

Reinforcing Partnerships in a Changing World

The EBC Report on the Japanese Business Environment
2025

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

CONTENTS

- Message from the EBC
- Message from the EU Ambassador
- Executive Summary
- Business fundamentals
 - Human resources
 - Intellectual property
 - Legal services
 - Retail & wholesale
 - Sustainability & Social Responsibility
 - Tax
- Financial services
 - Banking
 - Insurance
- Transportation and communications
 - Airlines
 - Railways
 - Telecommunications equipment
 - Logistics & freight
- Health science
 - IVD (In Vitro Diagnostics)
 - Medical equipment
 - Pharmaceuticals
 - Vaccines
 - Cosmetics & quasi-drugs
- Consumer goods
 - Liquor
 - Food & agriculture
- Industry
 - Automobiles
 - Automotive components & aftermarket
 - Aeronautics
 - Space
 - Defence & security
 - Materials
 - Energy

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Message from the EBC

Welcome to the 2025 edition of the European Business Council White Paper on the Japanese regulatory environment. This year's title, "Reinforcing partnerships in a changing world", reflects the growing importance of deepening economic and policy cooperation between Europe and Japan in an increasingly complex global context.

The EU-Japan partnership continues to strengthen through strategic frameworks such as the Green Alliance, the Connectivity Partnership, the Digital Partnership, and the ongoing evolution of the EU-Japan Economic Partnership Agreement (EPA). These initiatives are paving the way for enhanced trade, investment, and regulatory convergence across key sectors.

Yet, the geopolitical landscape presents new challenges. The war in Ukraine, tensions in East Asia, and the reassessment of traditional alliances are reshaping the global order. In this environment, Europe and Japan must /take on more prominent leadership roles, particularly in sensitive sectors such as defence, where industrial collaboration is both mutually beneficial and necessary.

Encouragingly, momentum is building. Governments are backing bilateral cooperation, and new agreements are being signed. The EBC sees significant opportunities for joint initiatives in defence and space technologies and recommends enhanced dialogue between the European Defence Agency (EDA) and its Japanese interlocutors (ATLA and METI).

The EBC continues to advocate for the harmonisation of standards. This is true for electrical appliances, medical devices, food and railways. These are all sectors with varied levels of harmonisation.

Several regulatory developments featured in this White Paper illustrate steady progress. In legal services, the re-registration process for foreign lawyers has been simplified, and professional requirements eased. In tax, Japan is encouraged to reduce administrative burdens, especially for low-value expenses under the new Qualified Invoice System. The food sector sees movement on mutual recognition of organic products, though challenges remain regarding additives and food contact materials. A major positive development is the anticipated improvement in lot code protection for alcoholic beverages. After years of EBC advocacy, we may soon witness critical regulatory changes that align with global best practices. Meanwhile, the inclusion of cost-effectiveness in the evaluation of in vitro diagnostics (IVDs) marks a significant shift toward value-based healthcare.

Environmental sustainability is another area gaining momentum. The growing use of Environmental Product Declarations (EPDs) calls for harmonised standards to avoid unnecessary complexity. In transport, progress is being made in both logistics and automotive sectors, although further alignment with international norms is needed. In aviation, Japan's Sustainable Aviation Fuel (SAF) mandate signals a shift toward greener travel, but questions remain around supply readiness. A clear roadmap is needed to support industry transition.

The EBC's work is made possible through the continued support of its stakeholders: European national Chambers of Commerce, corporate members, and partner organisations such as JAIA (Japan Automobile Importers Association), EFPIA European Federation of Pharmaceutical Industries and Associations), and IBA (International Bankers Association). We are also grateful to the Delegation of the European Union to Japan and to the European embassies in Tokyo for their collaboration and engagement.

As always, we extend our sincere thanks to our contributors. The EBC remains committed to fostering a transparent, predictable, and business-friendly environment where European and Japanese companies can grow and innovate together.

We look forward to building on this progress and working toward a future defined by shared prosperity, resilience, and deeper cooperation.

Laurent Depus

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

Valerie Moschetti

Chief Operating Officer
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European (EU) Chamber of Commerce in Japan

Message from H.E. Mr. Jean-Eric Paquet, the Ambassador of the European Union to Japan

I am very pleased to introduce the latest edition of the European Business Council's (EBC) White Papers. This annual document is a vital barometer of the European business environment in Japan and a testament to the powerful, enduring strategic proximity between the EU and our closest partner in the Indo-Pacific.

In a global landscape defined by uncertainty, the EU and Japan stand as twin pillars committed to upholding a rules-based international order. This shared commitment is concretely enshrined in our landmark agreements: the **Economic Partnership Agreement (EPA)** and the **Strategic Partnership Agreement (SPA)**. In recent years, the European Union and Japan have further reinforced their strategic engagement through the **Green Alliance** (2021), the **Digital Partnership** (2022), and the **Security and Defence Partnership** (2024).

At the **EU-Japan Summit in July 2025**, as our strategic focus has sharpened to address issues of resilience and economic security, this collaborative bond was further cemented by the launch of a new **Competitiveness Alliance**, confirming that the competitiveness of the European Union's economy is indeed interlinked with that of Japan. Together, we are working to safeguard innovation and strengthen critical infrastructure. This cooperation ensures that the operating environment for our businesses is not only reliable but resilient against global shocks.

Against this dynamic backdrop, the **voice of the European business community** – channelled expertly through the EBC – is indispensable. You are the direct link between policy and practice, identifying challenges on the ground and helping us refine our cooperation mechanisms. Your continuous engagement is essential to unlocking the full potential of our agreements and ensuring that the EU-Japan partnership continues to drive global growth and stability.

I encourage you to use this publication to reflect on the progress made and to actively contribute to the ongoing dialogue, as the success of our strategic relationship also relies on your insights, and your commitment to uphold a rules-based trade system that is both inclusive and resilient.

Jean-Eric Paquet

Ambassador of the European Union to Japan
Head of the Delegation

EXECUTIVE SUMMARY

The 2025 European Business Council White Paper presents key regulatory developments and ongoing challenges affecting European businesses operating in Japan. This year's edition underscores the importance of advancing EU-Japan cooperation through greater regulatory alignment, transparency, and mutual recognition.

Key Highlights:

- **Legal Services:** Meaningful reforms have eased the path for foreign lawyers (*gaiben*), including streamlined re-registration processes and reduced overseas experience requirements.
- **Taxation:** The EBC urges Japan to simplify procedures under the new Qualified Invoice System, especially concerning minor cash expenses, to reduce administrative burden.
- **Healthcare & IVDs:** A major step forward is Japan's decision to incorporate cost-effectiveness evaluations into its regulatory framework for in vitro diagnostics—aligning with long-standing EBC advocacy.
- **Food & Agriculture:** Progress continues on mutual recognition of organic animal products. However, concerns remain over the approval timeline for food additives, the short grace period for new food contact regulations, and the availability of English-language resources.
- **Liquor:** The Japanese government is now considering protection for lot codes on alcoholic beverages, potentially aligning with international standards after years of EBC advocacy.
- **Automotive & Materials:** As Japan integrates recycled plastics into its industrial policies, the EBC stresses the need for harmonisation with global standards. Recognition of standardised environmental data sheets is also vital to support Japan's decarbonisation objectives.
- **Defence & Space:** The EBC calls for enhanced industrial collaboration between Japan and the EU in defence and space sectors, including joint R&D, more flexible export policies, and stronger inter-agency cooperation.
- **Airlines:** With Japan's mandate to use 10% Sustainable Aviation Fuel (SAF) by 2030, the EBC raises concerns about supply readiness and calls for a clear, actionable roadmap.
- **Railways:** Although regulatory barriers persist, the EBC welcomes the move by JR East and JR West to develop joint standards and urges the reactivation of the EU-Japan Technical Expert Group.

Across all sectors, the EBC continues to advocate for fair, predictable, and harmonised regulations that support innovation, sustainability, and deeper EU-Japan economic integration.

Business Fundamentals

Human resources
Intellectual property
Legal services
Retail & wholesale
Sustainability & Social Responsibility
Tax

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HUMAN RESOURCES

Introduction

European invested companies in Japan are confronting significant workforce dynamics. The demographic challenge of Japan's shrinking workforce continues to be one of the main challenges in the Japanese market. This demographic constraint coincides with the workplace transformation caused by the COVID-19 pandemic which has fundamentally altered our understanding of work, productivity and organizational culture.

Moreover, the emergence of artificial intelligence and advanced digital technologies present both extraordinary opportunities and significant challenges for HR teams. These technologies promise unprecedented capabilities in talent management and predictive workforce planning, while simultaneously demanding a robust human-technology interaction ensuring its outputs are aligned with organizational values and ethical considerations. The EBC Human Resources Committee welcomes the activities initiated by the Japanese government, such as the August 2023 Study Group on HR Policy in the Digital Age, focusing on AI adoption in Japanese companies, to provide further guidance for companies in this new field.

On the important theme of digitalisation, the EBC Human Resources Committee further continuous to support the ongoing activities of the Japanese government in this area, with the passing of laws to promote '*electronic government*' and reduce the necessity for 'hanko' seals, along with the dedicated digitalisation agency. For businesses, this initiative provides opportunities to further benefit from productivity efficiencies from paperless processes and electronic documents by reducing the physical need to stamp 'hanko' seals on official documents. It is important that Japan continues these efforts. The EBC Human Resources Committee encourages the Japanese government to proceed improving online payment capabilities. Even in today's world, Japanese employees sometimes still have to visit the tax office or the Japan Pension Office in person to make payments in cash. A more progressive approach and a switch to more online payments would also lead to greater efficiency, benefiting companies and employees in the same way.

The EBC appreciates the government's labour market reform initiatives, whilst at the same time continues to encourage a broader dialogue on promoting productivity and flexible working, through measures that can be taken to improve the way work is done. The EBC Human Resources Committee is also encouraged by the trend among major Japanese manufactures to move towards more performance and merit-based pay schemes and personnel evaluation systems aimed at boosting motivation and productivity of their workforces, in the hope that this may also lead to greater mobility of workers, matching of transferable skill sets and experiences in the external labour market in Japan. Thus, as performance and merit-based remunerations are highly welcomed, consideration should be given to supporting job-based promotions and careers rather than the traditional route based solely on age and length of service.

Japan's labour market continues 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 to encourage 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, since both childcare and parental leave are not only crucial for young families, but also offer great opportunities to create a more flexible work environment and to introduce part time work or shared job opportunities to both women and men alike. In this context, it is vital that those returning from maternity leave or paternity leave are protected in their previous position and role. Towards this end, the EBC Human Resources Committee believes that further efforts to change attitudes and awareness in society about childcare and maternity/paternity leave should be actively promoted. Pivotal in the efforts for providing more women's active participation in the workforce will be an ongoing effort to promote remote or flexible work opportunities despite recurring return-to-office demands of companies after the pandemic. The EBC encourages the Japanese government to recognizing the critical link between workplace flexibility and female professional engagement.

Moreover, the EBC asks the Japanese government to further promote Diversity, Equity, and Inclusion in Japan. While gender parity presumably takes up the discrimination is not only limited to that but can be found in all aspects. Age, race, nationality, disability and sexual orientation are only a few examples in which discrimination can be found. By systematically dismantling systemic barriers and creating inclusive organizational ecosystems, the EBC HR Committee considers Japan having the chance to unlock unprecedented human potential, further drive innovation and secure long-term economic vitality.

Since introducing the Defined Contribution Pension Law of 2001, the Japanese government 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

■ Immigration legislation and policies

Yearly status report: some progress. In the aftermath of the pandemic, European companies are now once again able to bring personnel to Japan vital for the company, be it top management or specialists. However, the Government needs to continue to take an increasingly proactive approach to immigration policies and deregulation giving the shrinking labour market in Japan. 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 as well as regional Japan. As of late, visa applications are taking significantly longer to be processed which the EBC Human Resources Committee understands is due to limited resources within the Immigration Services Agency (ISA). This means that companies have difficulties in their human resources planning leading to delays in execution of projects and, consequently, also obstacles to foreign direct investments. Moreover, an inclusive immigration policy which extends spousal visa rights to partners regardless of gender, including e.g. also same-sex couples, and eases the process is desirable.

Recommendations:

- Provide a greater level of immigration policy transparency for businesses and permanent residents.
- Extend the scope of online visa applications and visa extensions. This would be in line with continued digitalisation of the Japanese administration and would support remote working.
- Lower the requirement for industry experience from ten to five years for those without a university degree.
- Formalise visa procedures for partners, regardless of gender, in marriage or equivalent relationship.
- 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.
- ISA should allocate more resources to speed up visa applications.
- Extend the scope of work visa for non-management, non-specialist jobs and ease the process to convert from student visas to non-management work visas
- Further digitalise the process for ease of administration.
- **Exploring the use of the MyNumber system for immigration purposes:** The MyNumber system can be leveraged to share information across different branches of administration for immigration purposes, such as visa renewals, status changes, and naturalization. Currently, applicants need to obtain documents from one branch such as the ward office or tax office to submit them to immigration, which can cause delays. By allowing applicants to grant, at their discretion, the immigration bureau access to information from other branches, the process would become more efficient and faster. This would increase overall efficiency and speed up the process, as processes would not be delayed due to missing documents. Considering the projected and desired increase in foreign professionals in Japan in the coming years, this would also ensure that the immigration bureau’s work load is sustainable and scalable.

■ Labour market regulations, flexibility & digitalisation

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 ongoing policies that allow more flexible approaches to working, greater female participation in the workforce, new ways of sourcing foreign labour and use of automated processes and artificial intelligence where meaningful and appropriate. 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:

- Encourage companies to create ongoing lasting policies to allow greater numbers of employees to continue 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.
- Introduce employment legislation and support 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 not be transferable. The same shall apply for corporate re-structuring with clear rules on how to compensate affected workers.

- Introduce legislation to speed up court procedures in labour disputes. Long court procedures lead to legal uncertainty and slows down corporate investments. The efforts of the Japanese government to digitalize court procedures to accelerate decisions are much welcomed by the EBC.
- Continue to actively promote the uptake of technology that contributes to boosting productivity in the workplace, including incorporating digitalisation and artificial intelligence into daily operations, while considering the interests and well-being of the human workforce.
- 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. Further promotion of office part-time jobs for working parents.
- Consider implementing a policy that grants remote work privileges to employees who meet predefined criteria, such as child-care obligations.
- 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 EBC believes that even with an increase of the threshold this will not solve the issue. The situation is similar for the threshold for health insurance and pension.
- Encouraging universities to enable their students to engage in internships during their university years can significantly enhance the connection between business and academia. This collaboration provides students with practical experience and insights into the skills that are in demand in the job market. The EBC Human Resources Committee supports the idea of promoting internship and vocational programs for university students, reflecting the changing needs of businesses. By sharing experiences from European best practices, such as the German dual education Vocational Education Training (VET) programs, the EBC is willing to support government initiatives in this area. 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.
- Promote job-sharing for blue-collar as well as white-collar office positions to provide more opportunities for parents to balance work life with home responsibilities.
- The transition from membership-based and seniority-based employment to merit-based specialist hiring, including support for mid-career hiring, is crucial for fostering a competitive workforce. The EBC Human Resources Committee is encouraged by the trend among major Japanese companies to move towards performance and merit-based pay schemes and personnel evaluation systems. This shift aims to boost motivation and productivity, leading to greater mobility of workers and better matching of transferable skill sets and experiences in the external labor market. Supporting job-based promotions and careers rather than the traditional route based solely on age and length of service is highly welcomed.

■ 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. This should be equally applicable for employed, self-employed or part-time workers. 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.
- Make similar amendments to iDeCo (individual Defined Contribution pension) limits.
- Extend the payback period and expand pay-back to include the company contributions for leaving expats.
- Commence negotiations for social security agreements with those European countries that Japan does not have an agreement with. We are grateful for Japan and European states concluding bilateral agreements.
- Ease the options for companies providing employee stock option plans.

■ Diversity, Equality and Inclusion

Yearly status report: slow progress. Japan, known to have the world's highest rate of seniority, also has one of the fastest population declining paces in the world. Its economy is bound to drastically change in the following decades due to a decrease in population of 30 million by 2050. To offset its shrinking labour force, Japan needs to bring more women into the workforce by supporting working mothers, reducing its gender pay gap (second largest among OECD countries) and giving them access to more stable jobs, as well as to integrate foreign workers. Japan, unfortunately, still ranks low on various indexes related to this issue.

Gender, age, race, disability and sexual orientation are only a few examples in which discrimination can be found. It is important to raise awareness at company level and implement improvement in those fields. Particularly against the backdrop of an impending ageing society and the associated increased threat of poverty in old age, special measures should be taken to counteract age discrimination.

Recommendations:

- Facilitating access to the Japanese labour market for foreign workers. The government should continue to take a proactive approach to immigration policies and deregulation, given the shrinking labor market in Japan.
- Improving awareness for companies to accept a diverse range of candidates
- To ensure that foreign workers can become effective and leverage their skills, companies need to create an inclusive and supportive environment. This involves providing comprehensive onboarding programs that help foreign professionals understand the local work culture and expectations. Additionally, the EBC encourages the provision of cross-cultural communication trainings to enhance the collaboration between Japanese and foreign workers. By preparing and creating a conducive environment, companies can enable foreign workers to thrive and contribute their unique perspectives and expertise to the organization.

■ Dispatch services

Yearly status report: new issue. Dispatch services are today a common feature of the Japanese labour market. Many companies use dispatch services to deal with sudden increases in demand, and also to find the right talent. There are, however, some limitations to the services that companies in this sector can provide.

Recommendations:

- Allowing temp staff companies to dispatch so-called day-labourers. This is currently not possible unless certain difficult-to-achieve requirements are met.
- Abolishing the "disclosure of information on margin ratio of temporary staffing agencies by business location" requirement for ease of administration.
- Enabling to include disabled dispatch workers in calculation of the employment rate of persons with disabilities with a defined factor.

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INTELLECTUAL PROPERTY

Introduction

While the market for branded products in Japan continues to flourish, its troubling counterpart—counterfeits—continues to thrive alongside it. As the volume of brand products sold online increases, Japan's e-commerce landscape has evolved into a complex marketplace containing various product categories: genuine items from authorized dealers, goods from parallel importers, new counterfeit products falsely labeled as "parallel imports," authentic second-hand items, counterfeit second-hand goods, and even openly marketed counterfeit products.

The use of SNS (Social Network Site) for the promotion or direct sale of counterfeit goods is widespread in Japan, just as it is in other countries.

In most countries outside Japan, the online marketplace is the primary battleground for combating counterfeit products. However, in Japan, issues related to the **"parallel imports" (which are permitted in Japan)** and **"second-hand"** markets play a significant role, making them distinctive aspects of counterfeit distribution in the country.

On the other hand, the sources of counterfeit goods are relatively straightforward, similar to those in many other countries. **China remains the top manufacturer and exporter of counterfeit products circulating in Japan, followed by Vietnam.**

In 2023, approximately **one million counterfeit items** were seized at customs. Considering that it is impossible for customs authorities to inspect all imported goods, this number likely represents only a fraction of the total volume of counterfeit products entering the country.

Until recently, it was a fact that a considerable number of consumers in Japan did not mind purchasing counterfeit goods. As a result, e-commerce platforms seemed to focus more on counterfeit prevention from the perspective of dealing with brand owners rather than protecting consumers.

However, as more consumers have come to prefer purchasing genuine products over counterfeits, these platforms have started adapting their services accordingly.

The shift in consumer awareness regarding counterfeit goods can be attributed to several factors:

- **The cooling of the frenzy for branded products**, driven by economic downturns
- **The emergence of AI**, which has highlighted new possibilities for counterfeit detection and prevention
- **A desire for self-correction based on observing others**, where, in this case, "others" refers to China, a country known for widespread counterfeit distribution

This last two transformation is a positive development and should be welcomed.

CtoC platforms, however, have made little real progress in their efforts to combat counterfeit goods.

Some platforms have partnered with second-hand goods dealers and industry associations to enhance authentication through human verification. However, manual authentication is both time-consuming and costly, limiting the number of consumers who use such services.

While certain platforms claim to utilize AI or image recognition systems to appeal to the general public, the effectiveness of these technologies in identifying or eliminating counterfeits remains insufficient. It is widely recognized that the term "AI" is often used as a buzzword, with its actual capabilities falling short.

Although there are high expectations for future technological advancements and innovations, existing measures should also be carefully reviewed and strengthened. These include stricter identity verification for sellers, systematic collection and analysis of buyer complaints, effective utilization of infringement data from takedown requests submitted by rights holders, and the blacklisting of malicious users.

When looking at BtoC platforms, major Japan-based BtoC sites have long been proactive in combating counterfeit goods.

For instance, in an effort to "cleanse" their marketplaces, they collaborate with brand owners to verify suspicious products. If a listed item is suspected of being counterfeit—such as when it is priced unusually low or flagged by consumer reports—they conduct test purchases to confirm its authenticity. If the item is found to be counterfeit, they take action, including removing the seller from the platform.

On the other hand, overseas-owned BtoC platforms still show little improvement. Issues remain, such as the inadequate enforcement of account suspensions and an overreliance on automated detection systems, leading to insufficient human-led monitoring and enforcement efforts.

In Japan, various sectors are engaged in collaborative efforts to establish frameworks for eliminating counterfeit products. Some of these approaches are even more advanced than those implemented in Europe and the United States.

Notably, the information-sharing and cooperation systems established between major BtoC and CtoC platforms and rights holders are highly developed and deserve recognition.

At the same time, there are areas where Japan lags behind and requires improvement. Below, is outlined the key issues and proposed solutions.

Key Issues and Recommendations

■ Continuation and Strengthening of Measures to Eliminate Counterfeit Products from Japanese and Foreign-Owned Platforms

Yearly status report: no progress. Foreign-owned BtoC platforms and some Japanese CtoC platforms continue to show or maintain a cooperative stance with rights holders. However, they appear to be placing greater emphasis on, or shifting towards, attempts to detect and eliminate counterfeit goods through AI and computer-based image analysis systems.

However, **it remains uncertain whether AI or computer systems can effectively detect and remove counterfeit products.** In particular, **the current capabilities of AI are far from reliable**, making it difficult to place full confidence in its effectiveness.

