



KEY MOMENT FOR REFORM

The EBC Report on the Japanese Business Environment
2005

The
European Business Council
in Japan

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The European Business Council (EBC) is the trade policy arm of the 17 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents more than 3,000 local European companies and individuals who are members of their national chambers of commerce. Around 360 of the companies participate directly in the EBC's 27 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

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

The EBC works closely with the Delegation of the European Commission in Japan and the embassies of European countries to co-ordinate policy proposals and facilitate European business in Japan.

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The EBC Report on the Japanese Business Environment 2005

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Message from the Chairman

It is my great pleasure to introduce the European Business Council's annual report on the Japanese business environment. This year we have entitled the report, *Key Moment for Reform: The EBC Report on the Japanese Business Environment 2005*. This underscores our view that Japan now has a unique chance to further its reform agenda and free its economy from the structural impediments that have retarded growth for so long. The current economic recovery holds long-term promise, making difficult reforms less painful. The result of the general election in September 2005 gave the government a stable majority and a solid mandate for wide-ranging reforms. It also swept many high-profile representatives of special interest groups, the renowned "forces of resistance," from power.

Four years have passed since Prime Minister Koizumi took office on the platform of fundamental reform of the Japanese economy. As a firm supporter of the policies, the EBC has developed a close working relationship with the government, actively contributing opinions and policy proposals from a European perspective. I am proud of the role being played by the EBC in this process. Many key government officials now embrace our arguments and work diligently to improve the business climate for foreign companies in Japan. The determination within many branches of government to move forward and thoroughly reform the system is not in doubt.

It is, however, discouraging to see how little of this positive drive has been translated into concrete improvements of the regulatory environment. The sector-specific chapters in this report show how some deregulatory initiatives have been hollowed out in the process of negotiation between parliament and the ministries, rendering the measures futile. Even worse, some deregulatory initiatives have undergone a metamorphosis to excessive regulatory oversight when substantiated in Cabinet orders and guidelines.

Arguably, the most serious set-back this year took place in the last minute drafting of the new Corporation Law, directly contradicting the essence of the deregulatory reform and investment promotion policies. The infamous article 821, abruptly prohibiting so-called pseudo-foreign companies from doing business in Japan on a continuous basis, was introduced without adequate notification at the final stages of the drafting process and to the surprise of both the foreign and Japanese business communities. Discussions that followed with the Ministry of Justice were highly confusing, projecting a picture of an unidentifiable force interfering in the legislative process for unclear reasons. I trust the government to follow-up the recommendation in the resolution attached to the law by the House of Councillors and revise the article before implementation.

The delay in introducing the triangular merger scheme within the Corporation Law was another disappointment to the EBC as we had enthusiastically supported this measure aimed at increasing investments into Japan. Current discussions on restricting the kinds of stocks that can be used in the scheme are even more alarming. If the strictest conditions now under consideration are imposed by cabinet orders, this "crown jewel" in the investment promotion policy may be unusable and never bring a single euro in new investments to Japan.

It is critical that the Japanese Government does not take undue comfort in the current cyclical economic upturn. Rather, it should leverage the recovery to accelerate the reform process with the strong mandate received from the voters. Moreover, Prime Minister Koizumi's reform drive should extend well beyond postal privatisation. This is the Key Moment to exercise leadership, create policy coherence, and most importantly, deliver reforms. Failure is not an alternative.

Richard Collasse,
Chairman, European Business Council in Japan
(President, Chanel K.K.)

Message from the Executive Director

The European Business Council in Japan (EBC) is pleased to present its 2005 White Paper, the fifth consecutive year of its publication. Entitled "*Key Moment for Reform: the EBC Report on the Japanese Business Environment 2005*", the report updates our views on the unresolved issues that still constrain European business and investment in Japan. Like the EBC itself, the report represents our diverse member companies, yet speaks with a common opinion on a variety of key issues. The EBC requests the Japanese government to consider our recommendations as practical measures to improve the business environment constructively

The EU and Japan together account for two-fifths of world GDP and their economies are integrated to an unprecedented degree. Participation of European companies in Japan has increased consumer choice, created numerous jobs and is contributing to the economy. However, the EBC remains concerned about the disproportionately high amount of time and resources tied up in overcoming the various issues facing European companies doing business or wanting to invest in Japan. With strong Japanese public support of Prime Minister Koizumi's reform platform, the outlook is promising. However, there is an urgent need for bold action by Japan's politicians and government officials in a number of fundamental areas. The EBC encourages Japan, for example, to improve the corporate governance of Japanese companies and facilitate cross-border corporate reorganizations through stock exchanges with appropriate tax treatment without any further unnecessary delays. We also urge the government to act quickly to revise Article 821 of the new Corporate Law in order to provide legal clarity in the statutes governing the operations of certain forms of foreign companies in Japan.

Many people and organisations deserve recognition for their contribution to the production of this year's EBC White Paper. I would first like to thank all of the EBC members for their ongoing contribution of time and effort to support the EBC's committees. Without the insight drawn from their industry experience, this publication could not have been produced. I would also like to thank the Delegation of the European Commission to Japan and the European national embassies in Tokyo for their expertise and support of EBC activities.

This year's report would not exist without the dedicated work of the EBC's Policy Director, Jakob Edberg. I would like to thank him for his professionalism in meeting the many and varied challenges of compiling the material, writing/editing the text, and preparing the layout for this publication in a very short time-frame. His valuable work has ensured that this publication will continue to serve as an important reference document addressing the key issues affecting European businesses in Japan.

Finally, many EBC members deserve recognition for their generous financial contributions that have allowed us to produce this report. The EBC is extremely proud to list these supports in the sponsors and supporters sections at the end of this publication and on our website. These members not only provide their time for participation in EBC activities, but also provide the EBC with essential intellectual and financial resources.

The EBC looks forward to continued cooperation with the Japanese Government, the Japanese business community, and the broader Japanese public in making the goal of meaningful reform a reality.

Alison Murray,
Executive-Director,
European Business Council in Japan

Introduction





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INTRODUCTION

Creeping pace of regulatory reforms

Another year with “structural reform” as the ultimate policy objective of the Japanese Government has passed, the fourth under the leadership of Prime Minister Koizumi. During this period, the EBC has developed a close working relationship with the Government, continuously providing specific recommendations on how to deliver this goal.

In recent years, we have seen the Japanese authorities making efforts to facilitate the fundamental approval processes for a large range of products in diverse sectors ranging from healthcare and animal health, through construction materials and tableware to cut flowers. Schemes for third party testing organizations have been introduced and certification entities have been increasingly empowered to facilitate the application process. A general shift towards more emphasis on performance rather than detailed prescription has made many standards, at least superficially, more compatible with relevant international standards such as ISO and CE/EN. Progress is slower in the food sector, but we can report some minor improvements this year, with hopes of more to come.

We have also noted improvements in our long-standing concerns on the general business environment. The liberalisation of legal practices achieved through the amended Foreign Lawyers Law implemented this year represents an important improvement, as does the strengthened protection of intellectual property rights. The Japanese government is clarifying the objectives and methods of inspecting financial service institutions through best-practice manuals and is showing improved respect for the integrity of the process. Futile firewall restrictions have been relaxed slightly in favour of a more sensible approach to safeguarding against potential conflicts of interests. Deregulation of insurance product sales through the bank channel, for example, will expand the range of products that banks can sell when implemented in December 2005.

Some improvements are discernable at a systemic level as well. Public comment procedures are more commonplace than before. With public documents accessible to the public, the policy process is gradually becoming more open, at least in principle. Although the no-action letter is not yet a widely-used practical tool, it may eventually prove to be an important means of furthering transparency and accountability. Moreover, the EBC holds hopes for an improved competition regime when the revised Anti Monopoly Act comes into effect in January 2006.

In theory, the list of modest improvements should be much longer and broader as creeping changes are underway in most sectors. In practice, however, surprisingly little reform has translated into genuine improvement of the regulatory environment. Potential improvements are heavily compromised by conventional patterns of implementation that appear to reflect the interests of the domestic industry and the regulating bodies themselves more than objective reform goals. In the worst case scenario, the end result is merely a change in the regulatory structure that levies adjustment costs on businesses with no or few benefits gained in terms of an improved business operating environment.

Reforms in reverse

Revision of the Pharmaceutical Affairs Law (PAL) implemented in April 2005 is a telling example of how changes made under the pretext of regulatory reform have had the reverse effect.

Introduction cont'd:

In reality, the altered certification scheme has made it substantially more difficult for companies to introduce pharmaceuticals, medical equipment, medical diagnostics, cosmetics and animal health products onto the market. The authorities are taking far too long to issue the practical guidelines that substantiate generic changes arising from the revision. These long delays are exacerbating the situation. Still, six months after the revised PAL was formally implemented, it is virtually impossible to initiate application procedures for many new products. Rising application fees, unclear price policies and large discrepancies between the range and specificity of requirements for product registration and approvals among third party testing organisations with an apparent lack of coherent policy, are major issues of concern.

Even worse, these new regulatory uncertainties and requirements have been superimposed on the continuing drastic cuts in reimbursement prices for pharmaceuticals, medical equipment and medical diagnostics. The likely impact of this mix of measures is profound. Rather than promoting efficiency, prosperity and improved medical services in the healthcare field, they are having a seriously deleterious effect on the industry, with the potential for dire consequences in some cases.

Regulatory reforms have had the reverse effect in the fields of telecommunications and liquor retailing as well. The liberalisation of liquor licensing triggered the creation of ever-increasing "Urgent Adjustment Areas," to which the deregulation does not apply. Applications for liquor licences, both new and expanded, are simply being put on hold. The new spectrum allocation policy, and also the Universal Service Fund to be introduced in early 2006 are seriously undermining the concept of fair competition in the telecommunications sector.

Corporation Law

The EBC welcomed the new Corporation Law as a major step in modernising Japan's legal structure. Yet again, despite reform, we are faced with set-backs that challenge the essence of Japan's overall goals of promoting reform and investment.

The EBC is disturbed by the last-minute inclusion of an article that may undermine the operation of many foreign companies in Japan. Article 821, banning so-called pseudo foreign companies from doing business continuously in Japan, was introduced into the corporation law at short notice and without an adequate period of public notification. It was discovered by many firms long after the legislation was passed by the Japan's House of Representatives, and only days before its expected submission to a vote in the House of Councillors.

The form of incorporation of most companies affected by Article 821 has been tailored to meet the demands of the Japanese regulatory environment in the first place. European Banks, which conduct universal banking in Europe, have to separate their business entities in Japan. This is because Article 65 of the Securities and Exchange Law, a firewall that EBC would like to see abolished, prohibits banks from conducting securities business and vice-versa. Given that two branches of one head-office can not be registered in Japan, this set-up has been chosen with the full knowledge and consent of the Ministry of Finance and the Financial Services Agency. With the law now having passed both houses of parliament, it is crucial for the government to deliver on its guarantees that the introduction of the article does not imply any change in regulatory practices. To eliminate unnecessary legal risks for foreign companies, it is imperative for the politicians and government officials to follow the intent expressed in the resolution attached to the law by the House of Councillors and revise the article as soon possible before implementation.

Even before discussions with the foreign business community on Article 821 intensified, another disappointment had emerged. Introduction of the eagerly awaited triangular merger scheme, which will enable foreign firms to use their own stock in a merger with a Japanese firm, was postponed.

It is critical that cross-border share-exchanges can at least occur through this scheme and that they receive full deferral on unrealised capital gains. Moreover, there should be no further limitations on the foreign stocks applicable to the scheme. The EBC fears that the direction of recent discussions is an indication that Prime Minister Koizumi's goals of promoting reform and foreign investment will yet again be undermined in the implementation of an otherwise welcome reform.

Key Moment for Reform

Even where regulatory reforms have not had a negative impact, more often than not, too much of the policy substance is lost in the process of implementation for the reforms to deliver their promises. Take for instance, the introduction of Public Finance Initiatives (PFI) and Public-Private Partnerships (PPP). These schemes have the potential to truly transform procurement procedures to the benefit of tax payers. Although many local Japanese authorities have mounted PFI/PPP projects, they have so far largely been variants of contractor-financing with deferred payments by the purchaser rather than true PFI/PPP projects. Most of these PFI/PPP projects have effectively restricted innovative solutions and are barely profitable, proving to be cases of putting a new name to old practices.

Some progress has been made in improving the product approval process and harmonising with international standards. However, a shadow remains cast over these advances because of the costly system of border inspection of many consumer products. The EBC has long since recommended that Japan model its system on the EU and the US, where ad random controls of products already in market circulation are used.

The EBC is encouraged by the leadership shown by Prime Minister Koizumi in the postal privatisation and pleased to see popular support for this tough pro-reform line in the September 2005 general elections. Due to firm leadership and resistance to compromise on vital issues, Japan Post will be split into four separate entities, all subject to corporate taxation as well as the rules and regulations applicable to the private sector. This is a crucial step in expanding private-sector involvement in areas traditionally dominated by the public sector. It is essential, however, that the framework for privatisation ensures a level playing field for private sector competitors in Japan Post's three core business lines: insurance, banking and delivery services. If it does so, postal privatisation could become an excellent show-case to demonstrate how real reform can be delivered.

The EBC urges the government to use its strong popular mandate for reform to re-focus and intensify the creeping reforms underway in order to transform and free the economy from its structural barriers to enduring growth. The combination of a strong political mandate and a cyclical economic upturn represents an historic opportunity to take difficult decisions, promote policy cohesion, and prevent vested interests from undoing crucial policies.

Now is the key moment for reform!

How this report is organised

This report consists of 29 chapters covering a wide range of sectors and business areas. Each chapter consists of a series of recommendations, and an assessment of the progress that has been made over the past year. Each chapter addresses the concerns of a specific EBC sector committee and derives from the collective first-hand experiences of the committee members who are doing business here "on the ground" in Japan. We hope that this report will serve as an important reference document for the Japanese Government and other authorities who are interested in finding ways to improve the business and investment environment of Japan.

Business Fundamentals

Human resources
Intellectual property
Retail, wholesale & distribution
E-Commerce
Legal services
Tax

HUMAN RESOURCES

Summary of outstanding issues:

■ Pensions

Recommendation

1. The defined-contribution (DC) pension scheme should be improved by increasing tax-exempt contribution levels, allowing matching contributions, and allowing planholders to borrow against their pension reserves.
2. Japan should conclude social security agreements with all European governments.
3. Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers. As an interim measure, the contemplated raise of the cap on maximum remittance from three to five years of contribution should be realized without delay.
4. Contributions to foreign-based pension plans should be subject to the same tax relief as contributions made to pension plans in Japan.

Current situation

1. No progress. The MHLW supports raising contribution levels, but has yet to secure support for this reform from the Ministry of Finance.
2. Slow progress. Social security agreements are being negotiated or have been concluded with Belgium, France, the UK, Germany, the US, and South Korea.
3. No progress. Refunds on mandatory contributions to Japanese pension plans are capped at a maximum three years/ approximately 1.5 million yen for departing expatriates. The rest is simply confiscated. MHLW has reportedly considered raising the cap, but it remains unchanged.
4. No progress. Expatriates affiliated with foreign-based pension plans are assessed on the contributions made to such plans on the basis that a benefit arises at the time of contribution, despite the fact that such benefits are likely to be taxed again upon retirement.

■ Dismissals

Recommendation

Regulations governing employee dismissals should be further clarified to enhance management flexibility and operational efficiency. Specific rules defining acceptable grounds for dismissal for economic reasons should be introduced along with a clear guidance of what would constitute a relevant severance payment.

Current situation

No progress. The Labour Standard Law was amended in June 2003 to allow for employee dismissals, but did not set out specific criteria for what would be considered reasonable compensation for severance.

■ Improving flexibility for foreign workers in Japan

Recommendation

Visa requirements for small-scale entrepreneurs and young people with specialised skills should be relaxed and the mandatory re-entry visa for foreign citizens already possessing an appropriate residence permit should be abolished. More flexibility should be applied to the evaluation of skills and certifications acquired abroad.

Background:

EBC Human Resources Committee Member Companies

Action Japan
Baring Asset Management (Japan)
Cambridge Transearch International
Chanel
DaimlerChrysler Japan
Danfoss
Givaudan Japan
Heraud & Associates
JAC Japan
LogicaCMG
Nokia Japan
Panache
Siemens-Asahi Medical Technologies
Swiss Reinsurance

Human resource management

Global economic pressures and changing circumstances in the Japanese business environment are forcing companies to re-evaluate their human resource management practices, with more focus on improving labour quality and management efficiency. The ability of companies to manage their human resources in an efficient and cost-effective manner will ultimately affect the health of the Japanese economy.

Dismissals

The EBC urges the Japanese Government to clearly state the rights and responsibilities of employers and their employees in restructuring and dismissal situations as it develops “follow-on” guidelines to the Labour Standards Law, which was revised in June 2003. The new law itself does nothing more than fix the discrepancy between the Labour Standards Law (which had been silent on the subject of dismissals) and the Japanese Civil Code (which recognised the right of employers to dismiss employees), while at the same time enshrining in very general terms, doctrines such as the “abuse of rights doctrine” that have been inconsistently applied by Japanese courts for many years. Moreover, a lack of generally accepted rules for severance payment is making reorganisations increasingly difficult as currently, there are no safe ways to counter unreasonable demands. The EBC firmly believes that this continued legal uncertainty makes it difficult for firms to respond rapidly to the changing circumstances of the Japanese business environment.

Securing a qualified labour supply

One of the greatest difficulties European firms continue to face doing business in Japan is securing internationally qualified Japanese employees for their Japanese operations. Unfortunately, Japan’s education and certification system does not effectively address the widening gap between competency levels and the needs of employers in today’s increasingly global economy, especially for skills in areas such as legal services, engineering, biotechnology, financial accounting, and IT. The EBC takes note of the efforts on the part of the MHLW to stimulate the inflow into Japan of labour possessing these skills, but believes that relaxation of immigration laws alone is not enough. Allowing foreign experts to perform their professions in Japan by accepting foreign certifications and licences is arguably a more viable approach. Granting work visas to people with proved special skills, but without a university degree or ten years working experience would be a rational first step to show that Japan is serious about attracting skilled foreign labour.

Pensions

The debate in the run up to the general election to the House of Representatives in September 2005 showed that pension reform continues to be a hot political topic in Japan. The EBC believes that simplifying the pension system and improving its financial solidity should be a priority for the government. With this in mind, the EBC supports a comprehensive revision of the Japanese pension system, including the amalgamation of the mandatory *kousei nenkin* and *kokumin nenkin* systems, as well as further reforms to the defined-contribution pension system to make this option more attractive to employees and employers alike. The EBC also encourages the Japanese Government to take a more global view in its social security policies. Bilateral social security agreements eliminating double pension costs should be signed as soon as possible. Provisions for foreign workers in Japan should also be made more flexible; for example, by eliminating restrictions on refunds of Japanese pension contributions to departing expatriates. Finally, the tax-relief that contributions to domestic pension plans currently receive should be made available for contributions to foreign-based pension plans as well.

INTELLECTUAL PROPERTY

Summary of outstanding issues:

- **Border control**

Recommendation Japanese authorities should hold parallel importers more accountable for the authenticity of the goods being brought into the country. Rights holders should have the right to intervene through judicial means in procedures for seizing suspected counterfeit goods at the Japanese border and the burden of proof should be shared between the importer and the rights holder. Civil and criminal sanctions provided under the Customs Tariff Law are insufficient to prevent attempts to and preparations for the import of counterfeits. Japan should revise the Trademark Law to widen the maximum 150-million-yen fine to apply to both physical and juridical persons who have attempted or prepared to import counterfeit goods.

Current situation Significant progress. On April 1st 2004, Japanese Customs started a system of allowing rights holders to obtain information on the importer of counterfeit goods. They are thus able to use this information more meaningfully for research on counterfeit distribution networks or to take legal measures. However, as the appraisal remains an administrative process, the case cannot be brought to civil court. From April 1st, 2006, the importation of products that are similar to famous and widely known brand goods as defined in the unfair Competition Prevention Law will be prohibited. The EBC will closely monitor the way in which the measure is implemented.

- **Fake goods on the Internet**

Recommendation Japanese authorities should hold Internet Service Providers (ISPs) more clearly responsible for controlling sellers on their auction sites and disclosing information on suspected infringements of intellectual property rights. Moreover, ISPs should be obliged to take more stringent measures against repeat offenders.

Current situation Sign of improvement. The Internet remains an easy way to dispose of fake goods in Japan, especially on auction sites. The government has expressed an intention to strengthen implementation of the law. In the meantime, the main ISP has introduced an identity control system and appointed staff for surveillance of Internet content. Although these measures have been instrumental in reducing the quantity of goods sold openly as counterfeits, little or no improvements can be seen in the field of counterfeits sold as genuine goods. Abolishing anonymity on the internet will not suffice to correct this situation. EBC believes that holding ISPs truly responsible for trade with counterfeit goods facilitated by their services is the only long-term solution to this problem.

