliveries have increased exponentially. Moving forward there are no signs that this trend is receding, and companies in the logistics and freight sector are struggling. This is true both from a regulatory perspective but also due to the labour shortage and the fragmented digitalisation. Moreover, companies struggle with Japan's high cost base, inadequate infrastructure, 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 providing the same service, resulting in inefficiencies and higher prices for users. The EBC appreciates the Government's efforts as of late and believes that it is on the right track. However, if the Government truly wants Japan to become a viable logistics hub for regional trade, it must now take account of all stakeholder perspectives and ensure the right regulation and infrastructure are in place.

With the entry into force of the EPA, the logistics sector became even more important as it facilitates and will continue to facilitate the ever-increasing trade between the EU and Japan. However, for this trade to reach its full potential it is important that customs authorities and other parties that are involved do not introduce measures that are not in accordance with the agreement, and instead support business to further expand EU-Japan business. There is, furthermore, a need to make certain that the agreement is applied in a consistent manner, independent in which EU Member State or Japanese Customs region products are imported.

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.

Finally, while MLIT has introduced positive reforms aimed at improving Japan's overall business infrastructure there is still some to do to remedy the challenges to shipping services. The development of Japanese container terminals is being initiated by local authorities rather than by central Government, such that 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 33<sup>th</sup> place globally in 2017 based on containers moved. Structural improvements are desperately needed if Japan wants to remain a vibrant shipping country.

## Key Issues and Recommendations

### ■ COVID-19

*Yearly status report: new issue.* Saying that the Coronavirus has affected the logistics and freight industry would be an understatement. Unfortunately, since the logistics sector also facilitates many other sectors, supply chain for many companies is also affected. While the EBC members are doing all in their power, an accommodating regulatory framework and a robust infrastructure are essential.

#### **Recommendations:**

The Government of Japan should:

- Issue clear guidance regarding use of ports in relation to operation and quarantine.
- Do its utmost to keep ports open with minimum changes to operations while ensuring that the necessary precautions are taken.

### ■ Future delivery modernisation

*Yearly status report: slow progress.* The final mile delivery in Japan can be hugely challenging, with service providers working extended hours and dealing with re-deliveries as a result of the consignee being away from home or unable to receive the delivery, even if the delivery is made within the agreed time window. Against the background of an overall tightening of the labour market and, in particular, a well publicised driver shortage, the EBC believes that a new approach is required to improve the sustainability and effectiveness of final mile deliveries. The situation has further worsened with the Corona virus.

#### **Recommendations:**

The Government of Japan should:

- Enable use of larger vehicles for inter-city movement to reduce the number of vehicles and drivers required.
- Allow and encourage the use of autonomous vehicles by delivery companies.
- Increase the subsidy for non-proprietary “open” parcel lockers and simplify the application process for such subsidies. In particular switching from the pre-installation to a post-installation application process should accelerate the deployment of parcel lockers. It is not uncommon that all boxes are already used.
- Educate the public about socially responsible delivery arrangements by highlighting the social and environmental costs of failed delivery attempts and encouraging the consignee to be home and able to receive the delivery within the requested time window or to choose alternative “delivery options”. Failed deliveries are still very common.

### ■ Labour shortage

*Yearly status report: limited progress* Given Japan’s projected population decline and ageing society, it is anticipated that the current shortage of available labour will continue, severely impacting the logistics sector as expansion of e-commerce drives up demand. The logistics sector is especially vulnerable as many of the long-haul drivers it employs have reached or are reaching retirement age. In order to continue meeting the demand for logistics services, it is important that the Government puts in place practical strategies to improve the availability of labour in the short- and medium-term. The EBC appreciates the various initiatives put forward by the Government. However, many of them do not quite hit the target but are held back by limitations either in scope or by administrative restrictions. There is a particular concern around the short-term challenge, since potential solutions such as the use of new technologies, including autonomous driving, and increased use of automation in freight handling will only become available in the long term.

#### **Recommendations:**

- Japan should ease its visa requirements to allow foreign temporary labour, particularly during peak periods of demand, such as Golden Week and around the end of the year.
- Japan should make it easier for logistics companies to use the Technical Intern Trainee Program.
- The authorities should support companies in setting up childcare provision, including through access to training and certification for childcare workers, to facilitate the employment of women in the sector.
- Japan should promote the importance of the logistics sector to encourage more female participation.



## ■ NACCS

*Yearly status report: new issue.* The NACCS (Nippon Automated Cargo and Port Consolidated System) is a well-used system in Japan for among other things customs clearance. While it gives direct access to the service of the Japan Customs, many other agencies and ministries are less connected to NACCS. This means that some data have to be duplicated. Examples of these data are: trucking, warehousing, forwarding activities, airlines and shipping activities.

### **Recommendation:**

- Japan should expand NACCS so that more data related to logistics can be included and accessed as well.

## ■ Authorised Economic Operator (AEO)

*Yearly status report: some progress.* The current system of AEO has not led to the anticipated easing of the administrative burden. In many cases, the burden has increased. The EBC seeks a system giving companies a simplified process and extended powers to handle matters without the 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 Japan
  - ✧ Allowing quarantine checks at transporters' own bonded warehouses
  - ✧ Reducing the physical examination of shipments
  - ✧ Allowing the use of digital archives

## ■ Digitalisation

*Yearly status report: no progress.* With ever increasing traffic, of not only physical goods, but also of accompanying documents, logistics companies are under increasing strains. While the core of the problem does not lie with a regulation or a standard, but rather with the behaviour of the stakeholders, the Japanese Government should support and promote a digitalisation of the sector. Currently, there are still many situations where orders are made either over fax or over phone or where documents are delivered physically. With an improved digitalisation, not only will logistics cost go down, but times from order to delivery will do the same. Needless to say digitalisation will also help to cope with the Coronavirus situation, as it is currently very difficult for the logistical sector to, for instance, work from home.

### **Recommendations:**

- The Government together with the various sector organisations should work to enhance digitalisation within the logistics sector. This would improve the competitive advantage of the Japanese market.
- Japan should look into reducing the amount of required documents that is required to be in paper form. This is particularly burdensome in regard to time stamps.

## ■ Retrospective application

*Yearly status report: new issue.* With the implementation of the EPA, and the need for additional information on the origin status, some companies decided not to apply for preferential treatment, and instead paid the third country duty. With the changes adopted by Japan Customs where importers making use of the statement on origin issued by the exporter do not have to provide any additional information this issue has thankfully been resolved. However, in Japan, contrary to the EU, there are very few chances to recover the paid duties. Implementing retrospective application would also increase the usage rate of the agreement, something that both Japan and the EU would benefit from.

### **Recommendation:**

- The EBC recommends Japan to introduce retrospective application of the EPA so that businesses can recover the cost of not being able to use the EPA despite products having EU origin.

# **Health Science**

**IVD (In vitro diagnostics)**  
**Medical equipment**  
**Pharmaceuticals**  
**Vaccines**  
**Cosmetics & quasi-drugs**

**Dr. Shinichi Eda, Ph.D**

Vice-Chair, Medical Equipment &amp; Diagnostics Committee

(Head of Medical, Quality &amp; Regulatory, Roche Diagnostics K.K.)

c/o Roche Diagnostics K.K.

Shinagawa Season Terrace, 1-2-70, Konan, Minato-ku,

Tokyo, 108-0075

Phone 03-6634-1111

Fax 03-5479-0561

# IVD (IN VITRO 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 rising national healthcare costs. It is clear the Japanese Government needs to reform the way the healthcare system operates while also re-evaluating its purpose. The EBC considers serious discussions on the value and role of clinical examinations (specimen examinations), which already play a significant part in medical practice, are crucial to achieving the Government's objectives of "improvement of the quality of medical care" and "optimisation of medical costs". It is imperative that healthcare in Japan continues not only to benefit from clinical examinations but also to realise their full potential in respect of improved diagnosis, treatment and prevention. This will only be possible through re-evaluation of their value and role by both medical care providers and medical system operators.

The medical reimbursement system for clinical examinations has been under discussion since 2007 between the Japanese Promotion Council for Laboratory Testing (JPCLT), *in vitro* diagnostic (IVD) industry associations, and the Ministry of Health, Labour and Welfare (MHLW). Since then, the results of an investigation into current problems and issues as well as as possible future directions have been announced, opinions have been exchanged and proposals and recommendations have been made both at "study sessions on medical diagnostics" and at "periodical meetings on the medical reimbursement system". The EBC applauds the fact that the Government has already recognised what is referred to in periodical medical reimbursement price revisions as the need for "quality enhancement of clinical diagnostics and faster examination" and that this led to a continuous rise in IVD fees. The medical reimbursement revision of 2016 introduced "Global Standard Examination Management Additions". Whether or not a facility qualifies for these additions depends on its ability to demonstrate "approved technological competence based on global standards". Furthermore, it is significant that the "Medical Law" was partially revised in 2018 to clarify ensuring the quality and accuracy of *in vitro* clinical testing. This has had a positive effect on the medical diagnostics sector.

Cooperation between the medical diagnostics industry and the pharmaceutical industry, and consultations with the Government are progressing on the increasingly important topics of personalised healthcare and companion diagnostics. The final objective is the introduction of relevant approval processes and the establishment of an insurance reimbursement system linked to drugs. The clinical application of advanced technologies, such as next-generation sequencing, is rapidly advancing. A system to evaluate the accuracy and quality of the tests made available through these technologies is required. Against this background, it is essential that the current medical system is streamlined and reformed so that personalised treatment can be expanded, the quality of medical diagnostics and medical care can be maintained and improved, and clinical diagnostics can 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 IVD tests and setting Health Insurance Points (HIP) based on their latest clinical value.

The EBC Medical Equipment & Diagnostics Committee and its IVD Sub-committee continue to advocate the value of clinical diagnostics in cooperation with the JPCLT and other IVD industry groups. We are also continuously ready to work with the MHLW and the PMDA (Pharmaceuticals and Medical Devices Agency).



B. Braun Aesculap Japan	Japan MDC	Otto Bock Japan
BioMerieux Japan	Japan Medicalnext Co., Ltd.	Philips Japan
Biotronik Japan	Lima Japan	PSP
Coloplast	LivaNova Japan	Radiometer
Dornier MedTech Japan	Medical U&A	Roche Diagnostics
Draeger Medical Japan	Medis medical imaging systems	Siemens Healthcare
Edaptechnomed	Medtronic Japan	Thermo Fisher Diagnostics
Elekta	Molnlycke Health Care	TKB
Integral	Nippon BXI	
Japan Lifeline	Novocure	

## Key Issues and Recommendations

### ■ Executable operation related to electronic package insert

*Yearly status report: ongoing.* There are specific package inserts depending on the properties of the IVD. Operation and maintenance corresponding to the provision of various attachments are required.

#### **Recommendations:**

- Japan should promote and simplify the use of electronic package inserts to provide appropriate and necessary information to users, taking into account the existence of package inserts specific to IVDs.

### ■ International harmonisation in definition and classification of IVDs

*Yearly status report: ongoing.* It is necessary to develop regulations based on the fact that IVDs for providing information necessary for medical care and prognosis/risk evaluation and IVDs using advanced technology are increasing. The International Medical Device Regulators Forum (IMDRF) is currently examining the corresponding IVD international classification standards.

#### **Recommendations:**

- For the purpose of international harmonisation, Japan should expand the definition (scope) of IVDs and properly classify and regulate them according to their intended uses and risks.