Future Challenges and the Need for Strengthened Measures

Given this situation, **existing measures should be re-evaluated and further strengthened**, including:

- **Stricter identity verification for sellers**
- **Systematic collection and analysis of buyer complaints**
- **-Effective utilization of infringement data obtained from takedown requests by rights holders**
- **Blacklisting and sharing of information on malicious users**

While there are high expectations for advancements in AI technology, **human oversight and the reinforcement of proven countermeasures should not be neglected.** It is crucial to continue and strengthen these efforts in a consistent and effective manner.

Recommendation:

- To strengthen the relationship between rights holders and platform operators, the government has already been working to encourage non-participating platform operators to join discussions on counterfeit prevention. This initiative should continue, **with a particular focus on increasing engagement with foreign-owned platform operators.**

Within these discussions, **there should be active exchanges of opinions on necessary countermeasures, aiming to eliminate the profit-driven mindset of platform operators and rebuild a shared societal understanding of counterfeit prevention.**

■ "Act on the Protection of Consumer Interests in Transactions on Digital Platforms"

Yearly status report: no progress. The "Act on the Protection of Consumer Interests in Transactions on Digital Platforms" was enacted in **May 2022**. With its enactment and enforcement, it appeared that many relevant platforms—albeit to varying degrees—reviewed their intellectual property protection measures.

However, as public attention toward the law has faded, there is a growing sense that the necessity of its enforcement, and even its very existence, is being overlooked.

Recommendations:

- The enforcement of identity verification for sellers and proper disclosure under the Act and the Act on Specified Commercial Transactions is insufficient.
- Therefore, the revision clause stipulated in the Act should be utilized to strengthen the legal framework.

■ Regulation of Counterfeit Advertising and Sales on SNS, as well as Recruitment of Sellers (Illegal "Yami-Baito" Jobs)

Yearly status report: New Issue. Recently, **investment fraud schemes impersonating celebrities have been spreading on SNS**, alongside **the recruitment of individuals for criminal activities such as fraud and robbery (so-called "Yami-Baito" illegal jobs)**, which has become a serious social issue.

These recruitment efforts are believed to be led by **organized crime groups**, including **anti-social forces** and **criminal organizations such as "Tokuryu" (anonymous distribution-based crime groups)** and **groups of Chinese nationals involved in illegal activities.**

Given these developments, **it is impossible to ignore the connection between counterfeit goods and such crimes.** Counterfeit product advertising, sales, and even the recruitment of individuals to sell counterfeits are all actively conducted on SNS.

Recommendation:

- When implementing measures to prevent SNS-based crimes, it is essential to also recognize the presence of intellectual property-related crimes and take appropriate action accordingly.

■ **Permission for the Import of "Trademark-Removed Goods"**

Yearly status report: no progress. There has been no progress on this issue. Cases continue to be observed where **customs authorities permit the import of goods from which trademarks have been removed after being identified as counterfeits and seized.**

Recommendation:

- Customs officials should be made aware that, as stated in Article 46 of the TRIPS Agreement and referenced in the WTO dispute settlement case against China (DS362), except in exceptional circumstances, the mere removal of illegally affixed trademarks does not justify allowing such goods to enter distribution channels.

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LEGAL SERVICES

Introduction

Foreign lawyers play a crucial role in Japan by facilitating international business, trade and investment. As Japan continues to expand its global economic presence, companies increasingly require legal expertise that bridges Japanese law with foreign legal systems. Registered foreign lawyers (*gaiben*) help multinational corporations navigate cross-border transactions, mergers, and regulatory compliance, ensuring smooth operations in Japan. Their knowledge of international legal frameworks enhances Japan's ability to attract foreign investments and maintain strong economic ties with global markets. Additionally, *gaiben* contribute to the development of Japan's legal profession by sharing best practices, fostering legal innovation, and supporting the internationalisation of Japanese law firms.

Furthermore, the expertise of *gaiben* is particularly valuable in areas like international property, competition law, and human rights, where international collaboration is essential. Moreover, foreign lawyers help Japanese clients navigate complex international disputes, providing insights into foreign judicial systems and arbitration mechanisms. By integrating global legal perspective, *gaiben* contribute to Japan's ability to adapt to an increasing interconnected world, strengthening its position as a major player in the international legal community.

Japan's recent legal reforms have eased regulations for foreign lawyers, expanding their ability to practise and collaborate within Japan. In 2020, we saw changes that allowed registered foreign lawyers to better represent clients in a broader range of disputes. Additionally, the required work experience for foreign lawyers to qualify for registration has been more flexible. Today two of the three year-requirement can be fulfilled in Japan. This adjustment facilitates integration into Japan's legal system and makes it easier for foreign legal professionals to establish long-term career in Japan. As a last point, the joint corporation system enables local and foreign lawyers to more effectively collaborate.

However, despite all the positive changes, the EBC believes that there are still improvements to be made to Japan's regulatory framework. The work requirement is still exclusive to the registration of foreign lawyers. This requirement does not apply for domestic lawyers (*bengoshi*). Ultimately, the EBC would like to see this requirement to be completely abolished. The registration process is also still very long. This is in particular true for foreign lawyers who have a background in less common European legislations. The EBC believes that Ministry of Justice (MoJ) and the *Nichibenren* can make better use of the collected expertise out there. The EBC Legal Service Committee would be honoured to serve as a reference point to explain the various legal system with a focus on how lawyers are registered or approved in that jurisdiction.

It is also important to point out that while arbitration rules have changed, there are still some details that would benefit from clarification.

The EBC will continue to take a close interest in the rollout 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: progress. In order to become registered as a *gaiben* in Japan, a foreign lawyer must have three years of professional experience in his/her respective home law, of which one 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. Progress have been made, including in the context of the EPA, only one years of work experience needs to be outside of Japan.

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.

■ 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 should 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.

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RETAIL & WHOLESALE

Introduction

The Japanese retail market remains one of the largest and most vibrant in the world. After many years during which the presence of European retailers was more or less limited to the luxury sector, the last 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. In most cases tariffs have been reduced to zero already on the day of entry into force. The EBC is also hoping for 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.

Key Issues and Recommendations

■ **Prohibitive import, testing and certification procedures**

Yearly status report: some progress. Despite improvement in the recent years and more and more international harmonisation, Japan still retains some testing and standards that are unique to Japan. This means that products in those will have to undergo duplicate testing and in extreme cases have to re-designed for the Japanese market. The EBC requests that more overseas approvals are recognised.

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. Examples of this would be Fahrenheit or miles per hour. There are already alternative non-SI units in use such as for pressure and in the aeronautic field.
- Deliberations on the upcoming policies on children's products should take in consideration European testing and approval schemes. Japan should avoid establishing a unique system for the domestic market.

■ **Denan Act or PSE requirements**

Yearly status report: new issue. Most electrical appliances on the Japanese market need to be labelled with a PSE symbol: either a so called *maru-PSE* or a *hishigata-PSE*. For this to be possible the products need to undergo the applicable testing and certification, and also be reported to the Japanese authorities as a "Notification of business," or Import Business Report, with information such as type classification, *katashiki*, and manufacture information. While some of these requirements are mirrored in other jurisdictions, Japan stands out in some respect. Every single product needs to be checked beforehand either at production site or a warehouse, and a report of this inspection needs to be kept for three years by importers. Furthermore, tests and approvals from Europe can only be partially used or not used at all as the Japanese standards are still not harmonized with international standards in the latter case.

Recommendations:

- 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. This is in particular important for products that have no established international standard.
- Japan should remove the need to inspect every product at the production site to align with IEC, international standards.
- Japan should better clarify the scope to make it easier to understand which products, or products categories, are covered by the legislation. Japanese authorities should furthermore provide written answers to questions related to this.
- Remove requirement for companies to keep certificates in paper form.
- Remove the need for an "Import Business Report", or at least only request it if needed.

■ **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. This is also something that is recommended by the EU-Japan Business Round Table.

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 long. This often means that labels are too complex for consumers.

Recommendations:

- The Labelling Act should be reformed to aid the consumer in understanding the product and to introduce flexibility for the retailer.
- Introduce the possibility of referring to websites for more information by using for instance QR-codes instead of having the information on a label affixed to the product.

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SUSTAINABILITY & SOCIAL RESPONSIBILITY

Introduction

In 2015, alongside the adoption of the Paris Agreement at COP21, the United Nations introduced its 2030 Agenda, outlining 17 Sustainable Development Goals (SDGs) to foster a sustainable global society. Japan promptly embraced this framework, launching national campaigns and institutional mechanisms to promote sustainability.

In 2025, Japan ranks 19th in the [global SDG Index](#), down one place from the previous year. While this remains a relatively strong position, key challenges persist, particularly in areas such as gender equality, climate action, resource efficiency, and biodiversity. These issues directly impact the business environment, influencing regulatory expectations, operational risks, and investor confidence.



From a European business perspective, the implementation of sustainability policies in Japan still appears largely symbolic. The widespread use of SDG branding in communications and campaigns is not always matched by regulatory clarity, enforcement, or financial incentives. This creates uncertainty for companies investing in genuinely sustainable practices and limits opportunities for market differentiation.

In energy and climate policy, Japan has yet to send strong and credible signals to support a decisive shift away from fossil fuels. Recent government announcements, such as halting the operation of inefficient coal plants, reiterate existing commitments but lack concrete timelines and mechanisms. Regulatory complexity, limited grid access, and policymaking structures dominated by legacy industry actors further slow the transition.

Japan's updated Strategic Energy Plan and NDC, which include a 73% emissions reduction target by FY2040, are steps forward. However, credible implementation will require clear planning and better alignment with international best practices, including a more level playing field for businesses offering proven low-carbon solutions including renewable energy.

On corporate disclosure, Japanese companies are increasingly active in frameworks such as CDP, SBTi, TCFD, and TNFD. In fact, Japan currently leads the world in the number of companies registered as early adopters of TNFD, reflecting growing awareness of nature-related financial risks. However, these climate and biodiversity commitments often lack concrete follow-through in terms of governance, risk management, and integration into core business strategy. As global expectations rise, it will be critical to move beyond disclosure and demonstrate measurable outcomes.

In the area of resource use, Japan continues to face high levels of food and plastic waste and lags behind in developing comprehensive circular economy policies. Despite increasing consumer awareness, demand for sustainable products

remains relatively low, in part due to limited labeling systems, insufficient regulatory guidance, and lack of public communication. Many European companies are ready to bring experience and innovation to this space, but clearer rules and incentives are needed to unlock their full contribution.

Gender equality also remains a critical issue for the business community. Japan ranked 118th in the [World Economic Forum's 2024 Gender Gap Index](#), the lowest among developed countries. Structural barriers to women's leadership and limited progress on work-life balance not only constrain the domestic talent pool but also affect international companies. European firms operating in Japan often face cultural barriers when attempting to implement global DEI standards, including gender equality targets set by their headquarters.

The European Business Council encourages the Japanese government to move from symbolic engagement to more consistent, transparent, and internationally aligned sustainability policies. Doing so will enhance business predictability, improve competitiveness, and create new opportunities for partnership and innovation. The EU-Japan Green Alliance could offer a foundation for advancing these shared priorities through structured public-private cooperation.

Key Issues and Recommendations

Japan has committed to achieving carbon neutrality by 2050 and improving sustainability performance across sectors. However, from the perspective of European businesses, policy implementation remains uneven, and many government signals fall short of what is needed to ensure market predictability, regulatory clarity, and alignment with international standards.

For companies, both domestic and international, operating in Japan, the lack of robust, science-based frameworks creates uncertainty and limits opportunities to invest in credible, future-proof solutions. Key areas such as renewable energy deployment, sustainability disclosure, gender equality, waste reduction, and climate governance require more ambitious targets, consistent regulation, improved transparency, and stronger enforcement mechanisms.

The EBC believes that moving from symbolic commitments to practical and inclusive strategies will not only support Japan's decarbonization and SDG goals, but also enhance the country's competitiveness, innovation capacity, and attractiveness as a business environment. The following recommendations aim to support a transition that is credible, fair, and aligned with international expectations.

■ Gender Equality at Work

Yearly status report: no progress. Japan remains the lowest-ranked G7 country in the 2024 Global Gender Gap Index, at 118th out of 146 countries. While this marks a modest improvement from 125th in 2023, it reflects persistent and systemic barriers to women's economic participation and leadership.

Recent government steps toward greater transparency, such as the legal requirement for large companies to disclose their gender pay gaps, represent meaningful progress. However, such measures remain insufficient on their own to close Japan's wide gender gaps, especially in leadership representation and work-life balance.

Recommendations:

The Japanese government should implement comprehensive policies to support gender equality in the workplace, including:

- Expanding access to affordable childcare and parental leave
- Promoting flexible work arrangements
- Closing the gender pay gap (the second-largest among OECD countries)
- Encouraging greater representation of women in leadership roles

Efforts should also focus on transforming workplace cultures and addressing unconscious bias to ensure inclusive career progression across all sectors. Stronger public policy engagement, beyond transparency requirements, is essential to drive systemic change.

■ Science-Based Sustainability Education for Adults

Yearly status report: new. Surveys suggest that public awareness of climate change in Japan is relatively high, and climate denialism is far less prevalent than in some other developed countries. However, this awareness has not translated into widespread behavioral change or strong public pressure for structural reforms. The emphasis on symbolic communication, such as superficial references to the SDGs, risks reinforcing a passive understanding of sustainability across all age groups.

There is a particular need to target adults, who hold decision-making power in government, business, and society at large. Given the urgency of the climate and ecological crises, meaningful action cannot wait for future generations to take the lead.

Recommendations:

The Japanese government should:

- Promote science-based sustainability education for adult learners through public media, local governments, and lifelong learning programs.
- Support the role of independent non-profit organizations in evaluating public policies and facilitating citizen education.

- Encourage companies across all sectors to provide sustainability education and training to all employees, beyond ESG and GX teams.

These measures would help close the gap between awareness and action, foster a more informed and engaged society, and strengthen the foundations for Japan's low-carbon and sustainability transition.

■ Regulations Against Greenwashing

Yearly status report: new. As interest in ESG and sustainability grows in Japan, so does the risk of greenwashing, where companies make misleading claims about the environmental impact of their products, services, or strategies. In the absence of clear legal definitions and active enforcement, misleading claims can persist unchallenged, eroding public trust and confusing both consumers and investors.

Civil society groups have raised concerns that the current advertising oversight mechanisms in Japan are not equipped to respond effectively to such issues, with some complaints remaining unanswered for extended periods. This highlights the need for a more robust and transparent regulatory framework.

Recommendations:

The Japanese government should introduce clear and enforceable regulations against greenwashing. This includes:

- Defining legal criteria for sustainability claims in advertising and product labeling
- Requiring companies to substantiate claims with verifiable data and alignment with recognized international standards
- Establishing independent review mechanisms and penalties for false or misleading sustainability claims

Stronger regulation would increase transparency, protect consumers, and ensure fair competition for companies investing genuinely in sustainability.

■ Consumer Awareness for Sustainable Food

Yearly Status Report: New. Consumer demand for sustainable food products in Japan remains relatively low compared to Europe. Despite growing awareness of environmental issues, sustainability considerations are still limited in everyday food purchasing decisions. This gap is driven by a lack of clear labeling, limited public communication, and weak differentiation in the marketplace.

Recommendations:

The Japanese government should strengthen consumer awareness and trust in sustainable food by:

- Supporting science-based, internationally recognized certification schemes
- Introducing regulated environmental labeling for food products
- Promoting sustainability-focused public procurement in schools, hospitals, and government facilities
- Running public campaigns to raise awareness about the environmental impact of food choices
- Enforcing rules against misleading claims in food marketing

These efforts would support Japan's environmental targets while opening new opportunities for businesses aligned with sustainability standards.

■ Reduction of Food and Plastic Waste

Yearly status report: some progress. Japan continues to face significant challenges in reducing food and plastic waste, both of which contribute to climate change and resource inefficiency. Each year, the country generates approximately 6 million tons of food waste, about one bowl of rice per person per day. Despite awareness campaigns and the 2019 Food Loss Reduction Promotion Act, regulatory measures remain limited in scope and ambition.

Similarly, while Japan has advanced systems for plastic waste collection and sorting, it remains one of the highest consumers of single-use plastics per capita globally. The 2020 ban on free plastic bags has had only limited behavioral impact, and excessive plastic packaging remains widespread.

Recommendations:

The Japanese government should strengthen efforts to reduce food and plastic waste at the source by:

- Setting more ambitious reduction targets and expanding producer responsibility
- Strengthening regulations on excessive packaging and single-use plastics
- Supporting innovation in packaging alternatives and circular economy models
- Promoting redistribution and upcycling initiatives for surplus food

- Expanding public awareness campaigns and collaboration with industry
- Accelerating waste reduction would support Japan's transition to a more resource-efficient, low-carbon economy and advance progress on SDG 12.

■ Strengthening Corporate Sustainability Disclosure

Yearly status report: Some Progress. Japanese companies are increasingly engaging in international sustainability disclosure frameworks such as TCFD, CDP, and, more recently, the ISSB standards. While this marks important progress in aligning with global expectations, the current focus remains largely on financial risk ("single materiality"), with limited attention to the broader environmental and social impacts of corporate activities. Additionally, while many companies now publish long-term climate or sustainability goals, there is often a lack of concrete, actionable transition plans showing how these goals will be achieved. Without clear milestones, strategies, and accountability, disclosure risks becoming a formal exercise rather than a catalyst for real transformation.

Recommendations:

The Japanese government should strengthen corporate sustainability disclosure by:

- Integrating double materiality, capturing both financial and environmental/social dimensions of impact
- Requiring companies to publish credible, time-bound transition plans alongside their targets
- Aligning disclosure rules with evolving international standards to ensure comparability and investor confidence

Improved disclosure would support transparency, fair competition, and effective climate and sustainability strategies across sectors.

■ Nature-Related Risk Disclosure

Yearly Status Report: New. Japan currently leads the world in the number of companies registered as early adopters of the Taskforce on Nature-related Financial Disclosures (TNFD), reflecting growing awareness of biodiversity and ecosystem-related risks. However, there is still a gap between early commitment and meaningful integration of nature-related risks into corporate strategy, governance, and decision-making.

As global frameworks such as the Global Biodiversity Framework (GBF) gain momentum, expectations are rising for companies and regulators to go beyond disclosure and support real-world outcomes for nature.

Recommendations:

The Japanese government should:

- Support the integration of nature-related risks into financial and corporate disclosure systems, building on TNFD guidance
- Ensure that TNFD commitments are accompanied by concrete risk assessments, targets, and governance mechanisms
- Promote alignment with international biodiversity goals and frameworks (e.g. GBF)

Bridging the gap between disclosure and action will help Japan safeguard natural capital, reduce systemic financial risk, and strengthen its leadership in global sustainability finance.

■ Sustainability in Supply Chains

Yearly status report: some progress. Japan has taken steps to address human rights risks in supply chains, but environmental sustainability remains under-regulated. Key issues such as greenhouse gas emissions, biodiversity loss, deforestation, and pollution linked to upstream and downstream activities are not yet systematically covered by legal obligations or disclosure requirements.

With the EU moving ahead with mandatory due diligence rules and sustainability reporting through the Corporate Sustainability Due Diligence Directive (CSDDD) and the Corporate Sustainability Reporting Directive (CSRD), there is a growing gap between international expectations and Japan's regulatory approach.

Recommendations:

The Japanese government should accelerate the development of environmental due diligence and disclosure requirements for companies, including:

- Clear expectations on identifying, assessing, and mitigating environmental risks in global supply chains

- Alignment with international best practices and evolving EU frameworks to ensure compatibility with trade and investment flows
 - Support for companies, especially SMEs, in building capacity to implement sustainable supply chain practices
- Improved supply chain regulations would enhance transparency, reduce environmental harm, and help Japanese and international companies operating in Japan meet global sustainability standards.

■ Renewable Energy Support, Coal Phase Out

Yearly status report: some progress. Japan has made incremental progress in expanding renewable energy, including developments in offshore wind and revisions to grid access rules. However, policy and financial support remain insufficient to unlock the full potential of decarbonized domestic energy sources. Regulatory complexity, limited market access for new entrants, and continued government support for controversial technologies slow down the transition.

At the same time, Japan's coal phase-out commitments remain vague. Recent announcements, such as halting the operation of "inefficient" coal power plants, mostly reiterate previously stated intentions. No clear timeline has been provided for a full exit from coal.

Recommendations:

The Japanese government should:

- Scale up investment and policy support for renewable energy, including streamlined permitting, improved grid access, and financial incentives
- Ensure a level playing field for domestic and foreign companies in the renewable energy sector
- Clearly signal the end of coal power, with a binding timeline and no loopholes based on unproven or high-emission technologies

A credible and ambitious transition strategy is essential to guide private investment and align Japan with its international climate commitments.

■ Carbon Pricing

Yearly status report: some progress. Japan has introduced carbon pricing mechanisms, including a modest carbon tax and the voluntary GX emissions trading scheme launched in 2023. While these are steps in the right direction, current price levels remain far below what is needed to drive meaningful behavioral change among businesses and consumers.

The voluntary nature of current instruments, combined with limited sectoral coverage and low price signals, means most greenhouse gas emissions remain largely unaffected. This weakens incentives for investment in low-carbon technologies and infrastructure.

Recommendations:

The Japanese government should strengthen its carbon pricing framework by:

- Introducing a robust, economy-wide system with meaningful price signals, whether through a carbon tax, emissions trading, or a hybrid model
- Expanding coverage to all major emitting sectors
- Setting clear timelines and predictable price trajectories to guide long-term investment decisions

A credible carbon pricing mechanism is essential to shift financial flows toward low-carbon solutions and ensure that Japan's climate targets are achieved efficiently and equitably.

■ Transparency and Governance in Energy and Climate Policymaking

Yearly Status Report: New. Concerns have been raised by civil society and academic observers regarding the limited transparency and diversity in Japan's policymaking processes, particularly in energy and climate-related committees. Studies have shown that advisory panels are often dominated by representatives from legacy industries, with limited inclusion of independent experts, NGOs, or younger voices.

This lack of diversity can contribute to policy inertia, erode public trust, and lead to unbalanced outcomes that are not aligned with international climate science or societal expectations.

