



TRADE, INVESTMENT AND THE REFORM NEXUS

The EBC Report on the Japanese Business Environment
2004

The
European Business Community
in Japan

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the Reform Nexus

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The European Business Community (EBC) is the trade policy arm of the 18 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 350 of the companies participate directly in the EBC's 26 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

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

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

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Trade, Investment and the Reform Nexus

The EBC Report on the Japanese Business Environment 2004

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Message from the Chairman

It is my great pleasure to once again introduce the European Business Community in Japan's annual report on the Japanese business environment.

We are into the second year of Prime Minister Koizumi's five-year plan to double the amount of foreign direct investment in Japan – with mixed results so far. Foreign investment is down, even though the economic situation in Japan has improved considerably from last year.

From a European perspective, this situation represents somewhat of a paradox. Many well-known European companies continue to do good business in Japan and add considerable value to the Japanese economy. But many firms continue to be turned off by the high costs involved in entering the market, and expanding their business once they are here. This represents a “lost opportunity” for the growth and development of the Japanese economy.

It is an undeniable fact that Japan is still the second largest market in the world, with high levels of income and high rates of savings. The Japanese are highly educated, curious and thirsty for new products and ideas. Japan is a recognised world leader in advanced technologies and manufacturing processes.

But Japan has been slow to modernise its economic structure to cope with increasing internationalisation. It is this other reality that is causing foreign investors to increasingly turning their eyes towards more dynamic countries in the region.

The Japanese Government, under the constant drive of Prime Minister Koizumi, is making efforts to improve trade and investment opportunities that truly help the country to recover. The EBC is impressed with the clarity and resolve with which Prime Minister Koizumi has pushed forward his reform agenda in areas such as fiscal decentralisation and privatisation.

The Japanese Government has already taken some measures to help foreign investors find their way in the Japanese jungle of regulatory complexities and I would like to express my gratitude to entities such as the Cabinet Office's Japan Investment Council (JIC), METI, JETRO, as well as many Prefectural Governors for encouraging reform throughout the Japanese administration.

But more needs to be done to increase the pace and scale of reform. Every year the EBC makes numerous recommendations to improve the efficiency of the Japanese regulatory environment. Many of these issues have been on the books for years. It is not until the Ministries and Agencies such as the FSA, MOF, MAFF, and MHLW take decisive action to address these issues that foreign investment will really start to increase in Japan.

This year's report has been entitled “Trade, Investment and the Reform Nexus” to drive home the point that further reform is necessary to convince foreign investors that investing in Japan is worth the effort!

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

Message from the Executive Director

The European Business Community in Japan (EBC) is proud to present its 2004 White Paper, the fifth consecutive year of its publication. Entitled *"Trade, Investment and the Reform Nexus: the EBC Report on the Japanese Business Environment 2004"*, the report highlights the unresolved issues inhibiting the development of European business in Japan.

The production of this report is always a massive undertaking. It synthesizes the views of hundreds of people from a wide range of professional backgrounds with the common desire to achieve a healthy and open place to do business. This goal is all the more important given the expressed desire of Prime Minister Koizumi and his Government to double foreign direct investment by 2008. This report, like the EBC itself, represents our diverse member companies, yet speaks with one voice on a variety of key issues. In the following pages, you will find our views, concerns and our recommendations based on our collective experiences "on the ground" here in Japan.

Overall, the EBC is recommending a bolder programme of reform. Achieving the ambitious goal of doubling foreign direct investment by 2008 will require decisive action to increase private sector involvement in the delivery of public services, increase business development in highly regulated areas such as health-care, and encourage cross-border corporate reorganizations.

Many people and organizations 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 valuable 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 in Japan and the European national embassies in Tokyo for their expertise and support of EBC activities.

The EBC's Policy Director, Casey Sedgman, deserves special recognition for the way in which he met the multiple challenges of compiling the material, writing/editing the text, and designing the layout for this publication. His valuable work has ensured that this publication will 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 allowed us to produce this report, and the EBC is extremely proud to be able to list these supports in the sponsors and supporters section at the end of this publication.

The EBC values the close relationship that has been developed between the Japanese Government and the European Business Community, and will continue to work hard to build trust in the Japanese market. In return, the EBC asks that the Japanese Government further strengthen its commitment to meaningful reform in the Japanese economy.

Alison Murray,
Executive-Director,
European Business Community in Japan.

Introduction





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INTRODUCTION

Promoting foreign direct investment

Experience has shown that foreign investment makes an important contribution to economic development. Economies benefit from the economic stimulus of increased competition, productivity and innovation. Companies benefit from increased access to the markets and resources of the global economy. People benefit from new employment opportunities and access to innovative products and services at competitive prices.

For Japan, foreign investment represents a “lost opportunity”. Japan’s FDI intake is the lowest amongst advanced industrialized nations, averaging barely 1% compared to GDP.

This fact has not gone unnoticed by the Japanese Government. In his speech opening the regular session of the Diet in 2003, Prime Minister Koizumi stated the Government’s goal of doubling foreign investment in Japan by the year 2008. In response to this policy initiative, the administration has revamped its investment promotion activities, establishing a “one-stop shop” for foreign investors and increasing overseas promotion through seminars and advertisements. Efforts are also being made to create an environment conducive for foreign investment.

Almost two years have passed since the Prime Minister’s bold policy announcement. Despite the best efforts of the Japanese Government, flows of FDI into Japan have dropped nearly 10% over this period.

The EBC has long argued that foreign investment into Japan will not increase on an average long-term basis until Japan’s underlying investment fundamentals improve. Japan is a rich, attractive market with a highly educated workforce and advanced technologies. But it is also an expensive, time-consuming place to do business. Investors in search of a reasonable return on their investment continue to look elsewhere in the region.

The need for decisive action

If Japan is serious about attracting foreign investment, it must demonstrate clearly to the rest of the world that it welcomes foreign investment and that it is willing to take decisive action to make it easier for foreign companies to both enter the Japanese market and pursue business opportunities once they have become established.

Many recent policy decisions have sent mixed messages to foreign investors. For example:

- Factor-based components such as capital and human resource costs were introduced into the Corporate Enterprise Tax in 2003. Few companies make a profit during their start-up period, and the extra tax burden associated with the factor-based portion of the Corporate Enterprise Tax will likely discourage investment in new ventures.
- The Japanese Government is planning to introduce “poison pill” measures into relevant corporate laws in order to give Japanese companies additional means of combating foreign takeovers.
- Reimbursement prices for medical equipment, diagnostics and pharmaceuticals have been drastically reduced over the past few years. If this situation continues, it will become increasingly difficult for producers in the health science sectors to invest in new product development and introduce innovative new technology to Japan.