- Interpretation of design and unfair competition laws**

Recommendation Protection of designs under the Design Law should be made more affordable and open by reducing application costs and modernizing examination procedures. Harmonization with the European rules on related design and priority documents would help to simplify the registration process. Japanese courts should also take a more stringent approach to the interpretation of similarity of designs under the Design Law.

Current situation No progress. The cost for design registration in Japan remains expensive. Strict criteria for foreign applications make design protection difficult. Furthermore, Japanese courts continue to take a very narrow view in interpreting counterfeits under the Design Law, depriving the law of its primary purpose since minor changes prevent counterfeit goods from being considered infringements.

Background:

Strengthening protection of intellectual property rights in Japan

The EBC welcomes the proactive steps taken by the Japanese government in many fields to protect intellectual property. Revisions to the Customs and Tariff Law have made it easier for companies to apply to customs authorities to seize suspected counterfeit products at the Japanese border and allowed rights holders to obtain information about the importers of suspected counterfeit goods. Moreover, the Ministry of Economy, Trade and Industry (METI) is now discussing legal measures to halt the importation of counterfeit goods taken to Japan for no commercial purpose, but as personal effects. Genuine efforts also have been made to strengthen the enforcement of the Provider Responsibility Restrictions Law.

In December 2004, the Metropolitan Police Department launched a preparatory examiner system in which police officers are trained by rights holders to quickly examine the authenticity of counterfeit goods. The objective is to facilitate the prosecution of street stall vendors of counterfeit products.

Despite these positive developments, counterfeits remain a very serious problem in Japan. More than half of the brand goods sold over the Internet through auction sites and other means are fake products. The following structural problems prevent Japanese authorities from effectively dealing with this problem:

1. Unlike in Europe, parallel imports are still authorized in Japan. Foreign suppliers and Japanese importers often distribute fake products under the pretext of parallel imports.
2. It is difficult for Japanese authorities to prosecute even obvious cases involving counterfeit goods, as the police are required to prove that the offender handled the goods knowing that they were counterfeit in order to prove criminal responsibility.
3. Although regional customs offices are no longer prohibited from employing technologies using image transmission via the Internet to appraise the authenticity or modification of a seizure claim, this practice is not formally recognised. Therefore, rights holders are still required to visit in person the Customs offices that are not using this practice, which adds to the administrative burden of seizure claims.
4. Since the current Trademark Law does not yet prohibit the possession of fake goods for “no commercial” purpose, importation of counterfeit goods into Japan for “personal use” either by mail or by hand-carry is allowed. This loophole is increasingly being abused by commercial importers, who import fake products in small quantities to reduce the risk of detection and by foreign exporters who use the same method to sell the counterfeit goods in the Japanese market.
5. The liability of ISPs with regards to the disclosure of personal information related to suspected rights violations is not sufficiently defined in Japanese law. As a result, rights holders have difficulty obtaining personal information from ISPs on suspected rights abusers necessary to pursue civil action.
6. It is extremely time-consuming for rights holders to continually monitor web sites for suspected infringements. Considering the numbers involved, recourse to judicial means to combat the sale of counterfeit goods over the Internet is not practical.
7. Despite recent improvements of the Patent and Trademark Laws, damages awarded to rights holders remain too low to reflect the impact of the infringement and to deter offenders from abuse of rights.

The EBC urges the various entities in Japan working on intellectual property rights issues to introduce concrete measures designed to combat this deplorable situation.



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RETAIL, WHOLESALE & DISTRIBUTION

■ The Japanese Retail Environment

Introduction Although overall sentiment is improving, news on the state of Japanese retail is mixed. While some retailers are reporting improved performance, others are continuing to lose ground with no clear trend being apparent among channels or regions. Despite many attempts at market entry, the number of successful overseas-based and independently-operated retailers remains small. Local structural and regulatory impediments continue to challenge import and distribution of well-known overseas brands and products. Utilisation of alternative merchandising schemes and global-scale logistics has proved to be difficult in Japan. The EBC encourages the Japanese Government to facilitate competition and participation of global retailers and wholesalers in the market by improving and further simplifying the regulatory framework. The EBC will continue to work for further regulatory relaxation in a number of key areas:

■ Large-Scale Retailing

Recommendation Applications for business licenses filed with local authorities under the Large-scale Retail Store Location Law (*Dai Ten Ricchi Ho*) should be processed in a fair and consistent manner. Streamlining the application procedures for LRSLL, Building Permits and Environment Impact Assessment (EIA) would reduce the administrative burden placed on applicants seeking to open new stores. Moreover, the Japanese Government should resolutely maintain its policy of facilitating establishment of new large-scale retailers in Japan by standing firm against calls for new restrictions on large-scale retailing.

Current situation Limited progress. There are no definitive rules that set out when and where to submit applications for a new store based on provisions set out in the LRSLL. Accordingly, the timing of submitting an application to government bodies depends on the applicant and there is no coordination between the LRSLL and the Building Permit procedures. In many cases, local governments have also imposed new conditions, making the process of opening a new large-scale store more complex. This largely occurs where the guidelines of the law are not clear, resulting in different individual interpretations among local government officials. Companies that are new to the market, or companies with less experience and fewer networks at the local level, are disadvantaged vis-à-vis their domestic competitors in this situation. The LRSLL application procedures in major cities requiring an Environment Impact Assessment (EIA) are even more complicated. Since the requirements of the LRSLL, EIA and Building Permits are similar, we urge the relevant authorities to coordinate the application procedures to avoid unnecessary duplication of the work needed to comply with relevant laws. The EBC has learned that expert groups within the Ministry of Economy Trade and Industry (METI) and the Ministry of Land, Infrastructure and Transport (MLIT) are proposing more stringent regulations to discourage the location of new large-scale commercial facilities on agricultural land in the outskirts of rural city centres. Any such regulations will only disadvantage consumers and certainly not contribute to the overall policy goal of attracting investments into Japan.

Outstanding issues cont'd:

EBC Retail, Wholesale & Distribution Committee Member Companies

CARAN d'ACHE Japan
Chanel
Club 8 Company
Copyrights Japan
DHL Japan
Exel Japan
Georg Jensen Japan
IKEA Japan
METRO Cash & Carry Japan
Nestle Purina PetCare
Tesco Japan
Tozai Group

Alcohol Licensing

Recommendation The effective halt on new licences and transfers of existing licences in the “Urgent Adjustment Areas” should be abolished without delay.

Current Situation No progress. Deregulation that began in 2001 has gradually liberalised liquor licensing in Japan. Unfortunately, the deregulations do not apply to an increasing number of regions designated as “Urgent Adjustment Areas.” The EBC regrets the decision by parliament in March 2005 to extend by another year these supposedly temporary measures.

To make matters worse, firms that already hold a large store liquor retail licence that allows for a limited scope of alcohol sales are not able to apply for a new wider-scope liquor licence until their current licence expires. If the large-scale store liquor licence has been granted in an “Urgent Adjustment Area”, any application for a wider-scope liquor licence is rejected.

The EBC notes that there has been no deregulation of liquor licensing for wholesale activities.

■ Prohibitive Import and Certification Processes

Recommendation Regulations governing the application process for import and sales/usage of products with particular consumer safety and health considerations should be harmonised with international practices.

The costly system of import approvals and border inspection of consumer products covered by the Food Sanitation Law (mainly tableware) and by the Products Safety law (mainly baby cots and chairs) should be replaced by a system of random control of products already in market circulation as exists in the EU and the U.S. When applying for an import approval under the current system, internationally used standards (ISO CE/EN) should be unconditionally accepted as equal to Japanese testing methods and data provided by Japanese testing institutes.

Moreover, notwithstanding the need for restrictions on formaldehyde emission on products such as building materials, textiles, and baby clothes, the EBC strongly believes that data generated by internationally accepted testing methods and standards (ISO CE/EN) should be sufficient to grant unrestricted sales and usage in Japan. Requiring additional testing in accordance with Japanese (sometimes looser) standards and testing methods of products already recognised as safe in Europe, creates an unnecessary regulatory burden and considerably higher prices for end-consumers.

Current situation Some progress. The EBC welcomes the decision in December 2004 to extend the validity period of tableware import approvals from one to three years, with a possible permanent extension provided the production process and constituent materials remain unchanged. However, the burden of border control of all shipments of products requiring import approvals in accordance with the food safety law still exists. Building materials, interior products such as kitchen and bathroom cabinets used in “areas of considerable exposure to living spaces” in newly constructed houses require special approvals from the MLIT. These approvals require testing in accordance with unique Japanese standards and methods at testing institutes certified by the Ministry.

The Product Safety Law imposes unnecessarily burdensome regulations on the sales of baby cots, baby clothes and other textiles requiring the retailer, directly or indirectly, to undergo expensive testing and marking solely for the Japanese market.



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E-COMMERCE

Summary of outstanding issues:

■ Promoting user trust

Recommendation The EBC urges the Japanese Government to continue promoting consumer confidence in usage of the Internet and electronic commerce. The EBC supports initiatives such as the “e-Japan Strategy,” and “U-Japan.” The EBC also puts much hope in effective implementation of a comprehensive regulatory framework designed to assuage fears over transaction and network security and the protection of personal information. At the same time, the EBC would like to stress again the importance of regulating the acquisition, custody, and use of personal information without inhibiting business development and practices.

Current situation Steady progress. The development of an environment in which corporations and individuals feel comfortable using the Internet for commercial transactions is paramount to the further development of e-commerce in Japan. Japan has made significant progress and is today one of the largest e-commerce markets in the world. The EBC believes new laws regulating the protection of personal information represent a step in a good direction, but is worried about the lack of clarity/transparency in their compliance and enforcement. Furthermore, the EBC is concerned that regulatory barriers inhibiting the full development of Japan’s e-commerce’s potential still persist.

■ Deregulating sales activities

Recommendation The EBC urges the Japanese Government to continue deregulating sales activities in sectors such as insurance and international air transport so that companies can make more use of the Internet to provide services to customers.

Current situation Limited progress in these sectors. A number of legal and regulatory hurdles continue to inhibit the development of sales (and after-sales service) over the Internet in the insurance and international air transport sectors.

■ Global approach

Recommendation The EBC urges the Japanese Government to continue working with the international community in developing a global approach to authentication and the recognition of electronic signatures, and to co-operate further in other areas affecting Internet sales such as taxation and IPR.

Current situation Many of the issues inhibiting the development of e-commerce in Japan (e.g. protecting privacy, ensuring transaction security, developing viable business models, etc.) are similar to the issues other countries are facing. Given the global nature of the Internet, it is imperative that Japan continues to develop its Internet strategies with this in mind.

Background:

EBC E-Commerce Committee
Member Companies

Barclays Capital (Japan)
Coface Japan

Overview of the e-commerce market in Japan

As a result of a concerted effort on the part of both the public and private sectors to promote competition in the provision of telecommunications services and improve information and communications technology infrastructure, Japan now has one of the highest Internet and wireless penetration rates in the world. Japan has gone from being one of the highest-cost Internet environments in the world to one of the lowest in the space of less than five years. This is truly a remarkable achievement.

Thanks to the rapid spread of broadband (close to 20 million subscribers) and wireless Internet, the growth of consumer-oriented e-commerce is starting to pick up. It is estimated that around 30% of manufacturers, retailers and wholesalers conduct business with other companies over the Internet and that 30% of all financial institutions have gone online with their consumer operations.

Some of the important phases of Japan's ambitious "e-Japan" strategy, such as low-cost broadband services, have been achieved. Now, the Japanese Government is turning its attention to promoting more use of its ICT infrastructure by focusing on the outstanding issues inhibiting the development of Internet-based transactions, looking "beyond 2005".

Promoting the use of the Internet for commercial & administrative transactions

Despite the rapid increase in broadband penetration rates in Japan, the EBC feels that use of the Internet for commercial and administrative transactions has yet to fulfil its potential.

Conservative attitudes towards procurement, low-levels of IT literacy amongst those in management positions, and concerns over credit trustworthiness, settlement and authentication continue to inhibit the development of e-commerce in the "business-to-business" (B2B) market. This is despite the fact that e-marketplaces and shared-infrastructure platforms offer clear opportunities for enhanced efficiency and business expansion for all companies, large as well as small.

The Japanese Government recognises these concerns, and the EBC looks forward to further policy initiatives supporting the development of e-marketplaces, with a special focus on addressing the needs of SMEs. The EBC encourages close co-operation with firms from Europe and other important trading partners, as policies enacted on the local level on issues such as authentication and encryption are likely to influence trade on a much wider scale.

The uneven pattern of development of the business-to-consumer market highlights technological, philosophical, legal and commercial barriers that have inhibited the development of the e-commerce in some sectors more than others. Until these issues are resolved, the market for digital content, educational services, etc. will remain underdeveloped.

Given this situation, it is important that regulations governing business models and commercial transactions continue to keep pace with the rapid development of information and communication technologies and foster entrepreneurial spirit and the introduction of new ideas into the marketplace. Businesses wanting to use e-commerce to increase operational efficiency, improve convenience, and provide new services to customers should not be prevented from doing so because of outdated rules and regulations governing sales activities in their business field. There have been several notable improvements in the regulatory environment governing electronic transactions over the past few years. Nonetheless, the EBC is disheartened at the high level of opposition from various Agencies and Ministries to the use of the Internet for activities within their regulatory jurisdictions, especially in the financial services and international air transport sectors.

LEGAL SERVICES

Summary of outstanding issues:

■ **New Corporations Law (passed by the Diet House of Councillors on June 28, 2005)**

Article 821:

Recommendation Japan should amend Article 821 of the Corporations Law before its implementation so as to prevent it from unfairly prejudicing companies with legitimate reasons for operating as branches in Japan. This would bring the law into line with the intent of the legislators as expressed in the resolutions attached to the Article by the Judicial Affairs Committee of the House of Councillors at the time of passage of the law.

Current situation New issue. Article 821 of the new Corporations Law provides that a foreign company cannot conduct continuous transactions through a branch in Japan if the branch constitutes the *de facto* principal office of the company or if the primary purpose of the foreign corporation is to conduct operations in Japan. In cases of violation of Article 821, the branch representative will be jointly and severally liable with the foreign corporation for any debts incurred by the branch.

The EBC is concerned that Article 821 may require many branches of foreign companies in Japan to reincorporate as Japanese domestic operations, forcing them to transfer their business and assets, and apply again for already acquired business licenses. On top of the (potentially huge) taxes triggered by transfers, reincorporation may also require companies to re-negotiate existing contracts as well as labour agreements. This would be very costly and constitute a major set back for a large number of companies that are contributing to the economic wealth of Japan, not to mention investment promotion policies.

In response to these concerns, the Minister of Justice gave repeated assurances in parliamentary Q&A sessions prior to the passage of the Corporation Law that no new regulatory restrictions would be imposed on foreign companies as a result of the introduction of the Article. In addition, the Judicial Affairs Committee attached a resolution to the Article clarifying the intent of the legislators to the effect that "... Article 821 will not cause any negative effect on existing foreign companies or future investment in Japan by foreign companies." and "In view of the effect that Article 821 of the Law has on foreign companies, it must be considered, whether it is necessary for the provisions to be revised." The Q&A sessions and resolutions attached to the Article are, however, not binding on Japanese courts. Retaining Article 821 in its current form creates needless uncertainty, and is not in the interests of anyone.

"Triangular" mergers / cross-border share swaps:

Recommendation Japan should introduce the "Triangular" merger scheme in accordance with the re-scheduled timeframe and without restrictions on the use/applicability through the currently anticipated ministerial guidelines. When introduced, it is critical that "triangular" mergers receive tax deferral with the same conditions on applicability and eligibility as those that currently apply to stock swaps permitted between domestic corporations. Eventually, straight cross-border share swaps should also be permitted, again with full tax deferral.

Summary of outstanding issues cont'd:

EBC Legal Services Committee Member Companies

Allen & Overy
Ashurst
Clifford Chance Tanaka Akita & Nakagawa
Freshfields
Haarmann, Hemmelrath & Partner
Herbert Smith
Janssen Foreign Law Office Registered Associate
Laurent Dubois Foreign Law Office
Linklaters
Lovells
Loyens & Loeff GJB Office
Orrick, Herrington & Sutcliffe LLP
Sonderhoff & Einsel Law Offices
Squire, Sanders & Dempsey L.L.P.
Tokyo Aoyama Aoki Law Office (Baker & McKenzie)

Current situation Limited progress.

Introduction of a “triangular” cross-border merger scheme under the new Corporation Law is a welcome first step toward full cross-border share swaps. The EBC regrets, however, the delay in implementation by 12 months and urges the government to use the time to ensure that tax deferrals are available when the scheme is introduced in the first half of 2007. It is, essential that the ministerial guidelines to be issued at the end of this year do not limit the use or applicability of the scheme.

■ **Poison pills:**

Recommendation In dealing with "poison pill" schemes, the EBC believes that excessive defensive measures should not be permitted, and priority should always be placed on the interests of existing shareholders. To avoid such defensive measures being used as tools merely to maintain the interests of existing directors, strict conditions for activating poison pills should be applied - ideally including the obtaining of the approval or endorsement of outside directors (*shagai torishimariyaku*) for implementation of the relevant scheme. Efforts should be made to ensure that "poison pills" are not used to block constructive proposals from new bidders.

■ **Liberalization of legal practice in Japan**

Equal opportunity to develop international law offices in Japan:

Recommendation *Bengoshi* employed by *gaiben* should be subject to the same regulations and standards as *gaiben* employed by *bengoshi*.

Current situation No progress. The Foreign Lawyers Law now allows *gaiben* to hire *bengoshi*. The Regulations prevent *bengoshi* employed by *gaiben* from giving advice in the name of the employing foreign firm unless there is a *bengoshi* partner in that firm. The EBC considers that this defeats the clear intent of the law.

Incorporated law firms:

Recommendation Foreign lawyers should also be permitted to incorporate their law offices as *bengoshi hojin*, and the limited liability status of home country or head office structures should be recognized in respect of the Japan offices of international firms.

Current situation No progress. Legislation introduced in 2002 enables only *bengoshi* to incorporate their law offices as *bengoshi hojin*. Foreign limited liability structures are not recognized.

Qualifying as *gaiben*:

Recommendation The procedures for qualifying as a *gaiben* should be streamlined. The requirement that a *gaiben* should have gained post-qualification experience in the country of primary qualification is unjustifiably restrictive and fails to recognize the growing number of foreign lawyers now devoting significant periods of their career to serving clients in Japan.

Current situation No progress. The system for registering as a *gaiben* remains unnecessarily complex, costly and time consuming. Geographical limitations defining "qualifying experience" are inexplicable in an era of global legal services. Regulations should support a system that encourages lawyers in international law firms to work long-term in Japan and should fully recognize all post-qualification experience in applications to become a *gaiben*. Currently, only one year of experience gained as a foreign-admitted lawyer working in Japan may be credited towards the three-year pre-requisite for qualification as a *gaiben*.

Summary of outstanding issues cont'd:

	<u>Cross-border legal advice:</u>
<i>Background</i>	Requirements affecting only foreign lawyers stipulating how they should relay advice to their clients in Japan received from lawyers outside Japan should be removed so that the position of clients of foreign lawyers and <i>bengoshi</i> is the same.
<i>Current situation</i>	<u>No progress.</u> There are more restrictions on foreign lawyers providing advice on third country law than exist for <i>bengoshi</i> . If these requirements are designed to serve a genuine need of Japan-based clients receiving legal advice in cross-border transactions, it is not clear why they only apply to foreign lawyers.
	<u>Miscellaneous:</u>
<i>Recommendation</i>	International firms should be permitted to establish branches in Japan on the same basis as incorporated Japanese law firms.
	<i>Gaiben</i> and <i>bengoshi</i> working in <i>gaikokuho kyodo jigyo</i> offices should be subject to the same ethical standards and practice management requirements as <i>bengoshi</i> (and in the case of <i>gaiben</i> , to the standards and requirements applicable in their home jurisdictions), not to a separate set of standards and requirements.



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TAX

Summary of outstanding issues:

■ **Accountability and Confidentiality**

Recommendation 1. The National Tax Agency (NTA) should provide rulings and clarifications, such as the rationale for additional assessments, in writing as a matter of standard practice, and not only for requests received under the formal *Kaito Bunsho* system. These rulings should be made available to the public in an anonymous format on a regular basis.

2. Existing legislation protecting taxpayer confidentiality must be strictly enforced.

Current situation 1. Some progress. Taxpayers may now seek written clarification on specific transactions as a result of changes to the *Kaito Bunsho* system enacted in March 2004. Despite this improvement, an overall lack of transparency and systematic accountability continues to impede the development of business in Japan. European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. This discourages much needed foreign direct investment.

2. Some progress. The EBC views any “leaking” of information protected by Japanese taxpayer confidentiality laws with extreme concern. The EBC welcomes planned changes of the Income Tax Law to terminate the publication of the annual list of top income taxpayers.