### ■ Rationalisation of regulations on IVD and streamline operations

*Yearly status report: some progress.* The Japanese authorities issued a notification to clarify the purpose and process of the pre-approval study in order to reduce the total review period and improve the predictability of the timing of obtaining approval.

#### **Recommendations:**

- Japan should introduce efficiency and rationalisation of application/examination work, including digitisation of submitted documents (paperless).

### ■ Evaluation of medical usefulness and innovativeness of IVDs

*Yearly status report: ongoing.* The medical usefulness and innovativeness of IVD have not been directly evaluated, and the evaluation of the performance and characteristics of new and improved items discussed and agreed at *Chuikyo* has not been published.

#### **Recommendations:**

- At the time of insurance coverage, the evaluation points for the medical usefulness and innovativeness of the listed IVD shall be specified.

### ■ Contribution to "Securing high-quality home medical care" through POCT

*Yearly status report: ongoing.* To build comprehensive community care, it is necessary to enhance home healthcare and strengthen the function of family doctors. Performing a POCT (Point-Of-Care Testing) at home medical care is expected to reduce the prognosis of patients with early understanding of patient conditions and cooperative intervention in acute care

#### **Recommendations:**

- A reimbursement system that appropriately evaluates POCT in the areas of cardiovascular and infectious diseases, which are particularly demanding.

**Mr. Hideaki Mori**

Chair, Medical Equipment & Diagnostics Committee  
(President & CEO, Siemens Healthcare K.K.)  
c/o Siemens Healthcare K.K.  
Gate City Osaki West Tower,  
1-11-1 Osaki, Shinagawa-ku, Tokyo 141-8644  
Phone 03-3493-7500  
Fax 03-3493-7654

# MEDICAL EQUIPMENT

## Introduction

The total cost of medical care for Japan in the 2016/17 fiscal year was 41.3 trillion yen, down 0.4% from the previous year. The slight fall is regarded as temporary and due to a significant decrease in anti-viral drug charges, hepatitis C drug treatments included. In many other respects, the main challenges remain as before, including changes to the overall disease profile driven by the ageing of the population and a rise in chronic conditions, and the promotion of medical innovation in parallel with controls on medical costs. However, healthcare delivery is becoming extremely complex, because of labour shortages stemming from the decreasing birth rate and an ageing population, shortages of specialists in ICU (Intensive Care Unit) pathology, and the decline in business or business failure of a significant number of hospitals and clinics.

In order to improve the situation, it is important to move from a focusing on the treatment of disease to a more holistic approach aimed at health maintenance and disease prevention; to utilise medical information and improve the efficiency of medical services in parallel, and to promote healthcare reform and especially technical innovation. Medical costs should be reduced by a combination of detecting abnormalities at an early stage through health monitoring, delivering accurate and specific diagnoses, sharing diagnostic results among healthcare institutions, and realising timely and efficient medical services, as well as by deploying and disseminating these improvements throughout the healthcare system. These actions will, in turn, reduce the burden on patients and increase the health of the general population and labour force, thereby contributing to social and economic growth.

Innovative European medical equipment, materials and services can help Japan to meet its healthcare challenges. To do this, Japan should align its regulations and processes with international standards, allow 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 overseas businesses to participate in the Japanese market.

In Japan, the introduction of PHR (Personal Health Record) has been promoted since FY2020, and online medical treatment for COVID-19 is also underway. Cloud integration and consolidation of medical institutions is required. It is hoped that the following measures will be continued: Efficient medical services will be provided by digitalisation of medical data; Cyber security implemented in Europe toward introduction of Medical equipment using IoT (Internet of Things) and AI (Artificial Intelligence); appropriate responses to GDPR (General Data Protection Regulation); and FDI (Foreign Direct Investment) measures that European companies can participate in.

The EBC Medical Equipment & Diagnostics Committee intends to continue working in cooperation with the Japanese Government, especially the Ministry of Health, Labour and Welfare (MHLW) and the Pharmaceuticals and Medical Devices Agency (PMDA) and other associated industrial organisations, and will present recommendations in order to help reform the Japanese medical system and industrial structure. The aim will be the deployment in Japan of not only excellent medical equipment but also advanced healthcare models and effective medical systems, where we believe Europe has much to offer.

B. Braun Aesculap Japan	Japan MDC	Otto Bock Japan
BioMerieux Japan	Japan Medicalnext Co., Ltd.	Philips Japan
Biotronik Japan	Lima Japan	PSP
Coloplast	LivaNova Japan	Radiometer
Dornier MedTech Japan	Medical U&A	Roche Diagnostics
Draeger Medical Japan	Medis medical imaging systems	Siemens Healthcare
Edaptechnomed	Medtronic Japan	Thermo Fisher Diagnostics
Elekta	Molnlycke Health Care	TKB
Integral	Nippon BXI	
Japan Lifeline	Novocure	

## Key Issues and Recommendations

### ■ Revision of insurance coverage and functional classification of insurance medical material

*Annual status report: no progress.* The functional categories of insurance healthcare materials were revised to eight new, eight fragmented, 15 rationalised, and 15 simplified classifications.

#### **Recommendation:**

- Japan shall continue to prove the insurance reimbursement pricing system based on the acceleration and clarification of the review process and the product features,

### ■ Foreign Price Reference System

*Annual status report: no progress.* The comparative level of foreign price adjustments for newly listed products was lowered from 1.3 to 1.25. The weighted average of 1.3 times or more was revised from 75/100 to a reduction of 50/100 for existing products.

#### **Recommendation:**

- Japan shall continue to create a system that takes exchange rate fluctuation risks into account while maintaining a comparative level.

### ■ Expansion of Insurance application system (C-Challenge) based on actual usage

*Annual status report: some progress.* The C1 Challenge based on the actual use has been institutionalised, paving the way for the re-evaluation. However, but the technical fee for the diagnostic treatment equipment is excluded from this re-evaluation.

#### **Recommendation:**

- Japan should introduce C2 Challenge of re-evaluation of diagnostic equipment just as is possible for Category 1 products.

### ■ Mutual recognition and global standards for clinical evaluation

*Annual status report: progress.* Japanese authorities encourage the usage of the prior consultation service of the PMDA in order to promote the use of overseas clinical evaluation results when applying for equipment.

#### **Recommendation:**

- The EBC request that the Japanese authorities continue the very successful work of promoting the use of overseas data.

### ■ QMS mutual recognition and global standards

*Annual status report: progress.* Some progress was shown in conformity with the global standards. Formal participation in the MDSAP (Medical Device Single Audit Program) assists further development of discussions for conformity with the global standards.

#### **Recommendations:**

- Japan should dispatch information through a formal QMS (Quality Management System) ministerial ordinance in English for conformity with the QMS global standards.
- Japan should eliminate the differences in requirements of the QMS ministerial ordinance, and conform with the global standards for the product group classification.

### ■ Mutual recognition and global standards of medical equipment license

*Annual status report: some progress.* The approval examination period of the PMDA was shortened by the enforcement of the Japanese PMDA law and performance was improved.

#### **Recommendation:**

- Japan should recognise EU approvals for Class 2 products as equivalent to Japanese approvals.

# PHARMACEUTICALS

## Introduction

Although overall healthcare costs in Japan are rising as the population ages, and use of certain innovative pharmaceuticals is growing significantly, total pharmaceutical spending has been well under control.

Japan's healthcare spending in fiscal year 2017 increased by 2.2% (0.9 trillion yen) to 43.1 trillion yen, and the drug cost was 9.5 trillion yen (+2.6%) as the price cut was not conducted. However, after the drug pricing system reform in 2018, the drug price revision has technically been conducted every year with the October 2019 price cut to reflect the consumption tax hike, although the decision to start the interim year price-cut is from April 2021.

The drug pricing system reform in 2020 was conducted based on the same concept as in 2018 that aims to simultaneously achieve "sustainability of universal health coverage" and "promotion of innovation" and to realise "release from nation's burden of healthcare cost" and "improvement of medical quality". In detail, the product criteria for the Price Maintenance Premium (PMP) was slightly improved such as addition of *Sakigake* products and products which add indication showing high innovativeness or usefulness in the criteria. On the other hand, under Comparator Method (1), when the comparator drug is subject to PMP, PMP portion of the comparator will be deducted after a certain time period. Additionally, a new repricing rule for change in indication, was introduced. These revisions have a huge negative impact on the pricing during the patented period. Therefore, we believe that it is impossible to mostly rely only on drug cost reduction to compensate and manage the social security cost, and thus other strategies should be considered.

Drug price revision has been basically conducted together with the medical fee revision every two years. However, it was decided to introduce interim year price-cut from 2021 and its target products to be decided by the end of 2020. According to the "Basic policy towards the fundamental reform of the pricing system", the price for products which have a big gap between the NHI Price and Actual Wholesaler-selling Price should be revised. Therefore, we believe the target products of the interim year price-cut should be limited to the products which have a big gap. We also believe that general impact of interim year price-cut on drug development in Japan should be considered.

For the first 12 months after a drug is price listed, prescription is limited to a maximum of 14 days, after which a further prescription is required. As a result, many physicians have limited use of the new products for a year after price listing. Given that Japan has robust safety measures, including the Risk Management Plan (since 2013), this 14-day rule for new drugs is outdated, and preventing patients from accessing the treatments they need. The Government's own Council for Regulatory Reform recommended the revision or elimination of this rule, and EFPIA supports their position.

Japan introduced a form of CEA/HTA (Cost-Effectiveness Analysis/Health Technology Assessment) from 2016 on a trial basis. Full-scale implementation was initiated from 2019. Unfortunately, the European experience shows that CEA/HTA can become a barrier preventing patient access to medicines and be a major administrative burden for academia, government and industry. Japan has sufficient measures to control drug expenditures, so CEA/HTA should not be allowed to become cost-containment measure. EFPIA believes that Japan should take into account the challenges faced in Europe and implement it with limited scope.

Japanese Good Clinical Practice (GCP) in clinical trials is now steadily aligning with global standards. "*Sakigake* designation system" and "Conditional early approval system", which had been implemented on a notification base, became legislated with newly established "Specific use drugs", and these amendments will be enforced on Sep 1<sup>st</sup>, 2020. The scope of Mutual Recognition Agreement was extended to include the product such as active pharmaceutical ingredients, sterile formulation, and biological medicines in July 2018. In addition, each manufacturing site will be targeted for GMP (Good Manufacturing Practice) compliance inspection according to the Amended Pharmaceuticals and Medical Devices Act (promulgated on Dec. 4, 2019). The full implementation of the mutual recognition of GMP between Japan and Europe should be ensured and the adjustment for global harmonisation of GMP future inspection is required.

## EFPIA Japan Member Companies

Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Bayer Yakuhin	Lundbeck Japan
Bracco-Eisai	Merck Serono
Chugai Pharmaceutical	Mylan EPD
CSL Behring	Nihon Servier
Ferring Pharmaceuticals	Nippon Boehringer Ingelheim
GE Healthcare Japan	Novartis Pharma
GlaxoSmithKline	Novo Nordisk Pharma
Guerbet Japan	Sanofi
Ipsen Pharma Japan	UCB Japan

## Key Issues and Recommendations

### ■ Drug pricing system

*Yearly status report: continuous negative progress and new issues.* The price maintenance premium (PMP), which was drastically revised with a negative outcome with the drug pricing system reform in 2018 was slightly revised regarding its product criteria in the pricing system reform in 2020. However, the revision was very limited and we believe that further revision is necessary to improve the pricing system during the patented period. Additionally, the introduction of a PMP portion deduction scheme for non-PMP products is expected to have a huge negative impact on predictability. With continuous reform of the pricing system, the attractiveness of the drug market in Japan has been declining significantly.