Introduction cont'd:

- Revisions to the Anti-Monopoly Act were watered down substantially from original Japan Fair Trade Commission proposals designed to strengthen Japan's competition policy.

Regulatory reform

Regulatory reform initiatives have resulted in noticeable improvements to the business environment in many areas of the Japanese economy, including high-profile areas such as insurance and telecommunications. But many areas of the Japanese economy, including medical services, agriculture, and education remain effectively closed to new-entrants.

Even areas that have been “deregulated” suffer from a persistent lack of transparency and clarity, which makes it difficult for firms to accurately predict the consequences of business decisions in Japan. This has an adverse effect on the investment environment, as firms hesitate to restructure their operations or pursue opportunities in new areas for fear of potentially adverse legal consequences. The EBC urges continued vigilance on the part of supervisory authorities to promote regulatory transparency and consistent application of the rules across industry sectors. The EBC also encourages further harmonisation of Japanese standards and conformance assessment practices with those in use throughout the rest of the industrialised world. Further reform in these areas would help reduce costs associated with introducing new products into the Japanese market, removing a major barrier to business expansion.

The EBC is encouraged by initiatives such as the innovative “Special Deregulation Zones” and the ongoing efforts of the Council for the Promotion of Regulatory Reform. But the EBC continues to be disappointed by the slow pace of reforms. There are many food additives in Japan, for example, that are in common use in both the EU and the US and are recognized as safe by the Joint FAO/WHO Expert Committee on Food Additives (JECFA), but are not allowed in Japan. In December 2002, the Ministry of Health, Labour and Welfare (MHLW) started a priority review process for 46 of these food additives. But not one has been approved, nearly two years after the start of this process.

In other cases, reform has not achieved the desired effect. Retail liquor licensing, for example, was deregulated with the elimination of minimum distance requirements and population controls, which took effect January 1st, 2001 and September 1st, 2003 respectively. But an increasing number of regions are being designated “Urgent Adjustment Areas” under a supposedly temporary measure designed to protect existing retailers from deregulation, and no new licenses (or transfers of existing licenses) are being issued in these areas.

Finally, reforms often lack an international perspective. Japanese city banks, for example, have been allowed to engage in trust and banking business concurrently since 2002. These reforms do not apply to foreign bank branches. Reforms to the Trust Business Law expected to pass the Diet in an upcoming session will expand the types of property that can be placed in trust and expand the types of corporate entities that may engage in trust business. These reforms will not apply to foreign bank branches. These developments call into question the commitment of the Japanese Government to establishing an open environment for trade and investment in Japan.

Cross-border corporate reorganisations

The EBC has long advocated reforms to facilitate cross-border M&A activity and an expansion of foreign investment in Japan. M&A already represents the largest portion of Japan's inward foreign direct investment, and the EBC is convinced that this amount would grow substantially if changes were made to Japan's corporate and tax laws to better facilitate cross-border corporate reorganizations. Revisions to the Commercial Code are expected to pass the Diet in

an upcoming session that will allow foreign firms to use their own stock as consideration in a “triangular-merger” with a Japanese firm.

The EBC supports this initiative. The EBC notes, however, that even if this reform is implemented, the types of cross-border reorganisations possible in Japan will still be significantly less than in comparable jurisdictions overseas. Of even greater concern is how the Ministry of Finance will treat the new types of cross-border share-exchanges that will be allowed under the revised Commercial Code. It is imperative that cross-border share-exchanges receive full deferral on unrealised capital gains, a measure currently available to wholly domestic reorganisations in qualifying circumstances.

Outsourcing to the private sector

The EBC is encouraged by recent policy initiatives designed to increase private-sector involvement in areas traditionally dominated by the public sector. The privatisation of Japan Post has perhaps the highest profile of these initiatives. The EBC also notes that progress is also being made through entities such as the Council for the Promotion of Regulatory Reform to encourage more private-sector involvement in government-driven markets.

The EBC believes that the Japanese Government can create a powerful new incentive for investment in Japan by increasing the use of Private Finance Initiatives (PFI) and Public Private Partnerships (PPP). European firms have historically been very strong in providing outsourced solutions in fields such as infrastructure development, healthcare, education, water treatment and waste management – areas traditionally funded, constructed, managed and operated by public entities.

There is much potential in Japan for alternative procurement methodologies given increasing levels of public-sector debt. The EBC urges the Japanese Government to step up the use of PFI and PPP by central and local government organisations and encourages more cooperation with Europe in this area, perhaps through a “demonstration” project in an area such as water management.

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.

In many of the areas covered in this report, there has been very little progress and the recommendations remain largely unchanged from previous years. Issues of long-standing concern include: air-travel pricing and distribution (see “Airlines”, pg. 34-35), counterfeit goods (see “Intellectual property”, pg. 14-15), transfer pricing (see “Taxation”, pg. 22-23), firewalls in the financial service sector (see “Banking”, pg. 28-29), food additives, (see “Food”, pg. 58-59), quasi-drugs (see “Cosmetics”, pg. 54-55), and product approvals (see “Insurance”, pg. 30-31, “Construction”, pg. 74-75, and “Health science”, pg. 44-51).

Other areas have been more active, including the privatisation of the Post Office (see “Insurance”, pg. 30-31), new methodologies for calculating interconnection fees (see “Telecommunications”, pg. 38-39), the establishment of the Food Safety Commission (see “Food”, pg. 58-59 and “Animal Health”, pg. 44-45), corporate restructuring and M&A (see “Taxation”, pg. 22-24), revisions to the Pharmaceutical Affairs Law (see “Health science”, pg. 44-51), liberalisation of legal practice in Japan (see “Legal services”, pg. 20-21), the Super-Hub Port initiative (see “Shipping”, pg. 36-37), and intellectual property protection for pharmaceutical development data (see “Pharmaceuticals”, pg. 50-51).

Business Fundamentals

Human resources
Intellectual property
Retail
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 plan-holders to borrow against their pension reserves.
 2. Social security agreements should be concluded with all major trading partners as soon as possible.
 3. Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers.
 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/1,416,000 yen for departing expatriates. The rest is simply confiscated.
 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.

- 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 dismissals, including what would be considered reasonable compensation for severance.

■ Regulations governing temporary workers

- Recommendation*
- Regulations governing job-categories that can be handled by temporary workers agencies should be further relaxed.

- Current situation*
- Some progress. Revisions to the Labour Standards Law in 2003 have increased the number of job-categories for temporary (or dispatched) workers (including, for the first time, jobs in the manufacturing sector), eliminated the three year limit on temporary employment for 26 different job categories, and increased the allowable employment contract period from one year to three years for others.