■ **M&A and Corporate Restructuring**

Recommendation 1. All capital gains for shareholders receiving shares in a foreign company under the triangular merger and other reorganisation schemes available in the New Company Law from 2007 should in principle be tax-deferred.

2. Rules and regulations concerning corporate reorganisation laws should be clarified to avoid giving unlimited discretion to the authorities in defining key concepts with respect to reorganisations. Various key terms (e.g. “business” and the “business continuity test”) should be defined more precisely.

3. Taxpayers should be able to obtain formal advance clearance on whether or not an intended reorganisation complies with the conditions for tax-qualified reorganisations.

4. The tax-treatment of in-kind dividends should be clarified.

Current situation No progress. The introduction of the triangular merger scheme has unfortunately been delayed by one year and strict new conditions (for example listing on a stock exchange in Japan) are under consideration. Furthermore, the Japanese government has not yet decided on the tax-treatment of capital gains resulting from triangular mergers. The EBC advocates an extension of the tax deferrals on capital gains currently available for mergers between Japanese companies to apply also to cross-border mergers. If the Government is committed to promoting investments to Japan, non-discriminatory treatment of foreign shares as currency in mergers with Japanese companies is the most important policy step to take.

Summary of outstanding issues cont'd:

EBC Tax Committee Member Companies

Aventis Pharma
BASF Japan
Bayer
Chanel
Dalpayrat Foreign Law Office
Haarmann, Hemmelrath & Partner
Henkel Japan
KPMG Tax Corporation
Loyens & Loeff/Loyens & Volkmaars
Mazars Japon
Nippon Boehringer Ingelheim
Novartis Pharma
Philips Electronics Japan
PricewaterhouseCoopers
Sonderhoff & Einsel
Deloitte Touche Tohmatsu

■ Consolidated Taxation

- Recommendation*
1. The requirement that only 100% subsidiaries may be consolidated should be replaced by a 50% threshold. Furthermore, the obligatory integration of all 100% subsidiaries if a group wishes to consolidate should be eliminated.
 2. The expiry of pre-consolidation period losses of companies when they enter the consolidated group should be eliminated as well as the obligatory taxable revaluation of assets of companies entering the consolidated group.
 3. Local taxes should be included in the consolidation.

Current situation No progress. Due to the above restrictions, the consolidated tax system in Japan is still not fully or actively utilised among Japanese corporate taxpayers in Japan.

■ Limited Liability Partnership (“LLP”)

Recommendation The EBC calls for a review of the restrictions on the Limited Liability Partnership (“LLP”) as they significantly complicate the usage of LLP as an investment vehicle.

Current situation The EBC welcomes new rules on transparent taxation for partners in the new LLP scheme available since August 1, 2005, through which double taxation on the enterprise and investor’s level may be avoided. Losses will not be “locked” into the business entity, but will be allocated to the investors and thus be less exposed to expiration. However, new partnership taxation rules since April 2005 impose withholding tax obligations and various loss limitations. While corporate tax rules allow for tax-exempt contributions in kind of assets and the roll-over of built-in-gains, such benefits are currently not available for contributions to an LLP.

■ Transfer Pricing

- Recommendation*
1. Transfer pricing assessments should not be based on the use of secret comparable information, nor on any information to which the taxpayer does not have access. Further, there should be consistency between the transfer pricing methodology for audit assessments, and that used for APAs.
 2. Less weight should be placed on special characteristics of the Japanese market.

Current situation Limited progress. The tax authorities continue to make transfer pricing assessments based on secret comparables to which the taxpayer has difficulty in confirming product or functional similarities. Moreover, the use of secret comparables for audit assessments is inconsistent with the transfer pricing methodology of APAs, where company-level profitability of public companies is commonly used. This inconsistency in the application of transfer pricing methodologies increases the difficulties faced by taxpayers.

■ Tax Treaties

Recommendation The Tax Committee encourages Japan to revise tax treaties with all European countries. The EBC welcomes new tax treaties that include the exemption of withholding tax on royalties, qualified dividends and interest like in the revised Japan-U.S. tax treaty

Current situation Japan is currently re-negotiating tax treaties with The Netherlands, Switzerland, France and close to signing a new treaty with the United Kingdom.

Summary of outstanding issues cont'd:

■ Article 821 of the new Corporation Law / Pseudo foreign companies

Recommendation Article 821 of the Company Law should be amended to ensure that law-abiding and tax-paying foreign companies with duly registered Japanese branches are not negatively affected.

Current situation New Issue Article 821 of the Corporation Law, which was introduced abruptly earlier this year, has caused deep concern as its wording may render the operating structure of many European companies in Japan illegal. A sudden reincorporation due to an unforeseen change in the legal structure would have massive tax implications triggered by the transfer of assets and employees into a new entity. The EBC appreciates that our concerns were reflected in the parliamentary Q&A sessions and in the resolution attached to the bill in June by the Judicial Affairs Committee of the House of Councillors. This resolution states that "Article 821 will not cause any negative effect on existing foreign companies or future investment in Japan by foreign companies...(and).. does not restrict or require a foreign legal entity to any specific types." The wording "In view of the effect that Article 821 of the Law has on foreign companies, it must be considered whether the provisions should be revised" opens the door for continued constructive dialogue between European businesses and the Japanese government to achieve an early amendment of Article 821.

■ Factor based Taxation

Recommendation The current factor-based taxation system should be revised.

Current situation No Progress Criteria other than profits such as capital, employee expenses, etc. are part of the Corporate Enterprise Tax that is applicable to firms with share capital over 100 million yen. Such a tax discourages foreign investment and defies global trends that are moving away from the use of criteria contravening the principle to tax in accordance with the ability to pay. The new factor-based taxation system places a high administrative burden on companies and will in general not allow foreign companies to obtain a full foreign tax credit on Japanese income.

■ Loss carry forward

Recommendation Tax losses should be made available for carry forward indefinitely, instead of the current seven-year limit.

Current situation Limited progress. Companies in Japan have been operating in a challenging economic environment for much of the last decade. The EBC encourages the Japanese Government to do all it can to improve the Japanese business and investment environment by helping companies obtain full relief for all losses. While the loss carry forward period was recently extended from 5 to 7 years for losses incurred in bookyears starting on or after FY 2001, the EBC notes that this period is much longer in most other industrialised nations, sometimes offering a loss carry back and often offering an indefinite loss carry forward

■ Stock Options

Recommendation The NTA should clarify the tax treatment of foreign stock-option income to eliminate the risk of double taxation, an issue addressed by the OECD

Current situation Some Progress The decision by the Supreme Court on January 25, 2005 that income from the exercise of stock options shall be regarded as "employment income" settles the issue regarding taxation of stock options programs, irrespective of whether the shares involved are those of Japanese companies or foreign overseas parent companies. As a result, elimination of risks of double taxation remains the last pending issue.

Financial Services

Asset management
Banking
Insurance

ASSET MANAGEMENT

Summary of outstanding issues:

■ **Single regulator**

Recommendation Japan should harmonise the rules and regulations governing the asset management industry under the new Investment Services Law to be implemented in 2007. The new legislation will provide an excellent opportunity to consolidate the two existing laws - the Investment Trust Law and the Investment Advisory Law - and to promote further consistency and efficiency in the market. Being the potentially most important change to the regulatory environment in recent years, the EBC believes that the process should be open and the views of the foreign firms properly taken into consideration.

Current situation No progress. Although they do not differ much in substance, the businesses of investment trust management and investment advisory services are regulated by separate laws with separate licensing, filing, and customer disclosure requirements.

■ **Sales and service of offshore funds**

Recommendation The EBC recommends that a common set of rules governing promotion of offshore products should apply to all investment advisory firms already licensed to do business in Japan without need to apply for an additional license to do business in this area.

Current situation No progress. Asset managers wishing to support the sale of affiliated products in Japan must apply for a side-business license from the Financial Services Agency (FSA) and Kanto Financial Bureau. These licenses are limited in scope, and do not allow for firms to take a proactive approach in marketing the offshore products of their affiliates.

■ **Consistency and transparency in licensing**

Recommendation The EBC urges the Japanese Government to review its licensing system to ensure more consistency and transparency in the application process. Regulations related to licensing, filing and customer disclosure should be further harmonised between the FSA, the Ministry of Finance (MOF)'s regional finance bureaus, the Japan Investment Trust Association (JITA), and the Japan Securities Investment Advisers Association (JSIAA). Regulatory burden associated with duplicated regulatory functions prevents efficient operations in the asset management sector to the detriment of consumers.

Current situation No progress. The FSA/MOF Finance Bureau has been reluctant to define and disclose the types of "side-business" that applicants may conduct. Different firms receive different authorisations depending on the scope of the application submitted, despite the underlying business objectives being similar between firms.

■ **NAV calculation**

Recommendation To avoid duplication of work, the calculation of Net Asset Values (NAV) should be done only by the Trustee for efficiency and consumer protection purposes in the case of Japan domiciled investment trusts. JITA Rules for calculation of NAV investment trusts should be clarified to comply with the recommendations of the Global Investment Performance Standards (GIPS) and with the calculation methodology used by institutional investors in non-investment trusts fund structures in Japan.

Current situation All investment trusts are calculated twice in Japan, once by the Trustee and again by the fund management company. Ambiguity in NAV calculation rules result in significant variations in NAV among firms managing similar assets with the same benchmark.

Background:

EBC Asset Management Committee Member Companies

ABN AMRO Asset Management
AXA Rosenberg Investment Management
Baring Asset Management
BNP Paribas Asset Management
Credit Agricole Asset Management
Credit Suisse Asset Management
Fortis Investment Management
Gartmore
HSBC Asset Management
ING Mutual Funds Management
PCA Asset Management
Pictet Asset Management
Schroder Investment Management
SG Asset Management
UBS Global Asset Management

Regulatory environment

Professional asset management of pooled assets is becoming increasingly important in Japan as the financial basis of the social security systems is steadily weakening. With the birth-rate at its lowest level ever and the baby-boom post-war generation starting to retire, even an unyielding economic upturn with a potentially increased tax base is unlikely to reverse the trend of decreasing revenues. This is happening at a time when interest rates have remained at historically low levels for a long period and is causing a clear shift in the market from a strong preference for traditional savings in bank (or post) accounts to an increased appetite for products with the potential for higher returns. By providing professional advice and innovative services on the increasingly complex market, global professional asset management firms can contribute to the more effective allocation of resources in the economy at large. The EBC believes it is counterproductive for the Japanese Government to inhibit this trend by unduly restraining the operation of global asset management companies. The regulatory environment needs to be improved to allow companies to provide customers with cost-effective services in a non-discriminatory manner.

The EBC supports a more macro-level approach to regulatory oversight of the asset management sector in Japan based on consumer-oriented disclosure guidelines that support the clear and meaningful disclosure of risk, risk-tolerance, investment results, historic returns, liquidity, fees, and related party transactions. The EBC notes ongoing measures being taken in other jurisdictions to promote the wider pooling of similar assets for different investors. This has had many beneficial effects: a significant increase in funds under management; a reduction of costs for end investors; the promotion of equal and fair treatment for all investors; significant growth in the number of providers and consequent increases in competition and choice for savers.

Encouraging the efficient management of assets

On a positive note, the EBC welcomes legislation enacted in July 2003 that allows the newly created Japan Postal Corporation to delegate the management of funds to licensed investment advisors. This was the last major investment pool in Japan that had been prohibited by law from employing the professional expertise of licensed investment advisors. The EBC welcomes every opportunity to share information with the Postal Corporation on the effective use of professional advisory services. The EBC also welcomes the decision on the part of the Postal Corporation to launch investment trust distribution services to individual investors in October 2005. Given the size and penetration of the postal corporation's country-wide network, this is expected to substantially contribute to a further expansion of the domestic mutual fund market.

The EBC feels, however, that much more could be done in Japan to encourage the efficient management of investments. Rules governing the types of securities that asset managers may deal in are much more restrictive than in other global markets, including certain types of hedge funds and other investment assets.

The EBC urges the Japanese Government to review its licensing system to ensure more consistency and transparency in the application process. The FSA/MOF Finance Bureau has been reluctant to define and disclose the types of "side-business" that applicants may conduct. Different firms have received different authorisation depending on the scope of the application submitted, even though the underlying business objectives do not differ substantially between firms. This lack of regulatory consistency calls into question the supposed neutrality of the regulatory environment and makes it difficult for firms to pursue new business opportunities for fear of non-compliance.

More progress is also sought in clarifying net asset value (NAV) calculations. Investment trust managers and trust banks holding investment trust assets have long felt obligated to calculate a fund's net asset value separately, even though "double NAV calculations" are not explicitly required by law. This duplication of work represents a significant additional cost to fund managers in Japan, a cost that is eventually passed on to consumers. Ambiguities in ITA Rules relating to currency rates used in NAV calculations result in significant variations in NAV and performance calculations.

BANKING

Summary of outstanding issues:

■ **Firewalls**

Recommendation The Japanese Government should abolish Article 65 of the Securities and Exchange Law to achieve full liberalisation of the Japanese financial market. At a minimum, companies in the same financial group should be allowed to build up common functional authorities under the same roof within a virtual holding company. Affiliated Companies should be allowed to share information on common clients. Client categories should be simplified.

Current situation No progress. Firewall regulations exist, allegedly, to prevent unfair trading between securities firms, banks and other financial services businesses. Japan's strict regulation clashes with the demands of European regulators for consolidated risk management and stands in stark contrast to the drive for efficient group management within the global financial industry. Although measures have been taken to relax firewall regulations between banks and securities companies at the retail level, they are not aimed at full liberalisation of Japanese financial markets or the establishment of an integrated financial industry in Japan.

■ **Trust banking**

Recommendation Japan should revise Article 1 of the Law on concurrent operations of the trust business on financial operations to enable foreign bank branches in Japan to engage in trust and banking businesses concurrently.

Current situation No progress. Japanese city banks have been allowed to engage in trust and banking business concurrently since 2002. These reforms do not apply to foreign bank branches. The revision of the Trust Business Law that passed the Diet in November 2004 expanded the types of property that can be placed in trust and expanded the types of corporate entity that may engage in trust business. These rules do not apply to foreign bank branches. The Financial Services Agency (FSA) has been considering initiating regulatory changes granting foreign banks the same rights as Japanese citibanks, but has not yet put any measures in place.

■ **Regulatory Environment**

Recommendation Rules and regulations should be applied more consistently. The overlap of functions between various regulators and Self-Regulatory Organisations should be eliminated and the overall burden of reporting requirements to these various bodies should be streamlined. The purpose, processes and legal sanctions for inspections conducted by the FSA, Securities & Exchange Surveillance Commission (SESC), Tokyo Stock Exchange (TSE), Japan Securities Dealers Association (JSDA), Ministry of Finance (MOF) and Bank of Japan (BOJ) should be clarified and put on consistent documents in order to avoid the present excessive administrative burden of duplicate inspections.

Current situation Some progress. A large number of regulators perform regular controls of Financial service companies in Japan. The EBC welcomes the recent movement by many regulatory bodies to reduce the number of duplicate inspections. Further streamlining of responsibilities and ensuring transparency of inspection objectives and processes as a common practice are essential to boost the credibility and efficiency of inspections and surveillance.

Background:

The need for further reform

The economic recovery in Japan is very much a function of the recent rejuvenation of the financial sector. The government has played a pivotal role in helping the banks to substantially reduce their ratios of bad loans, which for so long plagued the financial system. The privatization of Japan Post, the world's largest bank, is also welcome news as it may pave the way to stronger competition, provided the advantages enjoyed so far by Japan Post are eliminated. The EBC firmly believes that increased involvement of private players, domestic and foreign alike, will stimulate further growth in the financial sector and contribute to a more effective allocation of resources in the economy at large. It is therefore encouraging to see that Prime Minister Koizumi is committed to extending his privatization plans to other governmental financial institutions such as the Development Bank of Japan, Shoko Chukin Bank, and the Japan Bank for International Cooperation, as stated in his speech at the opening of the 163rd diet session in September 2005.

The EBC feels, however, that reforms undertaken this far have been largely corrective measures, tailored to help domestic players to overcome previous failures. Regulatory reforms have been too much focused on satisfying the needs of the retail banks and too little has been done to the financial sector as a whole. Further actions must be taken to eliminate unnecessary restrictions on the providers of financial services in Japan, eliminate disparities between treatment of foreign and domestic firms, and secure transparency and consistency in the application of rules and regulations.

Facilitating Global Competitiveness

The EBC believes that only through further reform will Japan's financial services industry be able to restore its position in the world market and ultimately provide a fully competitive array of financial products to Japanese consumers, industries and institutional investors. Competing with global market leaders in the home market is the best incentive for the industry to develop new products and obtain a competitive edge worldwide. Enabling global financial groups to fully engage in Japan is therefore essential.

Within this context, the EBC especially renews its request that Article 65, which prohibits banks from fully conducting securities business and vice-versa, be abolished. Firewall regulations separating financial service functions artificially prevent the establishment of an integrated financial industry in Japan. These barriers have been particularly detrimental to European financial services firms, as most are part of universal banking groups. Conflict of interests and customer protection can be dealt with through less restrictive regulations than sector segregation as has been successfully done in other financial marketplaces.

The EBC is disappointed that reforms allowing banks and securities firms to share common retail space and allowing banks to become agents of securities firms have not done more to rationalise the operational firewalls separating banking and securities business. The EBC is equally disappointed that reforms allowing Japanese city banks to engage in banking and trust businesses concurrently do not apply to branches of foreign banks in Japan. The Trust Business Law that passed the Diet in November 2004 does not resolve this discriminatory treatment.

Article 821 of the new Corporations law that passed the Diet in June 2005 also throws into question the depth of the Japanese Government's commitment to establish an outward-looking, globally competitive financial market. The article prohibits foreign so-called pseudo foreign companies to conduct business on a continuous basis in Japan. However, foreign securities firms have, with the full understanding of the MOF/FSA, mostly been set up in this manner to comply with the fire-wall restrictions. The EBC is encouraged that the government now understands this situation and trusts that it will follow the resolution attached to the bill by revising Article 821 before implementation in 2006, in order to remove any remaining legal ambiguity for both existing and new foreign entrants.

Finally, The EBC believes that implementation of the Basel II accord will provide a good opportunity for Japan to advance its position on the global financial market by *universally* conforming its capital requirements, supervisory routines and market discipline to global best practices.

EBC Banking Committee Member Companies

ABN AMRO Bank
ABN AMRO Securities (Japan)
Banca Intesa
Barclays Bank
Barclays Capital Japan
BNP Paribas
BNP Paribas Securities (Japan)
Calyon Capital Markets
Commerzbank
Deutsche Securities
Dresdner Bank
Dresdner Kleinwort Wasserstein
HSBC
ING Bank
Orrick, Herrington & Sutcliffe
Rabobank Nederland
RBS Securities Japan
Societe Generale Securities
Standard Chartered Bank
Swedbank



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INSURANCE

Summary of outstanding issues:

■ Sales of insurance products through banks

Recommendation All remaining restrictions on the sale of insurance products through financial institutions should be abolished.

Current situation Significant progress. Partial deregulation of sales through the bank channel will take effect in December 2005, expanding the range of products banks are allowed to sell to include certain single premium savings products. Complete deregulation is expected by the end of 2007. While the EBC welcomes the Japanese Government's commitment towards deregulation, there is disappointment with the slow pace of reform and the numerous sales practice restrictions that have accompanied partial deregulation.

■ Privatisation of Japan Post

Recommendation The privatisation of Japan Post should be implemented in such a way that ensures a level playing field in the market. The EBC recommends the complete separation of Japan Post's insurance, savings and postal savings business into independent privatised entities to prevent cross-subsidisation of loss-making business. Japan Post's *Kampo* insurance business should be subject to the same capital, solvency margin, tax and policyholder protection funding requirements as private sector insurers. Strict limits should be placed on the ability of Japan Post to expand its business until appropriate competitive safeguards have been established to prevent Japan Post from using its dominant position in existing markets to cross-subsidize new business.

Current situation Significant progress. At the time of writing, it appears likely that legislation will soon pass the Diet splitting Japan Post into four separate entities (mail delivery, savings, insurance, and post office network), all subject to corporate taxation as well as the rules and regulations applicable to private sector firms, taking effect in October 2007. Details on the ability of Japan Post to expand its business, however, remain unclear.

■ Policyholder protection

Recommendation The Japanese Government should consider ways to alleviate the substantial financial burden associated with pre-funding policyholder protection corporations in the life and non-life sectors. The EBC would like to see a post-funded arrangement introduced with calculation methods that take into account the economics of specific product classes and potential risks to policyholders. Only firms whose policyholders are protected by this system should have to contribute. In particular, Separate Account products need reconsideration. In principle, the EBC feels that the best way to ensure consumer protection is through macro-level supervision.