#### Recommendations:

- Restore the pricing system to have predictability and fairness to enable appropriate evaluation of innovation.
- Differentiate the interim year price-cut from the regular biennial price-cut, and restrict the target products to those products that have a big deviation rate.
- Consider reconstruction of the pricing system to a simple, easy-to-understand and transparent one as the current system has become extremely complicated due to repeated revisions.

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

*Yearly status report: lots of issues with many room for improvement.*

#### Recommendations:

- Any approach such as the current system in Japan, based largely or entirely on cost per QALY (quality-adjusted life year) thresholds risks inappropriate appraisal of drug value. Thus, additional factors should be adequately incorporated in the appraisal.
- The number of products assessed should be limited as Japan does not yet have a well-established HTA capability and at present is unable to assess a large number of products.
- HTA should not restrict or delay patients' access to new drugs.

### ■ International harmonisation (clinical trial environment)

*Yearly status report: some progress – room for improvement on the efficiency of clinical trials in Japan.*

#### Recommendations:

- Clinical trial environment in Japan is improving owing to various efforts to increase efficiency in clinical trials. However, more improvement is required in the area of cost optimization and in increasing the number of subjects per study site.
- Japan should further enhance the efficiency of drug development by taking advantage of the new guidelines on multi-regional clinical trials (ICH E17, GENERAL PRINCIPLES FOR PLANNING AND DESIGN OF MULTI-REGIONAL CLINICAL TRIALS) that was published in June 2018.

### ■ New systems related to new drug review and approval

*Yearly status report: some progress and new issues.*

#### Recommendations:

- Addition of "Priority review system" and legislation of "Conditional early approval system": According to the promulgation of the Amended Pharmaceuticals and Medical Devices Act on Dec. 4, 2019, "Pioneering drugs" (legislation of "Sakigake designation system"), "Specific use drugs, etc." designation system, and "Conditional early approval system" were established, which will be enforced on Sep 1<sup>st</sup>, 2020. For their operations, preparation of related laws based on the actual state and improvement in the relevant organisational structure are required.
- Legislation of (Post Approval Change Management Protocol) system: PACMP system has been established ahead of the application of TECHNICAL AND REGULATORY CONSIDERATIONS FOR PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT (ICH-Q12). The system will be enforced on 1<sup>st</sup> August 2021. For its operation, preparation of related laws is required based on the actual state in order to make the system easier to use.



**Mr Shinji Matsumoto**

Chair, Vaccine Sub-committee, Biologics Committee, EFPIA Japan

(Senior Expert, GlaxoSmithKline K.K.)

c/o GlaxoSmithKline K.K.

1-8-1 Akasaka, Minato-ku, Tokyo 107-0052

Phone 03-4231-5000

Fax 03-4231-5977

# VACCINES

## Introduction

At the 15th Vaccination and Vaccine Subcommittee (held in October 2019), a decision was taken to include the rotavirus vaccine in the National Immunization Program with start in October 2020, leaving only the WHO recommended mumps vaccine. Other existing gaps are the, 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), which are still not available in Japan. EFPIA Vaccine Subcommittee continues to work to reduce regulatory and policy-related barriers for the early adoption of combination vaccines.

In the summer of 2019, MHLW (Ministry of Health, Labour and Welfare) and the four industry associations (EFPIA, PhRMA, Japan Pharmaceutical Association, and Japan Vaccine Industry Association) began holding monthly consultations focusing on the following seven issues with the aim of revising the Immunization Act in 2021. ① Acceleration of NIP discussion and decision and improving predictability, ② Promotion of vaccine development with high development priority, ③ Enhancement of database and monitoring system, ④ Strengthening information transmission and improving transparency of discussion and process, ⑤ Ensuring a stable supply, ⑥ Suspected side reaction report, detailed investigation, etc., ⑦ Others (Vaccine industry vision, Nagoya Protocol, etc.)

Particularly, in each subcommittee of the Vaccination and Vaccine Committee, the representative of four industry groups argued that it is necessary to start NIP discussions before regulatory approval for a newly introduced vaccine for accelerating its inclusion in NIP. This was argued at the LDP (Liberal Democratic Party) vaccine study meeting as well.

The four industries associations, as a plan for stable supply of vaccines, compiled and appealed for a unified opinion on optimisation of national testing and necessity of national stockpiling. In addition, EFPIA made specific proposals such speeding up the national testing when introducing a new vaccine by providing samples to testing organisations from overseas manufacturers before importing products.

At the 5th LDP Vaccine Study Meeting (held in November 2019), the representative from EFPIA Japan Vaccine Subcommittee argued the importance to evaluate the overall value of vaccines and that more resources must be devoted to immunisation policies to improve vaccination policies. Many Diet members participating in the meeting expressed support for these proposals.

Through the above activities, EFPIA were able to present the current vaccine issues, not only to industry, the authorities, and academia, but also to politicians and the general public and were able to achieve positive results such as revision of the national testing system (abolition of sealing work, etc.).

MHLW has a strong desire to optimise the NIP vaccine price and the transparency of the pricing process as the next theme at the council with the four industry associations. Industry associations have just started preparing for this theme. EFPIA, together with PhRMA, will gather opinions on the pricing process from the perspective of a global company. It is important to recognise that vaccination is a different market than therapeutics, and that pricing is paramount to elicit vaccine innovation.

The EFPIA Vaccine Subcommittee continues its discussion to improve the vaccination environment with stakeholders by organising vaccine seminars. As one of the activities in 2019, EFPIA vaccine seminar (December 2019) was organised with “Thinking about Life Course Immunization” as the theme. With Dr. Okabe, Director of Kawasaki Institute of Health and Safety, as the Chair, several stakeholders from academia, government and media discussed obstacles to disseminate adult vaccines and their countermeasures at the seminar. Based on the discussions of Vaccine Hesitancy, which the WHO has raised as one of the ten threats to global health, all seminar members agreed that it is necessary to first establish correct mutual communication between the doctor and vaccinee in order to receive the vaccine in relief.

Actelion Pharmaceuticals Japan	Janssen Pharmaceutical
AstraZeneca	LEO Pharma
Bayer Yakuhin	Lundbeck Japan
Bracco-Eisai	Merck Serono
Chugai Pharmaceutical	Mylan EPD
CSL Behring	Nihon Servier
Ferring Pharmaceuticals	Nippon Boehringer Ingelheim
GE Healthcare Japan	Novartis Pharma
GlaxoSmithKline	Novo Nordisk Pharma
Guerbet Japan	Sanofi
Ipsen Pharma Japan	UCB Japan

## Key Issues and Recommendations

### ■ Incorporate WHO-recommended vaccines into NIP and promote the development of combination vaccines

*Yearly status report: progress.* It has been decided that NIP for rotavirus vaccine will start in October 2020. Regarding the NIP for mumps vaccine, MHLW evaluation vaccine subcommittee discussed that it is necessary to conduct a large-scale survey of more than 100,000 cases to realise the frequency of aseptic meningitis caused by existing mumps vaccination, which is difficult to conduct. This discussion may have made it more difficult for mumps vaccine to be part of the NIP. It is also true that discussions on development of priority vaccines such as combination vaccines have not progressed.

#### **Recommendation:**

- Regarding the NIP for mumps vaccine, the solution should be discussed thoroughly together with the academia such as the AMED (Japan Agency for Medical Research and Development) team study, and for the government, industry and academia to work together to aim for early NIP for mumps vaccine. These activities should lead to the early introduction of combination vaccines.

### ■ Securing a stable supply of vaccines

*Yearly status report: progress.* At The 22nd Vaccination and Vaccine Subcommittee R&D and Production and Distribution Subcommittee (held in December 2019), the four industry groups proposed measures to achieve stable supply. Regarding the efficiency of the national test, which is one of the obstacles to stable supply, revision of the national test system (elimination of sealing work, etc.) was achieved as a result. However, reaction on other proposals from the four industry groups (including national stockpiling and embed the national test in the MRA (Mutual Recognition Agreement)) are yet to be followed up.

#### **Recommendations:**

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

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

*Yearly status report: progress.* In July 2018 vaccines have come into scope of EU-Japan MRA on GMP (Good Manufacturing Practice) in July 2018, which is considered major progress. However, a great deal of time and effort is still needed to introduce and supply vaccines due to pharmaceutical regulations such as the lack of clarity in MRBP related to the timing of reviews, revision procedures, and criteria for listing. Also, even if the MRA is fully in effect, national testing still remains outside of MRA scope, thus it can still take more than six months before a vaccine is released onto the market after importation.

#### **Recommendation:**

- The quality standard of vaccines should be revised based on the latest science and technology as soon as possible. Additionally, the current MRBP should be abolished and its contents consolidated and integrated into the Japanese Pharmacopoeia in order to harmonise with other countries.

### ■ Awareness-Raising Activities to spread vaccinations for the elderly

*Yearly status report: progress.* EFPIA Vaccine Seminar with the theme of "Thinking about Life Course Immunization" was held, and the seminar concluded that it was absolutely necessary for two-way communication between doctors and vaccinee to promote vaccination.

#### **Recommendation:**

- The JMA (Japan Medical Association) and MHLW should communication guidelines in accordance with the WHO GACVS (Global Advisory Committee on Vaccine Safety).

## Vacant

c/o Bjorn Kongstad, Chief Policy Director  
European Business Council in Japan  
Sanbancho POULA Bldg. 2F  
6-7 Sanbacho, Chiyoda-ku  
Tokyo 102-0075  
Phone 03-3263-6222  
Fax 03-3263-6223

# COSMETICS & QUASI-DRUGS

## Introduction

The European Cosmetic and Quasi-Drugs sector works to ensure the quality, efficacy, safety, and environmental sustainability of its products 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, for example by helping them stay clean and healthy, protecting them against the damaging effects of extreme weather, preventing dental cavities, and enhancing 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. Many cosmetic and quasi-drug products can assist in these efforts.

Shipments of cosmetics in Japan were worth a total of 1,759 billion yen in 2019. In the same year, Japan imported cosmetics valued at about 282.5 billion yen, of which some 109.5 billion yen\* came from Europe, indicating that European cosmetic and quasi-drug products are popular with Japanese consumers as they account for a considerable share of imports. The import process was made 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. It is now possible for the applicant to decide the timing of a product change. The EBC applauds the MHLW for these actions.

However, European companies still face challenges in bringing 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 obtaining approval is too time-consuming or difficult in Japan. European 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. It is therefore considered to be difficult to deploy into the Japanese market promptly. Hence there is no choice but to change the ingredients in some cases. Furthermore, disclosure of information on effective ingredients and additives in quasi-drugs that are already approved in Japan is extremely limited, which is one of the reasons why such quasi-drugs require a long time to be introduced onto the market.

Parallel imports currently account for a substantial portion of the Japanese luxury cosmetics market. Some studies indicate that 11% of the units sold are parallel imports. Most are sold online via e-commerce portals. As these imports were not produced for the Japanese market, there is a risk that they are either not approved for Japan or do not have the proper labelling. There is also a risk that the imports may be expired products or products that have not been transported or stored properly and so could cause damage to consumers. The EBC calls on the Japanese authorities to make certain that all cosmetics sellers are subject to the same high standards when it comes to trader products, with a particular focus on formula registration, laboratory facilities, and labelling.