Background:

EBC Human Resources Committee Member Companies

Action Japan
Baring Asset Management (Japan)
Bayer
Cambridge Transearch International
Chanel
DaimlerChrysler Japan
Danfoss
Givaudan Japan
Heraud & Associates
JAC Japan
LogicaCMG
Nokia Japan
Oakwood
Orrick, Herrington & Sutcliffe
Panache
Siemens-Asahi Medical Technologies

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.

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. Moreover, the market for mid-career professionals is still underdeveloped, which inhibits the expansion of European businesses in Japan, as most firms still rely heavily on mid-career hires to fulfil their employment needs. The EBC supports Ministry of Education initiatives to increase IT and language training, promote extra-curricular job-experience activities through internships and other means, and encourage entrepreneurial spirit in the school-aged population.

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 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. The EBC would like to stress that this continued legal uncertainty makes it difficult for firms to respond rapidly to the changing circumstances of the Japanese business environment. This also has an adverse effect on the investment environment, as firms hesitate to restructure their operations for fear of potentially adverse legal consequences.

Pensions

Pension reform has become a hot topic in Japan following piece-meal attempts earlier this year to reform the national pension system. The EBC supports a more comprehensive review of the Japanese pension system, including the possible 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 social security contributions to departing expatriates. Finally, tax-relief that contributions to domestic pension plans currently receive should be made available for contributions to foreign-based pension plans as well.

Visas and work permits

The EBC feels that more could be done to encourage foreign investment by liberalising visa requirements for small-scale entrepreneurs in Japan. As well, many young people with specialised skills but without a university degree do not fulfil the 10-year experience requirement needed to obtain a work visa in Japan. This prevents companies from tapping into this global talent pool.

INTELLECTUAL PROPERTY

Summary of outstanding issues:

■ **Border control**

Recommendation Importers should be held 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 rights holder. Seizure claim procedures should also be improved, for example by introducing image transmission via the Internet.

Current situation Significant progress. On April 1st 2004, Japanese Customs started a system of allowing disclosure to import applicants and rights holders of each other's name and address at the time when appraisal procedures started for imported goods. The procedures permit rights holders to obtain information on the importer of counterfeit goods. They are thus able to use this information for research on counterfeit distribution networks or to take legal measures. However, as the appraisal remains an administrative process, the case cannot be taken to civil court.

■ **Fake goods on the Internet**

Recommendation Internet Service Providers (ISPs) should be more clearly held responsible for taking down and disclosing information on suspected infringements of intellectual property rights. ISPs should be also obligated to take more stringent measures against repeat offenders.

Current situation Signs of improvement. The Internet has become an easy way to dispose of fake goods in Japan, a problem that continues to grow. As well, ambiguities in the Law make it difficult for ISPs to provide personal information, which has made it difficult for rights holders to trace suspected violations and pursue civil action. On May 27th 2004, the Japanese government announced in the "Strategic Program for Intellectual Property 2004" that it will "enforce control of measures to be thorough about identification of auctioneer by management companies of internet auction site and to take down smoothly from the site right-violating goods". The EBC will pay attention as to how concrete measures will be taken.

■ **Interpretation of design and unfair competition laws**

Recommendation Protection of designs under the Design Law should be made more affordable and more open by reducing application costs and modernising examination procedures. Harmonisation with the European rules concerning related design and priority documents would help simplify the registration process. Japanese courts should also take a more stringent approach to the interpretation of the 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 the protection of intellectual property rights in Japan

Following the policy speech of Prime Minister Koizumi in February 2002, the Japanese Government established the Intellectual Property Strategy Council and published in May 2004 the “Strategic Program for Intellectual Property 2004”.

In this program, the Japanese Government announced its intention to crack down quickly on counterfeit goods and, in particular, to take action against persons possessing counterfeit goods as well as against auctioneers of Internet Service Providers.

This government initiative is showing some tangible results. For example, revisions to the Customs and Tariff Law that came into effect on April 1st, 2003 make it easier for companies to apply to customs authorities to have the importation of suspected counterfeit products suspended at the Japanese border. The amendment of this Law on April 1st 2004 allows rights holders to obtain information about importers of suspected counterfeit goods.

The EBC strongly supports this government initiative. However, despite these positive developments, counterfeits remain a very serious problem in Japan. It is estimated that almost all Italian brand goods distributed at Pachinko parlours are counterfeits. Notwithstanding signs of improvement, 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:

- Unlike in Europe, parallel imports are authorised in Japan. Foreign suppliers and Japanese importers often distribute fake products under the pretext of the parallel imports.
- 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.
- Technologies using image transmission via Internet for appraisal of authenticity or modification of seizure claim have been introduced in the US and in Europe. In Japan, the administration is prevented from introducing such innovative systems. Current procedures of appraisal by rights holders require them in principle to visit in person the Customs office that seized the suspected goods, which adds to the administrative burden of seizure claims.
- Since the current Trademark Law does not 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.
- 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.
- 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.
- Despite recent improvements to the Patent and Trademark Law, damage awarded to rights holders remains 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.

RETAIL

■ The Japanese retail environment

Introduction New entrants into Japan's retail sector face major challenges. They must drive down costs to enhance customer value, develop superior merchandising schemes, and respond to structural changes in the market such as the implementation of tax-inclusive price labelling (April 2004), the implementation of changes to liquor store licensing (September 2003), and ongoing restructuring of large domestic retailers. Despite these challenges, the EBC remains positive about the prospects for growth this sector, and hopes further progress can be achieved in the areas summarised below.

■ Large-Scale Retail Store Location Law (LSRSLL)

Recommendation Applications for business licenses filed with local authorities under the Large Store Location Law (*Dai Ten Ricchi Ho*) should be processed in a fair and consistent manner. Administrative burden placed on applicants seeking to open new stores should be reduced in line with the original intent of the law.

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 LSRSLL. The timing of the application submission to government bodies depends on the applicant and there is no coordination between the LSRSLL and the Building Permit procedure. Some companies start construction *before* holding public briefings in order to shorten their project lead-time. This is done at the company's own risk that subsequent changes may be required to their plans. Other companies wait until public briefings are held and their plans are fixed before starting construction, which is more in line with the spirit of the law. Companies that are new to the market, or companies that have less experience and fewer networks at the local level, are at a disadvantage vis-à-vis their domestic competitors in such a situation. In many cases, local governments have also imposed new conditions on applicants, making the procedure to open new large-scale stores more complicated. This tends to happen where the guidelines of the law are not clear, resulting in different interpretations depending on the contact person at the local government. The LSRSLL application procedures in major cities that require an Environment Impact Assessment (EIA) are even more complicated. Since the requirements of the LSRSLL, EIA and Building Permit are similar, we ask that the responsible authorities better coordinate the application procedures for these permits so that there is no unnecessary duplication of work needed to comply with relevant laws.