Recommendations:

The Japanese government should improve the governance of sustainability-related policymaking by:

- Ensuring balanced representation in expert committees, including civil society, academia, and independent scientific voices
- Publishing detailed minutes, voting records, and stakeholder inputs to enhance transparency
- Adopting international best practices for inclusive and evidence-based decision-making

Strengthening governance would increase the legitimacy and effectiveness of Japan's sustainability policies and support long-term societal engagement.

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TAX

Introduction

The past year has again been a challenging time. The strength of Japan's economy remains uncertain due to developments in overseas economic activity and prices, as well as the situation surrounding Ukraine and fluctuations in commodity prices. The EBC is grateful for the Japanese Government's efforts to continue proposing new and enhanced tax incentives aimed at revitalising and transforming the Japanese economy.

Notwithstanding the economic shocks due to external factors, the pace of technological change and digital transformation continues to accelerate. The EBC congratulates the establishment of the Digital Agency in September 2021 which is tasked with formulating a digital strategy and making policy recommendations to other ministries and agencies. Key initiatives are designed to stimulate research and development (R&D), bolster domestic production in strategic sectors, and enhance the competitiveness of Japanese enterprises. A notable feature of the reform is the introduction of an "Innovation Box" regime. This allows companies to deduct 30% of qualifying income derived from domestic transfers or licensing of certain intellectual property (IP), such as patents and copyrights related to artificial intelligence (AI) software developed through in-house R&D in Japan. The EBC welcomes these efforts and calls for further focus in these areas to ensure that Japan maintains its global competitiveness.

The Japanese Government has made ambitious pledges regarding climate change and creating a sustainable society, which are supported by tax reform proposals encouraging companies to reduce carbon emissions. The EBC considers that many opportunities remain to expand the scope and scale of tax incentives in this area which should have further positive impact on Japan's attractiveness to foreign investors and individuals.

Japan is an active member of the OCED and should be proud of its role in the continuing global debate on tax avoidance and changes to the international tax system, particularly its restraint on unilateral taxing of the digital economy. Following years of intensive negotiations to update and fundamentally reform international tax rules, the OECD has released Pillar Two model rules for the domestic implementation of 15% global minimum tax which are shortly expected to be introduced into Japan's tax laws. The EBC urges the Japanese Government to keep the rules as simple and practical as possible and consider the introduction of safe harbours. To date, bilateral trade and investment between Europe and Japan benefit significantly from tax certainty, the minimisation of administrative burdens for taxpayers and the mutual elimination of double taxation. The EBC encourages the Japanese Government to continue its efforts in this area. However, Japan's tax treaties with many Member States (i.e. Bulgaria, Czech Republic, Finland, 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. Further, no tax treaties have yet been agreed with Greece (under negotiation), Cyprus or Malta.

In summary, while the EBC appreciates the tax reforms undertaken so far by the Japanese Government, more work is needed to encourage and support inward investment if Japan is to become a competitive hub location for international business.

Key Issues and Recommendations

■ Tax policies to promote innovation

Yearly status report: some progress. Bold incentives are crucial for the Japanese Government to successfully achieve its policy objectives for digital transformation. Previous years' tax reforms further relaxed the requirements for the tax incentives for promoting open innovation and extended the applicability of the incentives, set to expire on 31 March 2022, by two years to 31 March 2024. A notable feature of the reform is the introduction of an "Innovation Box" regime. This allows companies to deduct 30% of qualifying income derived from domestic transfers or licensing of certain intellectual property (IP), such as patents and copyrights related to artificial intelligence (AI) software developed through in-house R&D in Japan.

Recommendation:

- Enhance the scope and scale of innovation tax policy to maintain and improve Japan's international attractiveness as a location for innovation, and consider targeted policies for foreign and start-up companies.

■ Tax policies to reduce carbon emissions

Yearly status report: some progress. The 2021 Tax Reform Proposals included a new "carbon neutrality investment incentive", which provides the opportunity for either accelerated depreciation or a tax credit for companies that invest in assets or infrastructure leading to reduced carbon emissions. The EBC supports the use of tax incentives as a tool to promote behaviour that will reduce carbon emissions, but as with many other tax incentives introduced by the Japanese Government in this and past tax reform proposals, the incentives do not go far enough to stimulate the desired results.

Recommendation:

- Greater use of tax incentives to encourage companies to reduce their carbon emissions. This may be done by one or more of the following: (i) increasing the scope of assets and infrastructure covered by the incentive, (ii) increasing the amount of the tax credit; (iii) simplifying the process for obtaining the tax incentives. Moreover, the Japanese Government should also consider more aggressive use of a high carbon tax as a penalty for failing to reduce carbon emissions, which may be more effective at changing corporate behaviour than the proposed carbon neutrality investment incentive, which rewards reductions in carbon emissions.

■ Centralise local tax

Yearly status report: no progress. While progress has been made in digitalising tax procedures to simplify administration, taxpayers who operate throughout Japan must still 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 due.

Recommendation:

- The EBC recommends centralising 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 taxpayer is located.

■ Income and Inheritance Taxes

Yearly status report: no progress. High income tax rates continue to negatively affect the attraction of new talent and the retention of long-term residents.

Recommendation:

- Consider further tax policy measures such as reducing rates or increasing thresholds to attract international talent and expertise that extend beyond the financial services industry.

■ Streamline expense settlement

Yearly status report: new issue. Japan has made significant strides in digital transformation, particularly through the adoption of cashless payments and secure data systems. Cashless payments and tamperproof systems, along with sensible rules on expense processing eliminated the need for receipts in a large portion of employee expense claims. However, the introduction of the Qualified Invoice System in October 2023 has inadvertently complicated

expense claim processing by newly requiring receipts for almost all transactions, even for small cashless payments. Previously, companies could rely on electronic transaction data from credit card companies for expense claims without needing receipts.

Recommendations:

- Extend the current exemption for travel expense receipts under 30,000 JPY to include a wider range of expenses or payments made using company credit cards by amending Article 49 of the Consumption Tax Act Enforcement Order.
- Eliminate the need for receipts in cases where cashless payments (e.g., company credit cards) automatically link transaction data to expense settlement systems by amending Article 30-9 of the Consumption Tax Act.
- Establish an automated system for payment data integration.
- Provide financial support and guidance to accomplish system updates. Ensure that payment terminal makers, payment network operators, card issuers, and international card brands are able to implement the requirements by providing subsidies to cover related expenses.

■ **Directors' compensation**

Yearly status report: no progress. There has been no further movement on recent tax reforms that relaxed the rules for the deductibility of directors' compensation. The rules governing the deductibility of director compensation do not go far enough to achieve the stated aims of the tax reform to develop Japan as a Global Financial Center.

Recommendation:

- Align the rules in line with international standards and allow deductions for directors' compensation in principle unless there is an identifiable risk that the level of compensation is excessive or unreasonable; or is being used to manipulate the level of taxable income.

■ **Extended tax return filing periods**

Yearly status report: no progress. 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. International comparison of the cost incurred for tax compliance shows that Japan has the highest level among developed countries.

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 further extensions in exceptional cases.

■ **Pillar Two model rules for domestic implementation of a global minimum tax**

Yearly status report: new issue. The rules and guidance published by the OECD define the scope and set out the mechanism for the so-called Global Anti-Base Erosion (GloBE) rules under Pillar Two, which will introduce a global minimum corporate tax rate set at 15%. The GloBE rules provide for a co-ordinated system of taxation intended to ensure large MNE groups pay this minimum level of tax on income arising in each of the jurisdictions in which they operate.

Recommendation:

- The EBC recommends that the introduction of Pillar Two rules in Japan should be minimise administrative burdens and be sensitive to the impact on and overlap with Japanese Controlled Foreign Corporation rules.

■ **Tax treaties**

Yearly status report: progress. Japan recently concluded new tax treaties with Morocco and Colombia and is in negotiations with several other countries to conclude new treaties or update existing treaties. The EBC welcomes treaties that include the exemption of withholding tax on royalties, qualified dividends and interest. However, its treaties with many EU Member States still need to be renegotiated and no treaties have been concluded with Cyprus, Malta or Greece (although a treaty with Greece is under negotiation).

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.

Financial Services

**Banking
Insurance**

Vacant

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BANKING

Introduction

The regulatory landscape for foreign banks in Japan remains marked by both longstanding structural issues and recent areas of incremental reform. While we commend authorities for the clear progress in certain domains such as updates to the AML framework and early steps toward a digital currency regime, the EBC believes that some hurdles remain, that impede the full and efficient participation of foreign banks in the Japanese market. These challenges are particularly evident in the Foreign Bank Agency Business framework, where the current dual-approval system remains cumbersome and out of step with global practices.

Japan's ambition to enhance its role as an international financial centre hinges on its ability to adapt its regulatory systems to the evolving needs of global finance. However, rules rooted in legacy concerns, such as the firewall regulations limiting joined-up banking and securities activities, continue to restrict operational flexibility. Similarly, while discussions are underway on syndicated lending and stablecoin infrastructure, the policy and regulatory responses remain either pending or incomplete.

The Japanese authorities have taken some commendable steps, including the establishment of working groups and forums to explore forward-looking reforms. Yet, the pace and scope of these efforts need to accelerate. Ensuring a level playing field for all market participants—foreign and domestic—requires coordinated adjustments across multiple legal frameworks, including the Banking Act and the Money Lending Act. Without such systemic changes, Japan risks limiting both its competitiveness and the attractiveness of its financial sector to international institutions.

The issues raised in this document reflect practical experiences and persistent concerns from the foreign banking community. They are presented alongside specific recommendations aimed at informing the ongoing dialogue between industry stakeholders and Japanese regulators, with the shared objective of promoting a more open, efficient, and globally integrated financial system.

Key Issues and Recommendations

■ Foreign Bank Agency Business

Yearly status report: no progress. The Foreign Bank Agency Business regime (FBAB) was introduced in 2008. Until then, the Japanese Banking Act had not clearly set out provisions governing cross-border banking services provided by banks, both Japanese and foreign.

While Japanese banks need only file a simple notification, foreign banks are required to obtain specific approval from the FSA if they wish to act as an agent or intermediary on behalf of their head office and branches outside Japan, even though such foreign banks already operate under a banking license in Japan.

In 2017, a partial relaxation was made, allowing foreign banks licensed in Japan to obtain an approval for multiple, rather than individual, overseas branches at once. However, these foreign banks licensed in Japan are still subject to various requirements, including the need to update the detailed profile of each overseas branch on whose behalf they act. The requirement is onerous, particularly for larger institutions with extended global presence. As a result, foreign bank tends to be restrictive in choosing branches covered by the FBAB.

No other major country has such a regime requiring another license/approval in addition to the initial banking license, and the current rule causes unnecessary constraints for foreign banks to provide adapted services to Japanese customers.

Recommendation:

- Japan should fundamentally review the regime in order to increase its profile as an international financial centre.

■ Cross-border payments

Yearly status report: partial progress. The global project to integrate ISO 20022 standards for cross-border payments is ongoing, with an implementation target date at the end of 2025. Meanwhile, under the leadership of G20, a global project is underway to further facilitate speedy and seamless cross-border payments by 2027.

Individual countries may differ in cross-border payments regulations, practices and infrastructure, and Japan is no exception. We encourage Japan to continue to promote user-friendly payment systems consistent with global systems.

Recommendation:

- Authorities and standard setters in Japan and abroad should agree on standardizing a common set of messaging format as early as possible so that financial institutions can prepare timely, ahead of implementation in 2027.

■ AML

Yearly status report: slight progress. In the area of Anti-Money Laundering (AML), Japanese authorities are preparing for the next round of FATF mutual evaluation, after shifting gears from a rules-based to a principles-based approach. In April 2024, the FSA revised its guidance, no longer requiring a strict time limit of 24 hours on the screening of persons under sanctions, and allowing customer “refresh cycles” other than the previously-prescribed “1-2-3 years cycles”, except in situations where additional, higher risks may be considered. Nevertheless, the establishment of a central repository of information on the Ultimate Beneficial Owners (UBOs) of companies, an area for improvement announced by the Government in August 2021 in response to the FATF’s evaluation report of Japan, appears to have encountered some delays. As of April 2025, there is no clear sign of progress on this issue.

Recommendation:

- The Government should expedite their work to establish a central repository of companies’ UBO information.

■ CBDC

Yearly status report: progress. In mid-2023, the FSA introduced a new regime for a Japanese version of Stable Coins, which must be fully backed up by legal tender. The regime, however, has been put on hold until banks establish sufficiently robust risk control and customer protection measures. Meanwhile, the BOJ launched the “CBDC Forum” in summer 2023 to review multiple aspects of CBDC with various financial service providers. The BOJ says there is no imminent need or concrete plan to issue CBDC in Japan, but they are preparing for the future. We monitor further developments.

Recommendation:

- We encourage the BOJ to continue to make timely public progress report on this issue.

■ Firewalls

Yearly status report: no progress. Since the introduction of Japanese Firewall Rules in 1992, restrictions on information sharing have been an obstacle for financial groups that run multiple entities such as banks, securities, asset management firms under the same umbrella and wish to efficiently operate their businesses. Although the FSA deregulated the rule in 2022, allowing for greater flexibility, the dual registration of sales personnel (e.g., for both bank and securities entities) is still not permitted.

Recommendation:

- In the context of efforts towards “Customers’ Best Interests Business Conduct” actively promoted by Japanese authorities, the EBC encourages Japan’s Financial System Council Working Group to restart the discussion, under the auspices of the FSA.

■ Syndicated loans

Yearly status report: new issue. The increase in overseas investments and acquisitions by Japanese corporates has led to a significant increase in the need for syndicated loans in foreign currencies (primarily US Dollars) and to a challenge for Japanese banks to support this activity given their limited access to non-Yen currencies. Large Japanese banks are therefore advocating for a deregulation of the Money Lending Act (MLA) that would allow foreign banks without a presence or banking license in Japan to participate in non-Yen syndicated loans arranged in Japan, thereby adding liquidity to this market and facilitating the arrangement of such loans. This is currently prohibited under the MLA which only allows participation in such loans to foreign financial institutions with established branches and licenses in Japan.

In summer 2024, the FSA launched a Working Group (WG) to discuss this request and released an interim report in early 2025, based on which further discussions are expected. From the standpoint of foreign banks operating in Japan, while such deregulation may benefit those who are strong in the arrangement of syndicated loans by allowing access to a broader pool of potential lenders outside Japan, it may also threaten the level playing field for foreign banks focusing on participation who complied with existing regulations and established a domestic presence and banking licenses in Japan.

Recommendation:

- Should the FSA accept the request and amend the MLA, they should ensure a level playing field by equally amending the Banking Act (e.g., the provisions setting out the Foreign Bank Agency Business regulations) which regulates foreign banks already operating in Japan.

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INSURANCE

Introduction

Population in Japan is shrinking fast (net 2000 decrease per day), population is aging fast (already 30% above 65 years old) and population is getting more and more lonely (nation-wide single households represented 38% in 2020 and should reach around 45% of total households in 2050).

Still, in this challenging context, premium income for insurance industry remains stable and profitability recovered after the COVID stress. Behind this apparent stability, the insurance industry made several negative headlines in the local news about relationship between insurance companies and agents and this may trigger changes in both non-life and life industry.

For life insurers, distribution is not evolving as much as expected.

Tied agents remain the strongest channel. Other agents such as independent financial planners or insurance shops work hard to approach younger generations and pure digital channels do not expand as fast as expected.

Compared to Europe, banks represent a relatively small distribution channel with a very limited scope. Banks do not distribute non-life products and life offering is mostly single premium whole life or fixed annuity products. Competition is very fierce on guaranteed rate of return.

Internally, action is very much on the preparation of the new Economic “ESR” solvency with the first reporting starting with J GAAP closing of March 2026. EBC members benefit from their parents’ experience in Solvency 2 and will contribute to this big step into a new era for the insurance industry in Japan.

European regulators and Japanese FSA share many common objectives. European regulators focus on “value for money” and “product oversight governance” while Japanese FSA is conducting monitoring on “FD” Customer oriented business with adding in 2024 the new “Product governance” dimension. EBC members are keen to contribute to this client focus approach.

Japanese FSA is also introducing in 2024 the Asset Owner Principles and this resonates very much with European approach towards stewardship and sustainability.

Climate risk is also on top of agendas in Europe and Japan.

More than ever, the society and individuals need protection in such an uncertain world. Insurance solutions are related to global issues such ageing well, inclusion and climate transition. EBC members are committed to contribute to deliver useful solutions to the Japanese market.

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. The FSA is steadily working toward the introduction of economic value-based solvency framework in Mar.2026, including the draft amendments to the "Regulation for Enforcement of the Insurance Business Act Pertaining to the Economic Value-Based Solvency Regulatory Framework" and others for public consultation in Oct.2024. Further alignment of local regulatory requirements with the approach of international capital standard such as Solvency II or ICS is crucial for international insurers in Japan.

This would enable them to use the same methodologies in all territories and better develop group-wide risk management strategies. Such a move would, furthermore, 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 information regarding the economic value based advanced regulation framework to the FSA on these issues.

Recommendations:

- Japan should accelerate reforms to achieve convergence between Japanese and global solvency standards such as Solvency II and ICS.
- Japan should consider the approval process of an internal model for risk calculation on a new solvency regulation to evaluate the risk characteristics of each insurer correctly.
- No application of double standards, meaning the internal model framework should be the reference for all reporting on regulatory capital ratios.
- 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.

■ Digitalisation

Yearly status report: some progress. The insurance industry in Japan has been traditionally paper-heavy, however, especially after Covid 19 use of digital solutions are accelerated to further simplify processes, instead of focusing on face to face with paper etc., for added value services. Moreover, the progress of AI technology is remarkable. The insurance industry in Japan is currently seeking the right way to use AI solutions to improve our services for customers, after careful consideration of preventive measures against the potential risks.

Recommendation:

- In setting rules for AI, Japan should continuously take a risk-based approach and carefully consider examples from other countries not to over-regulate, balancing the value creation aspect.

■ Expansion of Japan's role as an international financial centre

Yearly status report: Some progress. The EBC recognises and appreciates that the FSA established Financial Market Entry Office in January 2021 in order to simplify market entry procedure. A dedicated website has also been launched, in addition to the revised Cabinet Office Order to amend the Regulation for Enforcement of the Insurance Business Act. The EBC also appreciates the FSA's tremendous efforts to improve provisions of English material in recent years. The EBC believes simplification of procedures and provision of English materials support foreign entities not only to enter Japan's market, but also retain the business in Japan. In addition, there have been recent proposals to create a special zone for asset management in which administrative procedures can be conducted in English, in order to facilitate the entry of foreign asset managers and others into Japan. The ECB hopes that these developments will have a positive impact on the entry of foreign insurance companies. The ECB is also aware that regulations on asset owners will be considered, but since insurance companies are also asset owners, the ECB will take care to ensure that such regulations do not have a negative impact.

Recommendations:

- The FSA should expand the scopes of materials which can be submitted in English.

- The FSA should make effort to provide English summary at least on their important documents such guidelines, policies, etc. so that foreign insurers can more easily implement and follow them.

■ Personal Data

Yearly status report: Some progress. In line with the EU's GDPR, the regulation of the personal information protection is to be more restricted. The EBC recognises that discussion for the next amendment of the Personal Information Protection Law that is subject to a review every three years is under way which is led by the Personal Information Protection Commission (PPC). The EBC recognises that stricter regulation for use of high protected data such as facial photo data, introduction of injunction by consumer group and administrative monetary penalty system are being considered among other things. The EBC recommends that the FSA, together with PPC, secure clear provisions and issue swift guidelines in relation to the law amendment.

Recommendations

- The FSA should maintain collaboration with PPC in supervision over the evolving areas regarding data privacy to sustain appropriate and swift handling by insurers of personal data of customers.
- The FSA should make sure that the required procedures are not too much complicated and burdensome for the industry, considering the practicality.

■ Distribution practices under fiduciary duties

Yearly status report: some progress. We recognise that the FSA encourages insurers including brokers to conduct its fiduciary duties. Along with promoting fiduciary duties, the FSA has been discussing the product governance and the change of commission structure to be paid to distributors with both insurers and banks, especially for single premium foreign currency denominated products. 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:

- When discussing the product governance, the FSA should take the product licence system in account. (i.g. The notification system instead of the product licence is applied in Europe.)
- 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.
- The FSA should consider relaxing the restriction of abovementioned "koseiin kisei", beyond "third sector" products.
- 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.

■ 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. Proposing suitable insurance products based on a customer's specific needs will become more and more important. For securing effectiveness, banks would need to confirm a customer's intention properly by sorting out each customer's information and needs. From that point of view, the EBC believes it would contribute to the benefit of the customers that banks better utilise customer's private information and financial information to some extent when confirming the customer's intention. Following recent issues in the non-life industry, life insurers have also to review how they have been sending, sometime massively, seconded staff to support banks' product selection and distribution. If the number of secondees has to decrease at banks in the future, the question will be how banks are "replacing" such resources to ensure insurance sales continue to develop.

Recommendations:

- The FSA should consider easing the restriction on using personal and financial information of customers by banks without customer's prior consent
- 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.

■ Product approvals

Yearly status report: no 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. Recently, some product approvals have taken longer which in turn has had a negative effect on the process to introduce new products responding to customers' needs on the market. Especially under these circumstances, a smoother transition is needed when the FSA personnel is rotating, as this would lessen the burden of "having to start all over."

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.
- The FSA should make certain that personnel rotation affects the product approval as little as possible.

■ Fair competition in providing group insurance products to banks

Yearly status report: some progress. The EBC still continues to be concerned by the strong influence of Japanese life-insurers over Japanese banks as their major shareholders, while releasing stocks on non-life side had progress. 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.

Transportation

Airlines
Railways
Telecommunications equipment
Logistics & freight

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AIRLINES

Introduction

While COVID and its effects have subsided, the airline industry continues to face challenges. This is true not only in Japan, but also globally. During the COVID, flights to and from Japan were more than halved. Today, we are seeing inbound traffic that is more or less back to pre-COVID figures. Unfortunately, the outbound traffic from Japan to Europe is still only 65% of what it was pre-COVID 2019. The drop in international travel among especially older Japanese travellers is significant. To further illustrate the drop in outbound traffic, 30% of Japanese citizens held a passport in 2019. Today that figure is only 20%. It is difficult to say whether this will be the new norm, or whether the situation will revert to what it was five years ago.