The EBC believes that Europe and Japan have an opportunity to lead the way in the global 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. In addition, the EBC would welcome greater leadership by European and Japan in the International Cooperation on Cosmetic Regulation, 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. EBC strongly supports European and Japanese leadership in the ICCR.

\* Total imports from the United Kingdom, Belgium, France, Germany, Italy and Switzerland



## Key Issues and Recommendations

### ■ Regulations and systems for quasi-drugs

*Yearly status report: no progress.* The MHLW issued a notice of concern regarding the examination of approval of pharmaceutical shampoos, pharmaceutical rinses, and pharmaceutical soaps, and set out its examination guidelines. In July 2019, PMDA revised its application for manufacturing and marketing approval for quasi-drugs and presented a mock-up on how to treat products with the same standards and test methods as those of the attached specifications of approved products. These developments are expected to lead to improvements in the quasi-drug review system, but simplification and acceleration of the application and review process have not been assured. In addition, in order to facilitate the review process, a briefing for personnel in charge of the application for quasi-drug approval is held every year, and reviews are conducted based on the materials provided at the briefing sessions. However, the positioning of the materials is not clearly indicated. For instance, a new item is approved because it is identical to an already approved quasi-drug only when the precedent of approval has been presented, however, this is not mentioned at all in the notification, etc. issued by the MHLW.

#### **Recommendations:**

- MHLW should shorten the review period for quasi-drugs for which review guidelines have been created and which are believed to be identical to already-approved quasi-drugs.
- When submitting an application related to a quasi-drug that uses ingredients of the same standard as those contained in quasi-drugs already approved, re-examination of the pertinent contents mentioned in the separate sheet standard should be omitted in order to improve efficiency and shorten the review.
- When ideas concerning the review change, this should not only be announced at the explanatory meeting for PMDA staff in charge but also be announced by issuing a notification or clerical communication after gaining understanding from the applicants through the collection of opinions, etc. using public comments in advance.

### ■ Expansion of advertising representation for cosmetics and quasi-drugs

*Yearly status report: no progress.* Fifty-five efficacy claims were defined as permissible for cosmetics in Japan in 2000. In 2011, a further efficacy claim of "making fine wrinkles due to dryness less noticeable" was added to the list. Yet the scope of efficacy claims approved in Japan is still narrower than in Europe, which hinders foreign-made cosmetics based on the latest research and technology from entering the Japanese market.

Sector associations are currently studying the efficacy claim of "prevention of ultraviolet ray-derived photo-ageing" which may lead to a further expansion. In recent years, the promotion of self-care and self-medication is required for the realization of healthy long-lived social. Routine care by cosmetics and quasi-drugs, such as moisturizing care for atopic skin and the use of sunscreen products to prevent skin cancer, plays an important role in maintaining health and preventing illness, but current advertising regulations do not admit to emphasize its importance.

#### **Recommendation:**

- Regulations related to advertising expressions should be eased so that the role of routine care products using cosmetics and quasi-drugs, such as health maintenance and disease prevention, can also be promoted.

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

*Yearly status report: Slight progress.* The Government enacted the "Basic Act on the Advancement of Public and Private Sector Data Utilization" in December, 2016, which stipulates the use of necessary measures for determining online usage for administrative procedures in principle. However, in regard to cosmetics and quasi-drugs, notifications and applications have to be made using floppy discs or in paper form. On the other hand, export reports using the NACCS (Nippon Automated Cargo and Port Consolidated System) can be used electronically. Furthermore, the prefectural authorities, the PMDA and Customs are not linked, so separate procedures are required for notification and application concerning the manufacturing and sales of cosmetics and quasi-drugs, and presentation of the necessary material for import customs clearance. In FY2019, MHLW acquired budgets for online application and notification procedures such as pharmaceuticals and medical devices. However, it would be difficult to simplify and expedite the application process simply by submitting the file from the current MHLW version of the software for electronic applications such as medical products without changing the form or the

description of the application form and the registration form. The construction of a system which enables efficient administrative procedures which maximises the utilisation of an IT platform is expected.

**Recommendations:**

- 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.
- Improvements should be made to the specifications of the application form, the registration form, and the "MHLW-version software for electronic applications such as medical products" in order to simplify and expedite administrative procedures.

■ **Applying the same standards to all market participants**

*Yearly status report: new issue.* Ensuring safety is crucial, both from a legal and, more importantly, from a consumer perspective. Manufacturers and importers of cosmetics and quasi-drugs are therefore required to spend considerable resources implementing post-marketing surveillance and control schemes to monitor safety and quality. However, parallel importers do not always comply with these requirements, sometimes illegally using registered trademarks, importing versions of products that are not approved in Japan, and selling products with damaged or missing labels or that have passed their expiry dates.

**Recommendations:**

- Japan should ensure that everyone involved in the sale of cosmetics and/or quasi-drugs complies with the same legal requirements related to safety and quality.
- The authorities should support an industry-led campaign to educate consumers so that they have a better understanding of products sold by authorised suppliers and those that are not.

■ **Establishment of alternatives to animal testing**

*Yearly status report: Slight progress.* The restructured human corneal liberation method (RhCE method) has been newly introduced. This can be used as an alternative method for eye stimulus testing for quasi-drug applications. In Japan, however, the safety evaluation of quasi-drugs with new ingredients necessarily requires results from animal experiments for the hazard evaluation of that particular raw material. At the same time, in other countries, discussions are being actively promoted on the development of evaluation methods without using any animals, the establishment of safety evaluation methods, and the utilisation of animal experiment results carried out for purposes other than cosmetics, but the policy for safety evaluation of final products in Japan remains unchanged.

**Recommendation:**

- In light of recent significant changes in the concept of safety assessment of final products, Japan should establish risk assessment methods for final products using available scientific evidence in order to prevent unnecessary animal experiments, while promoting the development of alternative methods that do not use animals at all.

# Consumer Goods

Liquor  
Food & agriculture

**Mr. Bruno Yvon**

Chair, Liquor Committee  
(President, MHD Moët Hennessy Diageo K.K.)  
c/o MHD Moët Hennessy Diageo K.K.  
13F Jimbocho Mitsui Bldg.  
1-105 Kandajimbocho, Chiyoda-ku, Tokyo101-0051  
Phone 03-5217-9723  
Fax 03-5217-9751

# 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 3.5 trillion yen and growing consumption in several categories. Despite such figures, in terms of value, foreign liquor imports in 2019, at 305.4 billion yen (according to Japan Customs), accounted for a mere 9% of the total Japanese liquor market, including beer and beer-like products.

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, prioritizing business profit over consumer safety, to import products with lot codes that have been erased, tampered with or covered up. The EBC encourages the Japanese Government to take more proactive measures to protect the safety of Japanese consumers since 2010. The EBC appreciates the notice issued by the National Tax Agency (NTA) in September 2014 and the new liquor sales management training textbook/DVD, which was produced by the NTA in April 2017 and includes these concerns. Furthermore, the EBC recognizes the notice issued by the Ministry of Economy, Trade and Industry (METI), MHLW, and the Ministry of Agriculture, Forestry and Fisheries (MAFF) in July 2017, stating their concern regarding the presence of liquor products with erased lot codes in the market. The EBC continues to urge the Japanese Government to take further proactive measures to ensure the display of product lot codes for traceability. Japan Wines and Spirits Importers' Associations (JWSIA) submitted the request letter including legal expert's opinion paper regarding the quality assurance role of production lot codes as an integral element of a brand's trademark on 23<sup>rd</sup> June 2018 to NTA. The EBC supports JWSIA's action that the NTA will establish notice under article 86 of the Liquor Trade Association Act and introduce the legal regulations to eradicate the distribution of imported liquor without production lot codes.

The definition of wine and whisky is much looser than that in Europe. The definition of "Japanese wine" was amended and made stricter in 2015, however the "wine" is still loose. Japan should implement a stricter definition of "Japanese whisky" and "wine" for production process.

The EBC welcomes the smooth implementation of the EU-Japan EPA Significant additives to wine were approved by both Japan and the EU (25 items by Japan and 28 items by the EU) in the EPA negotiations, making it possible for Japan to import wines that use EU-approved additives. The first eleven items were approved by MHLW and NTA and the second eight items are still under the approval process. The approval process for the final nine items have not yet started. The MHLW and NTA should swiftly approve additives that are in common use among other industrialised countries.

The tariff on still wine and sparkling wine was completely removed entry into force of the EU-Japan EPA. The Japan-US Trade Agreement took into force on 1<sup>st</sup> January 2020 and tariff of still wine, 15% or 125 yen/litre whichever is lower, and sparkling wine, 182 yen/litre, will be gradually removed. The EBC urges Japan to completely remove all tariffs on all wines as anticipated.

Another aspect of the EPA that the EBC would like to put in a positive light is the agreed mutual protection of geographical indications (GIs) will ensure the protection of 139 liquor GIs from the EU.

A new liquor tax policy was formulated to reduce the tax on beer and to increase the taxes on *happoshu* and "new genre" beverages in three phases (in 2020, 2023, and 2026), ultimately making the tax rate for all these beverages a uniform 157 yen/litre. The tax on wine will be raised in two phases (in 2020 and 2023), ultimately making it equal to the reduced tax rate for sake. Although taxes on spirits will not be subject to the upcoming tax hikes, they are quite high at 370 yen/litre for products with less than 37% ABV (Alcohol By Volume) plus an additional 10 yen/litre for each additional percentage of ABV. The EBC objects to the increase in the tax on wine and urges Japan to reduce taxes on spirits.

## Key Issues and Recommendations

### ■ Decoded products

*Yearly status report: slow progress.* Original production lot codes fulfil an important role in any effective and efficient product recall or withdrawal process. However, the official notices 2014/2017 and liquor sales management training from 2017 have no binding force to prohibit the import and sales of any such products with lot codes that have been erased, tampered with or covered up. In June 2018, JWSIA submitted the request letter including legal expert's opinion paper regarding the quality assurance role of production lot codes as an integral element of a brand's trademark to NTA. The EBC supports JWSIA's action.

**Recommendation:**

- The Government of Japan should issue legislation with penalties, that forbids the wholesale or retail of liquor whose lot codes have been erased, tampered with or covered up.

### ■ Wine and whisky definition

*Yearly status report: no progress.* A 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 international accepted definition. Japanese whisky does not have any definition.

**Recommendations:**

- Japan should implement the wine definition in conformity with international specifications as used in the EU and the US and endorsed by the International Federation of Wines and Spirits.
- Japan should implement a stricter definition of “Japanese whisky” such as manufacturing method, distillation method, storage years, bottling location etc.

### ■ Additives

*Yearly status report: progress.* Wine additives were approved in the EPA negotiations, making it possible for Japan to import wines that use EU-approved additives. The first eleven items were approved by the MHLW and the second eight items are still under the approval process. The final nine items have not yet been processed.

**Recommendation:**

- MHLW should swiftly approve additives that are in common use among other industrialized countries.

### ■ Tariff on wine

*Yearly status report: good progress.* Tariffs on wine was abolished at the entry into force of the EU-Japan EPA. Japan-US Trade Agreement took into force on 1<sup>st</sup> January 2020 and tariff of wine will gradually remove.

**Recommendation:**

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

### ■ Geographical indications

*Yearly status report: good progress.* The mutual protection of GIs agreed upon through the EU-Japan EPA will ensure protection of geographical indications for 139 liquor products from the EU.