Current situation Some progress. The EBC notes the Financial Service Agency's (FSA) increased vigilance in monitoring the health of the insurance industry, as well as a commitment to investigating a post-funded policyholder protection scheme. The effective burden under the current scheme will be reduced starting from FY06. This was not a structural solution, however, and the EBC urges the FSA to develop a more sustainable means to ensure the protection of policyholders if a company fails.

■ **Reserving methodology for variable products**

Recommendation Reserving methodology for premium reserves, contingency reserves and solvency calculations should be revised to reflect the unique characteristics and variety of variable products, taking into account methodologies that have been developed overseas. The risks in each product need to be accurately reflected, and appropriate allowance given for risk management, such as through hedging and reinsurance. The aim is improved risk management, and further product innovation. In particular, the 10% restriction on the Alternative Method should be removed, and the rules amended to allow full stochastic modelling to reflect the underlying risks.

Current situation Limited Progress. The FSA has introduced new regulations to better reflect the characteristics of these products, including allowance for stochastic modelling via the Alternative Method. However, the heavy restrictions applied to this method prevent it from working as intended. The overall approach does not reflect the wide range in risk of products available in the market.

■ **Product approval process**

Recommendation The EBC urges the FSA to increase the efficiency and flexibility of the product and pricing approval process. Short term, the system for prior product approval needs streamlining to enable faster, more frequent and more innovative product development. Long term, the goal is to remove the barriers; e.g. through a “file & use” system.

Current situation Limited progress. The move to a notification system for some non-life commercial lines was a positive step. However, all life and most non-life products still require prior approval from the regulator before being put on sale. Application “windows” are limited and companies are often forced to wait to apply for the approval of new products. This increases costs and makes business planning difficult.

■ **Agency in-house distribution**

Recommendation The EBC maintains its long-standing request to eliminate the so-called *kosei-in* rule limiting life insurance products that can be sold by agencies in-house, and to allow life insurers to pay commission to corporate agencies that sell insurance policies to the agency itself (or affiliated companies).

Current situation Non-life insurers do not have this rule and are allowed to pay a maximum of 50% of the regular commission to corporate agencies that sell insurance policies to the agency itself (or affiliated companies). The same commission payment rule should be allowed for life insurers as well.

■ **Kyosai**

Recommendation The insurance business of cooperative societies (*kyosai*) should be subject to the same capital, solvency margin, taxation, and policyholder protection funding requirements as private insurers, to enable a level playing field for life insurance. Since *kyosai* provide the same services as the private-sector, all should have the same legal and regulatory requirements, including the Insurance Business Law (IBL) and FSA supervision.

Current situation Some progress. The IBL was amended recently to bring so-called “unregulated” *kyosai* under the limited supervision of the FSA. The EBC welcomes this first step, but notes that they will still not be subject to the same rules and supervision as private insurers. *Kyosai* such as *Nokyo Kyosai (JA Kyosai)*, *Kenmin Kyosai* and *Zenrosai* regulated under special laws are outside the scope of this recent reform.

Transportation & Communications

Airlines
Shipping
Telecommunications
Telecommunications equipment



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AIRLINES

Summary of outstanding issues:

■ Pricing and distribution

Recommendation The Japanese authorities should deregulate the distribution, pricing, and settlement of airfares in Japan so that carriers can offer competitive net fares in a transparent fashion directly to the consumer, including over the Internet. Foremost, the EBC recommends the gradual introduction of a wider range of advanced-purchase fares into the system. Ultimately a simple file-and-use system for pricing approval should be introduced and restrictions on the direct transfer of net-remittances on market fares sold through IATA travel agents should be eliminated.

Current situation No progress. The pricing and distribution mechanism for air travel in Japan remains extremely inefficient. Numerous restrictions continue to inhibit the development of direct sales to consumers, more so for air travel to Europe than for domestic or other international routes (most notably to the U.S.). This is contrary to practice in nearly all countries worldwide and is detrimental to the consumer. The EBC sees no justification for such restrictions and discriminatory treatment.

■ Airport Infrastructure

Recommendation The 2nd runway at Narita Airport should be extended to 2500 m as soon as possible, and existing facilities should be used more efficiently. Haneda Airport should be opened to regular international traffic on a non-discriminatory basis, flight movement per hour at Narita increased, and slots from the two runways at Narita pooled. Opening up Yokota airbase in western Tokyo for civil aviation should also be considered when air space control of the base is handed back to Japan in 2009.

Current situation No progress. The opening of the second runway at Narita in 2002 has had a positive impact on market access, though the runway is not long enough to accommodate large aircraft. The EBC is disappointed that the extension work will not be ready until 2009 at the earliest..

■ High Costs

Recommendation The Japanese Government should strive to reduce the costs associated with the provision of air transport in Japan by 50%. Prohibitive landing, navigation, and common user fees charged by airport authorities should be substantially reduced.

Current situation Some Progress. Absolute costs related to user charges in Japan remain the highest in the world. The EBC is therefore pleased to see that privatisation of Narita Airport last year has created a momentum for lowered landing charges. The EBC welcomes the negotiations on this matter now taking place between Narita International Airport Corporation, IATA, and international air carriers.

■ Effective Implementation of New Security Measures

New Recommendation When introducing new security measures, the government should ensure a transparent process and effective implementation. Foreign carriers need time to adapt and must be allowed to recover the extra charges imposed. Highest consideration must be given to ensure that the requirements do not violate international personal information protection laws. In order to facilitate the process, submission of technical documents in English should be accepted.

Background:

EBC Airlines Committee Member Companies

Air France
Alitalia
Austrian Airlines
British Airways
Cargolux
Finnair
KLM
Lufthansa
Scandinavian Airlines System
Swiss International Air Lines
Virgin Atlantic

The business environment: An overview

International air transport plays a vital role in the Japanese economy. Unfortunately, restrictive pricing and distribution mechanisms, high operating costs, and an underdeveloped infrastructure unnecessarily inhibit the ability of the airline industry to operate efficiently in the Japanese market. Given this situation, the EBC urges the Japanese Government to take all measures possible to modernise air transport facilities and the regulatory infrastructure. An improved infrastructure, more freedom in setting prices, and lower charges will enable international airlines to contribute to the Japanese Government's stated goal of doubling the amount of tourists visiting Japan by the year 2008.

Deregulating the pricing and distribution mechanism

Distribution, pricing, and settlement of airfares remain highly regulated in Japan. Airlines have limited means to sell their products and services directly and transparently to consumers. In Japan, airlines are only allowed to advertise and sell fares for international travel to and from Japan at rates officially approved by the IATA, or in the case of group travel, at lower rates set by the Ministry of Land Infrastructure and Transportation. As the rates set by the IATA do not accurately reflect current market conditions, most individual fares are repackaged group discount fares sold through licensed travel agents. This places European carriers at a disadvantage, as they do not have the economics of scale to set up their own de facto direct distribution channels through captive agencies and affiliated travel offices, hence have limited control over the final consumer price.

Infrastructure, landing shortages, and slot allocation

The EBC remains concerned about the overall infrastructure of the air transport sector in the high-volume Kanto region. The facilities at Narita are not commensurable with its role as the main international gateway to Japan and its facilities are used inefficiently (for example, by restricting flight movements per hour and by allocating slots for the two runways separately). The indispensable extension of the second runway to 2500 meters will not be completed until 2009 at the earliest, while Haneda remains off-limits for regularly scheduled international flights. The EBC believes it is high time to unconditionally review current policies on usage of the aviation infrastructure in the Kanto region with fair and effective usage of slots, access to down-town Tokyo, and transferability between international and domestic flights. Moreover, to ease the pressure for new slots, the EBC also encourages the Japanese Government to consider opening up the airbase of Yokota for civil aviation when air space control is handed back to Japan in 2009, as it is located just 25 kilometres from Shinjuku in central Tokyo. In addition, the EBC recommends that the slot allocation methodology employed at Narita be reviewed to improve efficiency, in view of the increasing level of bilateral economic exchange between Europe and Japan, and achieving more egalitarian slot allocation between American and European airlines.

Reducing the cost of doing business

Airlines doing business at Japan's major international airports have long been required to pay prohibitive landing fees, navigation charges, airport terminal rent, airport terminal common user charges, and cargo handling fees. These charges have made the cost of air transport in Japan the highest in the world. While we welcome the drive to lower costs initiated by the management of the newly privatized Narita airport, the EBC urges the Japanese Government to continually work towards reducing charges overall.

New Security Measures

Security has emerged as the leading concern for the airport industry worldwide. The EBC is fully committed to increased airline security and urges the Japanese Government to provide European carriers with a genuine chance to work towards that goal. In April 2005, carriers were required to hire extra aircraft protection services at very short notice and are not permitted to recover the new charges, which is an additional hardship. European carriers are also concerned that the Advanced Passenger Information System (APIS) under consideration may violate European personal data protection laws, thereby making its introduction problematic. Unique to Japan is also the mandatory translation of all technical documents, which makes the alterations in requirements even more troublesome.

SHIPPING

Summary of outstanding issues:

■ Port Developments

Recommendation The Japanese Government should engage European and other Foreign shipping lines in an exchange of views on Port Development Initiatives.

Current situation The Japan Foreign Steamship Association, including the European shipping lines, controls some 60-65% of all containerised traffic in and out of Japan. This volume through Japanese Ports combined with the international experience should provide a good source of expertise for the Ministry of Land Infrastructure & Transport (MLIT). Containerization is a global business and international experience can be of high value. The European lines would welcome the opportunity to have regular meetings with the MLIT and review opportunities to increase productivity and gain efficiency by mutual efforts. Port costs in Japan remain very high compared to international standards and improvements of such cost structures must be of interest and will widely assist Japanese industries.

■ Terminal operations

Recommendation The Japanese Government should support the establishment of new, competitive terminal operations, including those owned by the shipping lines themselves. A permission-based legal framework has been established, but further leadership on the part of MLIT is required to promote consistency in its practical application.

Current situation Limited progress. While the licensing system has been replaced by a “permission system” and the MLIT has committed itself to processing applications within two months of receipt, other requirements such as minimum employment levels continue to prevent the development of a competitive market for port services in Japan. To date, no foreign company operates its own terminals in Japan.

■ Competitive bidding for stevedore services

Recommendation Competitive bidding through open tenders should be supported.

Current situation No progress. While new changes to the Harbour Transport Law implemented in November 2000 do not specifically prevent subcontracting with multiple stevedore firms under confidential rates, in reality the concept of independent, competitive bidding is not possible in Japan.

■ Transparency in the supervision of port operations

Recommendation The supervision of Japanese port operations should be transparent, efficient, and fair and routine business matters should not be regarded as part of that process.

Current situation The Japan Harbour Transport Association (JHTA) still wields enormous discretionary power on the waterfront. Shipping lines wishing to make changes to their operations require approval from the JHTA. The process lacks transparency and effectively prevents shipping lines from seeking competitive and alternative services on the waterfront.

Background:

EBC Shipping Committee Member Companies

Hapag-Lloyd (Japan)
Maersk
P&O Nedlloyd (Japan)

Overview

Global shipping is a vital component of Japan's business infrastructure and the cost of shipping goods around the world has an immediate impact on the competitiveness of the Japanese export industries.

The costs associated with the provision of shipping services in Japan are widely acknowledged as being amongst the highest in the world. The EBC is disappointed that reforms aimed at improving Japan's business infrastructure have not done more to liberalise waterfront working practices, improve competition amongst waterfront industries and associations, and promote operational flexibility. Initiatives like the Super Hub Port have not yet resulted in any tangible improvements.

High costs are eventually passed on to the exporting and importing industry in Japan and undermine the competitive position of Japanese ports in the Asian region in the provision of trans-shipping services. Korea and China offer far more competitive services and have taken a large portion of the shipping business away from Japan. This situation has been exacerbated by the tendency of Japanese industry to move production overseas. The amount of goods being shipped from Japan has dropped over the past few years at an accelerating pace. In order to regain Japanese competitiveness it is imperative that the Japanese government implements further measures to reduce the costs associated with the provision of shipping services by promoting more competition on the waterfront.

Promoting competition on the Japanese waterfront

One long-standing concern that was not addressed in the 2000 Harbour Transportation Law amendments relates to the powerful influence of the Japan Harbour Transportation Association (JHTA). The JHTA is comprised of all major waterfront businesses, except shipping lines. All changes that might reduce employment or adversely affect working conditions require approval from the JHTA.

Through a process called "prior consultation," the JHTA reviews applications for changes to shipping line operations, and, after consulting with labour unions and other relevant parties, hands down a decision that shipping lines are effectively bound to accept. The issues dealt with range from extremely minor ones such as substitution of vessels, to more significant ones such as terminal and other operational changes resulting from the formation of new shipping line groups.

While the EBC is pleased to note that shipping lines have not recently reported any major trouble with the prior consultation process involving a number of both major and minor issues, the real test will come when a carrier contests a JHTA ruling to the MLIT under the so-called "Three Party Agreement" established in 1997.

The main concern is that the whole prior consultation system lacks transparency, and effectively gives the JHTA and its members a tool that inhibits shipping lines from seeking competitive bids for waterfront services.

As a result, port costs in Japan remain amongst the highest in the world. The Japanese Government fully realises this problem, but has not yet fully committed to promoting meaningful competition on the Japanese waterfront. Ultimately, shipping companies should be able to procure port services on a competitive basis, free from undue influence from organisations such as the JHTA.

Cabotage

Foreign shipping lines should be allowed to trans-ship their own overseas cargo on their own vessels in Japan similar to vessels under the Japanese flag. Granting foreign lines the same rights would benefit Japanese Ports as it would reduce the need to trans-ship these cargos in countries other than Japan.



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TELECOMMUNICATIONS

Summary of outstanding issues:

■ **Fixed-line interconnection and Universal Service**

Recommendation Non Traffic Sensitive (NTS) costs, which are being removed from the interconnection charge, should not be funded out of the new Universal Service Fund (USF).

Current situation Regress. The decision to exclude NTS costs from fixed interconnection charges has been weakened by new policies undermining its effect. An excessive period of five years has been given to NTT to phase out NTS charges. The EBC believes that rebalancing of charges should take no longer than three years.

Even more discouragingly, the key reason for activating a USF appears to be to cover NTS costs. This effectively undoes the competitive progress that was made by excluding these costs from the interconnection charge. Allowing NTT to recover these costs through a USF rather than through the interconnection charge effectively reinstates NTS costs as a de-facto tax on competitors and ultimately consumers.

■ **Strengthening competitive safeguards**

Recommendation In order to strengthen competitive safeguards against abuse of dominance, NTT should be obliged to notify and adhere to published tariffs in all market segments where it is dominant. Regulatory accounts across NTT's different horizontal businesses and vertically between the network and retail parts of those businesses should be published. Firewalls should be strengthened to prevent NTT from leveraging its dominant position in the local access network into new business areas.

Current situation No progress. Regulatory constraints have not been effective in preventing anti-competitive behaviour by the NTT group. In many ways, revisions to the Telecommunications Business Law enacted in 2003 have made this situation worse.

NTT is no longer obligated to price on tariff, which makes it difficult to police anti-competitive behaviour. There is evidence that NTT is actively leveraging its dominant position into new business areas, including cross-marketing of new services to its customer base in areas where it is currently dominant. Aggressive action must be taken to strengthen firewalls and ensure complete and transparent accounting separation horizontally across different business lines and vertically between network and retail parts of the business.

If these measures prove insufficient, the local access network should be separated from the rest of NTT's business, removing any ability for NTT to leverage its dominance.

■ **Spectrum**

Recommendation Japan should ensure that implementation of its recently announced spectrum allocation policy does not lead to concentration of the 3G spectrum in the hands of the dominant mobile operator.

Current situation New Issue. The recently announced spectrum allocation policy for the 1.7 GHz and 2.0 GHz spectra has the potential to result in concentration of the 3G spectrum in the hands of the dominant operator, thus causing significant damage to the competitive environment in Japan. The adopted methodology allocates growth spectrum based on current subscriber numbers only and fails to distinguish between dominant and non dominant operators. This approach ignores the unmatched advantages of revenues, volumes, scale and scope enjoyed by the dominant operator and accordingly provides an opportunity for the dominant operator to further consolidate its position through the concentration of spectrum.

The potential for concentration is exacerbated by the failure to require the dominant operator to take into account the previously allocated spectrum that can be refarmed for 3G. This policy creates a disincentive to refarming allocated spectrum for 3G usage while encouraging applications for new 3G spectrum in the 1.7 GHz band, thereby directly contradicting the overall policy goal of efficient spectrum allocations.

Japan should be prepared to amend the policy by introducing measures such as a spectrum cap or revised thresholds. Alternatively, the policy could be applied to prevent a concentration of spectrum by the dominant operator. The EBC is particularly concerned that an aggravated imbalance between operators will further distort competition in the mobile market.

■ **Institutional reform**

Recommendation Japan should reform the institutional structure of its telecommunications regulatory environment. NTT should be fully privatized and a regulator independent from both commercial interests and the government should be installed.

Less emphasis should be placed on intrusive micro-management, and more emphasis on explicit macro-level economic criteria designed to promote economic efficiency, innovation, investment, and effective competitive outcomes. More effort should be made to include public input in the decision-making process through a truly open public consultation process.

Current situation No progress. It is inappropriate for the Government to act as both regulator and shareholder. The MIC has wide-ranging statutory powers of intervention and control in the Japanese telecommunications sector. The absence of a clear separation between the Government as both owner and regulator introduces a high degree of uncertainty and unpredictability into the regulatory process.

Most other countries have independent regulators who are obliged to promote only the long-term interest of consumers and a competitive market environment.

Accountability could also be improved by strengthening the public consultation process. At present, important policy decisions are usually made before the public is given a fair chance to comment. This leaves the impression that the consultation process is artificial, with little or no influence on actual policy decisions.



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TELECOMMUNICATIONS EQUIPMENT

Summary of outstanding issues:

■ Mutual Recognition Agreement

Recommendation The EBC urges the Japanese Government, in cooperation with EU authorities, to implement all parts of the Mutual Recognition Agreement (MRA) signed between the EU and Japan without delay.

Current situation Limited progress. The EBC is disappointed with the slow pace of implementation of the MRA signed between the EU and Japan in 2001, especially in the designation of accredited testing bodies as stipulated under the agreement. Currently only two accredited testing bodies have been recognised. (TELEFICATION B.V. in the Netherlands was registered by the Japanese Government as the first accredited body in the EU on February 14, 2003 and CETECOM ICT Service GmbH followed on December 19, 2003)

■ Suppliers Declaration of Conformity (SDoC)

Recommendation SDoCs issued by European producers should be accepted in Japan without any additional testing or administrative requirements, not only for wired terminals, but for specified radio equipment as well.

Current situation Some progress. The EBC welcomed the introduction of SDoC by the Japanese Government at the beginning of 2004, as it has been introduced in Europe. However, the EBC is disappointed that this system is limited to wired telecommunications terminals, with limited application to wireless/radio equipment.

■ Harmonisation in requirements for UWB equipment

Recommendation The EBC urges the Japanese Government to harmonise technical requirements of UWB (Ultra Wide Band) radio equipment with the global and European standards.

Current situation The Japanese Government continues to study the regulatory framework to introduce radio equipment based on UWB technology. There are concerns with UWB since there is the possibility that it will interfere with existing radio systems on the bands between 2 and 10 GHz, including the bands used by IMT-2000 systems and systems beyond IMT-2000. The International Telecommunications Union (ITU) and the European Conference of Postal & Telecommunications Administrations (CEPT) are also working on the UWB issue in order to have globally and regionally harmonised technical requirements protecting the other radio systems. EBC expects the Japanese government to respect the conclusions reached by the ITU and CEPT for globally harmonised regulation.

Background:

EBC Telecommunications Equipment
Committee Member Companies

Alcatel Japan
Nippon Ericsson
Nokia Japan
Rittal
Siemens

Japan's IT policy

The Japanese Government has embarked on a national "IT Strategy" designed to improve the information technology infrastructure in Japan, with the goal of making Japan a leader in IT by the year 2005. Internet access costs have fallen dramatically and access to broadband infrastructure is now amongst the most developed in the world. At the same time, Japanese service providers are bringing new information and communications technologies in areas such as 3rd Generation (3G) wireless to commercial application faster than anywhere else in the world. This is an outstanding national achievement and is one of the few bright spots in an otherwise gloomy global market environment for information and communications technology.

Harmonisation

It is very important that the Japanese Government respect current trends towards globalisation as it implements its IT policies. The EBC supports an industry-led, global approach to standards and platform development, and is encouraged by signs that the Japanese Government supports these initiatives as well. The EBC appreciates the opportunity to contribute to Ministry of Internal Affairs and Communications (MIAC) policy committees as an official participant.