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 Haneda airport (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.

On a more positive note, 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 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.

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 support the transition to a more sustainable aviation sector, both airlines and governments are introducing and promoting the use of Sustainable Aviation Fuel (SAF). Achieving carbon neutrality will require an estimated 450 million kilolitres of SAF, yet only 300,000 kilolitres were utilised in 2022. A major obstacle to achieving this target is the limited supply of SAF. The EBC believes the Japanese government must take a more proactive approach by presenting a comprehensive roadmap that addresses supply chain challenges and outlines how these targets will be met.

Key Issues and Recommendations

■ 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.

■ Access to aviation fuel

Yearly status report: new issue. Aviation fuel is typically procured at the point of departure, including in Japan. However, recent changes have led to a reduction in the number of fuel suppliers, creating challenges for airlines in securing adequate aviation fuel. This issue has emerged amid a surge in inbound traffic to Japan, driven by a significant increase in tourism. In response, the Government of Japan has acknowledged the problem and announced measures to mitigate the situation. These include utilizing spare tankers to transport fuel from storage facilities to airports and increasing aviation fuel imports. To address the issue sustainably, the EBC calls for further structural reforms to ensure long-term stability in aviation fuel supply.

Recommendations:

- The Government of Japan should continue to implement the already announced plans.
- Japan should liberalise the regulations on who can transport fuel to open up for foreign owned transport companies.
- There should be an overhaul of the approval system on how is allowed to handle aviation fuel. Currently it takes far longer both for the approval and the training to handle aviation fuel compared to other markets.

■ Sustainable aviation fuel

Yearly status report: new issue. Japan, similar to many other countries, has announced that by 2030 airliners are required to use at least 10% Sustainable Aviation Fuel (SAF). There are, however, concerns that there will not be enough supply in Japan to fulfil this requirement.

Recommendation:

- Japan should immediately announce a roadmap for how it intends to support the supply of SAF to the market. This is also needs to cover the whole supply chain.

■ 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 has returned, 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.

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RAILWAYS

Introduction

While exceptions do exist, European suppliers have never had a great presence on the Japan market for railway related products. Despite plenty of efforts, the railway market in Japan continues to be a very domestic market.

On the other hand, Japanese railways manufacturers and railways operators face the reality of decreasing population, limiting the growth of their businesses and decreasing human resources for the operations and maintenances. One recent development is the announcement by JR East and JR West that they will be looking into the possibility of joint development of standards and testing schemes for railway related products and services. The EBC applauds this and will support the potential harmonisation of standards for the Japanese market. If successful this would prove a pivotal change to the fragmented system where, in principle, each operator has its own standards and assessment schemes. This has been pointed out by the EBC as an issue that prevents overseas suppliers to penetrate the Japanese markets, and to successfully invest in Japan. While it currently only involves two operators, albeit the biggest two, the EBC views this as a very important first step. The EBC, furthermore, believes that more operators should look at similar initiatives, and that it is important that the Ministry for Land, Infrastructure, Transport and Tourism (MLIT) takes an active role.

Promoting the globalisation of business amid such challenges, expanding the footprint and offering railways vehicles produced in the region at competitive prices rather than producing and exporting from Japan are the only opportunities for further growth. In this respect, Japan's railways can also be globalised, just as Japan's automobiles industry succeeded in globalising in the previous century. 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 aforementioned global expertise and references provide a good basis for continuing to deepen cooperation between the European Union's railways technology companies and Japanese railways companies looking for Win-Win opportunities.

The EBC commends the collaborative efforts of the European Commission and Japanese ministries, particularly the advancements achieved under the EU-Japan Economic Partnership Agreement (EPA). These include alignment on technical requirements, testing methods, and the acceptance of certifications based on international standards, as well as the extension of public procurement regulations to local governments.

Similarly, while the EU-Japan EPA did bring positive opportunities, the EBC emphasises the importance of building on this progress. Further harmonisation of regulations and standards, alongside the elimination of redundant certifications and testing, is crucial for enabling European companies to operate more effectively in Japan—and vice versa. The EBC also calls for the reactivation of the EPA's technical rules committee to advance mutual recognition of standards and approvals.

On the same note, the EBC believes that the Japanese market would benefit from a national testing and certification scheme which should be 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 for all operators in Japan. It would give the authorities a better oversight on what safety protocols are used when it comes to railway related systems and equipment. Furthermore, this would remove the need to perform an assessment including testing to be repeated and would be beneficial to all operators and suppliers in Japan, whether they are foreign or domestic. The EBC believes that the Ministry of Land, Infrastructure, Transport and Tourism together with Japanese operators should take a greater role to achieve this.

Key Issues and Recommendations

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

Yearly status report: no 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 such as cross acceptance for this industry. The EBC believes that it will be mutually beneficial for Japanese operators to work together with the European operators and suppliers to identify common requirements in new technologies such as 5G communication, train autonomy, AI/IoT (Artificial Intelligence/Internet of Things) for condition-based maintenance (CBM) and cyber security.

Recommendations:

- Japan should establish a working group to identify minimum common requirements acceptable to both private and public railway operators depending on the needs for railway service from society. This could be different for urban networks compared to non-urban networks, and for high speed lines compared to conventional lines and subways.
- 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.
- There should be a system for using certifications and tests results from one operator when marketing products to another operator, to avoid complete or partial repetition of testing already conducted.

■ **Domestic standardisation**

Yearly status report: new issue. In July 2024, JR East and JR West announced an initiative aimed at standardising equipment and components in conventional railcars. This effort seeks to sustain and advance the railway transportation business while ensuring stable transportation services. The initiative is partly in response to systemic changes in the domestic railway market, including shifts in passenger behaviour, a growing labour shortage, and declining domestic production capacity. The EBC views this initiative as a highly positive first step and hopes that other Japanese railway operators will either join this effort or establish their own harmonisation initiatives.

Recommendations:

- The EBC applauds the initiative by the two operators and recommends that all necessary support is given to secure its success.
- More operator shall either join this initiative or set up their own standardisation projects so that Japan can fully benefit from harmonisation of standards.
- It is imperative that the standards developed are made public so that European suppliers can meet and exceed them.
- Japanese authorities should take an active role to promote the completion of the announced initiative and others to come.

■ **Public procurement**

Yearly status report: slight progress. The public procurement market continues to be an important market and with the improved access thanks to the EU-Japan EPA, which resulted in the removal of the Operational Safety Clause. The EBC believes that the Central Government has a role to play to inform and support regional and local government on how to set up procurement procedures that are in line with the WTO GPA (World Trade Organization Government Procurement Agreement) and the EPA. The EBC would also like to point out that when public administration operators become government owned incorporated they are no longer covered by either the WTO GPA or the EPA. This means that the Japanese public procurement will decrease for every year.

Recommendations:

- The Government of Japan should ensure that, when planning renewal of systems with new technologies such as CBTC (Communication-Based Train Control) as well as planning new lines or line extensions, 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.
- The Japanese Government should promote off-the-shelf solutions.

- Incorporated companies that are owned by the government, whether one government such as Osaka Metro, or by several governments, like Tsukuba Express, should be covered by the EPA.
- The EU and Japan should work towards better cooperation and market access in relation to aid financed railway projects. Furthermore, call for tenders should abide by the WTO GPA and the rules on public procurement set out by the EU-Japan EPA.

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TELECOMMUNICATIONS EQUIPMENT

Introduction

Structural reforms under the Government of Japan's ICT Strategy have supported the introduction of high-speed, large-capacity ICT infrastructure, the lowering of communications costs, and the development of e-commerce and e-government. Internet access costs have decreased dramatically and access to broadband is now amongst the most developed in the world. Japan has introduced 5G for users and most investment now focuses on 5G. 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.

The EBC would, however, like to take the opportunity to thank MIC for removing the periodical field inspection requirement for 4G/5G mobile base stations. This is a positive move, and downsides should be minimum with improved remote monitoring technologies.

There are approximately 8.7 billion mobile phone subscriptions globally and 2.1 billion of these are 5G subscriptions. In Japan, which is considered a mature market characterised by advanced data services and the introduction of Long-Term Evolution (LTE) and 5G, smartphone penetration is already at about 97% and is driving mobile broadband growth. 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. For handling this growing demand on mobile networks, Massive MIMO is deployed worldwide for utilizing precious spectrums and sites more efficiently. This is important for 5G and future beyond 5G networks. EBC supports and hopes that Japan will identify how the Massive MIMO ratio, which is clearly lower in Japan, can be increased in the future.

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 Conferences 2019 (WRC-19) and 2023 (WRC-23), especially in relation to the identification of new harmonised spectrums for IMT. 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 and WRC-23 that are harmonised with other markets. Especially for the upper 6GHz band which was identified for IMT in WRC-23 for Region 1 including Europe, the EBC notes that the leading European companies in October 2024 sent an open letter to ask European Commission and European national administrations to make this band available for mobile service.

This area continues to be important for the telecoms industry, and after quite some development in 2018 to 2022, the situation has stabilised. However, the EBC continues to monitor the situation, also in regard to AI which has appeared as an important topic.

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-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, additional band (2.3GHz) in April 2022, and in a process to allocate 4.9GHz band in 2024.

Recommendations:

- Japan should continue working for globally or regionally harmonised spectrum allocations for mobile use.
- Japan should observe the outcomes of Agenda Item 1.2 of WRC-23, especially 6425-7125MHz which is identified for Region 1 and some countries in Region 2 and 3.
- Japan should engage actively in Agenda Item 1.7 of WRC-27.

■ Future-proof radio regulation for mobile equipment

Yearly status report: 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. It is worth pointing out that MIC has removed the requirement of periodical field inspections for 4G/5G mobile base stations. The EBC views this as a very positive step and fully supports the decision of MIC.

Recommendation:

- 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.

■ Harmonisation of fixed microwave regulation

Yearly status report: new issue. The MIC working group for 6/7 GHz microwave equipment is concluding that the regulation for antennas will be relaxed and will fulfil the ETSI standard of Class 3 and 4 antennas in Japan. This is very important for the users of microwave in 6/7 GHz bands. However, the regulation for interference is very complexed and the requirement for IRF (Interference Reduction Factor) will not be relaxed and a consequence of this there are no microwave short haul products based on ETSI standard available for Japan.

Recommendations:

- Japan should also make a study to investigate the relaxation of the requirement to accept ETSI Class 3 and 4 antennas for all licensed bands, such as 11/15/18 GHz.
- MIC should start a new study as soon as possible to update IRF for the other systems (broadcasting systems) so to enable the introduction of global standard equipment that complies with ETSI/ANSI specifications.

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LOGISTICS & FREIGHT

Introduction

The logistics and freight sector continues to face mounting challenges amid shifting global trade dynamics, rising costs, and evolving consumer expectations. While the immediate disruptions caused by the COVID-19 pandemic have largely subsided, the sector remains under pressure due to persistent labour shortages, fragmented digital infrastructure, and increasing demand for faster, more efficient delivery services.

At the same time, the rapid expansion of Business-to-Consumer (B2C) e-commerce continues to reshape the sector. Japan's B2C e-commerce market, now valued at over ¥22 trillion (approx. €140 billion), has seen consistent annual growth, driven by changing consumer habits and digital adoption. This trend puts additional pressure on both domestic and international logistics providers, who must adapt to higher expectations around speed, transparency, and cost-efficiency.

Given these pressures, it is critical that the Japanese Government ensures the efficient and reliable flow of goods—whether medical supplies, industrial components, or consumer products—by promoting policy alignment with international standards. Harmonisation of customs procedures and continued access to open ports and airports are vital. Clear and coordinated regulatory frameworks between Japan and its trading partners will help reduce friction, support businesses, and enable smoother trade flows.

European logistics and freight companies, through their global networks, provide significant value to Japanese consumers and businesses. As cross-border e-commerce volumes continue to rise, it is evident that Japan's regulatory and physical infrastructure must evolve to keep pace. Ongoing issues include a high cost base, aging and congested port infrastructure, inconsistent customs practices, and restrictions on foreign-owned companies in the domestic freight forwarding market. Furthermore, uneven application of regulations across similar service providers has led to inefficiencies and higher costs for end users.

The EBC welcomes recent steps taken by the Japanese Government, particularly in digital customs modernisation and trade facilitation. However, to transform Japan into a competitive and attractive logistics hub, further systemic reforms are required. This includes embracing stakeholder input, aligning domestic regulations with international norms, and investing in infrastructure modernisation.

As we have entered the sixth year of the EU-Japan Economic Partnership Agreement (EPA) trade flows are continuing to increase and highlighted the importance of logistics, as it enables deeper trade relations between the two regions. Regulatory clarity and harmonisation across all EU Member States and Japanese customs regions are essential for businesses to fully leverage the EPA's potential. The EBC would like to take the opportunity to thank both Japan and the European Commission for its hard work to remedy the issues regarding the verification of origin.

The introduction of Japan's Authorised Economic Operator (AEO) programme was expected to reduce administrative burdens and improve customs efficiency. However, many companies report that instead of simplifying procedures, the system has introduced additional compliance requirements. The EBC believes that a review and revision of the AEO framework is needed, with the aim of giving approved operators more flexibility while at the same time also taking more responsibility.

Finally, although the Ministry of Land, Infrastructure, Transport and Tourism (MLIT) has made some progress in business infrastructure reform, further efforts are needed to address inefficiencies in Japan's port system. Port development remains overly fragmented, often led by local authorities rather than coordinated through a national strategy. As a result, Japan continues to lose competitiveness in the region.

Key Issues and Recommendations

■ 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.

Recommendations:

The Government of Japan should:

- Support and enable use of larger vehicles for inter-city movement to reduce the number of vehicles and drivers required. This would also be inline with the new limitations on working hours for truck drivers.
- Allow and encourage the use of autonomous vehicles by delivery companies.
- 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. From 2024, legislation was introduced to prevent drivers from being able to work more than eight consecutive hours. This had a big impact on the domestic logistics sector.

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.
- As the issue with labour shortage is shared by Europe and Japan, the two economies should work closer on this issue.

■ Sustainability

Yearly status report: new issue. The logistics sector is active globally all over the world and plays a major role to reach a carbon neutral society. While there are some progress in Japan, the EBC believes that there is still plenty of improvements that can be made. We are at the same time fully aware that many of the policies are globally decided.

Recommendations:

- The Government of Japan should set goals and initiate subventions to stimulate the industry and the market to invest and use more environmental-friendly logistic processes.
- Japan should together with the EU take the lead to make the logistics sector more sustainable.
- As part of the working hours limitations, Japan should implement policies that make it possible to transport bigger loads, such as double or larger trailers.

■ NACCS

Yearly status report: no progress. 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 has to be duplicated. Examples of these data are: trucking, warehousing, forwarding activities, airlines and shipping activities. There are still many legacy components.

Recommendations:

- NACCS should be more accessible for non-registered companies. This would also improve the compliance efforts of companies.
- Japan should expand NACCS so that more data related to logistics can be included and accessed as well.
- Expanding the number of entries that can be made on one declaration. The current 99 lines are too few.

■ 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.
- Together with digitalisation, Japan should also modernise the process and just not make a manual process digital. Try to eliminate some of the requirements.

Health Science

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

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IVD (IN VITRO DIAGNOSTICS)

Introduction

COVID-19, which caused a pandemic for over three years, from December 2019 to 2023, highlighted the extremely important role of In Vitro Diagnostics (IVD) in diagnosing infections, understanding disease conditions, and predicting prognoses. Additionally, the importance of establishing an environment where accurate tests can be supplied and conducted stably was widely recognized.

Taking a helicopter view of the healthcare system in Japan, it is under increasing pressure to overhaul it due to the effects of the ageing society, declining birth rate, and rising national healthcare costs. Serious discussions on the value and role of diagnostics & IVDs are crucial to achieve the Government's objectives of "improvement of the quality of medical care" and "optimisation of medical costs". The current COVID-19 pandemic has greatly accelerated the discussion on these elements, not only in the field of medical practices, but also on the governance of the medical systems.

For example, based on the experience with COVID-19, an emergency approval system was introduced under the Pharmaceutical and Medical Device Act in response to outbreaks of emerging infectious diseases, but issues remain regarding the reimbursement system for emerging infectious diseases for which the timing and scale of outbreaks are difficult to predict. It is hoped that a system will be established in the future that will enable necessary tests to be made available to the medical community as quickly and appropriately as possible.

From the perspective of international harmonization, discussions are underway to revise the definition of IVD to include not only disease diagnosis but also prevention and risk assessment. Additionally, there are discussions on standardizing review requirements and improving reliance.

The medical reimbursement system for IVDs has been under discussion since 2007 between the Japanese Promotion Council for Laboratory Testing (JPCLT), IVD industry associations, incl. EBC, and the Ministry of Health, Labour and Welfare (MHLW). EBC acknowledges that these activities influenced the Government's policy and they led to rise in IVD fees. In addition, the "Act to Partially Amend the Medical Care Act" enacted in 2018 clarified the assurance of quality and accuracy in laboratory testing. Additionally, the revision scheduled for fiscal year 2024 recognized the introduction of marketability evaluation related to the assessment of innovations, as well as a challenge application system.

The clinical application of innovative technologies, such as next-generation sequencing, is rapidly advancing. In the current COVID-19 pandemic, it is re-acknowledged that "Speedy access to novel IVDs" and "proper reimbursement for diagnostic tests reflecting the clinical value" are critical elements for improving the quality of medical care and for promptly providing patients with advanced medical care.

Finally, digital health has become an important topic in IVDs. Diagnostic test results are more and more utilised as digital data in variety fields, e.g., diagnosis based on digital images, prediction of prognosis, among others. Under these circumstances, the IVD industry will put more focus on this new field.

The EBC Committee on Medical Devices & IVD and IVD Group will make recommendations for international coordination based on foreign trends. We will, moreover, continue to work with the JPCLT and other IVD industry organisations to contribute to healthcare by promptly introducing and appropriately using laboratory tests of high social and clinical significance, as well as to educate the general public about the value of testing.

Ambu
B. Braun Aesculap Japan
Beckman Coulter Japan
BioMerieux Japan
Biotronik Japan
CathWorks Japan
Coloplast
Corcym Japan
Dornier MedTech Japan
Draeger Medical Japan
Edaptechnomed

Elekta
Gunze Medical
Integral
Japan Lifeline
Japan MDC
Jin Healthcare Consulting
LivaNova Japan
Maruho
Medis medical imaging systems
Molnlycke Health Care
Nippon BXI

PARI Japan
Philips Japan
Radiometer
Roche Diagnostics
Siemens Healthcare
Telix Pharmaceuticals Japan
Thermo Fisher Diagnostics
TR3
Varian Medical Systems
Vorpall Technologies

Key Issues and Suggestions

■ Establish a system to prepare for emerging infectious disease outbreaks

Annual status report: Ongoing. The May 2022 revision of the Pharmaceutical and Medical Device Act established an emergency approval system. In September 2023, the "Cabinet Agency for Infectious Disease Crisis Management" was established in the Cabinet Secretariat to prepare for the next infectious disease crisis. In addition, Infectious Disease Control Department was newly established within MHLW. When the National Institute of Health Crisis Management is established in April 2025, we will advance our collaboration with it.

Recommendations:

- IVD industry and other clinical laboratory testing-related organizations should be involved in discussions on the development of a process and system for outbreaks of emerging infectious diseases.
- IVD related organizations should request the discussion on promoting the development of diagnostic tests related to emerging infectious diseases and on establishing a stable supply system are .

■ Global harmonisation in definition and classification of IVDs

Yearly status report: Ongoing In the next revision of the Pharmaceuticals and Medical Devices Act, there will be no changes to the classification and definition of IVD under the Act. However, the importance of regulations tailored to the characteristics of IVD has been recognized, and it will continue to be a topic of discussion.

Recommendation:

- EBC requests proper regulations for classification (currently classified under Pharma) and definitions/scopes, based on the special characteristics of IVDs.

■ Proper assessment of medical values and innovativeness of IVDs

Yearly status report: Good progress. The medical value and innovativeness of IVDs have not been directly reflected to reimbursement point discussion. In the 2024 revision of the medical fee, a "marketability premium" was recognized as one of the innovation evaluations in IVDs. Additionally, a challenge application system was also introduced.

Recommendation:

- One of the utilities of IVDs is "cost-effectiveness" (efficiency in healthcare). EBC requests the inclusion of cost-effectiveness evaluation as an assessment criterion for the usefulness and innovativeness of tests.

■ Contribution to "High-quality community medical care" through POCT

Yearly status report: Ongoing. To build an integrated community care system, it is necessary to strengthen primary care and the functions of family doctors. By conducting Point-of-Care Testing (POCT) in primary care settings, early assessment of disease conditions, appropriate patient management, and collaborative interventions with acute care can be expected to reduce the severity of patient outcomes.

Recommendations:

- IVD industries request
- the establishment of a medical fee system that appropriately evaluates Point-of-Care Testing (POCT) in primary care.

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MEDICAL EQUIPMENT

Introduction

Japan's national healthcare expenditure in fiscal 2023 reached a level exceeding 8% of gross domestic product, and aging and increasing chronic diseases continue to weigh heavily on healthcare financials. Promotion of medical innovation and optimization of medical expenditure are still the most important issues. However, the digitalisation of medical sites and improvement of labour productivity are not sufficiently advanced, and structural issues remain. In particular, uneven distribution of specialists and shortage of human resources, the damage to medical institution management due to delayed response to infectious diseases, as well as soaring raw material cost and exchange rate fluctuations due to geopolitical risks, pose a new threat to the stable supply system for medical care.

Under these circumstances, in order for Japan's healthcare system to continue functioning sustainably and stably, a paradigm shift is essential—one that not only reforms the system itself but also shifts the focus toward healthcare that maintains health and *prevents* illness. This transformation must be accompanied by the social implementation of technological innovations such as digital health and the safe and effective use of medical data to improve the efficiency of healthcare services.