**Recommendation:**

- The EBC urges and looks forward to the smooth implementation of the EU-Japan EPA.

### ■ Liquor taxes

*Yearly status report: no progress.* Japan will reduce the tax on beer and increase the taxes on *happoshu* and “new genre” beverages in three phases (2020, 2023, and 2026), ultimately to 157 yen/litre. However, taxes on wine will be raised in two phases (2020 and 2023), making it equal to the reduced tax rate for sake, at 100 yen/litre. Taxes on spirits, not subject to the upcoming tax hikes, are high at 370 yen/litre if less than 37% ABV plus an additional 10 yen/litre for each additional percentage of ABV.

**Recommendations:**

- Japan should promptly revise its liquor tax system for beer in accordance with the 2017 tax reform.
- The EBC objects to the increase in the tax on wine and urges Japan to reduce taxes on spirits.

## Vacant

c/o Bjorn Kongstad, Chief Policy Director  
European Business Council in Japan  
Sanbancho POULA Bldg. 2F  
6-7 Sanbancho, Chiyoda-ku  
Tokyo 102-0075  
Phone 03-3263-6222  
Fax 03-3263-6223

# FOOD & AGRICULTURE

## Introduction

Despite their global presence, European food and agricultural products have traditionally had difficulties penetrating the Japanese market. Although they could be found in regular supermarkets, the selection available was, with a few exceptions, limited to only a fraction of the potential. The situation was better in upscale and gourmet specialist shops, where price matters less.

With the implementation and entry into force of the EU-Japan EPA, the situation has very much changed. Already on the first day of the agreement, 1 February 2019, supermarkets could be seen marketing EU wine using the EPA as a marketing tool. Newly released trade statistics show a dramatic increase in imports of European food into Japan. This is however not to say that it has been without its problems. Many importers experienced difficulties with the application of the rules of origin, and in particular regarding how to certify origin. Much additional information was requested by the Japanese authorities, despite the use of the statement on origin issued by the exporter. It is therefore with great relief that EBC can report that the situation today is very different. Both the Japanese authorities and the European Commission have worked hard to improve the situation. The EBC hopes that with these changes the rate of usage will further increase and that agricultural trade between the two regions will continue to expand, and also that this can be an example of excellence when looking at other areas to improve.

For the potential to be fully reached though, Japan needs to improve the situation regarding the administration of Tariff Rates Quotas (TRQs). As we have now entered the third annual allocation period there are still outstanding issues. Some importers have been asked to show sales contract corresponding to the TRQ volume applied for. The EBC believes this is very burdensome and difficult, and asks of the Ministry of Agriculture, Forestry and Fishery (MAFF) to come up with a simpler solution. Moreover, the EBC believes that this is the reason for some of the categories not being used or underused. On the same topic, but on the other side of the spectrum are TRQs that are completely used. For some of these TRQs we are seeing companies or individuals that are not active in the corresponding sectors.

Apart from tariffs, various non-tariff food-related issues also impact the availability of European products in Japan. For example, Japan remains “out of sync” with other countries, in that it has still not approved a majority of food additives and enzymes declared safe by the Food and Agriculture Organisation (FAO) and the World Health Organisation (WHO). Sanitary and phytosanitary issues are of course included in the EPA. It should, however, be stated that the agreement currently only includes very general wording on what benefits suppliers and importers can foresee. It is therefore important that the two authorities continue to work in this field to improve the current situation, where duplicate testing has to be done for imported goods due to lack of harmonisation or mutual recognition of approvals of test methods.

An example of an area that could benefit from harmonisation is food contact materials. Japan is currently in the process of introducing a positive list system similar to what is in use in the EU and the US. This is something that the EBC supports. It is however important that Japan is harmonising with the approved materials in EU and the US. It is furthermore, vital that Japan includes provisions for the use of materials that are not included in the positive list. Both the EU and the US have provisions for this.

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. We very much hope that the EU-Japan EPA will ensure that tariffs are 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 Issues and Recommendations

### ■ Tariffs & quotas

*Yearly status report: good progress.* With the implementation of the EU-Japan EPA, and the removal or reduction of tariffs, EU products now have an improved market access. The EBC has big hopes that this will also translate to more European food products in the shopping bags of Japanese consumers. It is however important that these liberalisations are implemented without the use of stringent safeguard measures and that also TRQ administration is improved.

#### **Recommendations:**

- It is of utmost importance that the quota management system is transparent and easy to use.
- There should be no requirements that TRQ volumes applied for should already be covered by sales contracts.
- The lottery system that “covers” some of the TRQ is very difficult to use, due to low predictability. Japan should change the system for those quotas that are completely utilised to a system of allocation using historical data with a portion dedicated to newcomers.

### ■ Food additives, enzymes and processing aids

*Yearly status report: progress.* Differences in the lists of additives and enzymes approved by Japan and other major markets are still common. While the EBC has seen progress in Japan’s approval of additives, the approval process still remains an obstacle, and an overall lack of transparency. EU and Japan should use the EPA to further strengthen the work in this field. Despite announcements that the EPA would result in faster approval times, this has not been realised.

#### **Recommendations:**

- Japan should harmonise its definition of food additives to exclude processing aids which as per its definition do not remain in the product after it has been produced. The same should apply for nutrition fortifiers. Japan should ensure that standards of use in Japan are not in conflict with international standards of use.
- Japan should also harmonise the specifications of food additives, such as purity, definition of specific food additives and size of molecules.
- The Ministry of Health, Labour and Welfare (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.
- Japan should explicitly communicate why commonly used additives are not approved for use in Japan.
- Japan should make certain that approval times are decreased as discussed in the EPA. Currently, the consultation period can be very long.

### ■ Malt and quota management system

*Yearly status report: no progress.* Japan has had a tariff quota system for malt even before the EPA. To make use of the quota, a company must manufacture beer or import malt exclusively for the use of a particular brewery. With the EPA, an additional quota for EU origin malt has been established, to be administered in a non-discriminatory manner. However, in practice, application to the quota is limited to actual “consumers” of malt, i.e. manufacturing companies who can present a stable whole-year production plan and for whom the administrative overhead is worthwhile. Trading companies wishing to import on their own account, to cater to non-brewery demand, or smaller manufacturers with short-term or specialized small-quantity needs, are barred from utilising the new quota. As a result, the EPA malt quota has been completely unused in 2019.

#### **Recommendations:**

- Japan should abolish the tariff on EU malt so that there is no need for European suppliers to use the quota. This would be beneficial not only to European supplier but also to especially Japanese producers with smaller capacities or on spot demand.
- Japan should allow non-discriminatory access to trading companies to the malt quota, so they can cater to users who are size-wise unable or unwilling to apply for their own quota.

## ■ Food contact

*Yearly status report: new issue.* Materials that come in contact with food, such as wrapping, packaging, plates, cups etc have to fulfil the rules set out by the Food Sanitation Act. Japan is currently in the process of introducing a list of materials that would allowed to be used for the above-mentioned purpose. Several other markets are also using positive lists. MHLW has for this purpose asked for public comments and for industry to submit substances that they want to include on the list. This has also been done through the WTO notification procedure. However if there is no harmonisation as well as a procedure of exemptions as is the case in the EU and the US, European suppliers and Japanese buyers run the risk of not being able to import the products to Japan.

### **Recommendations:**

- Japan should allow resins allowed in the EU and the US.
- Japan should also introduce a system where materials can still be used without being on the positive list, similar to the EU and the US.
- Japan should make use of ISO standards as tests methods, as to avoid specific testing for the Japan market.
- Japan make use of a grace period of at least five years, just as the EU did.

## ■ Separate registration by each importer

*Yearly status report: new issue.* Some European suppliers are using either non-exclusive importers/distributors or using different distributors for different market segments. Currently, each importer has to register the products despite the products already being approved and registered by another importer. This creates additional administrative work. The EBC would like for there to be a system where the brand owner can appoint several importers that can share a registration

### **Recommendation:**

- Japan should create a system where a product registration can be shared by multiple appointed importers.

## ■ Testing and approvals

*Yearly status report: no progress.* Many European products undergo frequent and expensive testing to be approved for either importing or for selling on the Japanese market. Examples of these are: cyanide testing, radioactivity testing, microbiological testing, such as coliforms and heavy metals, etc. The EBC believes that in many cases it should be possible to use approvals and testing carried out in Europe. This is currently not possible in many cases due to non-harmonised test methods and standards.

### **Recommendations:**

- Japan and the EU should use the EPA to streamline test procedures by looking into what tests are necessary to eliminate double testing. The goal should be that products approved for consumption in one market should be allowed for consumption in the other market.
- Japan should furthermore make use of ISO standards as tests methods, as to avoid specific testing for the Japanese market.

## ■ Best before labelling

*Yearly status report: new issue.* Best before dates in Japan have to be written in a special order. Unfortunately the order for Japan is not commonly used outside of Japan. While ingredients lists do not change if the production methods says the same, best before dates constantly change and it can therefore be difficult for the producer to affix for the Japanese market, leaving the importer to do this.

### **Recommendation:**

- Japan should allow alternative best before dates if this is properly explained on the label of the products, such as DDMMYYYY



# Industry

**Automobiles**  
**Automotive components & aftermarket**  
**Aeronautics**  
**Space**  
**Defence & security**  
**Materials**  
**Energy**

**Mr. Kintaro Ueno**

Chair, Automobile Committee

(President and CEO, Mercedes-Benz Japan Co., Ltd.)

c/o Mercedes-Benz Japan, Co., Ltd.

Shinagawa Seaside Park Tower

4-12-4, Higashi Shinagawa, Shinagawa-ku, Tokyo 140-0002

Phone 03-6369-7200

Fax 03-6369-7126

# AUTOMOBILES

## Introduction

The sales of Japanese and foreign brands four-wheel vehicles in Japan totalled 5,195,134 units in 2019 (down by 1.5% from previous year). The sales of foreign brand four-wheel vehicles mainly from Europe totalled 299,439 units in 2019 (down by 3.2% from the previous year), fifth highest on record. Moreover, the sales of imported vehicles including Japanese and foreign brand vehicles totalled a high of 348,316 units in 2019. In 2020, the impact of the pandemic caused by COVID-19 is a serious growing concern. It impacts not only production lines, supply chains but also the market and as a result sales of four-wheel vehicles in Japan are at risk. EBC member companies will, however, continue introducing new models equipped with cutting-edge safety and advanced environmental technologies for customers in Japan. In light of these challenges, clear governmental support measures for the automotive industry and distribution network in Japan in particular are crucial both during the crisis but also for post-crisis recovery of the industry.

On February 1, 2019, the EU-Japan EPA came into effect. The EBC Automobile Committee highly appreciates the efforts and contributions of all parties concerned. The EU-Japan EPA is, an important achievement, signalling to the world that both the EU and Japan remain open for international business in a time when protectionism is rising and multilateral trade is under a growing threat. Today, and in the future, it is important for the contents of the EU-Japan EPA to be correctly implemented, and the EBC Automobile Committee will continue to carefully review the implementation process with the parties concerned. There are however still some outstanding issues related to Non-Tariff Measures (NTMs) discussed during the negotiations, where Japan retains unique regulations. These issues directly translate to increased costs, both for passenger and commercial vehicles for importers. In pursuit of international harmonisation, the EBC Automobile Committee will continue to seek “the complete elimination of the NTMs and realisation of the complete IWVTA (International Whole Vehicle Type Approval)”.