The EBC was pleased to note that the Japanese Government introduced the Supplier's Declaration of Conformance (SDoC) on January 26th, 2004. Such a system has already been introduced in Europe, which has made it easier for manufacturers to quickly introduce new products in the rapidly developing telecommunications market. Before SDoC, manufacturers were required to obtain third party certification from an accredited body. Now companies are able to assume responsibility for the technical conformance of their products without having to receive certification. Unfortunately, the SDoC process will only apply to a limited range of equipment in Japan. The EBC feels that the Japanese SDoC system should be as broad-based as possible, covering all wired terminal equipment and specified radio equipment, as it is in Europe.

The EBC urges the EU and Japan to cooperate even further on the harmonisation of mobile telecommunications standards and regulations, especially for UWB, 3G wireless technologies and beyond.

The EBC notices that the Japanese government will give new licenses to new 3G wireless operators for the 1.70 GHz and 2.0 GHz spectra at the end of 2005. The EBC urges the government to ensure that new operators follow the established license policies and adopt the IMT-2000 global technologies that have been specified by ITU.

Procurement

Fragmented qualifying procedures, sole sourcing, and selectively disclosed specifications for certain projects continue to inhibit foreign firms from supplying Japanese government entities with telecommunications equipment. The EBC urges the Japanese Government to make further improvements to areas such as disclosure, bid criteria/performance specifications, qualification procedures, and open bidding procedures to ensure that public sector procurement of foreign telecommunications equipment keeps pace with the private sector.

Health Science

Animal health
Medical diagnostics
Medical equipment
Pharmaceuticals

ANIMAL HEALTH

Summary of outstanding issues:

■ **Product approval process**

Recommendation The Japanese government should improve the product approval process for animal health products by streamlining and speeding up the administrative procedures and eliminating unnecessary and scientifically unjustified requirements of applicants.

Current situation Regress. A slow approval process delays the introduction of new animal health products to the Japanese market. High costs associated with applications discourage companies from applying in the first place. The creation of the Food Safety Commission in July 2003 has increased costs and extended application process times. The interpretation of published guidelines by the New Product Deliberation Committee (*chousakai*) is inflexible, and committee members frequently make requests to applicants that have no scientific or objective basis.

■ **National assay**

Recommendation Given the introduction of Good Manufacturing Practice (GMP) and an accelerating global trend towards self-regulation to ensure product conformance, the EBC encourages the Japanese Government to continue shifting from the use of the National Assay to test veterinary biological products. The national assay for vaccines should be replaced with a system that allows for speedy batch release through a simple notification report submitted by manufacturers based on in-house controls, as is common practice in Europe. The national assay requirement for all veterinary in-vitro diagnostics detecting antigens should be eliminated.

Current situation Limited progress. National assays are still required in Japan for biological products like vaccines and certain types of diagnostic products intended for use on animals. The Government is actively working on a seed-lot system for vaccines, but the schedule for the ensuing abolishment of the national assay has not yet been revealed. Currently, there are no plans to eliminate the assay for diagnostic products, although no such requirement exists for human-use diagnostics, not even for diagnostics of major infectious diseases such as Hepatitis and AIDS. In Europe, most governments accept the quality control laboratory of the manufacturer and do not require manufacturers to submit control reports for vaccines, nor samples for examination.

■ **Use of ruminant materials from BSE affected regions**

Recommendation Japan should permit the import of ruminant raw materials from BSE-affected regions if such materials comply with the requirements of the World Organization for Animal Health or carry the European Directorate for Quality of Medicines certificate.

Current situation No progress. The Japanese Government has banned ruminant materials sourced from BSE-affected countries, creating major supply problems for the producers of animal health products. The import of samples for use in new product development is also affected. The EBC advocates a risk-based approach to the BSE issue based on type of material, source of raw material, risk mitigation used in the manufacturing process, and target animal species in which the product is used.

Background:

**EBC Animal Health Committee
Member Companies**

Bayer Medical/Animal Health Division
Boehringer Ingelheim Shionogi Vetmedica
Intervet
Merial Japan
Novartis Animal Health
Virbac Japan

Product approval process

Too long an approval process for animal health products in Japan delays the introduction of products to the market and the high costs associated with applications effectively result in fewer products available to Japanese consumers. Despite global trends to streamline approval processes, Japan-specific data still have to be added to dossiers for new product applications, at times without apparent scientific justification. Moreover, administrative inefficiencies cause many delays. The establishment of the Food Safety Commission has exacerbated the situation as another layer of regulation has been added to an already cumbersome process. If these conditions persist, international animal health companies will be increasingly likely to stop developing products for the Japanese market. The EBC strongly recommends that:

1. Additional local clinical trials should not be required for human-use drugs already widely used by veterinarians and for which effects are well documented.
2. Guidelines for in-vivo bio-equivalence studies in animals should be swiftly introduced to enable the Ministry of Agriculture, Forestry and Fisheries (MAFF) to accept data from international trials and make local trials obsolete
3. Teratogenicity tests for companion animal products not intended for use in breeding animals should be eliminated.
4. MAFF should accept technical documents submitted with New Animal Drug Applications written in English, with only a summary in Japanese provided. As a precedent, the Ministry of Health, Labour and Welfare (MHLW) accepts this procedure for human drugs.

Risk assessment guidelines for antibiotic use in livestock

The Food Safety Commission (FSC) has developed a new set of risk assessment guidelines aimed at preventing the spread of antibiotic-resistant bacteria in the human population as a result of using antibiotics at sub-therapeutic levels as additives in livestock feed. The next step for the government is to develop guidelines for the use of antibiotics as animal therapeutic drugs. The EBC is committed to working together with the government to develop reasonable guidelines for practical risk assessment to avoid risks to human health from the use of antibiotics in animals.

Revisions to the Pharmaceutical Affairs Law

The new combined manufacturing and import license introduced by the revision of the Pharmaceutical Affairs Law (PAL) in April 2005 requires mandatory certification of local and foreign manufacturing sites. The revised law also requires that all new products imported to Japan should comply with Japanese Good Manufacturing Practices. With these new requirements added, the administrative burden on importers has increased substantially. Extensive application documentation is required with data about the foreign sites and detailed information about the responsible people employed there. The EBC urges the Government of Japan to facilitate the application procedures by asking solely for complementary information not already covered by the GMP regulations in the home jurisdiction of the applicant. Moreover, the screening of documentation should suffice merely as a GMP compatibility evaluation in those cases where the manufacturing sites have already been inspected and approved by an official body, such as the European Agency for the Evaluation of Medical Products (EMEA) or the Food & Drug Administration (FDA).

Brand specific listing

Japan should follow Europe and introduce brand specific (as opposed to compound) listing for antibiotic and other feed additives. The current system does not adequately recognize the significant expense, time, and sophisticated intellectual property involved in product development. Brand-specific listing would help clarify the manufacturers' responsibility vis-à-vis requests for the submission of safety data, not only for new products, but also for re-evaluations of existing products and other studies such as the Japanese Government's on-going investigation into the possible spread of antibiotic-resistant bacteria in humans after the use of antibiotics in animals.



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MEDICAL DIAGNOSTICS

Summary of outstanding issues:

■ Reimbursement pricing

Recommendation The EBC urges the Japanese Government to establish a more rational, transparent revision process for reimbursement pricing. Prices for medical diagnostics (In-Vitro Diagnostics) should better reflect their clinical value based on differences in quality (accuracy, specificity, laboratory certification), speed (emergency response, urgent test for out-patients), and contribution to comprehensive patient care (infection control, risk management, qualitative indications). Future price revisions should take into account the special value and role of diagnostics in health care and the fact that remuneration for medical diagnostics has dropped at a much quicker pace than for other medical products and procedures.

Current situation Regress. No information has been made public regarding the decision-making process for biennial revisions to reimbursement prices (e.g. how decisions are made, what the basis for price cuts is, etc.). Medical diagnostics expenses are merely perceived as another medical materials cost that can be cut and no due consideration is given to the unique role of properly conducted testing with diagnostics in lowering the total medical cost. Tests of a certain parameter are reimbursed at the same price regardless of differences in the economic or clinical advantages of individual products, including new products utilising innovative technologies.

■ Product approval

Recommendation The product approval process should be made more efficient. Application data requirements unique to Japan should be eliminated, a fast track review system should be introduced to expedite the approval process for innovative new products, requirements for the new product categories (D1/D2) should be clarified, and risk classifications should be based on global standards.

Current situation Some Progress. The introduction of a third-party/self-certification system based on risk classifications and strengthened safety measures are important, but insufficient steps in right direction. Moreover, practical guidelines substantiating the revision of the Pharmaceutical Affairs Law have not yet been issued, making it impossible to initiate application procedures for many products, a situation that has to be acutely addressed.

■ Diagnosis Procedure Combination (DPC)

Recommendation The Japanese Government should establish guidelines in consultation with the medical community to promote the effective use of medical diagnostics with the goal of improving the quality of care and reducing the risk of misdiagnosis.

Current situation New issue. DPC has been introduced in selected Special Function Hospitals since 2003. It is said that the introduction of this system has led to a reduction in the number of diagnostic tests performed, as hospitals focus on reducing costs and outsourcing procedures. The underlying infrastructure for diagnostic testing is likely to erode if this situation persists.

Background:

EBC Medical Diagnostics Committee Member Companies

BioMerieux Japan
Dade Behring
Ortho-Clinical Diagnostic
SCETI
Roche Diagnostics

The role of medical diagnostics in the healthcare system

Medical diagnostic reagents and equipment are used to perform diagnostic tests in hospitals, commercial laboratories and blood banks. They are an essential component of any healthcare regime, indispensable in preventing sickness, detecting and diagnosing diseases, ascertaining the side effect of drug therapy, and monitoring treatment. In the future, diagnostics will play an increasingly active role in improving patient quality of life and reducing total medical costs by helping to prevent nosocomial infections, reducing the length of hospital stay, monitoring drug treatment, and managing medical risks. Repeated cuts to reimbursement prices have reduced pricing levels below that of comparable overseas markets. This has reduced the incentive to invest in the development of new products for the benefit of Japanese patients.

The environment surrounding medical diagnostics in Japan

Reimbursement prices for medical diagnostic procedures and facilities were cut by 10% in the latest round of price revisions in April 2004. Reimbursement prices have now been cut by over 40% on a cumulative basis since 1998, with double-digit reductions in both 2002 and 2004. Further reductions are expected for 2006. The pricing environment for medical diagnostics in Japan has degenerated to a point that even diagnostic products with high clinical value are facing diminishing use, even if they are required for better patient care. Prices for most medical diagnostic products in Japan have dropped below comparable global levels, which has had an extremely severe impact on the profitability of diagnostics makers. If this situation continues, it will become increasingly difficult for producers to invest in new product development and introduce innovative new technology to Japan.

Medical diagnostics have become a favourite target of cost cutting following the introduction of the Diagnosis Procedure Combination (DCP) to special function hospitals in April 2003. As a result, the necessary infrastructure for providing quality patient care has started to erode.

As it stands, medical diagnostics have been unable to fulfil their proper and important role in the delivery of healthcare in Japan. Instead of further reducing reimbursement prices for medical diagnostic equipment and reagents, it is imperative that the Japanese Government promotes the use of medical diagnostics. The EBC feels strongly that in the long run this will help control total medical expenditures and improve the overall quality of healthcare in Japan.

Product approval

For many years the EBC urged the Japanese Government to introduce a product approval system based on risk classifications, with lower risk products subject to a simple notification procedure. In July 2002, the Pharmaceutical Affairs Law was revised introducing a third party/self-certification process based on risk classifications as has been introduced in Europe. The EBC welcomed this development, but notes that a number of important issues remain to be dealt with even after its implementation in April 2005. The EBC is deeply worried about the delay in issuing practical guidelines to substantiate the general changes following the revision. As of October 2005, guidelines are not available, making it impossible to initiate application procedures for many products. Rising application fees, unclear pricing policies and large discrepancies between the level of requirements for product registration and approvals among third party testing organisations are other issues of concern.

The EBC believes that it is imperative to avoid a situation in which, contrary to the original intent of the revision, the approval and registration process through third party testing organisations is more complicated than the ministry approval process. For example, some third party testing organisations have announced that they intend to conduct annual company audits, whereas the ministry has been auditing only once every five years to maintain approved product registrations.



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MEDICAL EQUIPMENT

Summary of outstanding issues:

■ Reimbursement prices

Recommendation The reimbursement price set by the Japanese Government for medical equipment should better reflect the technical sophistication of the product, research & development costs as well as the costs of requirements related to introducing the product to the Japanese market, such as running clinical trials. Additional consideration should be given to the cost of maintaining and operating medical equipment once it has been purchased.

Current situation No progress. Reimbursement prices are set by a reference price system that does not recognize the technical sophistication and innovative nature of the product. The mechanism deciding the exact price level is complex and opaque, but the trend is clear - prices are steadily cut across the line, resulting in a loss of ability to cover research and development costs. In the long-term, this reduces timely access to life-saving products in the Japanese market.

■ Product approval process

Recommendation The Japanese Government should issue concrete guidelines on how to proceed with applications under the revised Pharmaceutical Affairs Law (PAL) without delay. Old certification classifications should apply until their new counterparts are established. It is not acceptable to impose a 12-month extension of the time needed to evaluate product applications simply because the new certification procedures have not yet been decided.

Current situation Regress. The revised PAL implemented in April 2005 has complicated the product approval process, requiring substantially more documents and data. In addition to submitting an application and STED (summary of testing and experimental data), all applicants are now subject to QMS compliance investigations. Application fees have increased considerably since the revision while the examination remains equally inefficient. The PAL was revised under the pretext of regulatory reform as certification procedures were brought closer to ISO standards, but the revision has resulted in an even more complex and opaque process. The long time and high costs associated with bringing new products to the Japanese market are having a serious adverse effect on the type and quality of treatments available to Japanese patients.

■ Mutual recognition

Recommendation The EBC urges the Japanese authorities to co-ordinate medical equipment standards with their European counterparts to avoid unnecessary duplication in the product approval process. A Mutual Recognition Agreement (MRA) for medical devices should be negotiated between the EU and Japan as soon as possible.

Current situation No progress. The EBC is disappointed that the Mutual Recognition Agreement between the EU and Japan does not include medical devices.

Background:

EBC Medical Equipment Committee Member Companies

Agfa-Gevaert Japan
B.Braun Aesculap Japan
Biotronik Japan
Centerpulse Japan
Domier MedTech Japan
Draeger Medical Japan
Edaptechnomed
ELA Medical Japan
Elekta
Gambro
Laerdal Medical Japan
Lima Japan
Macopharma Japan
Nippon BXI
Philips Electronics Japan
Porges
Radiometer
Sata
Senko Medical Trading
Siemens-Asahi Medical Technologies
Smith & Nephew Wound Management
Smiths Medical Japan
Sorin Biomedica Japan

Healthcare reform

For European manufacturers of medical devices, there are few bright spots in the Japanese market. The Japanese Government continues to reduce the prices that it pays out under the insurance reimbursement system and is seeking ways to improve efficiency, including hospital reform through privatisation. The EBC is concerned, however, that the policy response to rising health care costs seems to be based less on clear long-term healthcare goals, and more on short-term measures designed to reduce costs by any means available. In addition to the steadily worsening downward adjustment of prices, new regulations are putting further constraints on exporters. It is particularly discouraging that the PAL revision, which aimed at shortening the approval times and streamlining the application process, has had the reverse effect. Product approval times are now longer and the application process has become more complex than before the revision. An appalling delay in substantiating the general rules through notifications and guidelines has exacerbated the problem. As a result, the introduction of technically innovative products is often delayed by several years resulting in Japanese consumers having access to new products long after they are introduced in Europe, the US, South Korea, and China.

Insurance coverage

In Japan, producers of medical equipment are required to file applications for medical insurance coverage so that medical institutions using these devices can recover the treatment cost. Re-examination of the fees paid to medical institutions under the current system is scheduled for April 2006. The authorities will likely base the revision on the policy of the previous revision in which prices were reduced across the board on the sole pretext of narrowing the price differential between Japan and other countries.

The EBC is very concerned that reimbursement prices set by the Japanese Government do not adequately reflect the economic and clinical benefits of individual treatments. Part of the problem stems from the classification criteria set out in the insurance system. If the number of functional categories continues to be reduced, this will further impede the establishment of an effective reimbursement mechanism that recognises the benefits of truly innovative technologies. On the other hand, the EBC welcomes the proposal to abolish mandatory inspections of products within several insurance categories, a measure that would contribute to the rationalization and simplification of the application procedure.

Regulatory environment governing product approvals

The EBC has long advocated reforms to the approval and monitoring process for medical treatments with the goal of reducing the time and costs associated with introducing innovative new treatments to the Japanese health care system. Recent regulatory changes have made the situation worse and the EBC would particularly like to focus on following issues:

- A reduction in the time needed to have a new treatment approved for sale
- A requirement only for manufacturers of end-use products and not foreign manufacturers of intermediary products to be examined and subject to QMS compliance requirements.
- Authorisation of not only foreign manufacturers, but also distributors/manufacturers handling the product in Japan to conduct the required product delivery controls. This is because foreign manufacturers are not necessarily well equipped to perform controls in accordance with Japan-specific standards
- Unconditional acceptance of clinical data generated overseas in line with the guidelines issued by the Ministry of Health Labour and Welfare as long ago as 1997

Costs are also likely to rise as a result of new electromagnetic compatibility (EMC) compliance regulations, introduction of mandatory bar-coding, filing requirements associated with the new product approval process, and upgrading of the quality control system to fulfil the demands of the revised PAL.

PHARMACEUTICALS

Summary of outstanding issues:

■ **Pharmaceutical pricing reform**

Recommendation EFPIA Japan urges the Japanese government to drastically revise the NHI price system to ensure significant price premiums for innovative new drugs.

Current situation Limited progress. An expert committee of the Ministry of Health, Labour and Welfare (MHLW) is currently reviewing requirements for innovation and utility premiums, as well as the relative importance of premiums in driving prices closer to international levels. We request a continued discussion on the Pricing Rules with the goal of reaching a mutually acceptable mid- to long-term basic policy.

■ **Improvement of the clinical study environment**

Recommendation The government should further improve the environment for clinical studies, including bringing Japanese Good Clinical Practices (GCP) closer to international standards. The authorities should also introduce without delay, new regional guidelines clarifying how data generated through international joint studies can be used in product certification applications in Japan.

Current situation Limited progress. The high level of requirements related to conducting clinical studies in Japan constitutes a virtual obstacle for parallel development of new drugs on a global basis. Accordingly, it jeopardizes Japan's ability to participate in international joint clinical studies. Failure to change Japan-specific GCP requirements is resulting in longer clinical trials to develop new products, increased trial costs and eventually, the hollowing-out of clinical studies in Japan.

■ **Review of the drug approval process**

Recommendation The Japanese Government should strengthen the newly created Pharmaceutical Medicine and Device Agency (PMDA) and work to streamline the drug evaluation and approval process. The Agency should also be better equipped to give advice and consultation on clinical studies.

Current situation Limited progress. One year has passed since the creation of the PMDA in April 2004, however, the organisation has not yet fulfilled industry expectations. The time needed to handle and review product applications and to consult on clinical studies is unacceptably long as the organisation is heavily understaffed. It is difficult to predict the time required to obtain approval under the current circumstances, making investment decisions risky.

■ **Intellectual property protection**

Recommendation EFPIA Japan urges the Japanese government to legislate eight-year data protection as soon as possible. If a new therapeutic indication is authorised, a one-year extension should be provided.

Current situation Limited progress. The Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ) sent a request for eight-year data protection to the Ministry of Health, Labour and Welfare (MHLW) in April 2004. A period of over one year has already passed since then without any progress made. The MHLW should immediately take appropriate action to comply with the recommendation expressed by FPMAJ.

**EFPIA Japan
Member Companies**

Actelion Pharmaceuticals Japan Ltd.
Amersham plc
AstraZeneca K.K.
Bayer Yakuhin Ltd.
Bracco-Eisai Co., Ltd.
Chugai Pharmaceutical Co., Ltd.
Fournier Japan
GALDERMA K.K.
GlaxoSmithKline K.K.
Guerbet Japan K.K.
Janssen Pharmaceutical K.K.
Leo Pharmaceutical Products
Lundbeck Japan K.K.
Merck Ltd.
Nihon Schering K.K.
Nihon Servier Co., Ltd.
Nippon Boehringer Ingelheim Co., Ltd.
Nippon Organon K.K.
Novartis Pharma K.K.
Novo Nordisk Pharma Ltd.
Pierre Fabre Dermo-Cosmetique Japon
Sanofi-Aventis Group.
Aventis Pasteur K.K.
Aventis Pharma Ltd.
Sanofi-Synthelabo K.K.
Schwarz Pharma Japan K.K.
Sero Japan Co., Ltd.
Solvay Seiyaku K.K.
UCB Japan Co., Ltd.
ZLB Behring Japan Ltd.

Background

Demographic changes, public financial constraints and the relative lack of competitive strength of the Japanese pharmaceutical industry pose great strains on the healthcare system. The government should conduct a comprehensive review and overall reform of the social security system. Japanese consumers should have access to innovative new drugs, similar to other highly industrialized countries. EFPIA Japan believes, however, that the reforms should promote innovation, a good environment for clinical trials, a well functioning review & approval system, responsible drug pricing rules and data protection.