The use of AI • IoT to monitor patient conditions, detect abnormal conditions at an early stage, and secure sharing of diagnostic findings enables timely and appropriate medical intervention. This helps to reduce the burden on patients, curtail medical costs, and thereby extend the healthy life expectancy and maintain the workforce.

Furthermore, securing a stable supply is an urgent issue. The segmentation of the global supply chain and the volatility of exchange rates and prices have a serious impact on Japan, which is heavily dependent on imports of medical equipment and pharmaceuticals. It is necessary to establish a strategic supply system and a transparent procurement system.

The key to the smooth introduction of innovative healthcare technologies is the development of an innovation assessment system and the improvement of predictability and speed in Insurance reimbursement. In Europe, UNBRERA (Unified Benefit-Risk Evaluation for Rapid Access) has been advocated as a more comprehensive system in addition to DiGA (digital health applications) as a framework for medical apps and digital treatments, and both rapid assessments based on scientific evidence and accessibility support are being achieved. In Japan, discussions should also take into account the introduction of a similar framework.

Although some functionality has been introduced to allow viewing of health checkup and medication information using the My Number Card, progress in integrating this with personal health records (PHRs) has been slow, and the overall vision for digital transformation in healthcare remains insufficient. For the social implementation of cloud-based medical infrastructure and software-based medical devices—such as the permanent establishment of online medical consultations, incentivizing healthcare institutions to adopt cloud systems through reimbursement revisions, and the use of telemedicine and remote caregiving monitoring—international harmonization is essential. This must take into account regulations such as the European Union's General Data Protection Regulation (GDPR) and cybersecurity measures. Continued efforts to promote foreign direct investment (FDI) are also necessary.

EBC Medical equipment and IVD Committee will continue to promote policy-making activities utilising the following in order to contribute to the structural reform of the Japanese healthcare system and industry by taking advantage of advanced European technologies and institutions.

- Access to regulatory and technological developments overseas, including in the Europe
- Insights from a diverse range of member companies and a highly specialised reimbursement committee
- A proven policy network with government agencies, the Japanese Parliament, and academic associations
- Strengthening private-sector policy proposals through collaboration with related domestic organizations

Based on these, EBC will continue to contribute to the upgrading of the Japanese healthcare system and the strengthening of the stable supply system, as well as to the enhancement of the global competitiveness of the healthcare Industry.

Ambu	Elekta	PARI Japan
B. Braun Aesculap Japan	Gunze Medical	Philips Japan
Beckman Coulter Japan	Integral	Radiometer
BioMerieux Japan	Japan Lifeline	Roche Diagnostics
Biotronik Japan	Japan MDC	Siemens Healthcare
CathWorks Japan	Jin Healthcare Consulting	Telix Pharmaceuticals Japan
Coloplast	LivaNova Japan	Thermo Fisher Diagnostics
Corcym Japan	Maruho	TR3
Dornier MedTech Japan	Medis medical imaging systems	Varian Medical Systems
Draeger Medical Japan	Molnlycke Health Care	Vorpal Technologies
Edaptechnomed	Nippon BXI	

Key Issues and Recommendations

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

Yearly Status Report: progress. Functional classification exceptions as a means to promote innovation are continuing. In addition, rapid addition as an effective means for eliminating device lag is continuing, which the EBC views positively. Integrating (rationalisation) of newly classified products in the C application with existing classifications is contrary to the innovation assessment of lowering the price of innovative products and raising the price of products that do not.

Recommendations:

- To ensure transparency and predictability, Japanese authorities should share the specific reasons for the rationalisation study and to secure the time to agree and consultation with the rationalisation proposal.
- The EBC recommends that newly established functional categories under Category C not be subject to revision for a certain period after their initial designation.

■ Foreign Price Reference System (Measures to Ensure Stable Supply)

Annual status report: no progress Under the previous revision (R4), if the highest price in the case of three or more foreign countries exceeds the additive average of the other prices by 1.6 times, it was revised to deem the highest price to be equivalent to 1.6 times the additive average of the other prices.

Recommendations:

- The EBC recommends the abolition of the Foreign Price Recalculation (FPR) system. In the event that abolition is not possible, the EBC recommends not implementing price reductions when the foreign average price (calculated without applying the outlier exclusion rule and using the arithmetic mean) is equal to or less than 1.0 times the domestic price, and easing the current 50% cap on price reductions.
- The EBC recommends that, from the perspective of ensuring a stable supply, functional classifications where the hospital delivery price exceeds the reimbursement price (i.e., inverse Z2 conditions) be excluded from the scope of the Foreign Price Recalculation (FPR) system.
- The EBC also recommends that products priced at 1.25 times the foreign price comparison level, as well as newly listed and repriced products, be excluded from review under the FPR system.

■ Treatment of the cost accounting method

Yearly status report: new issue. Base material prices for newly listed products are, in principle, calculated by the similar function comparison method. However, if the price is 0.5 times or less of the foreign average price there is a system for applying calculation using the cost calculation method. However, since there is no foreign price for products that have not yet been released in foreign countries, this rule is not applicable.

Recommendation:

- In order to secure the stable supply of the products which have not been released in foreign countries, the price lower limit in the cost accounting system should be used.

■ Clarification of unprofitable products (measures to ensure stable supply)

Yearly status report: new issue. The requirements and criteria for unprofitable product requests are unclear, making it difficult for companies to submit such requests.

Recommendations:

- The EBC recommends establishing clear criteria for cases where multiple products exist within the same functional category.
- The EBC also recommends that the Ministry of Health, Labour and Welfare (MHLW) provides support to academic societies in preparing request documents for the continued supply of essential products.

■ **Reevaluation of Insurance application system (challenges) according to actual usage**

Yearly Status Report: Progress. The C1 and C2 challenge mechanisms, which allow for re-evaluation based on actual usage data, have been institutionalised. This has opened a pathway for company-initiated re-evaluations. When obtaining the right to challenge, submission of a research protocol is required, and in some cases, trials to verify additional clinical usefulness may take a significant amount of time.

Recommendation:

- The EBC recommends that the evaluation period required to obtain the right to challenge (under the C1 and C2 mechanisms) be set at three years.

■ **Evaluation to improve medical treatment efficiency and reduce the burden on medical practitioners (work style reform/hatarakikata kaikaku)**

Annual status report: no progress. Since the cap system for overtime working hours will also be eligible for doctors from 2024, there is an urgent need to reform the way healthcare professionals work. It is said that ICT and task-shifting will be effective for these issues, and it is thought that the use of diagnostic imaging programs such as Medical equipment and remote ICU systems can resolve the excessive labour of doctors. However, under the current medical reimbursement system, these functions that contribute to workstyle reform are not being recognised or evaluated, and their adoption by medical institutions has been slow.

Recommendation:

- The EBC recommends that functions contributing to workstyle reform be appropriately recognized and evaluated under the medical reimbursement system.

■ **Scope of application of programmes for medical devices including artificial intelligence and insurance coverage**

Yearly Status Report: Significant progress. A new Japanese version of DiGA was approved in two stages and insurance was institutionalised. The evaluation and medical treatment system was also adopted at the initial phase, and the policy to control the barrier to entry of the start-up enterprises and to support the popularisation of the innovation was decided.

Recommendation:

- The EBC recommends continuing to propose the use of the “Selected Medical Care” system (*Sentaku Ryōyō*) as a second-step option within the two-step approval and reimbursement framework. The EBC also recommends highlighting functions that contribute to workstyle reform as a key discussion point in these proposals.

■ **Proper evaluation of nuclear medicine diagnosis and treatment.**

Yearly Status Report: Progress. A long-standing legal and regulatory double standard exists regarding the in-hospital production and delivery of positron emission tomography (PET) imaging agents used in PET scans, under both general law and the Pharmaceuticals and Medical Devices (PMD) Act. Additionally, while the reimbursement system previously covered PET imaging agents only through a bundled technical fee (due to the absence of an official drug price), a double standard has emerged with therapeutic PET imaging adjuncts, for which both a drug price and a separate technical fee for PET imaging have now been newly established.

Recommendation:

- PET examinations using PET diagnostic reagents are based only on previous applications for medical technology assessment proposals. The EBC proposes the establishment of a new medical fee system so that approval companies can apply for Insurance application for PET testing technology fees and diagnostic reagents.

■ **Global standards for clinical evaluation**

Yearly status report: negative progress. Devices used in clinical trials now include investigational devices, control devices, and combination devices, making it necessary to collect safety information in accordance

with Japan-specific regulations.

Recommendation:

- Japan shall review the status and requirements regarding the collection of safety information for reference devices and combination devices, and investigate the impact on the implementation of international joint trials.

■ **Audit system adapted to characteristics of program medical equipment**

Yearly status report: progress. Collaboration between the reinforced review departments within the Ministry of Health, Labour and Welfare (MHLW) and the PMDA, and the industry — efforts aimed at identifying and resolving issues.

Recommendations:

- Establishment of regulations and examination systems should be based on characteristics. The EBC requests that a new early approval system is introduced utilising real-world data.
- The EBC recommends that the basic concept for applying the two-step approval system to Software as a Medical Device (SaMD) be clearly outlined through official guidance or other means.

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PHARMACEUTICALS

Introduction

Although overall healthcare costs in Japan are rising with the aging population, statistics show that total pharmaceutical market has been well under control with the various pricing systems introduced in the recent years.

Pharmaceutical market: Japan's healthcare spending in fiscal year 2022 increased by 3.7% (1.66 trillion yen) to 46.7 trillion yen. Medical cost per capita is 373,700 yen which is an increase of 4.2% compared to the previous year. Although the pharmaceutical market size reported by Ministry of Health, Labour and Welfare has not been publicly available since 2017 data, it was reported to be 11.3 trillion yen, increase of 3.1% compared to the previous year, according to IQVIA. However, after the drastic pricing system reform in 2018, price revision in relation to the consumption tax increase on October 2019 was conducted on all products as well as the first off-year price revision was conducted in fiscal year 2021. As such, drug price revision has technically been conducted every year since 2018. A reduction of 120 billion yen (healthcare cost basis) was made in the price revision of 2024.

NHI pricing system reform: The drug pricing system reform of 2024 was implemented with the aim of "strengthening drug discovery capabilities and eliminating drug lag/drug loss". That was positive for promoting innovation, as including recognition of rapid introduction of innovative drugs into Japan and evaluation of drug development for pediatric use. It is critical to continue the positive flow of innovation to further enhance the attractiveness of Japan's pharmaceutical market as an investment target for the development of innovative drugs and to prevent new drug lag/drug loss.

Off-year price revision: As for the off-year price revision 2025, the pharmaceutical industry side had repeatedly argued that it is not the right timing to implement the revision, since the situation of inflation, price discrepancy between NHI and market price, concerns about stable supply, the situation of drug lag/drug loss, and the attractiveness of the Japanese market are different from those when the four Ministers agreed. However, the off-year price revision was carried out with "reduction of the national economic burden," "promotion of drug discovery innovation," and "securing of stable supply" as the basic principle. We consider that there were issues in terms of the flow toward innovation promotion through the system reform 2024, and policy consistency.

CEA/HTA (Cost-Effectiveness Analysis/Health Technology Assessment): Since the full-scale operation began in 2019, the system has been organized through revisions in every two years. The revision 2024 has improved the transparency of the cost-effectiveness assessment system to a certain extent, but still faces challenges. For example, the process is opaque and the criteria for selecting the items to be evaluated are ambiguous, there is insufficient scientific evidence to determine the cost-effectiveness, incentives for innovation may not function if the price adjustment range is expanded in the future, and patient involvement is limited. Reflecting upon the learnings from European countries, expanding the scope of CEA/HTA price adjustment and potentially being used as reimbursement decision-making may not only impede patient access to innovative medicine but may also lead to further drug-lag / losses as it undermines the predictability of prices. Additionally, all stakeholders, including academics, government and industries, are affected by significant operational burdens. The CEA/HTA must not become a system which leads to further drug price containment, as Japan already has several effective systems for controlling drug prices. The CEA/HTA should be maintained as it is since its principled position as complementary to the NHI system, as we can learn from the European lessons learnt of the significant challenges.

Introduction of new regulatory system: Recently, increasing number of drugs that are not developed in Japan in spite that those drugs are approved in overseas, so called 'drug loss', is becoming an issue in Japan, and MHLW panel reviewed regulations for drug development/approval to enhance introduction of medically necessary drugs, and also from the viewpoint of securing robust and efficient quality and stable supply of drugs, etc. As a result, notifications regarding orphan drug designation, pediatric development, and the necessity of Japanese data have been issued, and discussions have also begun on establishing a clinical trial ecosystem. Improvements to pharmaceutical regulations and systems should be continued to reduce drug loss and lag. Likewise in relation to management of manufacturing process, the introduction of moderate modifications (trials) are also being considered. In addition, during the discussion towards the revision of Pharmaceuticals and Medical Devices Act, it has been proposed to review GMP compliance inspections, etc,

and further discussions is expected to be held. Future considerations seek the establishment of a pharmaceutical regulatory system concerning quality, including GMP compliance investigations, with a view towards international harmonization.

EFPIA Japan Member Companies

Alexion Pharma	Ipsen Pharma Japan
AstraZeneca	LEO Pharma
Bayer Yakuhin	Lundbeck Japan
Bracco Japan	Merck Biopharma
Chugai Pharmaceutical	Nihon Servier
CSL Behring	Nippon Boehringer Ingelheim
Ferring Pharmaceuticals	Novartis Pharma
GE Healthcare Japan	Novo Nordisk Pharma
Genmab	Nxera Pharma Japan
GlaxoSmithKline	Sanofi
Guerbet Japan	UCB Japan

Key Issues and Recommendations

■ Drug pricing system

Yearly status report: some progress.

Recommendations:

- It is necessary to examine the impact of evaluation on the rapid introduction of innovative drugs in Japan and the development of pediatric drugs, which were enhanced through the drug pricing system reform 2024.
- The rules for calculating the price of new drugs should be designed to ensure that innovation is properly evaluated and to avoid significantly lower drug prices in Japan compared to those in Europe and the US.
- For post-launch, it is necessary to examine the way in which the drug price revision system should be, taking the latest situation of drug distribution into account.
- The current rules for calculating NHI drug prices have become a very complicated system due to repeated reviews, and should be revised to a simpler, easier-to-understand and more transparent system.

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

Yearly status report: No Progress. The expanded use of HTA including revision of price adjustment scope significantly impairs predictability with regard to prospective drug prices and access, thereby undermining the position of the Japanese pharmaceutical market in the globe.

Recommendations:

- Results of HTA should not impede or delay patients access to new medicines. Thus, the principle set out when the HTA system was introduced in 2019, which complements the NHI pricing system, should be maintained.
- The evaluation system should embrace assessments for additional benefits and values of new medicines, as the current system relies heavily on cost/QALY values. Therefore, it is necessary to incorporate additional evaluation items and to further improve the analysis and evaluation methods.
- Especially, medicines for rare diseases, including designated incurable diseases, should be thoroughly excluded from the scope.
 - There is absolutely no need for additional HTA selections for post-listing designation due to market expansion and/or additional indications, as multiple recalculation systems are already implemented.
 - If the post-listing designation mechanism were to be implemented, price adjustments beyond the initial additional usefulness premiums or equivalent could be possible, which would deviate from the principle of complementing the drug price system and should be strictly forbidden.

■ International harmonisation (clinical trial environment)

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

Recommendations:

- Although various efforts to date to improve clinical trial efficiency have improved the environment for conducting clinical trials in Japan, it is essential to make improvements to achieve more efficient clinical trial operations compared to international standards in order to continue to develop innovative drugs.
- Active discussions are being held among industry, government, and academia regarding improvements towards achieving efficient clinical trial operations. These improvements include the introduction of DCT (Decentralized Clinical Trial), promotion of RBA (Risk Based Approach) and cost rationalization, improvement of case accumulation capacity at individual sites, introduction of FMV (Fair Market Value) and consolidation of IRBs. Early realization of these improvements is anticipated.

■ New scheme related to new drug review and approval

Yearly status report: some progress.

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, "Senkuteiki Iyakuhin (Pioneering drugs)" (legislation of "Sakigake designation system"), "Specific use drugs, etc." designation

system, and "Conditional early approval system" were implemented on Sep 1st, 2020. For their operations, preparation of related laws based on the actual state and improvement in the relevant organisational structure and efficient implementation are required.

- Efficient implementation are required for the orphan drug designation and for the regulatory requirement to promote development of pediatric medicinal products. In addition, we propose improvement of the requirement for Japanese data (the need for Japanese Phase 1 studies in case of participation in international clinical studies).
- There is a room for further improvement in the approval review scheme for innovative new drugs in Japan compared to the U.S. and Europe. For example, in order for innovative new drugs to be approved in Japan without delay from the U.S. and Europe, a scheme similar to the Real Time Oncology Review in FDA, which is already in place in the U.S. and starts the review of new drug approval based on key results from a confirmatory clinical trial, should be introduced in Japan. We propose that a scheme similar to the Real Time Oncology Review, be introduced in Japan to shorten the period between a formal application and an approval.
- The PACMP system was established prior to TECHNICAL AND REGULATORY CONSIDERATIONS FOR PHARMACEUTICAL PRODUCT LIFECYCLE MANAGEMENT (ICH-Q12), but there appears to have been little progress in utilizing this system since its implementation on 1 August 2021 due to various factors. The relevant notifications and regulations should be reviewed to make the system more user-friendly.
- The following are proposed based upon the discussion in the MHLW panel: The review system of procedures for change control for the manufacturing process (including specifications and test methods, etc) and GMP compliance inspection system (inspection based on the risk of the manufacturing site, etc), and acceptance of the Western pharmacopoeia (USP/EP) as the official Pharmacopoeia equivalent to the JP.

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VACCINES

Introduction

On April 1, 2014, the "Basic Plan on Immunization," which is a medium- to long-term vision for future immunizations, was applied as a basic plan to promote immunization measures comprehensively and systematically in consideration of the history of immunization administration. The eight issues included in the plan are as follows.

1. Basic Policy on the Comprehensive and Systematic Promotion of Measures Related to Immunization
2. Matters related to the division of roles related to vaccination among the national government, local governments, and other related parties
3. Goals related to the comprehensive and systematic promotion of vaccination measures
4. Basic Matters for Promoting Measures for the Proper Implementation of Vaccination
5. Basic matters for promoting measures to promote research and development of vaccination and securing the supply of vaccines
6. Basic Matters for Promoting Measures to Improve the Effectiveness and Safety of Vaccination
7. Matters Concerning International Cooperation on Immunization
8. Other important matters related to the comprehensive and systematic promotion of vaccination measures

Though it states that "This plan will be reviewed at least every five years in accordance with the Immunization Act, and will be changed when deemed necessary," it has never been revised due to the pandemic of the COVID-19 and other reasons.

The EFPIA Japan Vaccine Working Team (VWT), in collaboration with three other vaccine-related Trade Associations (Japan Association of Vaccine Industries: JAVI, Japan Pharmaceutical Manufacturers Association: JPMA and Pharmaceutical Research and Manufacturers of America : PhRMA; collectively "4 Dantai"), made "Recommendations on the development of a promotion system from vaccine research and development to practical application and routine vaccination based on the Basic Strategy for Infectious Disease Prevention (excluding those related to the Pharmaceuticals and Medical Devices Act)." In August 2022, we submitted a request to the Immunization Office, MHLW.

Taking this opportunity, discussions between the Immunization Office and 4 Dantai were started to review the basic plan, and following points: "Incentivize the vaccines with high development priority," "Digitization of vaccination history," "Comprehensive and systematic promotion of measures related to vaccination," and "Review of the overall system for the purpose of life course immunization." 4 Dantai including the EFPIA Japan VWT, made statements on these four points at the 32nd meeting of the Immunization and Vaccine Subcommittee of the Health Science Council held on May 24, 2023.

Also at the same time, to simplify the national test of vaccines, we are proceeding with discussions between 4 Dantai, including the EFPIA Japan VWT, and the Pharmaceuticals and Pharmacies Division of MHLW. One of the issues is the speeding up and simplification of national test using the Summary Lot Protocol (SLP), which is strongly promoted through industry-government collaboration, and regular discussions are being held for the revision of the law. EFPIA aims to realize this by strengthening its efforts to reach out to national stakeholders and relevant authorities in collaboration with other organizations.

Furthermore, various modalities, including monoclonal antibody, have been developed to prevent infectious diseases in addition to vaccines, and antibody drugs for the prevention of RSV infection are already being used as NIP (National Immunization Program) in developed countries around the world. In terms of Japan's immunization policy, the EFPIA Japan VWT is advocating for those involved in policymaking while hearing to the opinions of legal experts to determine whether or not these are included in the "vaccines" under the Immunization Act.

Based on these findings, a revised draft of the "Basic Plan on Immunization" was released at the 66th meeting of the Immunization and Vaccine Subcommittee of the Health Science Council held on December 26, 2024, and many of the requests of the 4 Dantai, including the EFPIA Japan VWT, were incorporated into the changes, including the above, and will be notified by the end of this fiscal year pending final deliberations.

In the current revision of the basic plan for immunization, discussions were held while institutional studies related to NIP category A and B, which require revision of the Immunization Act, have not been started, so the EFPIA Japan VWT will play a central role in making requests, including a large-scale review of the Immunization Act, in cooperation with three other vaccine-related organizations.

EFPIA Japan Member Companies

Alexion Pharma	Ipsen Pharma Japan
AstraZeneca	LEO Pharma
Bayer Yakuhin	Lundbeck Japan
Bracco Japan	Merck Biopharma
Chugai Pharmaceutical	Nihon Servier
CSL Behring	Nippon Boehringer Ingelheim
Ferring Pharmaceuticals	Novartis Pharma
GE Healthcare Japan	Novo Nordisk Pharma
Genmab	Nxera Pharma Japan
GlaxoSmithKline	Sanofi
Guerbet Japan	UCB Japan

Key Issues and Recommendations

■ Raising awareness to increase vaccination for the adult and elderly

Yearly status report In Progress. In order to identify the real barriers to the spread of Life Course Immunization and to collect the opinions of academia to remove them, we held the "Life Course Immunization Seminar for the 100-Year Life Era". As a result, academia provided an opinion to the government to accelerate NIP discussion on Shingles vaccination.