Aiming for the introduction of Level 3 automated driving on expressways and Level 4 automated driving limited to specific areas, the Japanese Government plans to develop new regulations before the summer of 2020 based on the Road Traffic Act and Road Transport Vehicle Act which were revised in May 2019. The EBC Automobile Committee requests that Japan's new regulations on automated driving will be harmonised with international regulations in line with the deliberations being made in "the World Forum for Harmonization of Vehicle Regulations (WP29)".

Over the past years, traffic accidents caused by elderly drivers have become a serious social concern in Japan. As one measure for preventing such accidents, Japan has decided to introduce a system of driving licenses limited to vehicles equipped with safe driving support systems, and aims to enforce such a system in 2022. The EBC fully understands the importance of safety measures for all people including elderly drivers. The Committee, however, requests that the above-mentioned license system should be internationally harmonised and one that embrace wide-ranging advanced safety technologies equipped in European vehicles and should be based on the analysis of actual accidents.

Technical harmonization alone is not sufficient to open up markets. In Japan, under the FY 2019 tax revision, a certain reduction of automobile tax for newly registered vehicles was initiated for the first time since the establishment of the automobile tax. However, registered vehicles still have to pay twice the amount in automobile taxes compared to *kei*-cars. As mentioned in past EBC annual reports, Japan's unique standards relating to *kei*-cars have reduced opportunities for small foreign vehicles to enter the Japanese markets. The EBC requests that the Japanese government should further reduce tax burden on registered cars to eliminate the gap between registered vehicles and *kei*-cars.

As global warming countermeasures becomes more important, the automobile industry needs to take on the big challenge of reducing greenhouse gas emissions. Japan formulated the ambitious FY 2030 Fuel Efficiency (FE) standards for passenger cars last year, which will oblige improving FE by 44.3% compared with the FY 2020 standards. The EBC Automobile Committee will work to fulfil its responsibility by accelerating the introduction of automobiles with high energy efficiency including electrically driven vehicles. At the same time, the Committee requests the Japanese Government to introduce credit systems and flexibility mechanisms similar to Europe. The EBC also urges Japan to accelerate establishing internationally harmonised relevant regulations as well as to develop the required charging infrastructure in order to achieve the above ambitious FE standards.

The EBC Automobile Committee continues to support the goal of realising a truly open and fair market.

## Key Issues and Recommendations

### ■ Introduction of International Whole Vehicle Type Approval (IWVTA)

*Yearly status report: some progress.* The introduction of the IWVTA system in July 2018 became an important first-step. However, the harmonisation of the regulations on some main devices such as exhaust gas devices have not yet been achieved. Since Japan's unique domestic regulations still remain, the UN-R0 for mutual approval of certifications between Japan and the EU has not yet been utilised.

**Recommendations:**

- Japan should abolish its remaining unique regulations including the standards for exhaust gases.
- Japan should realise a complete mutual certification system by expanding the scope of the IWVTA system to cover all the requirements of the Japanese certification system in close cooperation with the European Commission.

### ■ Fuel Efficiency standards and electrification

*Yearly status report: a certain progress has been made.* The Japanese government announced the FY 2030 Fuel Efficiency (FE) standards for passenger cars in June 2019.

**Recommendations:**

- Japan should introduce credit systems and flexibility mechanisms in the interim review.
- Japan should develop charging infrastructure and establish regulations for high-voltage charging in order to accelerate the dissemination of electrically driven vehicles.
- Regarding the current FY 2020 FE standards for passenger cars, Japan should abolish the “90 percent rule” that inhibits the dissemination of electrically driven vehicles, and introduce the coefficient for converting the WLTP fuel consumption value to the JC08 fuel consumption value that is the basis for the FY 2020 FE standards.

### ■ International harmonisation of safety, automated driving and other regulations

*Yearly status report: some progress.* In December 2019, Japan decided to make it mandatory for car manufacturers to install the Advanced Emergency Braking System (AEBS) in all domestic vehicle models. Also, Japan plans to implement ministerial ordinances, etc. concerning automated driving by summer of 2020.

**Recommendations:**

- Japan should promote international harmonisation concerning the timing of applying the United Nations regulations, transportation infrastructure, road signs as well as the necessary wireless communication technologies.
- Japan should harmonise its requirements for automated driving systems, validation method of automated driving, data storage systems, cyber security/OTA and automatic steering function with UN regulations to be agreed in the World Forum for Harmonization of Vehicle Regulations (WP29).
- The Japanese Government should share information about the progress of the regulatory development in a timely manner in order to provide the opportunities for obtaining feedback from overseas to promote the international harmonization of policies and regulations. The EBC requests this to ensure that importers are not discriminated compared to Japanese OEMs (Original Equipment Manufacturers).

### ■ Tax system reforms including Kei-cars

*Yearly status report: some progress.* In FY 2019, a reduction of automobile tax was realised in all displacement categories for the first time since the establishment of automobile taxes for registered vehicles. However, Japan still imposes excessively heavy taxes on the purchase and ownership of automobiles compared with other countries, and the gap that distorts the competition between registered vehicles and kei-cars still exists.

**Recommendations:**

- Japan should simplify the structure of automobile taxation and further reduce the tax burden for users.
- The Japanese Government should further reduce automobile taxes and automobile tonnage taxes in order to secure fair taxation system between registered vehicles and kei-cars.
- Japan should show the future direction of changes in tax systems and incentives on a medium- and long-term basis so that European vehicle importers can prepare for future changes.

**Mr. Joaquin Martori**

Chair, Automotive Components & Aftermarket Committee

(Managing Director, Mahle Trading Japan Co. Ltd.)

c/o Mahle Trading Japan Co. Ltd.

3-2-6 Mita

Minato-ku, Tokyo 108-0073

Phone 03-6809-4382

Fax 03-3453-7887

# AUTOMOTIVE COMPONENTS & AFTERMARKET

## Introduction

2020 has unfortunately not started positive for automotive components manufacturers. The Coronavirus has had a disrupting effect on the supply chain. This is true for input materials that do not reach the components manufacturers in time as well as challenges to getting the finished components to the buyers in time. The impact is unfortunately also magnified by restrictions on travels. It is against this backdrop that the EBC Automotive Components & Aftermarket Committee is offering its recommendations to improve the market situation in Japan.

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, fostering an environment of 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 therefore dedicating resources to attracting business in Japan, investing in local infrastructure, and building knowledge of local technical requirements, 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.

One area where regulatory change would ultimately benefit Japanese and foreign firms is the auto components independent aftermarket (IAM). The EBC supports the position paper issued by the European Association of Automotive Suppliers (CLEPA) earlier this year, calling for a level playing field in Japan's IAM. At present, business is seriously constrained by restrictive practices; for example, when carmakers in Japan enter into supply contracts, they routinely prohibit the suppliers from selling the parts independently, a practice at odds with the situation in Europe and the US. In fact, EU law prohibits carmakers from imposing such restrictions in their parts-supply contracts. The EBC urges Japan to introduce a similar legal framework, allowing healthy competition and fair opportunities for all, so that end customers have a wider choice. The introduction of the motor block exemption legislation in the EU has proved very successful in creating a vibrant aftermarket for automotive parts.

The EBC recognises that the Japanese authorities have been making efforts toward regulatory harmonisation related to tyres. In addition to the implementation of UN/ECE (United Nations Economic Committee for Europe) regulation R117-02 (rolling sound emission, wet traction, and rolling resistance) by the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) in October 2015, 3PMSF (3 Peak Mountain Snow Flake) marked tyres have recently been recognised as Winter tyres by Japan Automotive Tire Manufacturer Association (JATMA)–Tire Industry and Standard Organisation in Japan. 3PMSF marked tyres have been approved in Europe through a regulation test to guarantee the right level of performance under winter condition. This decision also removes the necessity of additional winter testing for imported tires and is a very fair decision for import tire distributors.

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 implementation of the above-mentioned UN/ECE regulation R117-02 remains undecided. There are, furthermore, barriers in the replacement market because of the peculiarities of the Japanese distribution environment, which is fragmented and only partially integrated, making it difficult for foreign companies to access. Distributors in many other countries in Europe, and even in Korea, have opened up their brand policies from mono-brand to multiple-brands in retail in order to offer more choices to consumers.

Accessing consumers via garages, repair shops, and tyre shops is a critical factor for success in the Japanese replacement market. A recent survey 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 action aimed at limiting exclusive distribution arrangements and facilitating access for all firms, domestic and foreign, to the fragmented distribution market.

## Key Issues and Recommendations

### ■ Aftermarket

*Yearly status report: no progress.* Currently automotive components companies supplying Japanese vehicle manufacturers are restricted in respect of where they can sell their products on the Japanese aftermarket. As a result, in many cases Japanese consumers can only purchase original high-quality spare parts from dealerships tied to a specific car manufacturer. Strangely, no such restrictions apply to companies that make copies or non-original parts, which leads to the independent aftermarket being characterised by potentially lower quality and less safe products.

#### **Recommendations:**

- Japan should set up a legal framework that allows automotive components manufacturers to sell on the aftermarket similar to the EU's Motor Vehicle Block Exemption legislation. This would increase the options for Japanese consumers wishing to source original high-quality vehicle parts.
- Components suppliers should be permitted to apply their own trademarks or logos and their own part numbers to goods supplied to vehicle manufacturers.

### ■ Tyres

*Yearly status report: progress.* The EBC appreciated the recent actions taken regarding UN/ECE regulation R117-02 by the MLIT and also the 3PMSF marking for winter tyres by JATMA in Japan. However, the EBC notes that foreign manufacturers still face 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.

### ■ Globalisation of the automobile industry and promoting information exchange

*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. It is of crucial importance, both for Japanese and foreign firms, that Japan harmonises its regulatory framework to better accommodate the globalisation of the automotive components sector.

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.

#### **Recommendations:**

- Encourage the Japanese automobile industry, when procuring components and systems, to focus on the technical, commercial and logistics aspects of automobile production and to avoid excessive reliance on affiliated companies. Increased purchasing on a global basis and more emphasis on single platform development would improve the cost-effectiveness of the Japanese industry.
- Recognise foreign test results from accredited European agencies to avoid the necessity of re-testing for the Japanese market.
- Continue face-to-face meetings between leading representatives of European suppliers and the Japanese automobile industry, as these have led to increased understanding. The EBC also recommends that the scope of these meetings is expanded in future to include opportunities to meet at Japanese venues.



**Mr. Stephane Ginoux**

Chair, Aeronautics, Space, Defence & Security Committee

(President, Airbus Japan)

c/o Airbus Japan KK

Roppongi Hills Mori Tower, 19F

6-10-1 Roppongi, Minato-ku, Tokyo 106-6119

Phone 03-5775-3300

Fax 03-5775-0123

# AERONAUTICS

## Introduction

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 All Nippon Airways 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 was thought as increasingly open to consider cooperation with European manufacturers but still needs to be validated in real business opportunities. In addition, the Aeronautics, Space, Defence & Security Committee is looking positively at the new development of cooperation in the UAV / Urban Mobility domain initiated by the Ministry of Economy, Trade and Industry. The EBC is actively supporting these developments.

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, cooperation 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 Europe-Japan co-development.

The 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 7 December 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 European Commission to do so on behalf of the entire European Union. The European Commission is 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 encourages 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 deplores this situation, which may be keeping Japan from benefiting from the latest advances in safety standards.