■ Alcohol licensing

Recommendation "Urgent Adjustment Areas" (*Kinkyu Chosei Chiiki*) should be abolished and companies should be able to apply for a liquor license that allows for a broader scope of liquor sales under the new licensing scheme without having to wait for their large-scale store license to expire. Recent liberalisation of the retail liquor licensing system should be extended to wholesale licensing as well.

Current situation Some progress. Deregulation that began in 2001 has gradually liberalised liquor licensing in Japan. Unfortunately, a number of regions have been designated “Urgent Adjustment Areas” under a temporary measure designed to protect existing liquor retailers from deregulation. No new licenses or transfers of existing licenses will be issued in these areas until the “Urgent Adjustment Area” status is removed. If an area’s “Urgent Adjustment Area” status is renewed on a yearly basis, foreign firms will be taking a big risk investing in Japan.

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

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

■ **Regulatory burden associated with importing tableware**

Recommendation Regulations governing the application process for the import of tableware into Japan under the Food Sanitation Law should be relaxed by adopting similar import procedures as exist in the EU, as well as in other countries. The validity period for import approvals should be extended from 1 year to 5 years and the requirement that importers submit separate import applications and inspection tests for tableware of similar material, but which falls into a different size category, should be simplified or completely abandoned as it has little relevance to food sanitation. Furthermore, rules requiring separate applications and inspection tests for different colours/materials should be relaxed. Many colours and materials do not pose any health risk and importers should be able to import products containing these materials without having to navigate the time consuming and costly inspection process.

Current situation No progress. The import of tableware into Japan is governed by the Food Sanitation Law and the procedures for obtaining approval are quite complex. An import notification form must be filled out and a processing fee submitted for every tableware product, even for products of different size made of the same material, which increases the cost of importing these products into Japan. Furthermore, separate fees must be paid for each type of product, resulting in a time consuming and costly import procedure. Moreover, the import approval is officially valid for only one year.

The EBC Retail Committee is currently conducting a survey with regards to import rules in other countries with the goal of developing a more concrete set of proposals to simplify import procedures in Japan.

■ **Consumption tax**

Recommendation The EBC retail committee urges caution with regards to consumption tax policy in Japan.

Current situation New issue. The change to tax-inclusive labelling is widely thought to be the precursor to a consumption tax increase sometime in the near future. The EBC notes that the introduction and subsequent increase of the consumption tax in Japan had an immediate and lasting negative effect on the Japanese economy, and the retail sector in particular. A further increase would have a deleterious effect on Japan’s already weak and struggling retail environment.



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E-COMMERCE

Summary of outstanding issues:

■ Promoting user trust

Recommendation The EBC urges the Japanese Government to continue to promote confidence in the usage of the Internet to do business in Japan through initiatives such “e-Japan” and the effective implementation of a comprehensive regulatory framework designed to assuage fears over transaction security and the protection of personal information. At the same time, the EBC would like to stress 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. New laws will soon come into effect regulating the protection of personal information. The EBC supports this initiative, but is worried that a lack of clarity in the laws will create problems with regards to liability.

■ 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.

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 develops 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 sector 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 (more than 10 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.

As the initial phases of Japan's ambitious "e-Japan" strategy have been achieved, 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.

Promoting the use of the Internet for commercial and administrative transactions

Despite the rapid increase in broadband penetration rates in Japan, the EBC feels that the 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, even though 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 concerning 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 that want to make use of 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. While there have been a number of notable improvements in the regulatory environment governing electronic transactions over the past few years, the EBC is disheartened at the high level of opposition from various Agencies and Ministries concerning 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:

■ Liberalisation of legal practice in Japan

Recommendation Regulations currently being drafted by the *Nichibenren* should reflect the liberalising spirit of the amended Foreign Lawyers Law. Standards and requirements applied to different types of law firms should be kept to a minimum, and should be clearly justified when deemed absolutely necessary.

Current situation Progress. The amended Foreign Lawyers Law is due to come into effect in the spring of 2005. Integral to this process is the passage of new Joint Enterprise Regulations (the “Regulations”), currently being drafted by the Japan Federation of Bar Associations (*Nichibenren*). While the *Nichibenren* has allowed the views of foreign registered lawyers in Japan (*gaiben*) to be heard during the process of drafting the Regulations, the overall the drafting process has lacked the openness and spirit of mutual consultation that *gaiben* had hoped for.

In a number of respects the draft Regulations inexplicably seek to impose obligations and restrictions on *gaiben* and *bengoshi* operating in joint law operations that are not applicable solely to *bengoshi*. Examples include: burdensome obligations to explain the precise scope of authority of each lawyer working on a new client matter; different standards on ethics, reporting obligations and confidentiality; and new restrictions seeking to limit the ability of *gaiben* to hire and manage foreign lawyers with different jurisdictional experience to their own, despite the fact that there are no jurisdictional restrictions on the foreign lawyers that *bengoshi* can employ. Such discriminatory treatment should be avoided.

■ 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 Pyrrhic progress. The revised Foreign Lawyers Law allows *gaiben* to hire *bengoshi* thereby creating equality of business opportunity as *bengoshi* have always been free to hire *gaiben*. This positive development, however, is likely to be emasculated by the Regulations, which prevent *bengoshi* employed by a *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 and in effect would prevent *bengoshi* moving to *gaiben* firms.

■ Incorporated law firms

Recommendation Legislation introduced in 2002 which enables only *bengoshi* to incorporate their law offices as *bengoshi houjin* should also be made available to foreign lawyers.

Current situation No progress. In line with the current decisive move towards greater equality between Japanese and foreign lawyers operating in Japan, the potential benefits of incorporating a law office should not be limited only to *bengoshi*.

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 & Associates Foreign Law Office
Laurent Dubois Foreign Law Office
Lovells
Loyens & Loeff
Orrick, Herrington & Sutcliffe LLP
Sonderhoff & Einsel
Tokyo Aoyama Aoki Law Office

■ Multi-office law firms in Japan

Recommendation The long established restriction on law firms in Japan opening second offices should be liberalised immediately.

Current situation No progress. Major Japanese corporations outside Tokyo, for example in Kansai, wishing access to leading international firms must either travel to Tokyo or pay the cost of lawyers travelling to Kansai for short visits. Stays outside of Tokyo for extended periods run the risk of being deemed the creation of a prohibited branch office. Law firms in Japan should be free to respond to client need and, provided client service is not impaired, should be free to open offices to satisfy market demands.