Recommendation:

- The progress of the above review is slow, and it is necessary to appeal to the government in lockstep with the voices of other vaccine-related trade associations. To this end, it is necessary to regularly exchange opinions with other associations, take initiatives in collaboration with academia, which is one of EFPIA Japan's strengths, and conduct smooth discussions.

■ Further improvement of national test process and international harmonization of regulatory requirements

Yearly status report In Progress. As a result of long-standing discussions among industry, academia, and government, the national test process in Japan is gradually improving. As a way of national test, a policy was also presented that formulations that meet certain criteria could be examined only by SLP, and several products that were accepted for SLP-only examination in accordance with the standards were also selected.

On the other hand, many vaccines are required to be tested by the national standard, and it is still difficult to say that the double burden has been resolved. Imported products are exported from the country of origin after undergoing their national test, but even after importation, Japan's national test system often requires that Japan conduct tests again in accordance with Japan's unique biologics standards.

The submission of test samples for national test involves the National Institute of Infectious Diseases (NIID), the MHLW, and prefectural officials, and the coordination work is a burden on companies. Even in the case of paper-only testing using SLP, the revision of the Pharmaceuticals and Medical Devices Act proposes that the presence of prefectural officials is not required for sample extraction, but the method of sampling is basically sampling in Japan, and we believe that it is necessary to review the inefficient system. For example, if it is possible to randomly sample vaccines in advance at overseas factories and send them directly to the NIID, the lead time for the supply of imported vaccines will be shortened. Discussions continue to be held on how to improve the efficiency of direct provision of specimen samples and how to conduct national testing for SLP only.

On the other hand, it is necessary to discuss and confirm new operational changes to whether or not the national test will be necessitated by the Japan Institute for Health Security (JIHS), which will be established in April 2025. In addition, it is necessary to discuss whether the method of pre-approval inspection should really be a requirement for approval, or whether it will be abolished, and a new framework will be established if only technology is to be transferred to prepare for national test.

EFPIA Japan VWT will continue to request that products that have passed at least the national test in Europe and the United States be examined only by SLP, and that the national test be made more efficient, such as streamlining the submission of samples.

In addition, regarding the fact that it is very difficult to introduce bio-derived raw materials in Japan because the information on bio-derived raw materials contained in the Master Cell Bank/Master Seed of vaccines that have been widely used in Europe and other countries for a long time does not meet the bio-derived raw material standards, 4 Dantai, including EFPIA Japan VWT, has proposed a review of the bio-derived raw material standards, and AMED research groups are currently discussing them. Exemptions for vaccines with a clinical track record of 20 to 30 years have been formulated and studies are underway to make it possible to apply them.

Recommendations:

- Strengthen cooperation between the reviewers (Pharmaceuticals and Medical Devices Agency and MHLW) and the testing organizations (prefectures and NIID) to improve the efficiency of pharmaceutical review and assay functions.
- Review of sampling methods so that overseas manufacturing facilities can also take test samples.
- Reduction of the number of certified lots by utilizing SLP and expansion of SLP-only items, including newly approved products

■ **Promote the development of vaccines with high development priorities and accelerate discussions on NIP vaccination**

Annual Status Report: In Progress. It is noted in the draft revision of the next Basic Plan: "In order to expedite the study of NIP, we will start collecting and organizing the necessary information after development and before regulatory approval and consider making it possible to request the preparation of a Factsheet promptly after regulatory approval. In addition, we will consider regulatory measures such as PMDA consultation to support early practical application." It is an achievement that the next Basic Plan includes the early consideration of NIP of necessary vaccines, which has been continuously advocated in the "Incentivize Vaccines with High Development Priority" by 4 Dantai, including EFPIA Japan VWT. In addition, MHLW is currently selecting the next high-priority vaccine for development in accordance with the revised Basic Plan, and it is necessary to monitor it. Herpes zoster vaccines, high-dose influenza vaccines, and RSV vaccines have already been selected from EFPIA Japan member companies.

Recommendation:

- Improving the predictability of NIP is being incorporated into the government's basic policy, and we will promote the creation of clear criteria for NIP and the creation of a system that allows discussions on NIP to begin even before the vaccine is approved. In addition, the financial impact of NIP is touched upon in the next Basic Plan, and EFPIA Japan will propose the creation of an environment in which Japan citizens are protected from preventable diseases regardless of financial barriers.

Vacant

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COSMETICS & QUASI-DRUGS

Introduction

The European Cosmetic and Quasi-Drugs industry works to ensure the quality, efficacy, safety, and environmental sustainability of its products by investing in research and development of new ingredients and monitoring global developments in science. At the same time 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 consumers live a healthy lifestyle, 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.

The cosmetics shipment value in Japan in 2023 was 1.29 trillion yen. Japan imported cosmetics worth 377.07 billion yen in 2023, of which imports from Europe were worth approximately 121.58 billion yen*. This proves 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 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. There is also a low degree of harmonisation between Japan's 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. Europe 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 can therefore be difficult to deploy some products on the Japanese market promptly. 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 share of Japan's luxury cosmetics market, and 11% of sales were parallel imports, according to past research studies. 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 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, 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 Europe and Japan in the International Cooperation on Cosmetic Regulation (ICCR), which meets to discuss how to promote multilateral regulatory coordination and harmonisation to minimise barriers to trade, while maintaining the highest level of global consumer protection.

*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. In 2021, MHLW revised its approval standards for feminine care products, hair colouring products, permanent wave products, and medicated toothpastes, and issued a new notice. In addition, the standard for quasi-drug raw materials was revised as "the quasi-drug raw material specification 2021." In July 2019, PMDA revised the mockup for the application for marketing approval for quasi-drugs (cosmetics for pharmaceuticals) and added an illustration on how to treat the standard of the appended ingredients and the test method in the case where the standard is the same as the appended standard of the approved item. Along with these developments, progress has been made in improving the simplification and speed of application and examination operations. 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. As a recent topic, the Council for Promoting Regulatory Reform has asked the MHLW to consider transitioning to garbage and eye washes, which are thought to have less effect on the human body, in light of the need for the transition to quasi-drugs for some of the Group III Pharmaceuticals, and asked for a conclusion within FY2026.

Recommendations:

- For quasi-drugs deemed to be identical and similar to approval quasi-drugs, the review period should be continued to be shortened.
- When modifying the review approach, the changes should be clearly announced during the briefing session for practitioners applying for quasi-drug approval. Additionally, applicants should receive clear and concise explanations to ensure they fully understand the updates.

■ Efficiency of notifications and applications for approval of cosmetics and quasi-drugs

Yearly status report: no progress. In accordance with the Digital Procedures Act, MHLW began operating online submissions in May 2021 for certain notifications or applications related to quasi-drugs and cosmetics, which had previously been required to be submitted using floppy disks and other storage media. From July 2022, the scope of operations for online submissions has been gradually expanded. This was expected to improve convenience at the time of submission, but the system simply replaced on-line the submission of applications, notices, etc. prepared using the Ministry of Health, Labour and Welfare's electronic application software for Pharmaceuticals, etc. developed in April 2005. Even when an application is submitted online, a revenue stamp for payment of the fee or a return envelope, such as an approval or certificate issued on paper, is required to be sent by mail. In addition, in the event of a change in the notified matters, etc., a change notice shall be submitted for each item within a certain period of time after the change, with the exception of some cases. Therefore, a large amount of clerical work may occur in a short period of time on both the company side and the administrative side. If the changes are identical, more efficient operation should be possible, for example, by expanding the conditions under which multiple items can be notified of changes in a lump sum. In addition, due to the lack of linkage between prefectural, PMDA and customs systems, procedures are required for the present of notifications and applications related to the manufacturing and marketing of Cosmetics & quasi-drugs, notifications related to export products, and submission of documents required for import customs clearance. It is hoped that the establishment of a system that enables the simplification and streamlining of administrative procedures for Cosmetics & quasi-drugs permitting and import procedures will lead to the realisation of "digitalisation," which is stated in the national digital governance action plan.

Recommendations:

- Improvements to the Ministry of Health, Labour and Welfare's electronic application software for Pharmaceuticals, etc., simplification of application and notification preparation businesses by reconsidering the content of descriptions and the necessity of materials required to be submitted, and linkage between application software and online submission system should realize streamlining from preparation to submission and issuance of approval, etc.
- A one-stop service for administrative procedures should be realized by linking the application and notification system with the system used at the time of customs clearance.

■ Applying the same standards to all market participants

Yearly status report: no progress. 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.

■ Advertising representation for cosmetics and quasi-drugs

Yearly status report: no progress. Regarding the efficacies for cosmetics, 55 indications applicable to cosmetics were stipulated in the 2000 Notify of "Revision of the Scope of Indications for Cosmetics." In 2011, an additional indication was added to the indication of "Reduces the appearance of fine lines caused by dryness." 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.

The Japanese cosmetics industry is 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 realisation of healthy long-lived social. Daily care by cosmetics and quasi-drugs, such as wet care for atopic skin and use of suntan products to prevent skin cancer, plays an important role in maintaining health and improving the quality of life, and contributing to disease prevention and thereby curbing medical costs. Current advertising regulations, however, do not allow the importance of such care to be promoted.

It is also stated that "illustration of experience and presentation of indications for indications" should not be made because it is not objectively underpinned and there is a risk that consumers may be misled about the efficacy, etc. or safety. This is an important factor and often used by the consumer when choosing particular product. Furthermore, given the continuing trend of growth in the number of mail order users, the opinions of those experienced in use have become increasingly important information for consumers. If it is possible to post user experience statements in the advertising of cosmetics, it will be possible to respond to the diversification of consumer demand and to communicate a wide range of information to consumers.

Recommendations:

- Limitations on advertising expressions should be eased so that the role of routine care using cosmetics and quasi-drugs, such as health maintenance and disease prevention, can also be promoted.
- "Consumers' experience" should be allowed to be used in advertising.

■ Establishment of alternatives to animal testing

Yearly status report: Slight progress. The promotion of alternative method to animal experiment for the pharmaceutical application is of great interest to cosmetics companies, both European and Japanese, on the Japanese market. However, no new guidance has been issued since 2023 on alternative methods that can be used for regulatory filings. There are also testing methods that have limited coverage even with the existing guidance, and the hurdles for introducing cosmetic ingredients that are widely used in Europe to Japan remain high. In 2023, the International Cooperative Initiative on Safety of Cosmetics (International Collaboration on Cosmetics Safety: ICCS) was launched, and activities are being carried out with an emphasis on promoting the introduction of next-generation risk assessments (Next Generation Risk Assessment:NGRA) that do not rely on animal testing. However, discussions on NGRA and new safety assessment methods (New Approach Methodologies: NAMs) among Japanese regulators and on future administrative use are still in the very early stages.

Recommendations:

- Japanese regulatory authorities should promote more active use of alternatives to animal experiments, including NAMs, in regulatory applications. Japan should also actively promote initiatives for the future

adoption and regulatory integration of scientifically sound safety risk assessment methods that do not rely on animal testing, fostering innovation in the cosmetics industry.

Consumer Goods

Liquor
Food & agriculture

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LIQUOR

Introduction

Europe is the leading exporter of liquor and wine worldwide and the Japanese alcoholic beverages market is one of the largest in the world, behind only China and the US, with estimated annual sales surpassing 3 trillion yen. Foreign liquor imports in 2024 were at 384 billion yen (according to Japan Customs). Among the total imports, Europe, including Turkey, represented about 80%. This, however, is only a mere 13% of the total Japanese market.

In 2024, imports of wines came in at 151 billion yen and 98 billion yen for sparkling wines, including champagnes. Together, they took up about 47% of total imports of alcoholic beverages. This is by far the biggest segment of alcohol. European whiskies are also an important category with a value of 57 billion yen in 2024, followed by wine-based spirits such as Cognac and brandies (7.13 billion yen in 2024). Traditional local categories such as sake, shochu, beer, umeshu (plum liqueurs) and local brandy will continue to decline, as the consumer base is shrinking and younger demographics find other, trendier categories more appealing, such as wines and champagnes.

For many years, international alcohol industry importers and local leading producers in Japan have invested in building a portfolio of brands of a premium nature with high standards of quality. A product defect in relation to any of our brands can destroy brand equity and the reputation of brand owners at a global level. Traceability information enables efficient and targeted responses to product safety incidents, without serious trade disruption. Where a recall is deemed necessary, it is critical that the brand manufacturer's original lot code be easily identified to rapidly implement the recall. By implementing these provisions, Japan aligns itself to food safety measures adopted by other jurisdictions, including in the European Union, the United States, the United Kingdom and Australia. In the United States for example, US regulations prohibit the alteration, removal and/or destruction of any mark, brand or label on alcoholic beverage containers that are sold on the market.

The EBC has called on the Japanese Government since 2010 to take more proactive measures to resolve the issue and protect the safety of Japanese consumers. The EBC thus welcomes the NTAs intent to issue regulation to address the issue as expressed in meetings with the JWSIA and other sector associations this April and stands ready to work with the NTA on such draft regulation. We have been informed by the JWSIA that, in a meeting with the NTA, the agency shared their intention to take action to solve this issue. We believe that this opens up a window of opportunity to address this long-standing issue. This was then followed by another meeting with the NTA on 21 April 2023. During this meeting, the NTA indicated that it would like to exchange opinions with industry (JWSIA and other industry associations in the alcoholic beverages sector) toward the enactment of a system as an administrative measure limited (including the necessity of the system). JWSIA have agreed with that proposal and believe that we could gain a foothold and make real progress in resolving the lot-code issue in Japan.

Key Issues and Recommendations

■ Lot Codes and Decoded Products

Yearly status report: good progress. In Japan, the display of producer lot codes (traceability information) on liquor products is not mandatory, although it is recommended in the administrative guidelines of the Ministry of Health, Labour and Welfare (MHLW). The importance of traceability information has been recognized by regulators in key regions and countries of the European Union, the United States, Australia and Great Britain amongst others such as Singapore. 31 out of 34 OECD countries mandate the use of lot codes on the labels or containers of alcoholic beverages and prohibit the removal, tampering with and covering up of lot codes.

Recommendations:

To ensure the effective and efficient recall of prepacked food, we recommend putting in place regulation at the NTA level that:

- Specify that the lot identification system be based on the brand manufacturer's original lot code, which should be determined in each case by the producer, manufacturer or packager of the prepacked food. This specification is critical to ensuring that an importer, reseller or retailer cannot add a sticker with their own "lot identification" to cover the one originally put on the bottle during the production process, thereby nullifying the use of such an identification system for traceability purposes.
- Specify that tampering with / removing lot identification is illegal and that strict sanctions are foreseen to restrict the import, distribution, and sale of products without original lot identifications or with removed/tampered lot identification at the point of importation, as well as restricting the sale of products whose original lot code was in any way defaced or covered.

Moreover, to ensure that all businesses are able to fully comply with the proposed amendments, we would like to seek clarity on the following points:

- That lot codes are not required to be placed only on labels, but instead can be permanently affixed or displayed in other manners, including being embossed, laser-etched on bottles or applied by other means
- That if a system for registering lot codes with the authorities is established, the associated administrative requirements be kept to a minimum, in order to reduce burden and ensure efficiency for both the authorities and industry.

■ Wine definition

Yearly status report: no progress. A loose wine definition opens allows for a variety of products to be sold as "wine" thus misleading Japanese consumers and creating unfair competition for European wines, which meet the international accepted definition.

Recommendation:

- 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.

■ Alcohol drinking guideline and content labelling

Yearly status report: slow progress. In March 2021, a Cabinet decision mandated that the National Tax Agency (NTA) should promptly consider including alcohol content in grams on bottles and cans. Following this decision, the Ministry of Health, Labour and Welfare (MHLW) published the "Guidelines on Health-Conscious Drinking" in February 2024. These guidelines detail the potential health risks associated with harmful alcohol consumption and emphasize the need to consider individual health conditions when consuming alcohol. The guidelines define net alcohol intake thresholds that increase the risk of lifestyle diseases: For men: 40 grams or more per day; and for women: 20 grams or more per day. While the guidelines provide a framework for understanding alcohol-related health risks, the specific details on how to display pure alcohol content in grams on product packaging are yet to be confirmed.

Recommendations:

- The European Business Council (EBC) supports Japan's implementation of specific guidelines.
- The EBC urges Japan to follow international standards on serving units for alcohol gram presentation to ensure consistency and clarity for consumers.

These steps reflect good progress in aligning Japan's alcohol consumption guidelines and labeling practices with international health standards, promoting informed and responsible drinking habits among consumers.

- The EBC supports Japan implemented specific guideline, and urges Japan to follow international standards on serving unit for alcohol gram presentation.

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FOOD & AGRICULTURE

Introduction

With the implementation and entry into force of the EU-Japan EPA, together with the Switzerland – Japan FTA, European food has very much increased its presence in Japan. The EBC believes this trend will continue as more and more consumer on the Japanese market are experiencing high-quality food products from Europe. Similarly, supplier of food and agricultural products are now viewing the Japanese market as a market that is no longer out of reach.

One very important component of the EU-Japan EPA is the quota system, or the Tariff Rate Quotas (TRQs) in Japan. The 25 TRQs offer lower duty for a limited volume. While the administration of some of the TRQs during the initial period were difficult to apply improvements have been made. For instance, volume that has not been used are released earlier which the EBC very much appreciates. It is, however, difficult not to point out that some TRQs are still not optimally utilised. For instance, cream is covered by many different categories.

In addition to tariffs, a range of non-tariff, food-related barriers continues to affect the availability of European products in Japan. For instance, Japan remains out of step with international standards, having yet to approve many food additives and enzymes deemed safe by the Codex Alimentarius. Although sanitary and phytosanitary issues are addressed in the EPA, the agreement currently contains only broad language regarding the expected benefits for suppliers and importers. It is therefore crucial for both authorities to continue working toward greater alignment, particularly to address the issue of duplicate testing. At present, imported goods often require additional testing in Japan due to the lack of harmonisation or mutual recognition of test methods. While some progress has been made, re-testing for the Japanese market remains common.

The EBC is eager to collaborate closely with all relevant stakeholders in the Government of Japan and the European Commission to drive meaningful, positive change that supports the goal of offering Japanese consumers a broader selection of safe, high-quality food. We strongly hope that the EPA will deliver on its commitments—abolishing or reducing tariffs, harmonising standards, and enabling mutual recognition of market authorisations. The EBC Food & Agriculture Committee firmly believes these goals can be achieved without compromising food safety. Greater alignment will increase product variety on supermarket shelves, foster healthy competition in the food and agricultural sectors of both regions, and make European food more accessible—something we know Japanese consumers would welcome.

Key Issues and Recommendations

■ Food additives, enzymes and processing aids

Yearly status report: progress. Differences in the lists of approved additives and enzymes between Japan and other major markets remain common. Notable examples include iodised salt, amidated pectin, and TBHQ. While the EBC acknowledges progress in Japan's approval of certain additives, the overall process continues to present significant challenges.

The EU and Japan should leverage the EPA to further enhance cooperation in this area. Despite earlier expectations that the EPA would lead to faster approval times, there is still considerable room for improvement. In some cases, the regulatory logic appears inconsistent—for instance, sorbic acid is permitted in jams but prohibited if the jam is diluted, even though the concentration of the additive is lower.

Recommendations:

- Japan should harmonise its definition of food additives by excluding processing aids—substances that are no longer active in the final product after manufacturing.
- Japan should ensure that standards of use in Japan are not in conflict with international standards of use, such as potassium sorbate and nutrition fortifiers.
- Japan should also harmonise the specifications of food additives, such as purity, definition of specific food additives and size of molecules.
- Japan should not set up unique requirements/practices for enzyme registration. An example is artificial gastric digestion data.
- Japan should make certain that approval times are decreased as discussed in the EPA. Currently, the consultation period can be very long.

■ Food contact

Yearly status report: some progress. Materials that come into contact with food—such as wrapping, packaging, plates, and cups—must comply with the requirements set out in Japan's Food Sanitation Act. Japan has introduced a positive list of materials permitted for such use. However, this framework has posed challenges for foreign organizations, primarily due to the lack of timely and comprehensive information available in English.

One particular area of concern is mechanically recycled food contact materials, for which there appears to be no international harmonisation. According to the guidelines notified on 28 March 2024, mechanically recycled resins must comply with Japan's positive list. As a result, food products packaged in mechanically recycled synthetic resin cannot be exported to Japan unless the exporter can demonstrate that the source of the waste resin aligns with the Japanese positive list.

Although the positive list is now finalised, delays in publishing the amendments in English have caused many foreign packaging manufacturers to postpone their compliance assessments. Consequently, food manufacturers and importers face uncertainty regarding whether their products meet Japanese regulatory requirements.

Recommendations:

- Japan should allow resins allowed in the EU and the US.
- Japan should urgently that all legislation and official guidance is available in English. This would avoid any misunderstandings.
- Japan should provide guidance on how to know which polymer group a specific compound belongs to. Currently some compounds are classified differently in Japan.
- Japan should make it possible for overseas producers to apply directly in regard to having compounds approved, as this would deal with the issue of confidentiality.
- Japan should make use of ISO standards as tests methods, as to avoid specific testing for the Japan market.
- Considering current sustainability conscious circumstances, Japan should develop a scheme to accept mechanically recycled synthetic resin from waste resin in EU as food contact material. This would also be in line with sustainability goals.

■ Labelling

Yearly status report: no progress. 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 stay 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. Furthermore, with increased use of connected devices by consumer, the EU and Japan should engage in discussions on how to best come up with guidelines on how to use digital labelling to complement and for certain information replace printed labelling.

Recommendations:

- Japan should allow alternative best before dates if this is properly explained on the label of the products, such as DDMMYYYY. This is currently possible for pet food.
- The EU and Japan should discuss the use of QR codes and other digital solution as a labelling method to complement the labelling that is affixed to the product.

■ Testing and approvals

Yearly status report: no progress. Many European products are subject to frequent and costly testing to gain approval for importation or sale in the Japanese market. Examples include tests for cyanide, radioactivity, microbiological contamination (such as coliforms), and heavy metals. The EBC believes that, in many cases, testing and certifications conducted in Europe should be accepted. However, this is often not possible due to the lack of harmonised testing methods and standards between Japan and Europe.

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.
- Japan should abolish testing that has to be carried out at every importation.