**Recommendations:**

- The EBC encourages Japanese firms to diversify their sources of supply and consider the advantages of European products in the aeronautics field for the benefit of their customers, the general public, and shareholders.
- The EBC urges the Japanese authorities to facilitate greater use of equipment from European 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 harmonize product standards worldwide. Despite exchanges between Japan and Europe, slow progress has been made on this topic.

**Recommendations:**

- The EBC encourages the EU and Japan to conclude ratification of the agreement with the goal of implementing a Bilateral Air Safety Agreement as soon as possible in order to develop business opportunities between the EU and Japan by removing administrative hurdles.
- The EU and Japan should after the entry into force of the BASA quickly prepare to add additional activities, such as, maintenance, spare parts and training activities to BASA. These segments are currently not included in the agreement and industry believes that inclusion of these segment would be beneficial to both the European and Japanese aeronautical industries.

**Mr. Stephane Ginoux**

Chair, Aeronautics, Space, Defence & Security Committee

(President, Airbus Japan KK)

c/o Airbus Japan KK

Roppongi Hills Mori Tower, 19F.

6-10-1 Roppongi, Minato-ku, Tokyo 106-6119

Phone 03-5775-3300

Fax 03-5775-0123

# SPACE

## Introduction

The Committee on National Space Policy and the National Space Policy Secretariat (NSPS) established in the Cabinet office set Japan's space policies across all ministries and agencies. Space is treated as an important industrial and commercial sector and a national security asset. 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. Government policy now emphasises practical downstream applications of existing infrastructure while encouraging private startup-type initiatives in the areas of small satellites and launchers.

The government formed a "space operations unit" within the Air Self-Defense Forces (ASDF) of the Ministry of Defence. Some 20 members of the ASDF will monitor suspicious movements and electromagnetic interference against Japanese satellites. A planned optical telescope will monitor space debris and unidentified orbiting objects for space situational awareness purposes.

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. The Cabinet Office leads a joint government-industry task force on the export of space-related products.

The private satellite market 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)/ Meteorological satellite series and the broadcasting satellite (B-SAT) 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; two satellites have already been launched. The next major theme of interest for Japan's space authorities will be debris and space situational awareness. Japan's willingness to cooperate in satellite development programmes, however, still rarely extends to European companies.

Regarding launchers, more cooperation may be coming. Arianespace and Mitsubishi Heavy Industries have experience in operations cooperation, including a heavy launcher backup agreement. Japan is developing the H3 launch vehicle and Europe is developing Ariane 6, both due for a first launch in 2020 (Ariane 6) or in Japanese fiscal year 2020 (H3), and both in need of future upgrades. France's CNES (National Centre for Space Studies), DLR (The German Aerospace Center) and JAXA are working on Callisto, a reduced-scale reusability demonstrator. A full cooperation on future improved versions of both launchers would enhance their competitiveness and international contribution.

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.

While respecting Japan's space policies, the EBC believes that fewer all-Japanese consortia, less tied ODA and more work with Europe would bring gains in terms of budgets, national security, technology, and commercial success.



## Key Issues and Recommendations

### ■ General environment

*Yearly status report: protectionist risk.* The approval system for satellite projects and the handling of future PPP projects hold risks of protectionism. The EBC advocates increasing, not reducing, 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 continued Japanese cooperation with European space agencies. Space agencies on both sides can compare their projects at an early stage and take 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 is mostly interested in high technology components (solid state recorders, star trackers etc) for supporting its domestic programmes. The space agencies of both the EU and Japan cooperate and share data in science and research but have almost no industrially meaningful cooperation. However, the quantity of inquiries and topics under investigation are significantly increasing.

#### **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 among others. 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: some progress.* Europe and Japan are developing their respective next generation heavy-lift launchers almost simultaneously. Their space agencies are cooperating on some items of future enhancements. A plan for a balanced mutual backup agreement to reduce delays in launching government satellites was evaluated positively by Japan’s space authorities in the past, but no agreement is in sight due to lack of political leadership.

#### **Recommendations:**

- Europe and Japan should step up cooperation on the future evolutions of their respective new generation launchers. Ariane Group and the new structure of Europe’s heavy launcher industry make it easier to realise industry-led cooperation on development.
- 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.

### ■ Space debris and situational awareness

*Yearly status report: some progress.* Near-Earth space is a key resource for society, as crucial as Earth-bound resources. Space debris threaten vital current space systems and the availability of the resource for future projects. New micro-satellite constellations and other projects make a strong “space situational awareness” indispensable.

#### **Recommendation:**

- Japan and Europe should continue increasing the scope of their cooperation in space situational awareness.

**Mr. Stephane Ginoux**

Chair, Aeronautics, Space, Defence & Security Committee  
(President, Airbus Japan KK)  
c/o Airbus Japan KK  
Roppongi Hills Mori Tower, 19F  
6-10-1 Roppongi, Minato-ku, Tokyo 106-6119  
Phone 03-5775-3300  
Fax 03-5775-0123

# DEFENCE & SECURITY

## Introduction

In recent years, the security challenges and issues, which Japan has been facing, are becoming extremely complex and diverse. There have been an increasing number of cases of unilateral actions in an attempt to change the status quo by enforcement without respecting the existing international law.

The emergence of state expansionism and increased uncertainty in certain parts of the world including the east Asian region combined with the shift in US foreign policy to focus more on the US mainland have changed the security environment for Japan. Furthermore, the terrorist threat and asymmetric warfare are growing in gravity, while the importance of the new security domains such as Cyber and Space are rapidly emerging in addition to the traditional domains of Land, Sea and Air. Thus, national security can no longer be addressed and understood only from a traditional geopolitical perspective and are difficult to be solved by individual countries.

Under the circumstances, while keeping Japan-US alliance as the fundamental and the crucial part of Japanese national security strategy, Japan is facing an increasing need for international cooperation and is trying to position itself within a broader global security relationship with its focus on enhancing the bilateral defence cooperation. Specifically, Japan has recently enhanced bilateral defence relationships from traditional exchanges to deeper cooperation in a phased manner by appropriately combining various means including joint exercises and capacity building assistance, defence equipment and technology cooperation.

Especially in terms of the defence equipment and technology collaboration, Europe has been playing a very important role as Japan's one of the closest and oldest allies that shares universal values and playing a central role in working to address common challenges to global security.

In this regard, the progress has been very remarkable. The Japanese Government is committed in developing its defense relations with European countries and has concluded a number of different bilateral agreements on defence equipment collaboration such as with the United Kingdom in 2013, France in 2015, Germany and Italy in 2017. Further discussions towards bilateral agreements with other European countries such as the Netherlands, Spain and Sweden are now underway. Moreover, European companies are being approached by Japanese companies looking to collaborating in third-country markets third-country prospects, such as in the ASEAN countries. However, despite the existence of these bilateral agreements, it has to be noted that only few cooperation projects have been identified and are currently in progress.

The EBC welcomes this trend of enhancing the bilateral defence cooperation and expects the Government of Japan to more actively promote the defence equipment and technology aspect of the collaboration, which would open up a window for European companies to participate in the international co-development programs.

## Key Issues and Recommendations

### ■ Procurement

*Yearly status report: no progress.* The EBC appreciates the fact that introduction of European products in the land and sea domains has been increasing. To the contrary, the visibility of European products in the air domains remains extremely limited. As this trend may be derived from Japanese traditional preference of having US defence equipment, the EBC believes that the transparency of the procurement in those domains shall be improved, and more fair opportunity shall be given to European companies.

**Recommendation:**

- The Government of Japan should regard the use of European defence equipment as a part of fostering the security collaboration with European nations, and should strategically promote it. It would significantly benefit the operation of the Self-Defence Forces in terms of Life Cycle Cost reduction and would benefit both European and Japanese industries throughout the increased international collaboration opportunities.

### ■ Industrial collaboration

*Yearly status report: no progress.* The EBC notices that the increase in the Japanese defense budget during the last few years is mostly benefiting the US industry, which absorbs almost all the increase. At the same time, only a few Japanese companies are trying to be active on the global market. To make matters worse, strict export control, especially in terms of third country transfer, is discouraging companies and leading to missed out collaboration opportunity with European companies.

**Recommendations:**

- In order to foster cooperation between Japanese and European industries in the defense domain, especially with the view of addressing third country markets, the Government of Japan should present a more precise framework in terms of practical expectation (main technologies, operating field, priorities) and actively motivate Japanese companies to enter into a cooperative mode with their European counterparts.
- The EBC recommends a closer dialog between the European Defense Agency (EDA) and its counterparts in Japan, ATLA (Acquisition, Technology & Logistics Agency) and METI (Ministry of Economy, Trade and Industry), to promote industrial partnerships between Japanese and European companies.
- The Government of Japan should also clarify its political policies regarding transfer to third-party countries and should either operate the three principles of defence equipment transfer in a more flexible way or revise them, to avoid their becoming an obstacle to cooperation between Japanese and European industries.

**Mr. Carl-Gustav Eklund**

Chair, Materials Committee

(Representative Director, President, Hoganas Japan K.K.)

c/o Hoganas Japan K.K.

Akasaka Shasta East 6F, 4-2-19 Akasaka

Minato-ku, Tokyo 107-0052

Phone 03-3582-8280

Fax 03-3584-9087

# 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 products related to environmental technology. These advanced technologies depend on 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.

The EU-Japan Economic Partnership Agreement has removed tariffs in the materials sector. This will give European suppliers a competitive edge in the Japanese market. Moreover, it will give a boost to Japanese industries able to source key materials at lower prices. However, not all imports will benefit from tariff removal, since many European companies have a global presence and not all their production is conducted within the EU.

Chemicals normally fall within the competency of the Ministry of Economy, Trade and Industry (METI), which is involved in the task of harmonising 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.

One example of the issues raised by the MHLW approach relates to a European cement containing aluminium oxide (CAS 1344-28-1). According to the MHLW list, any product containing more than 1% of aluminium oxide must have a label warning how it should be handled. The problem arises from the fact that this particular substance (CAS 1344-28-1) is not regarded or registered as hazardous in Europe. As a result, the same product ends up with a number of non-homogeneous labels, pictograms and safety data sheets that create unnecessary doubts and confusion about its safety.

Following the production of advanced materials, components and final products, the Japanese industry is generating a steadily growing amount of industrial by-products as well as later down the road end-of-life objects (some of these are considered as hazardous waste under the Basel system and/or as "waste" according to the Japanese system). These by-products and end-of-life objects often contain an important amount of non-ferrous metals (precious metals, technology metals) of which some are considered critical for the industry. Recovering these key metals is therefore key to the Japanese industry while being instrumental in implementing a circular economy approach in Japan.

It is, however, impossible to fully close the loop if waste shipment and treatment in world-class facilities are made difficult by authorities. Indeed the recovery of these metals cannot always be carried out in Japan for valid reasons being for instance that the technology is not available in Japan, the recycling capacity is not sufficient in Japan or the economics of recycling in Japan are less advantageous than recycling in Europe for the benefit of Japanese customers.

Exporting of these by-products and end-of-life products out of Japan to Europe to be treated in world-class facilities remains a difficult endeavour in many cases and ambiguity in what Japan considers waste is not a facilitating factor. These difficulties in exporting out of Japan represent missed opportunities for European companies willing to offer their best technologies to Japanese customers. This situation also leads to Japanese customers stockpiling their by-products which could be at the expense of safety and environment in local communities. Last but not least, stockpiling represents lost value for Japanese customers who would prefer recovering the value of the metal content by having these by-products treated in Europe if relevant for them.