Pharmaceutical pricing reform

The proportion of drug costs in the national medical care expenditure has decreased from about 30% to 20% through a series of biennial drug price revisions conducted by MHWL. The size of the pharmaceuticals market remains, however, unchanged at around 6 trillion yen despite high pressure for cost reduction. EFPIA Japan is particularly concerned to see exceptional price reductions of products that have been re-priced due to market expansion and also of long-listed drugs. This goes against the principle of National Health Insurance Drug Reimbursement revision, which is aimed at reflecting market prices in the reimbursement levels. Since the rules for premiums were introduced 5 years ago, only one in two products launched have qualified for innovation/specialty premiums and only one in 31 products qualified for utility premiums, with an average premium rate of merely 3.7%. The premium and reimbursement policies do not provide incentives for developing innovative products.

Improvement of the clinical study environment and drug approval review

The environment for clinical studies in Japan has improved significantly following the introduction of the new GCP regulations and the International Conference on Harmonisation of Technical Requirements for the Registration of Pharmaceuticals for Human Use (ICH) guidelines. Compared to the situation in other countries, it is still very difficult to carry out large-scale clinical trials in Japan. Complicated regulations result in high costs and troublesome recruitment of patients. The number of clinical trials carried out in Japan is now as low 400-500 per year.

Intellectual property protection

The Japanese Government established a strategic headquarters for promoting Intellectual Property rights within the Cabinet Office in 2003. As a result, an Action Plan including over 500 measures has been published. The list includes several items directly related to the pharmaceutical industry, such as regulatory data protection, research-tool patents, patent protection for medical treatment, and patent protection for genetic and regenerative treatments.

In Europe, new pharmaceutical legislation including provisions enhancing the protection of regulatory data was approved in 2004. In the latter part of 2005, the so-called “8+2+1” data protection formula was introduced. This means that generic manufacturers can submit an authorisation request 8 years after an innovative medicine is launched on the market, but will only receive approval to start marketing the generic copy after 10 years. If new therapeutic indications are authorised, the protection of data can be extended to 11 years. Moreover, in September 2004, the European Commission (EC) adopted a proposal to regulate medicinal products intended for paediatric use. The EC proposes a six-month extension of the exclusive patent awarded by the supplementary protection certificate (SPC) for products with a potential therapeutic benefit for children. EFPIA Japan supports the request by the FPMAJ to the MHLW in April 2004 to introduce an 8-year data protection period in Japan.

Consumer Goods

Cosmetics
Cut flowers
Liquor
Food

COSMETICS

Summary of outstanding issues:

Regulatory reform of cosmetics

Recommendation

The EBC urges the Ministry of Health, Labour and Welfare (MHLW) to:

1. Work towards harmonising the positive lists between the EU and Japan, and establish a mechanism enabling swift acceptance of ingredients that are widely used or recently recognized in the U.S.
2. Work towards harmonising the classification of cosmetics by product categories between the EU and Japan, and introduce a self-regulatory system for product differentiation based on verifiable scientific data.
3. Simplify the standard administrative procedures for the importation of cosmetics.

Current Situation

There is a pressing need to further harmonise Japan's positive list of UV filters, preservatives, and coal-tar colours with that of the EU. Competent authorities in Japan and the EU should liaise more closely, share safety data globally, and work for mutual recognition of safety data. The scope of cosmetic product categories is much narrower in Japan than in Europe. In 2001, the list of efficacy claims was expanded to fifty-five marketing claims, but most permissible claims are too general to allow for significant product differentiation. This is severely limiting choices for the end consumers and constitutes a disincentive for further product development. The recent revision of the Pharmaceutical Affairs Law (PAL) significantly increased the administrative burden on importers of cosmetics products.

■

Regulatory reform of quasi-drugs

Recommendation

The EBC requests the MHLW to substantially reduce standard application times by simplifying the product approval process. Moreover, the ministry should immediately simplify the approval process for products consisting only of already accepted ingredients and products for which the approval standards have been established.

Current Situation

Receiving approvals for quasi-drugs is still associated with numerous costs and requires significant time. In particular, it takes an unjustifiably long time to process applications for products consisting only of already accepted ingredients, products recognized as being equal to existing quasi-drugs, quasi-drugs containing new additives, and products for which the approval standards have already been established. The EBC believes that the introduction of a voluntary ingredients labelling system in 2006 will present a good opportunity to simplify the application procedures for quasi-drugs.

■

Establishing alternatives for animal testing

Recommendation

Japan should work actively to introduce alternative tests. The authorities should promptly accept internationally recognized alternative tests such as those specified by the OECD guidelines.

Current Situation

A ban on the selling of cosmetics manufactured by manufacturers with animal experiment programs will be introduced in 2009 in accordance with the seventh amendment of the Cosmetics Directive. Japan should take part in the creation of international alternatives to animal experiments. It is crucial that utilising internationally accepted alternative testing methods will not obstruct the ingredient registration and product approval process. This issue should be discussed as a priority subject of the CHIC (Cosmetics Harmonization and International Cooperation).

The situation in the Europe

All products manufactured and sold in Japan as quasi-drugs are classified as cosmetics in Europe. Positive and negative lists regulate manufacturing and sales practices, but the system is based on self-regulation controlled by ad-random inspections of products in market circulation. The seventh amendment of the EU Cosmetics Directive in 2003 resulted in a ban on CMR substances (both categories 1 and 2) and animal tests, as well as requirements for labelling of allergenic ingredients in fragrances and best-before labelling. Since 2004, EU authorities have banned the use on animal tests for which there are alternatives available. A complete ban on the sales of products subjected to tests using animals will become effective in 2009, with the exception of three animal tests for which the development of alternative methods has proved difficult.

Revision of the Pharmaceutical Affairs Law

The new scheme for imported cosmetics introduced by the revision of PAL in April 2005 has made the importation of cosmetics cumbersome. Three notifications – one each for manufacture, marketing and importation- are now required on a per product basis. Given the high number of new products and the speed of new introductions in the cosmetics industry, the MHLW should simplify the system. These difficulties were exacerbated by the MHLW, which adopted the notifications and released the clarifying guidelines at short notice - dated the day before formal implementation of the new law, but in reality released subsequently. The EBC urges the Government of Japan to provide the industry with adequate preparation time when it revises the legal structure governing their businesses.

Improving the cosmetics business environment

European makers often are forced to reformulate their products specifically for the Japanese market. This will not change until Japan's positive list of UV filters, preservatives, absorbers, and coal-tar colours is harmonised with the EU's positive list. The mandatory safety evaluation prior to registering new ingredients that are already in wide use in Europe and the U.S. and included in their respective positive lists is too long. In Japan, the allowable marketing claims are too standardised. Although the number of marketing claims was increased to fifty-five with expansion of this list in 2001, most claims allowed are too general to allow for significant product differentiation. This is very different from the situation in Europe where efficacy claims are based on verifiable data, which is the responsibility of the manufacturer. The EBC urges the government to allow a company to make efficacy claims based on self-regulation for the differentiation of products backed by verifiable scientific data. False declarations can be controlled by the current Premiums and Representations Law. Recently, many imported cosmetics products from manufacturers who are not respecting the Good Vigilance Practices (GVP) and Good Quality Practices (GQP) are circulating on the Japanese market. The government should take urgent measures to ensure the quality, efficacy and safety of those products.

Improving the business environment for quasi-drugs

The EBC Cosmetics Committee repeats its recommendations on quasi-drugs from previous years by advocating improvements to address the following concerns: 1) The unjustifiably long time needed for standard administrative processing for quasi-drug approval and partial amendment; 2) The lack of transparency and public disclosure regarding ingredients that have already been approved; 3) Restrictions on the use of cosmetic ingredients to be newly used in quasi-drugs. The Japan Cosmetics Industry Association will introduce a system of voluntary full-ingredient labelling from 2006. The EBC is deeply concerned that the system does not go far enough in helping end-consumers making enlightened choices. While most of the ingredients in quasi-drugs are commonly used in cosmetics, Japan will not use the International Nomenclature of Cosmetic Ingredients (INCI) on the labels, which is confusing to consumers.

CUT FLOWERS

Summary of outstanding issues:

■ Plant quarantine regulations

Recommendation The Japanese authorities should extend the list of non-quarantine organisms to include all non-harmful organisms found in cut flowers. The EBC urges the Japanese Government to focus on the main insects (mites, aphids and thrips) and to accelerate the process to abolish zero tolerance of all organisms common in Japan. In addition, quarantine inspectors should be required to compile a quarantine report specifying the precise names of pest species found in order to avoid arbitrary judgements and superfluous fumigation.

Current situation Limited Progress. The EBC welcomes the expansion of the non-quarantine list in April 2005 and encourages the Government of Japan to continue along this road until plant quarantine regulations are in line with the GATT's Sanitary and Phytosanitary chapter. Further steps should be taken to ensure impartiality and thoroughness in the quarantine inspection. The process lacks transparency as importers often are ordered to fumigate without being advised properly about which pests have been found in their shipments.

■ Capacity problems at Narita

Recommendation The EBC recommends further improvements at bonded warehouses and dispatch areas, especially at Narita where the largest volumes of imports are handled. Cold storage capacity must be improved substantially, inspections should be made in the cooled storage space and fumigation facilities should be installed next to storages, all to avoid exposure to highly damaging heat. Inspection capacity must be increased substantially in order to secure fair and efficient implementation of the strict inspection rules, especially during peak seasons.

Current situation No progress. Inspection capacity has improved somewhat over the last few years, and processing fees charged for holidays and overtime have come down. While there are cooler temperature-controlled warehouses available from May through to October, capacity is limited and prices remain high. The facilities are not able to deal with the volumes of cut flowers and other perishables now received.

■ Fumigation costs

Recommendation The EBC encourages further competition in the provision of fumigation services to help reduce fumigation costs at Japanese airports. If high costs persist, the EBC recommends proactive intervention by the Japanese Government, for example through the introduction of price caps.

Current situation No progress. Prices have not been reduced and remain approximately five times higher than at airports in countries with similar restrictions, such as New Zealand. Some 42% of all imported carnations, equivalent to about 60 million stems, were fumigated in 2004. The average fumigation cost per stem was about 2 yen or 5% of the wholesale price.

Background:

The market for cut flowers in Japan

The market for cut flowers in Japan is one of the largest in the world. Despite a high cost structure, domestic producers maintain their stronghold on the market. Whereas countries like Germany, France and the USA import more than 50% of the flowers they consume, the share of imported flowers in Japan remains at around the 10% mark. Structural factors such as excessively strict plant quarantine regulations, lack of cargo handling capacity at Narita, and lack of competition among fumigation companies make imports of perishables very costly, risky and difficult. Although no stated policy to obstruct the import of cut flowers exists, the above-outlined obstacles have raised an effective trade barrier that many foreign and Japanese importers find hard to believe is merely the result of an inadequate infrastructure.

Main barriers to trade

Restrictive Japanese plant quarantine regulations are by far the largest barrier to trade in cut flowers. In theory, zero-tolerance is applied only to organisms that are considered to be harmful on the basis of the Sanitary and Phytosanitary chapter of the GATT Uruguay Round Agreement. In 1996, the risk assessment chapter was added to Japan's plant quarantine law. Until recently, this revision has not had a beneficial effect on cut flower imports, as the Japanese Government does not make a practical distinction between harmful and non-harmful organisms. Insects such as thrips, mites and aphids, for example, have not been included in the list of non-quarantine pests, even though they are widespread in Japan. The Japanese Government has now started to meet EU requests by increasing the number of non-quarantine pests in the list from April 2005. The EBC appreciates this move and requests the authorities to include all organisms that are widespread in Japan, especially thrips, mites and aphids, in the non-quarantine list. Having said this, the EBC notes an increase in the fumigation of imported flowers from 17% in 2003 to 20% in 2004 and urges the government to facilitate the inspection process and reduce the number of superfluous expensive fumigations.

The infrastructure at Japan's international airports is also in desperate need of improvement. Fumigation, cooling, and warehousing costs are amongst the highest in the world, due in part to ineffective competition between companies offering airport facility services. The EBC had hoped that a Japan Fair Trade Commission investigation into collusion between fumigation service providers at Narita Airport would lead to lower port-of-entry costs for cut flower imports. So far, this has not been the case.

In addition to the high cost of port services, the facilities themselves are highly congested and insufficient to guarantee quick shipment handling. It takes too long for shipments to be made available for inspection and customs procedures after arrival and it takes too long for the shipment to be distributed after clearance. Time to delivery and temperature control are the key success factors in the trade of perishables as they have a direct impact on the level of claims and thus on customer satisfaction.

The EBC recognizes recent attempts to improve airport inspection procedures by extending inspection schedules, reducing holiday and overtime fees, and increasing the number of plant quarantine inspectors. We urge the Japanese Government to continue working in this direction. Eventually, the EBC would like to see a system of *ad random* inspection replace the current re-inspection of pre-inspected flowers at port of entry. This has been a long standing request, but no action has yet been taken.



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LIQUOR

Summary of outstanding issues:

■ Product definition

Recommendation Product definition in Japan should conform to international specifications as defined in the EU and the US and endorsed by the International Federation of Wines and Spirits.

Current situation No progress. Product definition standards for alcoholic beverages are still very loose in Japan. Many brands of Japanese "whisky" and "liqueur" would not qualify for the use of such terms in Europe. This allows Japanese producers to market lower-cost products that do not meet internationally accepted product specifications, including products with geographical indications. This is misleading to Japanese consumers.

■ Licensing

Recommendation The EBC strongly endorses deregulation of liquor retailing in Japan and urges the Japanese Government to further simplify liquor licensing for both retail and wholesale channels. The "Urgent Adjustment Areas" (*Kinkyu Chosei Chiiki*) should be abolished without delay.

Current situation Regress. Although the Japanese Government started to deregulate the retail environment by eliminating minimum distance requirements between retail licensees and population control, the policy has been effectively undermined by an increasing number of designated "Urgent Adjustment Areas", to which the deregulation does not apply.

The EBC is very disappointed that this supposedly temporary measure was prolonged for another year by the parliament in August 2005, putting applications for new licenses as well as transfers of existing licenses within the areas on hold for at least one more year. Furthermore, firms already holding a large store liquor retail license that allows for a limited scope of alcohol sales are not able to apply for a new wider-scope liquor license until their current license expires. If the license is in an "Urgent Adjustment Area", the application is rejected.

The EBC notes that there has been no deregulation of liquor licensing for wholesale activities. Several types of wholesale liquor licensing exist, and separate licenses are required for each sales office operated by the manufacturer, importer or distributor of liquor products.

■ Tariffs

Recommendation The EBC urges the Japanese Government to continue working towards the eventual elimination of tariffs on imported liquor products.

Current situation Some Progress. The Japanese Government has drastically reduced the tax rate on non-*shochu* liquor over the past five years in compliance with a WTO ruling issued in 1996.

Background:

EBC Liquor Committee Member Companies

Allied Domecq Spirits & Wine
e.s. Japan
Heineken Japan
Maxxium Japan
MHD Diageo Moet Hennessy
Pernod Ricard Japan

The Japanese liquor market

The Japanese market for Western style spirits and wine is one of the largest in the world. *Shochu* accounts for almost 85% of the distilled liquor market (not including liqueurs), with whisky and brandy making up most of the difference. However, despite liquor tax reform which greatly reduced the tax differential between *shochu* and other spirits, there has been little change to the market share of imported spirits such as whisky and vodka.

Wine is the only liquor category in which imports command a market share in excess of 60% and on the whole the prospects for wine imports in Japan remain positive in the long term. Consumer interest in wine has increased dramatically in urban areas and the Japanese are increasingly drinking wine with meals. On the supply side, the appearance of a wide variety of reasonably priced wines, retail deregulation, and improved quality control will contribute to an improved market environment. Having said this, the current consolidation in the distribution chain is resulting in a heavy downward pressure on prices on the supply side. The EBC urges the Government of Japan to exercise caution in raising consumption taxes under these circumstances as a raise cannot be passed on to consumers and hence will hit suppliers as they will be forced to absorb the tax increases.

Tax Reform

Japan's liquor tax regime discriminated against imported spirits for over 50 years. GATT Panels ruled against this practice in 1987, but this resulted in only minor improvements. The EU, Canada, and the US referred the issues to the World Trade Organisation, which upheld the complaint in 1996. As a result, Japan has reduced the tax differential between imported brown spirits and local *shochu* from 600% to just 3% since this ruling. For white spirits such as gin and vodka, tax discrimination has disappeared completely.

Liquor tax reform has significantly changed the whole face of the industry. In an attempt to win back market share from *shochu*, most companies have passed the tax savings onto the consumer. As a result, over the past seven years the Japanese spirits market has gone from being one of the most expensive in the world to one of the least expensive.

Ironically, tax reform has not had much effect on the market share of imported spirits. Low-priced, white spirits, liqueurs and RTD's ("ready-to-drink") are the only categories growing. For imported whisky and brandy (cognac) to have a long-term future in Japan, greater efforts are required to stimulate consumer demand and exploit the unique image, character, and heritage of these spirit categories.

Product definition

One of the keys to the development of European brand image in the Japanese market is the establishment of meaningful generic definitions for the major categories of internationally traded spirits such as brandy (cognac), gin, vodka and whisky. Currently, product definition standards for spirits are very loose in Japan. This enables Japanese companies to lower production costs by marketing products that do not conform to international product definition standards. The EBC is also concerned that Japan does not provide any recognition or protection for European liquor products with geographic indications such as Bordeaux wines, Scotch Whisky, and Cognac. Japanese producers are allowed to market products using European geographical indications, even though the indication may be unrelated to the actual product being sold. Ultimately, this is misleading to the Japanese consumer and represents a significant barrier to the development of the import market for European liquor products.

FOOD

Summary of Outstanding issues:

■ **Food Additives**

Recommendation The Japanese government should ensure that objectives for the approval of 46 specified additives set out in the Ministry of Health Labour and Welfare's (MHLW) document of March 2005 are achieved according to plan or faster. As well, standards of use for common preservatives such as sorbic acid, potassium sorbate, sulphur dioxide and benzoic acid should be reviewed so as not to penalize imported food.

Current situation Some progress. So far, 3 of the 46 additives have been approved: Calcium Stearate on 24 December 2004, Nitrous Oxide in March 2005, and Hydroxypropyl Cellulose on 18th August 2005. Designation of Natamycin is expected by winter 2005. Moreover, 8 flavour components have been approved so far. Since March 2005, the MHLW has been preparing and issuing a clear schedule showing the approval status of each additive on a monthly basis. It is encouraging to see some real progress on this major issue affecting many food companies and importers.

It is vital that the Food Safety Commission (FSC), which is the body responsible for the actual risk assessment, also makes efforts to ensure that this process continues to accelerate until all 46 additives have been approved. The EBC also urges the authorities to modify standards of use for additives already approved in Japan so as not to discriminate against the importation of European food. The importation of many European foods containing far lower levels of common preservatives, such as sorbic acid, potassium sorbate, sulphur dioxide and benzoic acid, than many Japanese foods is not permitted. This situation must be addressed.

■ **Testing of Food in the Market Place**

New Recommendation Local authorities (public health centers) exercising duties under paragraph 24 of the Food Sanitation Law as food inspectors of products in market circulation should be obliged to communicate a violation to the manufacturer or importer before notifying the retailer.

Current situation Retailers tend to panic and take excessive measures when the food they sell is found to contain substances not accepted in Japan (many of which are widely used in Europe and the U.S). This has substantial financial and environmental consequences as the wholesaler often is forced to dispose of the product in question as well as affiliated products, all of which may be perfectly safe. There are many reasons why (carry over for instance) an additive forbidden in Japan may be detected in a product that normally does not contain that substance. The manufacturer should be given the opportunity to investigate the problem and find a sensible solution together with the authorities before the alarm bell is raised and the market is thrown into panic.

■ **European Beef**

Recommendation Japan should review restrictions on EU beef imports without delay. Conditions on resuming U.S. beef exports should also apply to beef exports from Europe.

Current Situation No Progress Japan imposed a complete ban on the import of beef from European countries on or before January 2001 and since then, has not been willing to discuss conditions for lifting this ban. In contrast, the Japanese authorities have proactively

Current Situation cont'd sought conditions for lifting the ban on U.S. beef imposed in December 2003 after the emergence of BSE in the USA. In May 2005, the Food Safety Commission recommended that meat derived from animals younger than 20 months should be considered safe for import, a recommendation that was endorsed also by the MAFF. The European beef industry, in contrast to the U.S, is perfectly capable of tracing and guaranteeing the age of individual animals, but the Japanese government declines to re-evaluate the ban on European beef on the same conditions.