■ Organic

Yearly status report: progress. The EU and Japan have maintained an organic equivalence arrangement for plant-based organic products since before the EPA. Thanks to successful improvements over the years, this arrangement now functions effectively. However, it is limited to products of plant origin and excludes organic products of animal origin.

Given the EU's strong offering of organic products, the EBC encourages the EU and Japanese authorities—together with EU Member States—to pursue discussions aimed at expanding the scope of the agreement to include animal-based organic products. It is worth noting that Japan already has comprehensive organic equivalence agreements with the United States, Canada, Switzerland, and Australia, covering both plant and animal products.

As the current arrangement for plant-based products is set to expire in 2026, it is also essential that the EU and Japan begin negotiations toward a new bilateral organic equivalence agreement to ensure continuity and broaden its scope.

Recommendation:

- The EU and Japan should continue the positive talks on mutual recognition of organic foods with animal origin.

■ Shelf-life and sustainability

Yearly status report: new issue. While this issue is not based on any law or regulation, food products or beverages that do not have at least 2/3 left of the shelf-life when reaching the supermarkets, or any other retail outlet, are difficult to sell. This poses a particular challenge for European products, which often require longer transportation times due to distance. However, the issue also affects domestic products that, despite still being safe for consumption, are often discarded as they approach the end of their shelf life—contributing unnecessarily to food waste.

The EBC believes that authorities have a responsibility to promote greater sustainability within the food and beverage sector. A study conducted by the Ministry of Agriculture, Forestry and Fisheries on consumer attitudes toward sustainability could provide a useful starting point for further discussion and policy development.

Recommendations:

- Japan should promote sustainability in the food and beverage sector and as part of this better explain that food can safely be bought and consumed during the shelf-life.
- Increase consumer awareness of the importance of sustainable food products, from farm to table, including supply chain, packaging and labelling.

■ Tariffs & quotas

Yearly status report: good progress. With the implementation of the EU-Japan EPA and the corresponding reduction or removal of tariffs, market access for EU products has improved. The administration of tariff rate quotas (TRQs) has also become more efficient, despite initial teething problems. The EBC is optimistic that these developments will lead to a greater presence of European food products in the shopping bags of Japanese consumers. However, it is essential that these liberalisations are carried out without resorting to overly stringent safeguard measures and that the administration of TRQs continues to improve.

Recommendations:

- TRQ11 should be re-defined so that drink related products (coffee and tea) and food related products (food preparations and dough) are put in two different TRQs.
- The TRQ23 is currently subdivided into many categories. This makes it difficult to get an overview of the segment.

Industry

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

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AUTOMOBILE

Introduction

This report provides an overview of the Japanese motor vehicle market as a whole, and specific proposals for the following issues that the EBC Automobile Committee considers to be challenges: **(1) electrification/Green transformation (GX), (2) Digital transformation (DX) (including automated/autonomous driving), (3) introduction of International Whole Vehicle Type Approval (IWVTA), (4) automobile recycling, and (5) tax reform.**

[Japan's overall motor vehicle market]

Looking back at the domestic motor vehicle market in 2023, the number of new vehicles sold (registered vehicles and kei cars combined) was 4,779,086 units (up 13.8% from the previous year) and sales of registered vehicles alone also increased, reaching approximately 3.03 million units. Sales of foreign-brand four-wheelers, mainly European cars, in 2023 increased 2.5% year-on-year to 248,329 units, marking the first year-on-year increase in two years since 2021. In particular, sales of imported BEVs reached 22,890 units, exceeding 20,000 units for the first time. It was 1.6 times the result of 2022, posting record high figures for five years in a row.

In the first half of 2024, the number of new vehicles registered was about 1.4 million units, which was the first time in two years that first-half sales fell below the previous year. Sales of foreign-brand vehicles were down 7.2 percent from a year earlier to 113,887 units.

(1) Electrification/Green Transformation (GX)

Imported EVs continued to sell well at 10,785 units, up 16.7 percent from a year ago. The background to this is the ongoing and seamless subsidy policy for electrified vehicles, which JAIA had requested, contributed greatly. We would like to express our gratitude once again. In this rapidly changing market, EBC Automobile Committee member companies will continue to accelerate the introduction of BEVs, PHEVs and other new models equipped with advanced safety and environmental technologies. Meanwhile, compared to other major G7 countries, Japan still has many challenges to overcome in terms of selling xEVs and installing the infrastructure necessary for their widespread use, although some progress has been made. Last year, establishing a study group on promoting the development of charging infrastructure, the government published the "Guidelines for Promoting the Development of Charging Infrastructure," in October doubling the previous target for the installation of chargers by 2030 from 150,000 charging points to 300,000 sockets. The EBC hopes that the government's infrastructure development policies will be steadily implemented in the future.

As it is necessary to accelerate the spread of xEVs, which contributes to achieving carbon neutrality, we request the government to continue to provide uninterrupted, ongoing support for subsidies for the purchase of xEVs, and to consider broad and flexible review of eligibility requirements for subsidies. In addition, to achieve carbon neutrality, it is important not only to focus on electric passenger cars, but also on electrifying commercial vehicles such as buses and trucks and using hydrogen.

Further, we would like to express our gratitude to the authorities for the system reforms made to electrical technology standards last October, which have made it possible to provide high-voltage, high-output (DC1,000V/350kW) charging at levels comparable to those in Europe and the United States. Going forward, since basic charging is still not sufficient, particularly in urban areas, it will be important to improve basic charging facilities, including in apartment complexes and improve public charging facilities around residential areas to supplement it, promote the installation of chargers on public roads, as well as create mechanisms for temporary exits to alleviate charging congestion on expressways as en-

route charging (for example, use of chargers outside expressways near interchanges), and develop charging infrastructure in tower parking lots and mechanical parking systems, etc. We hope that the installation of chargers on public roads will further expand and will be rolled out to regional areas.

Furthermore, regarding the reuse and recycling of batteries, which are essential for promoting electrification, the European Battery Regulation came into force in July, providing clear provisions on recycling and reuse, etc. We will continue to closely monitor developments in other countries, including this regulation, and will work closely with relevant authorities and businesses to take appropriate measures to promote the recycling and reuse of batteries throughout their life cycle.

(2) Digital transformation (DX) (including automated/autonomous driving)

The Japanese government launched the Mobility DX Study Group in FY2023 to address themes related to wireless and technology connections, including automated/autonomous driving, and the EBC Automobile Committee has been closely monitoring the content of the study group. In May of this year, the study group published the Mobility DX Strategy, setting DX as a competitive axis alongside GX in the future of automobiles and mobility. In particular, it states that Software Defined Vehicles (SDVs) will be regarded as a competitive area and promoted from 2030 to 2035. The EBC Automobile Committee will continue to gather information with an eye toward the evolution of automated/autonomous driving technology.

We will also continue to call for the international harmonization of radio and communication technologies and for system reforms to bring software updates via OTA into line with the times, as it has previously requested.

(3) Introduction of International Whole Vehicle Type Approval (IWVTA)

Regarding safety and regulatory harmonization issues, the EBC Automobile Committee has continued to work toward the complete abolition of NTM and the realization of a "full IWVTA (International Whole Vehicle Type Approval)" as one of its most important issues. The Automobile Committee will continue to review implementation status with relevant parties and will continue to request further promotion of international harmonization of vehicle regulations and the realization of a "complete IWVTA."

(4) Automobile recycling

A major development regarding automobile recycling was the announcement of proposed ELV regulations in Europe last July. In Japan, discussions are also underway regarding the use of recycled plastics as part of promoting the circular economy. The EBC Automobile Committee will continue to closely monitor the progress of the institutionalization of recycled plastics in Japan.

(5) Tax reform

Finally, with regard to taxation, in order to promote the spread of next-generation vehicles that contribute to carbon neutrality, we would like to request to avoid any system reform that leads to an increase in the burden on users, and consider tax reforms to accelerate the spread of these vehicles, and make auto-related taxes simplified with user burdens drastically reduced, as we have stated before.

The EBC Automobile Committee continues to support the EU and Japan's goal of achieving a truly fair and open market.

Key Issues and Proposals

■ Electrification/Green transformation (GX)

Annual status report: Progress made. We are extremely grateful that the government has implemented the subsidy program for purchasing xEVs seamlessly and continuously in the FY2024 budget (FY2023 supplementary budget), and has also requested approximately 100 billion yen for FY2025. Additionally, the government launched a study group last year on promoting the development of charging infrastructure. In response, the system was revised in September 2024, making it possible to charge at high-voltage, high output (DC 1,000V/350kW) on par with Europe and the United States. In addition, Tokyo and other local governments are expanding subsidies for purchasing xEVs. Starting in 2025, Tokyo will require the installation of charging equipment in all new apartment buildings.

Recommendations:

- We would like to request that the government continue to provide uninterrupted support for subsidies for the purchase of xEVs and that broad and flexible consideration be given in the review of eligibility requirements. In order to achieve carbon neutrality, it is important not only to focus on electrified passenger cars, but also on electrified commercial vehicles such as buses and trucks and using hydrogen.
- Furthermore, from the perspective of shortening charging time and increasing convenience for users, it is necessary to improve the charging conditions by quantitatively and qualitatively expanding basic charging, en-route charging, and destination charging, and particularly by implementing measures such as deregulation aimed at increasing output power. Specifically, we request the following:
 1. The current basic charging system is still insufficient, so improve basic charging facilities, including those in apartment complexes, and public charging facilities around residential areas to supplement them.
 2. In suburban areas, the majority of users live in detached houses, but since there is currently no subsidy for installing standard chargers, subsidies for basic charging equipment, including for detached houses, should be enhanced.
 3. Early realization of expanding subsidies for standard chargers over 6kW
 4. Early realization of institutional deregulation for high-voltage chargers, etc. and expansion of subsidies for chargers installed in shopping malls, etc.
 5. Supporting the promotion of installing chargers on public roads
 6. Eliminating congestion on expressways due to en-route charging (e.g. proactively utilizing chargers off expressways near interchanges)
 7. Development of charging infrastructure for mechanical parking systems, including tower parking systems, in urban areas, which remains an urgent issue.
- If an institutional framework is considered to promote the recycling and reuse of batteries, it will be important to establish an appropriate scheme so that imported vehicles will be able to comply. If calculation of the carbon footprint (CPF) of batteries is required, we would like you to consider introducing it in an internationally harmonized manner.

■ Digital transformation (DX) (including automated/autonomous driving)

Annual status report: Progress made. The government announced its Mobility DX Strategy in May 2025. It stated that it would promote public-private partnerships and cross-industry collaborative efforts in the areas of SDVs, mobility services, and data utilization, and it is important to keep a close eye on its progress, along with the Early Harvest Project for autonomous driving. Regarding the CS/SU management system conformity certification, which was a prerequisite for the application for approval of SU for in-use vehicles, which we have been requesting since last year, we highly appreciate the timely action of the authorities to enable overseas OEMs to utilize the CS/SU management system conformity certificates they have obtained from their overseas authorities. However, it would be desirable to further streamline procedures for obtaining approval for software updates for vehicles in use. *Annual status report: Progress made.*

Recommendations:

- In order to realize swift market action and improve convenience for consumers, the government should review the streamlining of application procedures for permits for specified modifications to registered vehicles.
- In the light of the fact that in-vehicle software can now be updated quickly over-the-air and that electronic vehicle inspections using advanced OBD (on-board diagnostics) are beginning to be introduced, in the future, we should consider introducing a more rational electronic vehicle inspection system that utilizes ISO 20730, as well as a recall system that is in line with the times, assuming greater use of Over-the-Air (OTA) technology.
- 433.92MHz: In November 2024, Japanese government ensured that TPMS/RKE using the 433MHz band would be partially harmonized by the end of the fiscal year, for which EBC automobile committee appreciates very much. However, full harmonization with EU/USA regulation has not been achieved, and we hope that reforms will continue to be made for fully international harmonization.

■ Introduction of International Whole Vehicle Type Approval (IWVTA)

Annual status report: Some progress made. We are grateful to the authorities for their initiatives which have led to progress in international harmonization of regulations and certification year by year and the reduction of many non-tariff barriers towards the realization of a complete IWVTA. However, although international harmonization is progressing, even after the introduction of the IWVTA system in July 2018, the harmonization of regulations for devices subject to the IWVTA is insufficient, such as those for exhaust gas, fuel economy, and electricity consumption of passenger cars (UN-R154). In addition, there are still devices and systems that are not covered by IWVTA and therefore the use of IWVTA (UN-R0) has not progressed. In particular, Japanese government agreed to work together on the streamlining of vehicle certification since autumn last year, and have been holding detailed discussions since then. We submitted requests outlining the following: 1) Consistency of application documents for vehicle type designation, etc. with those for IWVTA, and 2) Regarding information that is not directly required for vehicle certification review and is necessary for procedures such as inspection, registration, and modification, the necessary data should be submitted to the authorities at the time when that information is required, and we have begun reviewing certification procedures such as certification implementation guidelines together with the government.

Recommendations:

- Japan should aim to establish a complete mutual recognition of whole vehicle type approval (IWVTA) between Japan and Europe at an early date.
- Aiming for IWVTA, we should move forward with international harmonization of Japan's unique requirements, such as the definition of identical vehicle types.
- Furthermore, we should proceed with streamlining completion inspections for type designations that utilize equipment type approvals obtained overseas.

■ Automobile Recycling

Annual status report: New. The use of recycled plastics in automobile recycling is being considered, and if automobiles become a target product, it will be necessary to consider how to respond to the imposition of usage plans, regular reports, and the obligation to use recycled plastics, etc. In Europe, a draft ELV regulation was presented last year, and consideration is being given to making the use of recycled plastics, including those derived from automobiles, mandatory.

Recommendations:

- On the premise that we support the promotion of a circular economy itself, if automobiles are included in the products for which the mandatory use of recycled plastics is required, we would like to ask that the timing and content of implementation be internationally harmonized, taking into account trends such as the European ELV regulations that are scheduled to be enacted in the future, and that consideration be given to providing a sufficient preparation period for implementation.

■ Tax reform

Annual status report: Some progress made. A fundamental review of auto-related taxes is scheduled to take place by the end of fiscal 2025, when the current eco-car tax incentives expire.

Recommendations:

- The penetration of electric vehicles (EVs) in Japan is currently at a low level, and it is necessary to accelerate the spread of xEVs, which will contribute to achieving carbon neutrality. System reforms that lead to increased burdens on users should be avoided, and we request that tax reforms be considered to accelerate the spread of xEVs, such as EVs, PHEVs, and FCVs.
- Japanese car owners are subject to excessive and complicated taxes compared to other countries. We would like to see simplification of auto-related taxes and a drastic reduction in the burden on users (such as the abolition of the environmental performance levy on automobile purchases).

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AUTOMOTIVE COMPONENTS & AFTERMARKET

Introduction

The automotive industry is transforming at a breathtaking speed. With the introduction of autonomous technology, electric vehicles, and connected cars, for example, entire supply chains are being uprooted as new business models continue to inspire investors and shape the course companies take.

Something of significant importance behind these dramatic changes is a country's standards for the automotive industry and the firms that supply it. For the members of the EBC Automotive Components & Aftermarket Committee, it is vital to stay in sync with the automobile manufacturers and the Government of Japan in regard to this key area.

The automotive components industry continues to face a range of persistent challenges. Ongoing shortages of semiconductors and other key materials, combined with evolving geopolitical tensions and shifts in consumer demand, have continued to impact production and delivery schedules across the sector. Although governments and industry leaders are taking steps to address these issues, a quick resolution remains unlikely. In light of these conditions, the EBC Automotive Components & Aftermarket Committee presents its recommendations aimed at strengthening Japan's market environment and supporting long-term industry resilience.

Globalisation and intense competitive pressures have made outsourcing of automobile component development and supply a clear trend in the European automotive industry. This shift has fostered an environment characterised by lower risk, competitive pricing, and greater flexibility.

Historically, European component manufacturers that found success with Japanese transplants in Europe rarely progressed to become suppliers for parent companies in Japan. However, recent changes in the Japanese automotive sector are creating new opportunities. In response, many European firms are allocating resources to win business in Japan—investing in local infrastructure, gaining insights into technical requirements, and cultivating stronger relationships with Japanese clients.

In this context, the EBC highly values ongoing, structured dialogue between European component manufacturers and Japanese carmakers. Such engagement is seen as essential for information exchange, deeper mutual understanding, and the long-term development of mutually beneficial business opportunities.

The harmonisation of standards between Japan and the EU continues to be a key issue. This includes the mutual recognition of testing standards so items that have been approved in the EU can more easily be brought into Japan (and vice versa), as well as the streamlining of regulations for chemical substances of concern, for example. The EU and Japan should also work together to set — and roll out globally — certain standards and specifications for new technologies in the automotive industry, such as autonomous driving, hydrogen cars, and safety standards. If these goals are realised, consumers on both sides will benefit from faster access to better vehicles and components.

One area where regulatory change would ultimately benefit Japanese and foreign firms is the auto components independent aftermarket (IAM). At present, business is seriously constrained by restrictive practices; for example, when carmakers in Japan enter into supply contracts, the contracts 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.

Key Issues and Recommendations

■ Harmonisation

Yearly status report: progress. The EBC appreciates the success of the harmonisation originating from the EU-Japan EPA. This is nothing short of a success. Following this positive step, the EBC hopes that for new technologies, such as automated and connected driving, safety standards, recycling regulations, and electric and alternative fuel vehicles this will continue. It is important that the momentum is not lost.

Recommendations:

- To continue on the harmonisation work so that new technologies do not risk running into the need of double-testing or in worse case scenario not being able to be introduced to the market. This is of utmost importance if European and Japanese manufacturers want to remain competitive on, not only on the home markets, but also on global 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.

■ 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 and also lead to more competition.
- Components suppliers should be permitted to apply their own trademarks or logos and their own part numbers to goods supplied to vehicle manufacturers.

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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.

In June 2020, the EU and Japan signed a Bilateral Aviation Safety Agreement (BASA) which should enter into force after its ratification by the parties. The EBC welcomes this initiative, which will remove the duplication of oversight activities and will support mutual safety recognition between the EU and Japan. However, it remains of utmost importance that the authorities continue working to further deepen the agreement and ensure that previously uncovered areas—such as maintenance, spare parts and training activities—are duly addressed. The EBC stands ready to support this process and welcomes any opportunity to be involved.

We would also like to highlight the signing of the Japan-EU Agreement on Bilateral Air Services between Japan and the EU Member States in 2023. The EBC hopes this milestone will further strengthen EU-Japan cooperation in the aviation sector and lead to tangible joint projects between innovative European and Japanese companies.

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.
- Deepened cooperation between European and Japanese companies would allow for the advanced technology that many Japanese companies have developed to reach the global market. This is particularly relevant for sectors such as new energies, especially hydrogen.
- 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. The EBC welcomes the signature on June 22, 2020 of the BASA between the European Aviation Safety Agency and its Japanese counterpart, the Japan Civil Aviation Bureau. Such an agreement will enhance air safety worldwide and enable cooperation in the aviation safety domain, including certification, testing and maintenance of aeronautical components, air operations, flight crew licensing, air traffic management and airports. It will also reduce the transaction cost of exporting aircrafts, while ensuring high levels of safety in partner countries and helping to harmonise product standards worldwide. Despite the signature of this agreement between Japan and Europe, its ratification remains to be achieved.

Recommendation:

- With the entry into force of the BASA, the EU and Japan now need to add additional activities, such as, maintenance, spare parts and training activities to the BASA. These segments are currently not included in the agreement and the EBC believes that the inclusion of these segments would be beneficial to both the European and Japanese aeronautical industries.

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SPACE

Introduction

Japan's space policy aims to (1) ensure security in space, (2) help to alleviate disaster and environmental problems, (3) expand space exploration, and (4) use space industry to propel economic growth and innovation. While the space plan extolled progresses achieved by Japan's space industry and technology, it also pointed out that the world had advanced faster, and that Japan had been left behind. In June 2023, Tokyo unveiled a Space Security Initiative which labelled space “a major arena for geopolitical competition for national power over diplomatic, defence, economic, and intelligence, as well as the science and technology innovation that support these national powers”. At the same time, it also unveiled a new Space Basic Plan detailing budgetary support for innovation in the private sector as an area of business growth.

Space security, market growth for the space industry and the ever-growing importance of space utilisation have led to a shift from government-led space development to a new era of public-private initiative. The Government supports start-up companies involved in small satellites and small launchers, and deploys policies encouraging downrange applications of existing infrastructure. Many of these ventures hire quite a few foreign employees and include international activities in their programs from the beginning. The EBC would wish the Japanese Government to actively promote cooperation and integration of Japanese and European ventures.

In March 2021 SKY Perfect JSAT and Airbus Defence and Space signed a procurement contract for the Superbird-9 communications satellite. It was the first time that a Japanese satellite operator selected a European satellite. The EBC warmly welcomed this development and hoped for an increase of lively Japan-Europe industrial.

Regarding government satellites, since 1990 those with business and practical applications have been procured through international tenders. Up to now they have included the Multi-functional Transport Satellite (MTSAT) and Meteorological satellite series. Direct bids by foreign companies are legally possible, but the tender documents should be written in Japanese, and there are some other legal and practical “glass barriers”; for instance, most of the communications and announcements are done in Japanese.

Regarding launchers, international development competition has heated up, and the demand for lower launch costs is reaching an unsustainable level. Japan has developed H3 and Europe Ariane 6. The first flight of H3 failed in March 2023 but it was successful in four more launches. On the other hand, the first test flight of Ariane 6 successfully occurred in July 2024 followed by the picture perfect first commercial launch in March 2025. Its commercialisation is already very successful.

Concerned by Japan's technological lag and future loss of competitiveness, experts have started work on a concept and a strategy towards a next-generation “revolutionary future space transport system”. A committee established by the Ministry of Education, Culture, Sports, Science and Technology (MEXT) to study a roadmap towards its realization is considering a rapidly upgraded version of H3 for government missions and private missions to the Moon and Mars. Its simultaneous, albeit longer-term subject is a fully re-usable space plane for point-to-point (such as Tokyo-Paris) high-speed commercial travel with an estimated market of tens of billions of euros. It mentions the importance of international cooperation in these developments. Regarding re-usability of the revolutionary future space transport system, France's space agency CNES (National Centre for Space Studies), Germany's aerospace center (DLR) and JAXA are working together on Callisto, a reduced-scale reusability demonstrator.