## Key Issues and Recommendations

### ■ Tariff issues

*Yearly status report: good progress.* With the entry into force of the EU-Japan EPA, tariffs have removed on metals with EU origin. This is something that benefit not only European suppliers but also the Japan industry that is depended on these products and being under pressure from low cost countries. However, due to the global nature of the material sector some metals will not be able to benefit from the EU-Japan EPA. For this to be achieved Japan will have to remove tariffs on a worldwide basis. Moreover, industrial materials imported into 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.

**Recommendations:**

- Japan should remove import tariffs from all industrial raw materials, irrespective of the site of production.
- Japan should rationalise its tariff classification regime and develop a strategy to improve consistency between Customs offices in classification rulings and simplify dispute resolution mechanisms.

### ■ Chemical Substance Control Law

*Yearly status report: some progress.* With both the EU and Japan now having introduced their own 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.

**Recommendation:**

- Japan and the EU should harmonise their registration systems or mutually recognise test results and supporting documents, and also make certain that products are not classified differently in the two regions.

### ■ Workers' safety labelling for chemicals

*Yearly status report: no progress.* 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, eg. alumina. There is also a lack of information in English.

**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.
- EU and Japan should better harmonise this area to avoid the need for different labelling

### ■ Waste shipment out of Japan for treatment in European world-class facilities

*Yearly status report: new issue.* Regarding waste shipment from Japan to Europe, still too many details are being requested (some of these requests are not always relevant) for the notification process of Basel waste. The treatment by authorities of notifications is very slow (it typically takes up to one year). In most cases notifications are provided for one year which means that little time is left to ship once notification agreement is received from the Japanese authorities. Authorities are still classifying too 'easily' the shipments as waste whereas the material to be shipped is a product for the European company on the receiving end and responsible for a recovery step.

**Recommendations:**

- Review the amount and type of data needed by Japanese authorities during the notification process.
- Speed up at authorities the notification process to bring it to an acceptable level similar to the speed of other countries.
- Japan should allow the use of multiple shipping lines during the duration of the notification.
- Japanese Government should allow negative value material to leave Japan using transparent guidelines.
- Review Japanese system for waste classification to enable a closed loop system for scarce metals between Japan and Europe.
- A fast-track system between Japan and Europe should be implemented for pre-authorised facilities.



**Mr. Taku Nioka**

Chair, Energy Committee

(Representative Director, Rittal K.K.)

c/o Rittal K.K.)

Kaneko-Daiichi Bldg. 7F, 2-5-11, Shin-Yokohama,

Kohoku-ku, Yokohama, Kanagawa 222-0033

Phone 045-478-6885

# ENERGY

## Introduction

Japan's electrical utility industry used to be run by ten regional Electrical Power Companies (EPCOs). While liberalisation of the electricity markets was initiated in the 1990s, real change was only triggered through reforms introduced by the Ministry of Economy, Trade and Industry (METI) following the 2011 Great East Japan Earthquake, which revealed weaknesses in the existing system.

As the first step to address those weaknesses, 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 creation of non-fossil value trading in May 2018 and the implicit auctions starting from October the same year are certainly a progress. The ongoing discussion about how to establish capacity, ancillary-service, real-time markets are expected to result in fair and transparent processes enabling healthy competition.

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 Japan's nuclear plants were shut down and a programme of safety reviews and upgrades was initiated, which is still ongoing. Between 2015 and 2018, nine reactors restarted. However, the pace of these restarts slowed down (no restart in 2019) and some reactors have or will have to shut down again temporarily because of legal actions and/or delays in completion of newly introduced counterterrorism measures.

In July 2018, the Japanese Cabinet approved the 5<sup>th</sup> Strategic Energy Plan which is a policy document formulated by the Government under the Basic Act on Energy Policy from 2002. The plan presents the basic direction of Japan's energy policy, based on fundamental principles, namely, "safety," "energy security," "improvement of economic efficiency," and "environmental suitability", named 3E+S. The 5<sup>th</sup> Plan consists of:

- Renewable energy: Lay foundations to use as major power source with cost reduction, overcome system constraints and secure flexibility of thermal power
- Nuclear power: Lower dependency on nuclear power generation to the extent possible and restart of nuclear power plants and continuous improvement of safety
- Fossil fuels: Promote independent development of fossil fuels upstream, etc., effective use of high-efficiency thermal power generation and enhance response to disaster risks, etc.
- Energy efficiency: Continued thorough energy efficiency and integrated implementation of regulation of Act on Rationalizing Energy Use and support measures
- Promotion of hydrogen/power storage/distributed energy

The new plan aims for a reduction of greenhouse gas (GHG) of 26% in 2030 (from the base year 2013) and 80% by 2050. The concerns about the investments in new coal-fired power plants were reviewed and some have been cancelled which is in line with the global direction coping with Sustainable Development Goals (SDGs).

The EBC believes that the ties between Europe and Japan in the energy area should be further strengthened to facilitate commercial exchange, achieve consensus on common standards, enable attainment of the CO<sub>2</sub> emissions targets of COP21, facilitate access to energy at the lowest possible cost based on Cost Benefit Analysis (CBA) and achieve further energy cost reductions through the promotion of fair and open competition.

The next 6<sup>th</sup> Strategic Energy Plan will be revised and released in 2021. The EBC is looking forward to be actively involved and to provide the appropriate support.

## Key Issues and Recommendations

### ■ Transmission and distribution

*Yearly status report: some progress.* Japan's transmission network is centred on its production sites, with the main transmission at 500kV. The frequency converter stations (FC) connecting the 50Hz and 60Hz networks offer only limited additional capacity. Furthermore, the limited interconnections between the individual EPCOs 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 between regions, enables large integration of renewable into the system and also enables long cable connection by subsea or land.

#### **Recommendations:**

- The legal unbundling in April 2020 should implement regulations that will ensure security of supply and fair market mechanisms based on wider grid interconnections and look into increasing ownership or operation separation to further ensure the independence of Transmission and Distribution System Operators (TDSOs).
- Japan should do more to increase interconnection capacity between TDSOs, achieving fair electricity transactions and encouraging mergers between TDSOs for logical and reasonable decision making.
- The TDSOs should look into further harmonisation of technical standards by integrating individual requirements and also adopting European standards for products and systems to achieve cost efficiency.
- Japan should further introduce a new grid management system, such as the “non-grid connection”, which was experimentally introduced in Chiba, to utilise a larger portion of existing grid capacity.

### ■ Nuclear energy and nuclear safety

*Yearly status report: some progress.* In the 2018 Basic Energy Plan, the Japanese Government confirmed that nuclear energy would remain a core constituent of the Japanese energy mix. However, the pace of the restarts of idled reactors decreased. In addition, several reactors will have to be shut down temporarily from 2020 due to delays in construction of anti-terrorism facilities. It will also be necessary in the near future to address the issue of ageing plants, not only through plant lifetime extensions, but also through replacement of reactors, some set to be 60 years old by the mid-2030s. Furthermore, it is essential that nuclear long-term sustainability is based on a reliable and efficient approach to safety concerns, smooth implementation of a back-end policy for recycling spent fuel, and final disposal of radioactive waste.

#### **Recommendations:**

- Japan should increase cooperation with international organisations to improve global nuclear safety.
- Japan should accelerate the restart of the idled reactors to achieve the 2030 decarbonisation objectives.
- Japan should promote fuel multi-recycling to reduce waste and further boost energy self-sufficiency.
- The Japanese Government should develop a long-term plan for the replacement of ageing reactors to achieve the energy mix targets, including maintaining sufficient manpower to restart the current fleet and its future replacement.

### ■ Wind energy

*Yearly status report: some progress.* The development of wind energy is essential for Japan to reach its CO<sub>2</sub> emissions targets. Modern and cost-efficient 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. Tohoku EPCO's “grid access process”, NEDO's “floating wind farm demonstration” and the “new law for off shore wind farm development” were encouraging. Now with the 1<sup>st</sup> round of zoning process for promotional areas close to finalisation and awaiting bid openings, the offshore wind markets in Japan are gaining momentum.

#### **Recommendations:**

- Japan should facilitate the development of on-shore as well as off-shore wind farms by reducing unnecessary regulations that add to their cost and development time, especially in relation to environmental impact assessment requirements and cabotage rules.
- Japan should adopt and recognise internationally accepted certification standards and international accreditation for wind turbines and their componentry. This would increase both domestic and foreign direct investment, and support Japanese technology exports.



- Japan should establish a standard for compensation to fishermen, to ensure that subsidies for offshore wind power is used efficiently and transparently.
- Japan should focus on and officially support development in areas with good wind conditions and access to consumption centres to enable investors to build utility-scale wind farms.
- Since Japan's offshore wind potential is located in deeper waters, Japan should continue to play an active role in supporting the development of the floating offshore wind industry. As this is globally an emerging technology and industry, Japan can still position itself as an industrial hub (supply chain) for this industry. The focus should now shift from technology demonstration to cost improvements through changing the support focus to larger scale floating wind farms.
- Japan should introduce regulations for offshore wind development in the economic zones too, and not only for territorial water, since most of Japan offshore wind potential is located in the former.

## ■ Solar energy

*Yearly status report: some progress.* The principal impediments to sustainable growth of utility and commercial-grade solar energy are: the so far rather discouraging reverse auction system, cumbersome procedure for obtaining special permits for land re-zoning for non-agricultural use, and the prospect of potential curtailment in certain power grids, which affects project financing. 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.

While Japan has focused extensively on solar power as a renewable energy source, the EBC believes that it must continue to encourage development of this important source of renewable energy. This must be carried out ambitiously with realistic targets, aimed at increasing the safety and reliability of the energy supply.

### **Recommendations:**

- Adopt and recognise internationally accepted certification standards for solar modules, system components and design qualifications, rather than enforcing existing “Japan-only” component 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.
- Incentivise and create standardisation programmes for the EPCOs to use 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.
- Incentivise rooftop PV (PhotoVoltaic) installation as an alternative to power plants in remote areas requiring substantial land conversion.
- Encourage further grid interconnections, utilise existing pump storage power generation plants, use and improve battery storage, and consider new technologies, such as conversion to hydro for further PV integration.
- Legislative bodies should avoid imposing additional or differing safety requirements on the emerging 1500V technology in order to facilitate plant development applying this latest technology without making changes to the relevant authorisation process.
- For FIT projects, project developers are now forced to remain with previously selected PV modules and applied plant capacity, if they wish to maintain the earlier FIT (Feed-In-Tariffs) agreements. This practice not only results in failure to take advantage of recent technical developments, but in some cases has also resulted in unfavourable detail design. A certain level of flexibility with respect to design variations would easily avoid such situations, while maintaining the goal to clear the project pipeline.

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President & Representative Director  
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### Executive Directors

Leon Esben Ota, Nanami Mie Brandt  
 c/o Royal Danish Embassy  
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 Sanbancho KS Bldg. 5F, 2-4 Sanbancho  
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Halldor Elis Olafsson  
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 Minato-ku, Tokyo 108-0074  
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Emiko Myler  
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 DSM Japan Engineering Plastics  
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 Minato-ku, Tokyo 105-0011  
 Tel: 03-5404-8308; Fax: 03-5404-8352

### Office Manager

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 Tel: 03-3665-1991; Fax: 03-6203-8165

### Operation Manager

Taiko Niimi  
 2F, Kobuncho 243 Bldg.,  
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