■ Qualifying as a *gaiben*

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

Current situation Little 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 recognise 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*.

■ Cross-border legal advice

Recommendation 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 *bengoshi* vis-à-vis is the same.

Current situation No progress. There are more restrictions on foreign lawyers providing advice on third-country law than exist for *bengoshi*. 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.

■ Alternative dispute resolution (ADR)

Background The ADR *Kentoukai* has been reviewing the legislative framework governing the conduct of out of court dispute resolution carried out in Japan. As part of its deliberations, the ADR *Kentoukai* has considered whether professional involvement in ADR involves the practice of law and whether a licensing system should be introduced for the first time to regulate ADR professionals. The EBC feels that a licensing system is unnecessary. If introduced, it should be made clear that applying for a license is voluntary, and the procedures and standards for licensing should be reasonable and not burdensome. Furthermore, any new ADR legislation should make clear that dispute resolution institutions and individual arbitrators and mediators are not practising law and are not in violation of the Lawyer's Law by virtue of acting in this capacity. Finally, provision should be made so that the functioning of ad hoc international arbitration and mediation, and of international institutions such as the International Chamber of Commerce, the American Arbitration Association and the London Court of International Arbitration, as well as other similar institutions, is recognised under Japanese law.

TAX

Summary of outstanding issues:

■ **Accountability**

Recommendation 1. The National Tax Agency should provide rulings and clarifications such as the motivation of 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 to establish a written body of precedent.

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 tax authorities in Japan. 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. Japanese tax authorities seem to be taking this problem seriously, and the EBC urges for progress in this direction.

■ **Consolidated taxation**

Recommendation 1. The requirement that only 100% subsidiaries may be consolidated is too restrictive and should be replaced by a 50% threshold.

2. The expiry of pre-consolidation period losses of companies when they enter the consolidated group should be eliminated.

3. The obligatory taxable revaluation of assets of companies entering the consolidated group should be eliminated.

4. The obligatory integration of all 100% subsidiaries if a group wishes a consolidation should be eliminated.

5. Local taxes should be included in the consolidation. The taxation system related to Corporate Inhabitant Tax (*hojin-jumin-zei*) and the Corporate Enterprise Tax (*hojin-jigyo-zei*) should be simplified as much as possible in order to reduce administrative burden in the preparation of related local tax returns.

Current situation No progress. It is not likely that the consolidated tax system in Japan introduced in 2002 will be fully or actively utilised among Japanese corporate taxpayers in Japan unless the issues outlined above are addressed, despite the fact that the 2% surtax levied on consolidated tax accounts expired as of April 2004.

■ **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 five to seven 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.

■ **M&A and corporate restructuring**

Recommendation

1. In order to be consistent with tax regimes in other jurisdictions, corporate reorganisations and share-for-share exchanges involving foreign shares should be allowed under the Commercial Code and capital gains for Japanese shareholders receiving foreign shares should be tax-deferred in all cases.
2. Rules and regulations concerning corporate reorganisation laws should be clarified in order to avoid giving unlimited discretion to authorities in defining key concepts. Various key terms (e.g. “business” and the “business continuity test”) need to 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 qualified reorganisations.

Current situation No progress. As of April 9, 2003, the Law on Special Measures for Industrial Revitalisation allows cross-border “triangular” mergers if a company is in distress and if the company’s revitalisation plan is approved by the Japanese Government. However, the Law fails to address taxation and thus the rules for qualified tax-neutral mergers do not apply. It is noteworthy that to date no foreign company has used this law to acquire a Japanese company and that there have been only two cases at a domestic level.

We welcome changes to the Commercial Code expected to pass the Diet in an upcoming session that will allow cross-border stock-for-stock mergers, likely under the “triangular merger” formula. In order to establish a strong and internationally recognised M&A market in Japan, the EBC strongly urges the Japanese Government to ensure that when changes to the Commercial Code come into effect, the same tax-deferral rules on capital gains currently available for mergers between Japanese companies are extended to cross-border stock-for-stock mergers.

■ **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.

Summary of outstanding issues cont'd:

<i>Recommendation cont'd</i>	<p>2. There should be consistency between the transfer pricing methodology for audit assessments, and that used for Advance Pricing Agreements.</p> <p>3. Less weight should be placed on special characteristics of the Japanese market.</p>
<i>Current situation</i>	<p><u>Limited progress.</u> The tax authorities continue to make transfer pricing assessments based on secret comparables about which the taxpayer has difficulties in confirming product or functional similarities. Moreover, the use of secret comparables for audit assessments is inconsistent with the transfer pricing methodology of Advance Pricing Agreements, where company-level profitability of public companies is commonly used. This inconsistency in application of transfer pricing methodologies increases the difficulties faced by taxpayers.</p> <p>The tax examiners continue to place too much weight on the belief that the Japanese market has special characteristics and barriers to entry, with the result that marketing intangibles of Japanese entities are given greater value than is actually deserved.</p>
<p>■ Stock options</p>	
<i>Recommendation</i>	<p>The NTA should clarify the tax treatment of foreign stock-option income to eliminate the risk of double taxation, an issue recently addressed by the OECD. Also, consistency with the tax treatment of domestic stock-option income should be ensured.</p>
<i>Current situation</i>	<p>At least two recent rulings by the Tokyo High Court have ruled that income from the exercise of stock options cannot be deemed 'occasional income', as opposed to regular 'salary income', which is taxed at a higher rate. These rulings reverse previous lower District Court rulings that challenged the NTA's reclassification of stock-option income as 'salary income' in 1998. This has resulted in substantial confusion as to how income from stock options will be treated in the future. Regardless of the outcome of these judicial proceedings, it is imperative that future treatment does not discriminate against income received from exercising options on foreign stock, as was the case in the past.</p>
<p>■ R&D and IT tax incentives</p>	
<i>Current situation</i>	<p>A 10%-12% tax credit is now available for qualified R&D expenditures (and not only on the increase in R&D spending, as it used to be in the past), a tax reform welcomed by the EBC. However, enterprises that have R&D facilities in Japan but are reimbursed for these expenses from outside Japan will not qualify for this tax credit.</p>
<p>■ Factor based tax</p>	
<i>Current situation</i>	<p>Criteria other than profits such as capital and employee expenses became part of the Corporate Enterprise Tax effective April 2004, applicable to firms with share capital over 100 million yen. It is disappointing that such a tax has been introduced as such taxes discourage foreign investment and defy global trends moving away from the use of criteria contravening the principle to tax in accordance with the ability to pay. The new Corporate Enterprise Tax will (in general) not allow foreign companies to obtain a full foreign tax credit on Japanese income.</p>

Financial Services

**Asset management
Banking
Insurance**



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ASSET MANAGEMENT

Summary of outstanding issues:

■ **Single regulator**

Recommendation Rules and regulations governing the asset management business should be harmonised as soon as possible. This would encourage the two existing industry associations to merge, which would further promote consistency and efficiency in the market.