Launcher activities regarding small satellites and constellations have been more dynamic than expected. However, not only is the future outlook of individual initiatives uncertain, but integrating satellite manufacture, launch and services into a single company would also not increase their accessible market. As both H3 and Ariane 6 will need improved versions, a full cooperation on these would be conducive to drastically lower costs and innovation avenues, leading to more competitiveness and more international contributions. It is also probably indispensable in order for Japan and Europe to maintain their independent space transportation systems.

Key Issues and Recommendations

■ General environment

Yearly status report: protectionist risk and evolution of the international market. The current approval system for satellite projects and the future handling of public-private partnership (PPP) projects in Japan carry the risk of increasing protectionism. The European Business Council (EBC) strongly advocates for enhanced trade and cooperation—not retrenchment. Greater openness to European industry would benefit Japan, particularly given that many European technologies are available without the restrictions of “black-box” technology policies.

Both regions operate under constrained development budgets and limited government demand. To sustain a viable space industry and preserve independent access to space, Japan and Europe must urgently consider forming a strategic partnership.

Following Russia’s invasion of Ukraine, the suspension of Soyuz launcher operations by Arianespace, along with delays to the Ariane 6 program, have severely impacted Europe’s launch capabilities. In this context, the concept of a Japan-Europe mutual backup arrangement for institutional satellite launches is gaining increasing relevance and strategic value.

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.
- The European Space Agency (ESA) should consider establishing a permanent representation in Japan.
- Japan should also encourage more cooperation between the Japanese and European space industries on satellite platforms and ground systems.
- The EBC believes that boosting Japan-Europe cooperation is indispensable in order to respond to the rapidly changing space environment and common threats, and requests that action be taken to make this possible.
- The discussion of Japan-Europe mutual backup cooperation regarding institutional satellites should resume.
- An agreement regarding the treatment of sensitive information should be signed between Japan and Europe (ESA, EC, ...) to facilitate the mutual backup of institutional satellites.

■ 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 numbers 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 suppliers at a disadvantage.

■ Launchers

Yearly status report: hope for progress. Europe and Japan have developed their respective next generation heavy-lift launchers Ariane 6 and H3 almost simultaneously. Both sides will need to develop enhanced versions to stay competitive. As many development items will be the same, cooperation will be mutually beneficial.

The space agencies of both parties are already 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. Now we need to establish a concrete framework to implement such a backup scheme.

Recommendations:

- Japan and Europe should step up cooperation on the future evolutions of their respective new generation launchers. ArianeGroup 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. Japan and Europe have a shared problem in making core small launchers of solid motor rockets, because micro-debris may arise from combustion gases ejected by solid motors. Both Japan and Europe are leaders in debris policies, and there is a high awareness about preserving the space environment.

Recommendations:

- Japan and Europe should continue increasing the scope of their cooperation in space situational awareness.
- Japan and Europe started a cooperation discussion on the Post Mission Disposal devise. A strong support by JAXA is appreciated.
- We recommend that Japan and Europe consider cooperating at government level on the debris problem incurred by the operation of core solid motor launchers as well as the soil contamination problem.

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DEFENCE & SECURITY

Introduction

Since the onset of the Ukraine conflict in February 2022, Japan has emphasized the enduring implications of the war on the Indo-Pacific region, as highlighted in its 2022 defence white paper. Europe, significantly affected by the invasion, has also implemented policies to address the aggression. The European Business Council (EBC) believes this geopolitical situation necessitates deepened cooperation among like-minded countries. Closer to Japan, rising tensions due to Chinese announcements regarding Taiwan underscore the need for Japan and Europe to demonstrate the same resilience and support as shown to Ukraine. Any threat to a free Indo-Pacific must be taken seriously.

The emergence of state expansionism and increased uncertainty in various parts of the world, including the East Asian region, combined with a shift in U.S. foreign policy focusing more on the U.S. mainland, have altered the security environment for Japan. Furthermore, the growing gravity of terrorist threats and asymmetric warfare, along with the rapid emergence of new security domains such as cyber and space, in addition to the traditional domains of land, sea, and air, indicate that national security can no longer be addressed solely from a traditional geopolitical perspective and is difficult to be solved by individual countries.

Under these circumstances, while maintaining the Japan-U.S. alliance as the fundamental and crucial part of its national security strategy, Japan faces an increasing need for international cooperation and is positioning itself within a broader global security relationship, focusing on enhancing bilateral defence cooperation. Specifically, Japan has advanced bilateral defence relationships from traditional exchanges to deeper cooperation in a phased manner by appropriately combining various means, including joint exercises, capacity-building assistance, and defence equipment and technology cooperation. Joint exercises between Japan and the EU, or between Japan and some member states in the Indo-Pacific area, reflect a shared vision for maintaining the rules-based international order. At the same time, they promote maritime security in the region, protect the world's maritime domain from all traditional as well as non-traditional threats, and enhance prosperity through peaceful and stable oceans.

In terms of defence equipment and technology collaboration, Europe has been playing a very important role as one of Japan's closest and oldest allies that shares universal values and plays a central role in addressing common challenges to global security. While remaining the main partner for Japan, the U.S. cannot necessarily support Japan in all situations, and stronger relationships with Europe in defence should positively contribute to coping with regional expansionism threats as an additional deterrent. Closer cooperation with Europe in the defence field could also induce new opportunities in public procurement and foster collaboration between industries.

In recent developments, on November 1, 2024, Japan and the European Union announced a new security and defence partnership, marking the EU's first such agreement with an Indo-Pacific country. This partnership includes joint military exercises, defence industry exchanges, and cooperation in cybersecurity and space defence. Both Japan and the EU expressed concerns over regional tensions involving China, North Korea, and Russia, emphasising the need for strengthened cooperation in security and defence.

The EBC welcomes this trend of enhancing bilateral defence cooperation and expects the Government of Japan to pursue and more actively promote the defence equipment and technology aspect of the collaboration, which would open up a window for European companies to participate in international co-development programs. Furthermore, the new policy implemented by the European Union to favour industrial cooperation in defence between member states and open to third parties such as Japan under specific conditions should be explored by the Japanese government as a promising new perspective.

Key Issues and Recommendations

■ Procurement

Yearly status report: no tangible 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 and/or dual use equipment as a part of fostering the security collaboration with European nations and widen its supplier base. The Government of Japan should strategically promote collaboration and consider EU industries as partners of choice to deliver the next Mid Term Defence Plan 2023/2028 and beyond. 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 tangible progress. The EBC notices that dialogues and agreements between the European countries and Japan is ever flourishing. This is something that the EBC both supports and views as very positive. However, unfortunately this close cooperation between our authorities is not mirrored on the private side. Collaboration between European and Japanese companies in the defence area is still far and few. The increase in defence spending announced by Japan should be a catalyst to further industrial collaboration. The EBC would like to emphasise that collaboration would not only target the Japanese market, but also the European market and global market. We believe that this would be equally beneficial to the Japanese defence sector.

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 continue to 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. More specifically, Japanese officials could also explore and promote in a beneficial way, joining as a third party, the new defense initiatives implemented by the European Union to foster industrial cooperation between member states in specific areas of mutual interest.
- 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.

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MATERIALS

Introduction

Japan has developed vast knowledge and expertise in processing and recycling materials and is at the forefront of many technologies, such as those used to produce rechargeable batteries for hybrid vehicles, nanotechnologies for manufacturing semiconductors, and 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.

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 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.

The hazard classification of chemicals may vary in different regions, mainly because the standards and regulations adopted by different regions may differ. For example, Europe adopts the CLP regulation (Classification, Labelling and Packaging), while Japan adopts the GHS (Globally Harmonized System) classification standard. In addition, even if the same chemical substance has the same proportion in different mixtures, its hazard classification may be different. This is because the overall hazard of the mixture depends not only on the hazard of the single component, but also on the interaction between the components and the specific use of the mixture. Example substance is, Chloroform (CAS No. 67-66-3): In Europe: According to the EU CLP regulations, chloroform is classified as a carcinogen (Carc. 2), a reproductive toxicant (Repr. 2), and a specific target organ toxicant (STOT RE 2). In Japan: According to Japan's GHS classification standards, chloroform is classified as a carcinogen (Carc. 1B), a reproductive toxicant (Repr. 1B), and a specific target organ toxicant (STOT RE 1) Then, the label also should be different.

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.

Continuing on the same topic, the issue of sustainability in the sector has experienced a drastic change in the last couple of years. Japan has committed to become carbon neutral by 2050. Some actions have already been implemented but many other policies also need to be executed. For this EBC Materials Committee this is a very important issue, as the very future of our planet is at stake. The EBC believes that "materials" can play a pivotal role.

Key Issues and Recommendations

■ 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. Some harmonisation was achieved thanks to the EU-Japan EPA but many areas are still either not harmonised or the registration has to be done separately.

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.

■ Life Cycle Assessment (LCA) and Environment Product Declaration (EPD)

Yearly status report: new issue. LCAs and EPDs are becoming more common both as suppliers are disclosing the information as part of their transparency efforts and as buyers are requesting this to fulfil their environmental goals and requirement. In the EU, some standards, such as EN 15804+A4 for the construction related materials, and platforms for EPD, such as Environdec, are being used. In Japan we have Ecoleaf. As more and more data are being covered by LCA and EPD it is important that there is harmonisation between various systems to avoid that additional costs. This can become significant considering the number of products of a given company. It should be mentioned that some collaboration already exists. Usage of Product Category Rules (PCR) should be promoted and harmonised to reduce the efforts on EPDs of products within the same category. The EU is slightly more advanced/ahead in the efforts due to the already started implementation of CBAM.

Recommendation:

- Japan and the EU should harmonise or mutual recognise LCA systems and EPD. Both in so far as standards and registration platforms. Moreover, the promotion of PCR and the harmonisation should also be covered by this exercise.

■ 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: some progress. The notification process of Basel waste takes longer in Japan than in other countries. This is mostly due to review time of the documents needed for the notification. This is the reason the Basel waste shipment in Japan takes more than double compared to other countries. It is unique to Japan, involving two ministries: the Ministry of Economy, Trade, and Industry (METI) and the Ministry of Environment (MOE). While METI reviews in a timely manner, MOE usually takes about two months review the application, even when all the documents are complete.

Recommendations:

- The authorities, especially MoE, should speed up the review of the application, including supporting documents, to bring it to an acceptable level similar to the speed of other countries.
- 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.

■ Advanced materials

Yearly status report: new issue. Possible cooperation on advanced materials with focus on sustainable energy generation, storage, transmission (super conductors) and utilisation. Materials which help to create environmentally and climate-friendly technologies eg. fuel cells, but also advanced materials enabling/improving new production processes such as additive manufacturing. Energy transition require more and more international cooperation and can only succeed if the EU and Japan combine their expertise. This is of utmost importance in order to have better control over vital supply chain.

Recommendation:

- The EU and Japan should further its collaboration in the field of advanced materials.

■ Tariff issues

Yearly status report: good progress. With the entry into force of the EU-Japan EPA, tariffs have been removed on metals with EU origin. This is something that benefits not only European suppliers but also the Japan industry that is dependent 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.

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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 in 2020, with the creation of a baseload power market, capacity market, balancing market and non-fossil value trading market which 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 2021, METI announced the 6th Strategic Energy Plan which 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 6th Plan consists of the 2030 energy mix targeting 2050 carbon neutral with pillars consisting of energy mix of renewable energy, nuclear power and thermal generation.

The 7th Strategic Energy Plan is scheduled to be released in early 2025. 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 CO₂ emissions targets, 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. Carbon pricing as a financial incentive is also something Japan needs to consider achieve the emission reduction target by settlements between different Ministries.

The EBC is looking forward to being actively involved and to provide the appropriate support.

Key Issues and Recommendations

■ Auction system for wind power

Yearly status report: some progress. Japan has had a number of auctions to award offshore wind projects. While METI has indeed improved the rules and guidelines, the EBC still believe that there is a need for a wholistic effort to make certain that the projects are sustainable. Currently there is a risk of race to the bottom.

Recommendations:

- Japan should adopt a more balanced model for grid infrastructure development.
- Japan should provide clarification on the implications of transitioning from the Feed in Tariff (FIT) to the Feed-in Premium (FIP) model for Round 1 projects.
- Japan should expand capital expenditure offsets. These mechanisms are vital for improving bankability and lowering the cost of capital.
- Japan should ensure a fair and transparent CPPA (Corporate Power Purchase Agreements) market.

■ Wind farm certification

Yearly status report: new issue. Japan should implement a significant improvement on the offshore wind farm certification process. The current setup has been inducing lengthy and unpredictable process which serves as a bottleneck for earlier financial closure and subsequent COD. Below are several suggestions for improvement.

Recommendations:

- **Duration for certification:** The certification process should be completed in 1 - 1.5 years which is typical in Europe. It currently takes 3 - 4 years in Japan.
- **Due to high workload for certification,** ease the Japan accreditation of international bodies such as DNV, BV.
- **Transparency in design codes:** The design codes and guidelines should be upgraded to provide more clarity on the acceptable design processes (e.g., setting up design conditions, the design methodologies and techniques, allowable criteria). This minimizes ambiguities and provides more transparency and predictability in certification process. This also reduces the time currently consumed in certification process for endorsing any new process/methodology to fill in such ambiguities. Additionally, ambiguities in design codes should be proactively clarified by the government with assistance of subject matter experts (not limited to academia) and should not be implemented in certification process of any commercial project as this would definitely increase the burden of developers and stretch out the duration of certification process.
- **Step-by-step approval process:** The submissions (e.g., Design Basis-A, B and C) should be reviewed, commented and/or approved within a pre-determined duration (e.g., 2 weeks). Currently, the submissions are approved only at the end of the certification process. This setup hinders efficient certification process as this allows, for instance, Design Basis-A to be reviewed and commented many months after its submission. This practice would extend the duration of certification process because it would require re-dos of relevant design works as most of early submissions are inputs for subsequent design processes.
- **Document-based review process:** The certification process should be document-based approach. Namely, developers furnish documents which contain all information necessary to justify the proposed design and certification body returns the documents with its comments (e.g., Approved, Approved with comment or Not approved). This provides more transparency and efficiency than the current setup. The current practice is meeting-based approach and most of the communication is made verbally. There is also constrain in time and opportunity as such meeting is held only once in every one or two months and the duration is only 2 hours. It is quite a challenge for developers to explain their design details and receive comments.
- **Language:** English language should be allowed in all communications. This will open opportunity for non-Japanese-speaking experts which have extensive knowledge and experience in offshore wind to contribute in certification processes and will enhance the quality and efficiency of the certification.

■ 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. The Organization for Cross-regional Coordination of Transmission Operators (OCCTO) ensures network balance by designing national Master Plans. It is encouraging to the ongoing discussion to connect Hokkaido and Tokyo area with HVDC subsea cables.

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 could look at processes in place in Australia, the Middle East or South America to run international tenders dedicated to new HVDC domestic links. International tendering would allow foreign expertise and capital to flow into the country to accelerate and derisk the development of these massive and complex HVDC transmission projects, which are nevertheless unavoidable to strengthen the grid and evacuate the upcoming renewable energy produced in Hokkaido and Kyushu. Japan could easily combine the opening to foreign investments and the need to secure national interest around these strategic assets by putting in place safeguarding measures (equity ownership limitations, local content requirements, cybersecurity rules, mandatory involvement of EPCOs in the design and O&M phase, etc.)
- Japan should develop an action plan 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.

■ **Marshalling port**

Yearly status report: no progress. Japan should expand/upgrade the already-selected marshalling ports (Akita, Noshiro, Kashima and Kitakyushu) and/or develop additional marshalling ports and make them ready preferably by 2027 so that all or most of the round 2 and 3 projects would be able to start their offshore installation campaign from 2028 and to make the wind farms operational by 2030. Considering the ambition of Japan to introduce 5.7GW offshore wind capacity by 2030 and the rapid growth in a unit capacity of offshore wind turbines, we recommend Japanese authorities to take into account the following elements to ensure marshalling ports would not hinder the mentioned Japan's ambition.

Recommendations:

- A single marshalling port should have sufficient capacities and functions which can support installation of foundations and/or wind turbines equivalent to 1-2 GW every year. In specific;
 - Large area for storing foundations, turbines, cables, etc. and for preassembling works
 - Long and/or multiple quays to allow several vessels for unloading and/or loading out simultaneously
 - Sufficient bearing capacity for assembling and storing a tower for a 20MW wind turbine
 - Sufficient bearing capacity at quay side where a next generation Jack Up Vessel (e.g., 3,200 ton lifting capacity) can jack up for loading out foundations for a 20MW turbine.
- A single marshalling port should have sufficient capacities and functions which can support installation of foundations and/or wind turbines equivalent to 1-2 GW every year. A marshalling port should be large enough to attract and encourage companies to start providing the services necessary for offshore wind development (e.g., bunkering, food/water supply, vessel repair & maintenance works) with reasonable price.
- A large marshalling port should allow itself to have emergency response capabilities (e.g., rescue, salvage, prevention of oil pollution) which is also essential for offshore wind development.

■ **Nuclear energy and nuclear safety**

Yearly status report: some progress. Currently comprising about 8% of Japan's electricity mix, the nation's 6th Strategic Energy Plan targets a nuclear share of 20-22% by 2030. Achieving this will require the restart of 25-28 reactors. Of Japan's 33 operable reactors, 14 have been restarted so far. In 2024, Tohoku EPCO's Onagawa 2 reactor (825 MW) and Chugoku EPCO's Shimane 2 reactor (820 MW) marked the first boiling water reactors (BWRs) to restart since 2011, a notable milestone. Looking ahead, more BWRs, including Kashiwazaki-Kariwa 7 in 2025, are

anticipated to resume operations. The recent decisions to allow extension of existing reactors' lifetime are favourable, nonetheless, uncertainties remain about Japan's ability to meet the 2030 target.

Beyond restarting existing reactors, Japan is also investing in next-generation reactor technology to help meet future energy needs. Mitsubishi Heavy Industries, in partnership with Kansai EPCO, Hokkaido EPCO, Shikoku EPCO, and Kyushu EPCO, is developing the "SRZ-1200," a 1.2-gigawatt advanced light water reactor, expected to be completed by the mid-2030s. This aligns with Japan's broader strategic direction, and the upcoming 7th Strategic Energy Plan is expected to maintain similar nuclear targets, reflecting Japan's commitment to nuclear power as a core element of its energy mix and climate goals. In relation with the development of new nuclear capacities, the utilities are compelled, regulation wise, to dismantle the existing reactors which have been fully stopped.

Closing the overall nuclear cycle and especially the fuel cycle is also identified by the actors as a huge stake for the coming years and decades, as many utilities are facing limited capacities to store the spent fuel and as the geopolitical situation leads to more energy sovereignty.

Japan's restart of nuclear plants also has global implications, potentially easing Europe's winter energy concerns by freeing up liquefied natural gas (LNG) for the global market. Rising electricity costs, up 20% for households and 30% for businesses over the past year, are pushing the government to consider further subsidies and cash relief measures for utilities, households, and businesses. Notably, Japanese utilities like Kansai, Kyushu, and Shikoku EPCOs, which restarted nuclear plants, reported profits in 2023, highlighting the potential for nuclear restarts to stabilize costs.

However, the sharp depreciation of the yen continues to drive up import costs, with coal prices tripling and natural gas doubling within the last year.

Recommendations:

- **Enhance International Cooperation:** Japan should continue to strengthen collaborations with international organizations to elevate nuclear safety culture and foster a constructive dialogue between operators and safety authorities.
- **Accelerate Reactor Restarts:** Efforts to restart idle reactors should intensify to meet 2030 decarbonization goals.
- **Promote a Closed Nuclear Fuel Cycle:** Implementing a closed fuel cycle would help reduce waste and improve energy self-sufficiency. Restarting Rokkasho Reprocessing Plant is crucial to this effort, as it will enable Japan to recycle spent fuel, decrease its reliance on imported resources, and improve fuel sustainability over the long-term.
- **Plan for Reactor Replacement:** The government should prioritize long-term strategies for replacing aging reactors to sustain the energy mix, ensuring a sufficient workforce to manage current and future reactors.
- **Expand Site Capacity:** Encouraging the dismantling and decommissioning of obsolete reactors would free up space for future projects. Japan could benefit from the expertise developed in Europe to facilitate this process.

■ **Supply chain constraints**

Yearly status report: no progress. The industry has already seen some indication that supply chain capacity to support Japanese projects would be insufficient in coming years. The following measures should be undertaken to address this issue.

Recommendations:

- Japan shall develop a robust supply chain which can supply sufficient products and services when required. (Vessels capability is very short compare to the overall need, plus additional constraints with cabotage law should be adapted to compensate the current lack of capability within the Japanese supply chain). Excessive expectations for the formation of domestic supply chains could be an obstacle to accelerating development of offshore projects. It is necessary to create an environment in which domestic and foreign suppliers are balanced and can make large investments based on future market size projections.
- Increase market predictability for supplies by shortening the time between bidding and the start of operations with regulatory reform of permitting procedures (e.g. Wind farm certificate, EIA) and providing a long-term roadmap for project formation. Expanding the scale of each offshore wind project to 1 GW or larger level would enhance the market predictability.
- Establish and implement strategic policies to enhance the competitiveness of Japanese suppliers in international market while welcoming non-Japanese suppliers to Japan for providing their products/services which are

already proven in international market. These two concepts should not be regarded as conflicting with each other. Both policies would support each other in facilitating the robust supply chain of the offshore wind in Japan and Asia.

- Allow to employ products, services, specifications, inspection methodologies, etc. which comply with international codes and standards but might not be aligned with Japanese ones. This would attract and encourage more non-Japanese suppliers to provide their products and services to Japan. Japan shall be an attractive market for non-Japanese suppliers because the offshore wind supply chain is “Seller’s market” now and is expected to remain so for the next several years. This means suppliers enjoy and will enjoy luxury to select markets which are more profitable and less risky. It is worth noting that some suppliers are showing their reluctance for entering Japan or continuing their business here.