■ Revised JAS Law Related to Organic Products

New Recommendation The new JAS law, effective from March 1, 2006, poses recurrent excessive administrative and financial burdens on a number of European Certifying bodies that have been accredited to certify compliance with JAS-standards. The EBC proposes that organisations registered under the old system should be allowed to continue their certification activities by submitting additional data only. All organisations registered under the old system should be able to renew their accreditation without excessive recurrent costs, such as those related to regular inspection visits. MAFF should provide all information and also accept application documents in English.

■ Phytosanitary Border Control

Recommendation Japan should extend its list of non-quarantine organisms to include all non-harmful organisms found in fruits and vegetables.

Current Situation Some progress. Japan has made some progress by recognising that the current list of non-quarantine organisms needs updating. Several organisms were added to the list in April 2005, but many more should be added. This would lead to fewer fumigations and a quicker inspection process. Fumigation costs remain unreasonably high.

■ Fruit & Vegetables with Torn Nets

New Recommendation The Japanese Government should revise its regulations to allow fruit and vegetables arriving with torn nets to be imported and not be destroyed as they pose no phytosanitary risk whatsoever.

■ Perishable Products

New Recommendation The capacity to receive and adequately handle perishable products at Narita Airport should be increased without delay. In particular, pre-inspected perishables should be accepted without further inspections, and plant quarantine inspectors should shift from passenger facilities to the cargo area, where all inspections should be carried out.

Current Situation Narita Airport receives the highest value of perishable product imports in the world, but is ill-equipped to handle the demand. Efforts are being made to reduce the overall customs clearance lead time, but no special scheme is in place to speed up the crucial clearance of perishables.

■ MRL for Lindane

New Recommendation The provisional Maximum Residue Limits (MRL) for Lindane in cacao beans and processed cacao products should be set in accordance with ALARA-levels (as low as reasonably achievable), which are currently applied in most European countries.

Current situation A reduction of Lindane residues in agricultural usage has resulted in considerably lowered levels of Lindane in European Food. However, Lindane remains present in the environment and detectable levels of the substance can be expected in agricultural products such as cocoa beans for many years. The proposed provisional MRLs of 0.002 mg/kg for Lindane in cacao beans and a uniform MRL of 0.01 mg/kg for Lindane in processed cacao products are unjustifiably low and will be extremely difficult for any manufacturer to attain.

■ Chocolate Tarrifs

Recommendation The EBC asks the Government of Japan to match the import duty rates on all chocolate at 10%. In Japan, chocolate confectionery for retail (generally understood to be in packs of 500 g or less) is subject to an import duty rate of 10%. However, chocolate for professional use is subject to much higher duties: 29.8% for dark and milk chocolate and 25% for white chocolate. The EBC can see no justification for such a difference as higher duty rates on chocolate intended for professional use ultimately discriminates against Japanese confectionery producers as well as consumers. The EBC requests that an import duty of 10% be applied to all chocolate regardless of sales channel or pack size.

Current situation No progress. Although an official request has been made to the government regarding this issue, no progress has been made and no satisfactory reason has been given for this anomaly.

Background

Broadening Japan's Food Horizons

Japan seriously lags behind its main trading partners in the development of its food market. With its many rich traditions and well-developed food market, Europe has much to offer curious and quality conscious Japanese consumers. People in Japan have less choice and must pay considerably higher prices for European food than possibly any other developed economy in the world. This is due to overly restrictive and cumbersome regulations as well as punitive duty rates.

More choice through access to the world's leading products and ingredients would benefit not only consumers, but also the food industry since Japan has a long tradition of importing products, refining them, and creating new and interesting products and/or blends. Although Japanese food producers are seeing increased worldwide demand for their added-value products, their potential is hindered by the lack of availability and high cost of quality ingredients.

The EBC believes it is high-time for the Government of Japan to shift the policy focus from protection to sophistication and increased interdependence. The goal of the EBC Food Committee is for all high quality foods readily available in Europe to be accessible in Japan at reasonable prices.

Food Safety

In Japan, food safety remains high on the agenda. By adopting food safety policies that have proved to be well-functioning in the EU, misdirected measures that too often disadvantage well-meaning food producers and importers could be avoided. Furthermore, regulatory consistency should be also applied to food safety policies. Applying different conditions to different exporting countries supports neither consumer safety nor consumer confidence.

A Positive Development

Since last year's EBC White Paper, there has been at least one positive development. The EBC has strongly argued for the importance of swiftly approving the 46 substances recommended by the Ministry of Health Labour and Welfare (MHLW) in Dec 2002 for priority review. Therefore, the announcement by MHLW in March 2005 to speed up and make the approval process more transparent is a welcome development. For the first time, clear goals have been set; the MHLW is now committed to reducing the time for its initial evaluation from an average of 0.6 to 1.1 substances per month. Moreover, the MHLW has indicated that it will refer all 46 substances to the Food Safety Council (FSC), which is the body responsible for risk assessment, by March 2008. Although progress is still too slow, the EBC appreciates the efforts on the part of MHLW and is hopeful that the ministry and, in particular, the FSC will continue to accelerate this process.

Industry

Automobiles
Automotive components
Aeronautics
Space
Defence
Construction
Materials
Environmental technology



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AUTOMOBILES

Summary of outstanding issues:

■ **Harmonisation of technical standards**

Recommendation The EBC encourages the Japanese Government to speed up the adoption of UN-ECE Regulations and to consult closely with other UN-ECE members before introducing new domestic requirements.

Current situation Japan's regulatory regime has changed markedly in response to the globalisation of the automobile industry. Japan's membership of the UN/ECE 1958 Agreement on the Mutual Recognition of Type Approval for Vehicles etc. has accelerated the harmonisation of her technical standards with international norms. But there are still some areas where Japan has unique national technical requirements.

■ **Environmental legislation**

Recommendation The EBC urges the Japanese Government to formulate its environmental policies in such a way that they do not impose a disproportionate burden on imports.

Current situation European importers share the concern of the Japanese Government to reduce the impact of the automobile on the environment. The EBC hopes, however, that fuel efficiency targets, more stringent emission regulations, and legislation for the disposal of end-of-life vehicles and car batteries will be implemented in such a manner that these policies do not act as a de facto barrier to imports. The EBC urges that diesel emission standards should be set at a level that can be met by technologies used to meet the requirements of other sophisticated car markets

Background:

EBC Automobile Committee Members

ACEA
Audi Japan
BMW Japan
Citroen Japan
DaimlerChrysler Japan
Fiat Auto Japan
Ford Japan
General Motors Asia Pacific (Japan)
Jaguar & Land Rover Japan
Nicole Automobiles
Peugeot Japon
Porsche Japan
Premier Automotive Group
Renault Japon
Volkswagen Group Japan
Volvo Cars Japan
Volvo Nippon

Overview

Japan is the largest market in Asia for European car exports. Imports of foreign branded vehicles rose strongly in the early 1990's to reach 311,000 units in 1996. Since then, imports have declined along with the market as a whole. At 240,000 units in 2004, imports were still well below the peak. This represents 5% of the total passenger car market, including mini cars ("kei" cars). European brands have a share of more than 85% of the import car market (excluding cars exported to Japan from the overseas transplants of domestic manufacturers).

The European participation in the Japanese car market is not restricted to direct sales. Several European companies have taken equity stakes in Japanese automakers to work together not only in Japan, but in other markets, especially in Asia. Other European companies have formed alliances with their Japanese counterparts to share R&D or product development.

Global harmonisation

The globalisation of the automobile industry has given European and Japanese automakers a common interest in the international harmonisation of technical standards. While competing fiercely in the market place, the two industries cooperate to reduce the regulatory burden on the industry.

In 1998 Japan became the first country in Asia to accede to the UN/ECE 1958 Agreement on the Mutual Recognition of Type Approval for Vehicles etc., which provides that vehicle devices that have received type approval according to ECE Regulations in one contracting party are exempt from testing in any other signatory country where those regulations have been adopted.

Environmental policies

METI recognises that diesel passenger cars have a potential role to play in helping Japan meet her CO2 reduction targets. But the Japanese government has set its NOX emission standards at a level which, in effect, excludes diesel passenger cars from the Japanese market. This deprives Japan of the benefits of improvements in fuel economy that diesel technology can confer.

In cooperation with the Japan Automobile Importers Association (JAIA), the Automobile Committee has urged METI to ensure that the proposed scheme for the mandatory recycling of car batteries does not impose costs on car importers that are not equally borne by domestic car manufacturers.

Deregulation

The EBC Automobile Committee works closely with the European Automobile Manufacturers Association (ACEA) and the Japan Automobile Importers Association (JAIA) to devise common positions on regulatory issues that affect the interests of European importers. JAIA represents the importers on the various government consultative bodies that discuss policy towards the automobile industry. But the EBC Automobile Committee maintains its own direct links with government officials who are regularly invited to attend informal meetings with committee members.



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AUTOMOTIVE COMPONENTS

Summary of outstanding issues:

■ Globalisation of the automobile industry

Recommendation The EBC urges the Japanese automobile industry to focus more on the technical, commercial and logistical aspects of automobile production in the procurement of components and systems. Increased purchasing on a global basis and more emphasis on single platform development would further benefit the cost-effectiveness of the Japanese industry.

Current situation Limited progress. The EBC welcomes the opportunity that internationalisation presents for innovative European firms to strengthen their relationship with Japanese automobile manufacturers in developing new products and sharing technical expertise. European firms are not tied to specific European automobile manufacturers, and have products proven to the rest of the auto industry. 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. Many firms are also reassessing their procurement strategies.

Having said this, European automotive component and system manufacturers continue to face numerous challenges in promoting European technical expertise to automobile manufacturers in Japan. In general, Japanese manufacturers are still reluctant to outsource product development on a global basis and procure from non-traditional sources. Japan-specific requirements are common, and it is not unusual for specifications to differ between domestic and overseas production, even within the same company.

■ Promoting information exchange

Recommendation The EBC strongly supports the continuation of face-to-face meetings with top representatives from the Japanese automobile industry. The EBC feels that these meetings have led to a greater understanding between European component manufacturers and Japanese carmakers, and hopes that the scope of these meetings will be expanded in the future to include Japanese venues as well.

Current situation Face-to-face meetings between the European Association of Automotive Suppliers and Japanese car manufacturers were established in 1995 to promote information exchange between European and Japanese companies. These meetings have proven to be an extremely effective venue to discuss issues of mutual concern relating to products, platforms, global strategies and other important matters affecting the industry. The next meeting will take place on November 2005 in Torino, Italy, and the EBC encourages top-level Japanese industry participation. The EBC also sees much potential in the Japan Society of Automotive Engineers' (JSAE) Automotive Engineering Exhibition and the annual congress/paper presentation scheduled for May 2006 in Yokohama.

Background:

EBC Automotive Components Committee Member Companies

A. Raymond Japan
BASF Japan
Behr Japan
Bosch
DuPont Shinto Automotive Systems
Faurecia Japon
Henkel Japan
Knorr-Bremse Commercial Vehicle Systems
Nihon Inalfa
Osram
Sachs Automotive Japan
Seric
Siemens VDO Automotive
ThyssenKrupp Automotive Japan

The changing circumstances of the Japanese market

More and more European automotive components firms are dedicating resources to attracting business in Japan by investing in local infrastructure and improving technical competence with the goal of promoting more direct contact and closer relationships with Japanese clients.

European firms are looking to take advantage of opportunities in Japan that have surfaced as a result of the recent transformation of the Japanese automobile manufacturing sector. Globalisation and intense competitive pressures at home and abroad have forced Japanese manufacturers to reassess procurement strategies, placing more emphasis on global procurement and cost-effective product development. At the same time, the European automotive component industry's relationship with Japan has intensified as a result of the development of Japanese car manufacturers' transplant operations in Europe and in other parts of the world, including China. In the long run, the EBC sees globalisation of the Japanese car industry as a very positive development – one that will likely lead to increased opportunities for European firms in the future.

Unfulfilled expectations

Unfortunately, European automotive component and systems manufacturers continue to face difficulties in promoting European technical expertise to the Japanese automobile industry, mainly due to continued reluctance in outsourcing product development on a global basis. Japanese firms are still uneasy about divulging proprietary information to outsiders, continuing to favour traditional suppliers for product design and production. It is also still often necessary to provide “Japanese solutions” to customers in order to adhere to company-specific specifications, which defies the global trend towards single platform development and volume production. Many firms report that while Japanese manufacturers have indeed shown more interest in procuring from European suppliers over the past few years, this interest has not translated into significant business development. In general, European firms have been more successful in generating business in other Asian countries, including at Japanese transplants in China.

Encouraging further outsourcing of product development

The outsourcing of automobile component development has emerged as a clear trend in the European automobile industry. The European system offers lower risks at less cost with greater flexibility and the EBC hopes that this system will be adopted more fully in Japan in the future. This would lead to a more competitive structure that would promote lower costs and more innovation.

What European firms can offer

The EBC seeks to reassure Japanese companies that European firms are committed and reliable partners in any product development relationship. European automotive component and systems producers have much to offer to the Japanese automobile industry. European automotive component and systems manufacturers have a reputation for innovation, technical expertise, efficiency, quality and personal attention that Japanese automobile manufacturers have come to expect from their suppliers. Furthermore, European companies are in an excellent position to provide support to the development of Japanese manufacturing capability outside of Japan, for example transplants in Europe or in the rest of Asia.



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AERONAUTICS

Summary of outstanding issues:

■ Promoting competition

Recommendation Procurement decisions should be made on a competitive basis free from political influence. 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, shareholders, and the general public.

Current Situation Although European manufacturers of commercial aircraft, engines, components, and navigational equipment offer state-of-the-art technology at internationally competitive prices, the European share of the Japanese market for commercial aircraft and related equipment is still considerably less than the worldwide average.

The legal limitation of foreign participation into the capital of Japanese aeronautical firms is also an important hindrance to European investments and presence in Japan (see: Aeronautical Law article 4).

■ Promoting industrial co-operation

Recommendation The EBC is looking to increase industrial co-operation between Japan and Europe, in particular in the field of commercial aircraft, engines, components and navigation systems.

New challenges lie ahead in the development of innovative solutions designed to meet future needs in civil aviation. The EBC considers these challenges as a great opportunity to significantly enlarge the scope of cooperation between Japan and Europe. The EBC encourages the Ministry of Economy, Trade and Industry (METI) and other government affiliated institutions to openly promote and fund collaboration with European companies in a similar manner as with American firms.

Current Situation Co-operation in commercial aircraft development is still heavily biased in favour of North America. METI's support for the Boeing 787 programme should not limit the potential of future collaboration with Europe. The EBC is still convinced that there are mutually beneficial opportunities for co-operation between European and Japanese firms. METI's support on the Trent 1000 engine and the recent agreement on supersonic technologies should show the way for more aeronautic co-operation.

Background:

EBC Committee of Aeronautics, Space and Defence Member Companies

AgustaWestland
Airbus Japan
Alcatel Japan
Arianespace
BAE SYSTEMS International
Barco
Eurocopter Japan
Rolls-Royce International
Safran
Snecma
Thales Avionics Japan
Thales International Japan
Turbomeca Japan

The Japanese aeronautics industry

Since the end of World War II, the Japanese aeronautics industry has been trying to rebuild a domestic capability with strong financial support from the Japanese Government. Attempts by the Ministry of Economy, Trade and Industry (METI) to promote Japanese independence in the field of aeronautics through national projects have not achieved the level of success expected. Japanese companies still rely heavily on defence contracts, which account for over 60% of their total aerospace turnover, and on partnerships with Boeing for commercial contracts.

The Japanese aeronautics market

The Japanese market for large commercial aircraft and helicopters is one of the largest in the world. Historically, this market has been dominated by the United States.

The EBC hopes that Japanese companies will deepen their understanding of what European commercial aircraft offer – state-of-the-art technology and passenger comfort that is well recognised around the world. The EBC urges JAL, ANA, NCA and other airlines to consider European commercial aircraft for future fleet renewal or modifications.

Co-operation in commercial aeronautics development

The cooperation between Kawasaki Heavy Industries (KHI) and Eurocopter on the BK117 helicopter, and also between Mitsubishi Heavy Industries (MHI)/ Kawasaki Heavy Industries (KHI) and Rolls-Royce on Trent 1000, are encouraging examples of successful cooperation between European and Japanese industries.

However, due to the long-standing relationship with North American companies, the Japanese Industry is sometimes reluctant to work together with European businesses.

Proactive collaboration with successful European companies would certainly enable Japanese companies to strengthen their position in commercial aeronautics. By participating in 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 is much room for large-scale joint development programs between Japanese and European Industry, especially in the field of transport aircraft, and urges the Japanese Government and Industry to give serious consideration to such an initiative.



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SPACE

Summary of outstanding issues:

■ Satellites

Recommendation The EBC supports development cooperation between Japan and Europe and welcomes increased interest in a new scale of Japan-Europe collaboration. We particularly encourage the development of ever-closer ties between the Japan Aerospace Exploration Agency (JAXA) and Europe's space agencies. We encourage the space agencies on both sides to discuss their respective plans in new application areas from an early stage in order to take full advantage of every opportunity for more Japan-Europe cooperation.

Current situation Close relations have long been maintained between the Japanese and European space agencies (ESA and individual countries' national space agencies). New interest has been shown recently on both sides for expanded cooperation and more discussions have been taking place. Although there have been a few exploratory moves by some companies, concrete cooperation in satellite development remains very limited. Industrial cooperation in new application areas is only possible when promoted by the space agencies.

■ Launchers

Recommendation The EBC supports increasing cooperation between the Japanese and European space authorities, and strongly hopes that both current and future discussions will bring about balanced, fruitful and active cooperation vis-à-vis their respective heavy-lift launchers. For technical and programmatic reasons this cooperation should be comprehensive and systematic. We hope that the new H-IIB launcher project will help to solidify existing cooperation initiatives. The EBC strongly supports discussions by Japanese and European companies on commercial and industrial cooperation in the field of launchers and space transportation in general.

Current situation Japan and Europe are the world's only major space powers with the problem of maintaining independent access to space without a large and supportive government market. The Japanese and major European space authorities have been studying a possible agreement to back up each other's governmental launch missions based on the principle of reciprocity, which is possible only between Japan and Europe. This addresses both the problem of major government mission delays in case of technical problems with one of the two national launchers, and the challenge of preventing a one-sided flow of such delayed government missions away from the delayed launcher. Moreover, the Japanese and European space industries are coming closer together as they work towards further cooperation on a commercial, as well as industrial basis.

Background:

EBC Committee of Aeronautics, Space and Defence Member Companies

AgustaWestland
Airbus Japan
Alcatel Japan
Arianespace
BAE SYSTEMS International
Barco
Eurocopter Japan
Rolls-Royce International
Safran
Snecma
Thales Avionics Japan
Thales International Japan
Turbomeca Japan

Japan and the space sector

Japan is one of the leading nations in the field of space. H-IIA launchers give it independent access to space. A lighter launcher, the Galaxy Express, is now under development, and a heavy-lift derivative of the H-IIA launchers is on the drawing board. Japan also builds state-of-the-art technological and scientific satellites at the rate of one or two per year, but budgetary pressures are particularly severe. New satellite development plans have also been delayed. Japan's space industry has been successful in ground infrastructure and satellite equipment.

However, Japan's space industry lags in the world market due to low domestic volumes. The satellite industry relies almost exclusively on scarce government orders after U.S. pressure forced much of the government market to open to international competition in 1990. Most of the responsibility for the H-IIA launcher is being transferred to the private sector in the midst of a satellite market depression. Higher hopes are now pinned on future exploration programs.

Unfortunately space activities often suffer from low interest among the Japanese public. Having said this, the public supports international cooperation if it is for the common good and in a peaceful context.

Satellite systems

A US-Japan agreement requiring the international tendering of many Japanese government satellites has resulted in a relatively open satellite market. European satellite makers entered Japan's satellite market later than their U.S. counterparts and have yet to sell any satellites in Japan. But Japanese customers are now showing increasing interest toward European made satellites. This is due to increased efforts by European makers to provide information about their satellites, and to better recognition worldwide of the excellent track record of European-made satellites, which have particularly high quality and reliability. Another factor is opaque and unreliable U.S. export control policies in contrast to Europe, which has adopted a transparent policy towards Japan.

Japan often uses international cooperation to reach technological and industrial excellence through contacts with advanced partners. However, cooperation in satellite development remains heavily biased towards the U.S., particularly for high-cost programmes close to national security. A larger share of satellite equipment, however, is now being manufactured in Japan. Political influence and pressure have had an adverse effect on the commercial development of both the Japanese space industry and the European space industry in Japan.

New developments could be in the making, however, as a result of meetings in recent years between European and Japanese space authorities and agencies. European and Japanese space industries have steadily grown sufficiently confident to cooperate, and discussions give hope for progress. Europe has much to offer in terms of proven and innovative technologies, with few political strings attached and no particular export restrictions to Japan.

Launchers

The Ariane launchers have been successful with Japan's commercial satellite operators, and a relationship of trust has been established with Japan's industry and space authorities.