Current situation No progress. Even though the management of investment trusts and that of investment advisory services does not differ much in substance, each business is regulated by a separate law with separate licensing, filing, and customer disclosure requirements – an effective duplication of administrative procedures, the cost of which is eventually passed on to consumers.

■ **Sales and service of offshore funds**

Recommendation A common set of rules governing the promotion of offshore products should apply to all investment advisory firms already licensed to do business in Japan with no need to apply for an additional license to do business in this area.

Current situation No progress. Asset managers that wish to support the sale of affiliated products in Japan must apply for a side-business license from the 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. The EBC feels that the promotion of products managed by overseas affiliates constitutes a part of an asset manager's core business and that firms should not have to apply for additional licenses.

■ **Feeder funds**

Recommendation Japan Investment Trust Association rules should be amended to allow onshore feeder funds to invest wholly in a single offshore fund.

Current situation No progress. Japan Investment Trusts Association rules stipulate that baby funds can invest in a single mother fund only if the mother fund is managed by the same fund management company. Since offshore funds managed by group affiliates do not qualify as a mother fund under this definition, this regulation effectively prevents onshore feeder funds from investing wholly in an offshore vehicle.

■ **Placing orders for affiliates**

Recommendation The EBC urges the Japanese Government to revise the Investment Advisors Business Law (and/or relevant Guidelines) to allow asset managers licensed in Japan to place orders to buy or sell Japanese securities on behalf of group affiliates.

Current situation No progress. Most major financial markets allow asset managers to place orders in domestic markets on behalf of overseas group affiliates. This allows global asset management firms to pool group transactions, reduce dealing costs, reduce client transactions costs, and reduce the risk of front-running for one group of clients over the interests of others. In Japan this is not possible without a securities business license, an impractical solution for asset management firms given the costs involved in setting up the necessary firewalls, etc.

Background:

Regulatory environment

Professional investment management makes an important contribution to people's savings, security, and quality of later life. It is important that the regulatory environment facilitates access to professional asset management services, as this is ultimately in the best interest of consumers.

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. More emphasis should be placed on the concept of "investor sophistication". In this way, the FSA would be able to devote more of its limited resources to those in real need of protection, while at the same time expanding investment options (including alternative investments such as hedge funds) available to sophisticated institutional investors such as banks, insurance companies, and pension funds.

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 increase in competition and choice for savers.

Encouraging the efficient management of pooled 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 feels, however, that much more could be done in Japan to encourage the efficient management of pooled assets. 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 structured products.

The EBC urges further harmonisation of regulatory requirements related to licensing, filing and customer disclosure between the FSA, the Ministry of Finance (MOF)'s regional finance bureaus, and the two main self-regulating organisations in the asset management sector in Japan, the Japan Investment Trust Association (JITA) and the Japan Securities Investment Advisors Association (JSIAA). Regulatory burden associated with duplicated regulatory functions prevents efficient operations in the asset management sector, which is ultimately detrimental to consumers.

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. The EBC believes that the net asset value of an investment trust should be calculated independently of the asset management company for consumer protection purposes. The EBC urges the FSA to support efforts by industry to seek commercial solutions to this problem.

EBC Asset Management Committee Member Companies

ABN AMRO Asset Management
Baring Asset Management
BNP Paribas Asset Management
Credit Agricole Asset Management
Credit Lyonnais International Asset Management
Credit Suisse Asset Management
Fortis Investment Management
Gartmore
HSBC Asset Management
ING Mutual Funds Management
Meiji Dresdner Asset Management
PCA Asset Management
Pictet Asset Management
Schroder Investment Management
SG Yamaichi Asset Management
UBS Global Asset Management



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BANKING

Summary of outstanding issues:

■ **Firewalls**

Recommendation The Japanese Government should abolish Article 65 of the Securities and Exchange Law in order to realise the full liberalisation of the Japanese financial market.

Current situation No progress. Although further 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.

■ **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 overall burden of reporting requirements to these various bodies should be streamlined.

Current situation Some progress. The EBC welcomes recent movement by the various regulatory bodies in Japan to reduce the number of duplicate inspections. The EBC urges further streamlining of responsibilities to reduce the likelihood of divergent interpretations.

■ **Penalties and sanctions**

Recommendation The system by which the Japanese Government punishes violations should be improved by ensuring consistency and transparency in the application of administrative sanctions. At the same time, the integrity of the inspection and penalty process should not be compromised by breaches of confidentiality and indiscriminate use of the media.

Current situation Limited progress. The current administrative sanction system does not give fair treatment to all firms as the application of penalties is unpredictable and haphazard and the effect of a suspension or improvement order ultimately depends on market conditions and the volume/mix of business for each firm. Confidentiality during inspection followed by transparent public announcements of violations/sanctions would ensure that there is a consistent approach and that the penalty is not exaggerated unnecessarily.

■ **Trust banking**

Recommendation Foreign bank branches in Japan should be able to engage in trust and banking businesses concurrently.

Current situation New issue. 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. Reforms to the Trust Business Law expected to pass the Diet in an upcoming session will expand the types of property that can be placed in trust and expand the types of corporate entity that may engage in trust business. These reforms will not apply to foreign bank branches.

Background:

Securing the competitiveness of Japan's financial markets

The EBC feels strongly that the key to promoting investor confidence in Japanese financial markets lies in the ability of the Japanese Government to implement concrete policies designed to enhance the transparency of the financial industry's balance sheet, enhance regulatory efficiency, and create a competitive market environment that encourages the development of innovative solutions to meet the needs of Japanese institutions and consumers.

The EBC recognises the efforts of the Japanese Government in recent years to revitalise the financial sector, but is disappointed that reforms have not gone far enough 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.

Regulatory reform has for the most part been tailored to meet the needs of domestic retail banks, and not the financial services sector as a whole. The EBC is disappointed that recent reforms allowing banks and securities firms to share common retail space and subsequent reforms allowing banks to become agents of securities firms did not do 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. Further reforms to the Trust Business Law likely to pass an upcoming session of the Diet do not resolve this discriminatory treatment, which calls into question the supposed commitment of the Government to establishing an outward-looking, globally competitive financial market in Japan.

The need for further reform

The EBC feels strongly 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.