To maintain independent access to space despite severe budgetary constraints and a small government market, the Japanese Government is transferring many responsibilities of the current H-IIA launchers to Mitsubishi Heavy Industries (MHI). However, the current market situation makes it hard to introduce yet more launchers into an already overcrowded and fragile commercial market. The home government launch market will remain essential for the foreseeable future.

Cooperation between the Ariane 5 and H-IIA launchers is slowly taking shape. In the commercial arena, Arianespace, MHI and Boeing Launch Services are cooperating to make it easier for customers to shift their satellites within this group in the case of technical problems with one of the group members' launchers. On the other hand, Europe's and Japan's space authorities are discussing the implementation of a similar, but separate and bilateral scheme between Ariane 5 and H-IIA for the mutual backup of Japanese and European government missions.



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DEFENCE

Summary of outstanding issues:

■ **Non-tariff barriers to trade**

Recommendation The EBC urges the Japanese Government to increase transparency in defence procurement, and encourages a more thorough and fair assessment of European products for future defence requirements. European companies have much to offer the Japanese Defence Agency (JDA) in terms of inter-operability, technical expertise, real-world operational experience and worldwide competitive pricing, but until now the procurement process has prevented access to these products. The choice of defence equipment should be based on operational, technological, and cost-effective merit whenever politically possible.

Current situation Despite the success of AgustaWestland with the JMSDF (Navy), there have been few encouraging signs recently that Japan is prepared to select a European solution, even when such a solution meets a unique requirement or provides best value for the taxpayers' money. The EBC would like to increase the European presence in the Japanese Defence sector. However, the procurement process still lacks transparency and the assessment of European equipment remains insufficiently balanced. Further improvement is still necessary before European firms can truly compete on an equal basis with Japanese and US firms.

■ **Industrial co-operation**

Recommendation The Japanese Government stated on 10 December 2004 that the policy on industrial cooperation with foreign countries on weapons technology was to be modified to allow Japan/US exchange of R&D and technologies, specifically in the Ballistic Missile Defense (BMD) project. It was hinted also that industrial cooperation with other foreign countries would be studied on "a case by case basis". EBC takes this statement as an indication that the Japanese government is intending to expand international industrial cooperation beyond BMD and the US. The EBC, therefore, kindly requests specific details on how, and under what conditions, the regulations concerning defense industrial cooperation could be eased toward the European countries looking for co-development projects in Japan.

Current situation For the time being, Japan prohibits co-development involving the exchange of defence-related information, including specifications for military equipment, with all countries except the US. Modifications to the three principles of Japanese defence (no technology exports, no product exports, no exchange of information related to armaments) are now being considered, but no conclusion has been reached yet. The EBC urges the Japanese Government to take this opportunity to start meaningful discussions with its European counterparts and support the development of mutually beneficial partnerships between Japanese and European companies. This will give Japanese industry and governmental agencies access to new technologies and processes developed to meet the requirements of real-world operational experience.

Background:

EBC Committee of Aeronautics, Space and Defence Member Companies

AgustaWestland
Airbus Japan
Alcatel Japan
Arianespace
BAE SYSTEMS International
Barco
Eurocopter Japan
Rolls-Royce International
Safran
Snecma
Thales Avionics Japan
Thales International Japan
Turbomeca Japan Japan

The Japanese defence market

Japan's current 5-year defence plan includes an arms procurement budget of around 4 trillion yen, of which an estimated 85% will be spent on weapon systems developed and built locally. Products built under license from US manufacturers or directly imported from the USA, make up most of the remaining 15% of Japan's defense hardware market and so on.

With a few exceptions, European defence sales to Japan have consisted mainly of minor equipment or components for Japanese-made weapon systems, a situation that has yet to improve.

European involvement in Japan's defence market

As with many other sectors of the Japanese economy, the European defence industry faces a number of non-tariff barriers to trade that limit European involvement in the Japanese market. The Japanese defence procurement process lacks transparency, creating difficulties for foreign companies to understand the timing, the parties involved, and the requirements of new programmes. This is compounded by a lack of fair competition, and often a reluctance of the Japanese defence establishment to receive product information in due course. The defence establishment remains relatively uninformed about European products, and this lack of exposure leads to narrow views on defence and procurement policy. As a result, European defence firms face an uphill battle in their efforts to both increase co-operation in product development with Japanese companies, and, even when necessary or urgent, to sell ready-to-use, state-of-the-art equipment to the Japanese Government.

American political pressure surrounding the trade imbalance, financial incentives to buy American products through the Foreign Military Sales programme, and Japanese fears of non-interoperability with the US have further restricted European access to the Japanese defence market.

While the EBC recognises the important role the US plays in the Japanese security structure, the EBC feels that the Japanese attitude towards interoperability is often overstated. Limiting foreign procurement to American products has not guaranteed interoperability with the US. Instead, this policy has restricted Japanese access to innovative European solutions to inter-operational problems. As a counter example, the closest ally of US, the United Kingdom, has fully interoperable forces equipped almost entirely with European designed systems.

Opportunity for change

Japan's current economic climate, combined with increasing tensions in the region, expanding international roles for Japan's defence forces, and major new initiatives such as the Missile Defence programme, are placing tremendous pressure on defence procurement budgets. The large number of key projects to be implemented in the near term cannot be accommodated within the present fiscal budget without significant re-evaluation of the procurement policy and a much greater focus on cost-effectiveness. The EBC encourages Japan to take advantage of this opportunity for change. A more transparent and competitive procurement process would increase Japan's access to off-the-shelf, cutting-edge technology defence equipment, enabling the Japanese Government to obtain higher value within their defence budget.

European companies offer worldwide competitive pricing and combat-proven equipment. Moreover, since there is no security alliance between Japan and Europe complicating political relations, Europe can offer full technology transfer with no "political strings" attached. This would be of great benefit in ensuring military readiness in an era of fiscal constraint.

CONSTRUCTION

Summary of outstanding issues:

■ **Public procurement**

Recommendation Procuring entities should place more emphasis on obtaining “value-for-money” through the establishment of effective quality/performance evaluation and management systems. Public work contracts should not be used as means to promote policy goals such as improving conditions for small and medium sized companies.

Current situation Limited progress. European firms find it much easier to supply innovative materials, designs, and techniques to the private sector than to the public sector in Japan. The EBC welcomes recent government efforts to improve disclosure of information on public works projects. However, this has not yet resulted in any substantial improvement in the transparency of the procurement process or reduction in construction costs in Japan. Insufficient effort is being made to ensure “value-for-money.” Moreover, quality control and assurance measures are in many cases non-existent. Local authorities maintain an official policy of sharing work among many contractors, a practice that indirectly invites bid-rigging.

■ **PFI/PPP**

Recommendation Public-Private Partnership (PPP) projects should be performance based, giving the operator (private company) clear goals to fulfil, but freedom in choosing the means of delivery. Successful implementation must be duly rewarded to stimulate competition.

Current situation Private Finance Initiatives (PFI) and Public-Private Partnership (PPP) schemes implemented in Japan to date have not achieved their true potential for value enhancement for the taxpayer, as they are largely a variant of contractor-financing (with deferred payments by the purchaser) rather than true PFI/PPP projects. Most projects effectively restrict innovative solutions and are barely profitable.

■ **Mutual recognition of standards for Construction Materials**

Recommendation The governments of the Japan and the EU should initiate discussions with the goal of establishing mutual recognition of JAS/JIS and CE/EN standards for building materials. Accreditation procedures for foreign testing bodies under the JAS/JIS as well as the Special Ministerial Approval schemes regulated by the Building Standard Law should be streamlined.

Current situation Limited progress. Building materials exported to Japan are tested according to both European and Japanese standards, although most tests are very similar. Given the complex certification schemes, very few testing institutes have been accredited to test building materials for Japan (one institute is testing for JAS gluelam, sawn lumber standards and two others for formaldehyde-emitting products under the Ministerial approval scheme).

Background:

EBC Construction Committee Member Companies

Bovis Lend Lease Japan
Clestra Hauserman
Currie & Brown (Japan)
Saint-Gobain Hanglas (Japan)
Schindler Elevator

The business environment: an overview

Government regulations and inefficiencies in the structure and management of the construction sector prevent the creation of a market environment based solely on cost-effective merit. In the face of continuing fiscal constraints, this has not gone unnoticed by the Japanese Government. The Ministry of Land, Infrastructure and Transport (MLIT) has been actively encouraging consolidation within the industry and has started to impose stricter qualification criteria on general contractors bidding for public works projects. For large-scale public civil engineering works projects, tenderers are now permitted to propose alternative designs and construction methods. However, disinterest on the part of local authorities means that the benefits of this initiative are not exploited.

Despite well-intended policies tailored to increase competition and promote alternative solutions, little has changed in practice. This is reflected by a continuously low level of foreign involvement in the Japanese construction industry. A number of European firms operate in niche areas of the market, but these examples are limited in both scope and scale. As policies have not yet produced the desired outcome, the government needs to implement new firm measures to rationalise the construction industry. Restricting the widespread *amakudari* practice (private sector employing retired ranking officials) within the construction industry would be an important step to take.

Regulatory burden

In Japan, it is almost impossible to sell building supplies directly to end-users especially for new building projects. Except for small projects (less than 5 million yen in value) a company needs to hold a permit (*kensetsu gyo kyokasho*) to be a contractor or a direct subcontractor of a general contractor (*zenecon*). To obtain this permit, a company must have a resident management staff member having more than 5 years of relevant experience in the same company or in another company in the same field. Small foreign firms that cannot find an appropriate person are forced to make “go-between” side-deals with a permit-holding subcontractor, which increases the costs of doing business in the Japanese market.

At the very least, the ceiling price system (*yotei kakaku*) for public tenders should be abolished and requirements for bid participation relaxed. Requirements peculiar to the construction of public works, such as the requirement for locally qualified and licensed engineers for all projects over 25 million yen, and burdensome inspection requirements not experienced in private sector projects should be eliminated.

The cost of setting up local representation, obtaining licenses, registering under the *keishin* system, and bidding for projects remains prohibitive for European contractors. The ability of European firms to build using innovative designs, imported materials, and modern construction methods – the key to their competitive advantage – is effectively eliminated by over-regulation, resistance to change by local officials and complicated procedures to obtain the necessary approvals. Although the Building Standard Law now essentially is performance-based, detailed specifications formulated under previous regulations are still widely used, thereby obstructing proliferation on the market of high-quality alternative (foreign) materials. Depending on usage, construction materials must undergo thorough tests for fire safety, strength characteristics, stability or formaldehyde emission, all according to Japan-specific methods.

Finally, the EBC urges the government to avoid repeating the mistake of rejecting superior technology and know-how by responding only to the domestic industry’s call for unique Japanese solutions when introducing new standards. The concept of sustainable or “green” buildings will sooner or later be translated into standards and rules. Drawing from the vast European experience of environmental solutions and construction, the EBC would be happy to engage in dialogue with the government on the policy choices and practices available.

MATERIALS

Summary of outstanding issues:

■ Tariffs

Recommendation The EBC urges the Japanese Government to eliminate all tariffs on industrial raw materials. This would give Japanese key industries access to high quality products at competitive market prices.

Current situation No progress. Tariffs are by far the largest barrier to trade in industrial materials with Japan. The most common industrial materials are truly global products, sold worldwide under transparent prices. Even the smallest tariff-induced price differential makes it difficult for European producers to compete. Japan is the only major industrial power in the world to apply duties on refined nickel products such as nickel metal (used in the stainless steel and high-nickel alloys industries, import code 750210000, tariff 44 yen/ kg), ferro-nickel (used in the stainless steel industry, import code 720260010 / 720260090, tariff 3.3%) and nickel oxide sinter (used in the stainless and alloy steel industries, import code 750120210 / 750120100, tariff 3% / 44 yen/kg). These products represent more than 90% of all Nickel imports to Japan and are subject to tariffs ranging between 3% and 3.3%, or 44 yen/kg. This is difficult to justify as much of the domestic production is exported. The largest smelter of ferro-nickel in Japan, for instance, exports more than half of its production. This greatly distorts competition not only in Japan, but also in export markets.

Japan allows consumers to import some of these materials from a very limited number of countries with no or significantly lower tariffs under the so-called General System of Preference (GSP). Import of materials for industrial use from these countries remains, however, very small. Japanese consumers of industrial materials in industries such as stainless steel, electronic components, battery production, automobiles, plating or aeronautics, face increasingly stiff international competition and would benefit from cheaper commodity procurement. Abolishing tariffs on industrial materials would substantially improve that situation.

■ Tariff classifications

Recommendation The EBC urges the Japanese Government to rationalise its tariff classification regime and develop a comprehensive strategy to improve consistency between Customs Offices on classification rulings, improve transparency of classification methodology and test results, and strengthen dispute resolution mechanisms.

Current situation No Progress. European suppliers of industrial materials in Japan are occasionally subjected to arbitrary tariff classifications and revisions. Customs Offices do not apply classification rules on a consistent basis and there is no appeal mechanism available with which to challenge a classification ruling. This is a problem not only for products entering the market for the first time, but also for well-established products subject to sudden classification reviews.

Background:

EBC Materials Committee Member Companies

Elkem Japan
Eramet Japan
Falconbridge (Japan)
Hoganas Japan
Treibacher Schleifmittel Japan
Umicore Marketing Services Japan

High duty rates on key industrial inputs harm Japanese consumers

High tariff rates on imported industrial materials significantly increase commodity procurement costs for Japanese consumers vis-à-vis their Chinese and Korean competitors in particular. This adds to the problems Japanese firms continue to face in important sectors such as steel, electronics and machining, which are facing increasing global competition for their products. As one of the largest consumers of industrial materials in the world, Japan would greatly benefit from unrestricted access to high quality products at competitive market prices.

Japan has demonstrated a reluctance to further reduce tariff rates on these and other products on a unilateral basis before formal negotiations start on tariff reductions under the auspices of the new WTO round. The EBC feels that it would be in Japan's interest to take immediate, unilateral action to reduce tariffs on all remaining industrial materials considering the fact that these products represent vital inputs for Japanese industry. The EBC Materials Committee, representing a large, important sector in European industry, urges the Japanese Government to eliminate tariff rates on imported industrial materials.

Nickel

The extensive tariff scheme on refined nickel significantly increases the procurement costs for Japanese consumers at a time when many Japanese companies in sectors such as stainless steel production are facing new challenges from competitors, particularly in Korea and China. Tariff-induced price incentives have seriously distorted the structure of nickel production in Japan and failed in their original aim to secure domestic nickel supplies. Japanese nickel producers have increased production to cover fixed costs despite stagnant domestic demand. This has led to a situation where Japanese nickel producers now export over 30% of their production. This makes little economic sense as Japan is in effect subsidising foreign consumption.

The EBC believes that the current situation is also unfair to European producers, since they are forced to compete with Japanese producers who are protected at home. Europe does not impose import duties on processed nickel products and for some other nickel products such as nickel hydrides, Japanese producers freely sell their products to battery producers in Europe, while European producers are forced to pay a duty for products sold to battery producers in Japan. Regardless of the economic costs involved, high tariff rates on processed nickel products have long been justified by Japan as a means to secure stable nickel supplies. On the contrary, Japan is in fact putting itself at risk by imposing high tariff rates on processed nickel products, as it does not have any nickel ore supplies of its own. Countries that produce nickel ore will continue to strive to have their ore processed locally. Competition for nickel feed will likely increase between Japan, Korea, Taiwan and China, and it will become increasingly more difficult for Japan to secure supplies of nickel feed in the future. The EBC notes that China, facing supply shortages of its own, has decreased import duties on refined nickel products to 1%.

Fused aluminium oxide

Fused aluminium oxide is used in the refractory industry and abrasive industry for grinding wheels, sand paper, or loose grain applications like grinding and polishing of glass, electric components. Imported fused aluminium oxide is subject to a 3.3% tariff, though most imports come from countries enjoying tariff exemption under the Generalised System of Preferences. However, some categories that are not produced domestically cannot be purchased from tariff-exempt sources. In other words, duty is being applied to some products that are not even produced in Japan. This increases the price for imported fused aluminium oxide and effectively penalises the Japanese end-user. This situation is exacerbated by a shortage of supply.



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ENVIRONMENTAL TECHNOLOGY

Summary of outstanding issues:

■ **Attitudes towards environmental remediation**

Recommendation The EBC urges the Japanese Government to improve education on environmental remediation in Japan and promote the development of new technologies to help deal with these problems.

Current situation In Japan, environmental problems such as the illegal dumping of waste, high levels of soil contamination, low levels of plastic recycling, and an aging waste management infrastructure abound. Environmental remediation should not be regarded as an expense – the development of new technologies to deal with these problems also generates important economic benefits, and these should be emphasised.

■ **Regulatory structure**

Recommendation Japan should further strengthen the regulatory regime governing environmental protection and the environmental business, with special emphasis on consistent application and enforcement of the rules.

Current situation Limited progress. The environmental technology sector in Europe is regulatory driven. While the regulatory regime governing environmental protection and environment-related businesses is highly developed in Japan, the current situation is not always conducive to the introduction of innovative solutions to environmental problems.

■ **Government procurement**

Recommendation The use of Private Finance Initiatives (PFI) and Public-Private Partnerships (PPP) should be further encouraged in Japan. The EBC urges more Japanese/European cooperation in the development of Japan's PFI strategy to draw on the wealth of European experience in this area.

Current situation Some progress. Private Finance Initiatives and Public-Private Partnerships are gaining popularity in Japan. These means have long been applied in Europe for the funding of entities traditionally financed, managed, and operated by public authorities. European firms specialising in this field would like to enter the Japanese market, but conservative attitudes towards alternative service delivery continue to obstruct these initiatives. In the water sector, for example, public works development continues to be dominated by equipment manufacturers and construction firms. No private company is able yet to provide comprehensive operation management to help boost performance. This has resulted in high initial capital investment, high running costs, over-capacity, and a growing debt burden on municipalities. The EBC urges authorities from the EU and Japan to continue sharing information on the potential of PFI/PPP to enhance the development and delivery of public services in their respective jurisdictions.

Background:

**EBC Environmental Technology Committee
Member Companies**

JBS
ONDEO Degremont Japan
Royal Ten Cate
TUV Rheinland Japan
Veolia Water Japan

The environmental technology sector in Japan

While many expected a boom in the environmental technology field in Japan, in reality the market has not lived up to this promise. Part of the problem lies in the lack of a comprehensive strategy to deal with the numerous environmental issues that Japan currently faces in areas such as soil remediation, waste management, and water treatment. Private and public sector entities also remain hesitant to divulge the extent of the environmental problems they are facing. Until this attitude changes, the market potential in Japan for environmental technologies is likely to remain unfulfilled.

Soil remediation

The EBC is encouraged by a number of recent developments that bode well for the future of the soil remediation sector. The new Soil Contamination Measures Law, for example, creates a strict new environment for the remediation of contaminated soil sites, which will likely result in increased interest in soil remediation technologies in the immediate future. However, the long-term impact of this reform will depend to a large extent on the ability of the regulatory authorities to effectively implement these new guidelines. The EBC also remains concerned about the regulatory environment governing the soil remediation practices themselves. The Japanese Government has yet to develop clear guidelines regarding site characterisation standards, sampling and testing procedures, risk-based decision models for determining remediation urgency, and a comprehensive timeframe for cataloguing and cleaning up polluted sites. Many testing methodologies differ substantially from accepted international practice, and testing costs are much higher than they are in Europe. The EBC feels that increased competition in site assessment and testing services would benefit the environment and help society by reducing the costs associated with remediation.

Waste management

Recent changes to Japanese waste management regulations have included amendments to the Waste Management Law in 1991, 1997, and 2000; the introduction of the Containers and Packaging Law in 1995; the introduction of a new home appliance recycling law in 1998; introduction of the laws for the promotion of a recycling society, construction recycling, food recycling and green purchasing in 2000; and new dioxin emission standards that took effect in December 2002. Despite the strong legal structure governing the waste management sector in Japan, a number of important questions remain: What will happen to the large number of industrial waste incinerators that are not compliant with new dioxin standards? How will Japan fight illegal dumping given that the new legal environment may in fact encourage more use of this “disposal” method? Will the Japanese Government develop financial support systems to promote recycling of substances such as plastics, which historically has been low in Japan? These and other uncertainties in the application of waste management regulations need to be addressed before European investors are confident about the future of the waste management business in Japan.

PFI

The EBC is encouraged by official government support for the development of Private Finance Initiatives and Public-Private Partnerships in Japan. European firms have historically been very strong in alternative service delivery in fields such as water treatment and waste management, and the EBC hopes that this experience will lead to new opportunities in the Japanese market. The EBC urges the Japanese Government to continue promoting the use of PFI/PPP by actively supporting local government PFI initiatives. For their part, European firms can contribute experience in advanced approaches to public construction in areas such as design-and-build turnkey methodologies and in the operation and management of public services. This will help reduce costs, increase reliability, and improve service quality.

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