The EBC 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 done in other financial markets.

At the same time, the EBC urges the Financial Services Agency (FSA) to continue working towards securing transparency and fairness in the application of laws and regulations. The EBC notes recent efforts on the part of the FSA, SESC, TSE and JSDA to coordinate inspections, but feels that the benefits of this coordination will not be fully realised until regulatory processes are streamlined, reporting requirements are reduced, and duplicate regulatory functions are eliminated.

More should be done to ensure transparent and consistent application of relevant laws and regulations. While the EBC welcomed the introduction in 1998 of a Public Comment system designed to collect opinions on changes in policy from interested parties and the recent introduction of a Japanese-style "no-action letter" system, the EBC questions whether these two mechanisms are being utilised to their full potential. With regards to the Public Comment system, the EBC wonders if sufficient time is being given to interested parties to make comments in order to fairly evaluate policy proposals from a wider perspective. Comment periods currently vary in length from one week to about one month. As for the "no-action letter" system, the EBC notes that relatively few replies have been issued by the FSA since the system was introduced three years ago. The small number of issues being addressed by the system may indicate that it is not being effectively utilised, possibly due to the long time that it has taken to receive a reply (on average two months), or a perception by the industry that it is not strongly supported by the FSA.

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)
Caylon
Caylon Securities
Commerzbank
Credit Agricole Indosuez Securities
Deutsche Securities
Dresdner Bank
Dresdner Kleinwort Wasserstein
HSBC
HSBC Securities Japan
ING Bank
Orrick, Herrington & Sutcliffe
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INSURANCE

■ 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 policy-holder 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. The privatisation of Japan Post is high on the agenda of the current Japanese Government. Under current plans, *Kampo* will be subject to the same requirements as private sector insurers, in return for the right to expand its business. The EBC supports the privatisation of Japan Post and its three core businesses: postal services, savings and insurance. The benefits of privatisation will only be realised, however, if the Japanese Government establishes a framework for privatisation that ensures a level playing field in the market.

■ Sales of insurance products through financial institutions

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

Current situation Significant progress. The Japanese Government has pledged to completely deregulate the distribution of insurance products through banks and other financial institutions within three years. The EBC supports this decision – the EBC has long argued that financial institutions should be allowed to distribute all product classes without restrictions. The EBC urges the Japanese Government to implement this deregulation immediately, and not wait the full three years as is currently being debated.

■ Policyholder protection fund

Recommendation The Japanese Government should consider ways to alleviate the substantial financial burden associated with pre-funding policy holder protection corporations in the life and non-life sectors.

Current situation No progress. The Japanese Government had promised a complete review of the system following a decision at the end of 2002 to inject more money into the life fund, but this review has not yet started. 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 principle, the EBC feels that companies who have prudently managed their business should not be required to pay the price of another insurance company's failure and that the best way to ensure consumer protection is to promote more prudent macro-level supervision.

■ **Reserving methodology for variable products**

Recommendation Reserving methodology for premium reserves, contingency reserves & solvency calculations should be revised to reflect the unique characteristics & variety of variable products. The EBC favours a stochastic approach that links reserve and solvency levels to underlying risks through the use of Conditional Tail Expectation calculations (as opposed to a cash flow scenario model or factor-based methods), as this would encourage better risk management and allow for further product innovation.

Current situation Changes expected. The FSA is currently reviewing reserving methodologies for variable products with new guidelines expected as early as November. It is unclear, however, whether or not the EBC's preferred approach will be allowed under the new rules.

■ **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 in order to create a level playing field in the life-insurance market. Since *kyosai* provide the same services as their private-sector competitors, all should be subject to the same legal and regulatory requirements, including the Insurance Business Law and FSA supervision.

Current situation No progress. Like private insurers, *Kyosai* such as *Nokyo Kyosai (JA Kyosai)*, *Kenmin Kyosai* and *Zenrosai*, offer a wide-range of life, non-life, and third-sector insurance products to the general public, since any consumer can pay a nominal fee to become a member of one of these cooperatives. Unlike private insurers, *Kyosai* pay low corporate taxes, are not required to pay into policyholder protection funds, and are not subject to the Insurance Business Law and FSA supervision.

■ **Product approvals**

Recommendation All requirements for prior product approval and pricing involvement by the Financial Services Agency (FSA) should be abolished.

Current situation Limited progress. While the development in 1999 and subsequent enhancements of a notification system for certain non-life commercial lines were definitely steps in the right direction, the need for comprehensive deregulation of pricing and policies remains in both the life and non-life sectors. The EBC feels that there is no need for the regulator to be involved in the approval of new products, even personal lines, as this only serves to stifle the introduction of innovative insurance products at competitive prices.

■ **Agencies and in-house distribution**

Recommendation The EBC notes that pressure from incumbent suppliers on independent agents (especially on former non-life sales trainees) continues to inhibit new life insurers from building a distribution network through independent agencies. As well, the EBC maintains its long-standing request to eliminate the so-called *kosei-in* rule limiting products that can be sold by agencies in-house and allow life insurers to pay a commission to corporate agencies that sell insurance policies to the agency itself (or affiliated companies). Non-life insurers are allowed to pay a maximum of 50% of the regular commission in similar circumstances and the same should be allowed for life insurers as well.

Transportation & Communications

Airlines
Shipping
Telecommunications
Telecommunications equipment



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AIRLINES

Summary of outstanding issues:

■ Pricing and distribution

Recommendation The distribution, pricing, and settlement of airfares in Japan should be deregulated so that carriers can offer competitive net fares in a transparent fashion directly to the consumer, including over the Internet. As a first step, the EBC recommends the gradual introduction of a wider range of advanced-purchase fares into the system, for example business class fares. 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 US). 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 continued discriminatory treatment.

■ High cost structure

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. Competition in the operation of airport facilities should be promoted.

Current situation Worsening situation. Absolute costs related to user charges in Japan remain the highest in the world, even as average yields continue to decline. While international airports in other jurisdictions have been adjusting their landing charges to reflect depressed market conditions following the outbreak of SARS and the war in Iraq, nothing has happened in Japan. The EBC welcomes the recent decision to privatise Narita Airport, but it remains to be seen whether or not this will lead to a reduction in airline operating costs.

■ Airport infrastructure

Recommendation Total international capacity should be further expanded to satisfy demand in the Kanto region. The 2nd runway at Narita Airport should be extended to 2500 m as soon as possible. In the meantime, existing facilities should be used more efficiently. Flight movement per hour at Narita should be increased, slots from the two runways at Narita should be pooled, and Haneda Airport should be opened to regular international traffic.

Current situation Some progress. The opening of the second runway at Narita in 2002 has had a positive impact on market access, though the EBC is disappointed that the runway is not long enough to accommodate large aircraft. While the downturn in market conditions has alleviated some of the immediate pressure on Kanto-area airports, the adequacy of Kanto-area airport infrastructure will continue to be an important issue in the medium to long term as demand increases and the new generation of large body aircraft comes on line.

Background:

EBC Airlines Committee Member Companies

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

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 underdeveloped infrastructure unnecessarily inhibit the ability of the airline industry to operate efficiently in the Japanese market. With passenger levels down 40% year-on-year, airlines are working hard to improve operating efficiency. Given this situation, the EBC urges the Japanese Government to do all that it can to modernise air transport facilities and regulatory infrastructure to help combat this business downturn for the benefit of both the users and suppliers of air transport services in Japan. Only in this way will international airlines be able 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

The distribution, pricing, and settlement of airfares remain highly regulated in Japan. Airlines have limited means to sell their products and services directly to consumers in a transparent fashion (including over the Internet) as has become common throughout the rest of the industrialised world. 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, 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 sold in Japan are repackaged group discount fares sold through licensed travel agents. This places European carriers at a distinct 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, and therefore have limited control over the final consumer price. While the Japanese Government has taken modest steps recently to deregulate the sale of advance-purchase fares for international travel, numerous restrictions continue to inhibit the development of direct sales to consumers. This is ultimately detrimental to the consumer, as the consumer ends up paying the mark-up generated by this complex retailing system instead of the regular commission (7% in most markets).

Reducing the cost of doing business

Airlines doing business at Japan's major international airports are required to pay prohibitive landing fees, navigation charges, airport terminal rents, airport terminal common user charges, and cargo handling fees that make the cost of air transport in Japan the highest in the world. This ultimately has an adverse effect on the Japanese economy, as these costs are eventually passed on to the consumer through higher prices and reduced service. The EBC urges the Japanese Government, in co-operation with airport authorities, to continue reducing fees charged to airlines. The EBC welcomes the recent decision to privatise Narita Airport, and hopes that this will lead to an increase in operating efficiency.

Airport infrastructure, landing shortages, and slot allocation

The EBC remains concerned about the overall quality of the infrastructure that underpins the air transport sector in the high-volume Kanto region. Even with the opening of the 2nd runway, the facilities at Narita are not commensurate with its supposed role as the main international gateway to Japan. Haneda remains effectively off-limits for regularly scheduled international flights, and Narita continues to use existing facilities inefficiently; for example, by restricting flight movements per hour and by allocating slots for the two runways separately. The EBC feels that resources currently being used to upgrade infrastructure in the Kansai region should be reallocated to the Kanto region where they are needed the most. In addition, the EBC recommends that slot allocation methodology employed at Narita be reviewed with the goal of improving efficiency, while respecting the increasing level of bilateral economic exchange between Europe and Japan, and achieving more equal treatment regarding slot allocation between American and European airlines.

Access to market data

Market data collected by Japan Airlines (JAL) on European routes is not made available to rival carriers, even though common market data collected from rival carriers is made available to JAL. Access to comprehensive market data is an important to all carriers in Japan, and the EBC urges JAL to extend the same treatment to rival firms that it currently receives in overseas markets.

SHIPPING

Summary of outstanding issues:

■ Super Hub Port initiative

Recommendation The Japanese Government should involve European and other Foreign shipping lines in discussions on the Super Hub Port initiative.

Current situation The Japan Foreign Steamship Association, including the European shipping lines, has requested to be included in the Super Hub Port Selection Committee, but this has been turned down by the Port and Harbour Bureau of the Ministry of Land Infrastructure and Transport (MLIT). Foreign shipping lines control some 60-65% of all containerised traffic in and out of Japan and were, therefore, surprised that they were not welcome to assist with their expertise. It would be beneficial for the MLIT to make use of the foreign expertise. The three port areas for the Super Hub initiative have now been chosen, but it is so far not transparent to foreign shipping lines how the desired efficiencies and costs savings can be achieved and passed on to terminal users.

■ Terminal operations

Recommendation The Japanese Government should support the establishment of new, competitive terminal operations, including those owned by shipping lines themselves. In addition, the requirement that new labour companies maintain employment levels at 1.5 times that of existing labour companies should be abolished.

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, 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 require approval from the JHTA.

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 remains a vital component of Japan's business infrastructure and the cost of shipping goods around the world have an immediate impact on the competitiveness of Japanese exports.

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. The costs associated with the provision of shipping services in Japan are widely acknowledged as being amongst the highest in the world.

These costs are eventually passed on to the end-user in Japan. High costs also undermine the competitive position of Japanese ports in the Asian region, for example in the provision of trans-shipping services.

This situation has been exacerbated by the tendency of Japanese industry to move production overseas. In some trade lanes the amount of goods being shipped overseas from Japan has dropped over the past few years. In order to regain Japanese competitiveness it is imperative that the Japanese Government implement measures designed 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 concerns 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. Issues that require JHTA approval through this process 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 reported any major trouble recently 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 the fact 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. The government should encourage relevant parties to streamline the whole process and make it more transparent to all concerned.

As a result, port charges in Japan remain amongst the highest in the world. The Japanese Government fully realises this problem, and has started the Super Hub Port initiative. Still, for operational costs to come down, the Japanese Government should commit itself to promoting meaningful competition on the Japanese waterfront. The higher costs are eventually passed on to the end-user in the form of higher freight rates to and from Japan, which has a negative impact on the Japanese economy as a whole. Ultimately, shipping companies should be able to procure port services on a competitive basis, free from undue influence from organisations such as the JHTA.

45-foot containers

The EBC repeats its long-standing request that inland transportation of 45-foot containers be permitted on designated routes in Japan. The use of such containers remains prohibited, despite widespread use throughout Asia and most global shipping markets. Allowing 45-foot containers would have a positive impact on transportation costs, traffic problems and pollution.



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TELECOMMUNICATIONS

Summary of outstanding issues:

■ Fixed-line interconnection

Recommendation Japan should take immediate steps to reduce interconnection charges to levels comparable with other major telecommunications markets.

Current situation Changes expected. The EBC has long advocated changes to Japan's interconnection calculation methodology to bring interconnection charges in line with international benchmarks. In August 2004, the Information and Communications Council released a report recommending, amongst other things, that non-traffic sensitive costs (NTS) be excluded from interconnection charges and the current retro-active settlement method be replaced by a forward-looking methodology that allows carriers to know in advance and with certainty how much they will be paying in interconnection charges. The EBC welcomes the general thrust of these proposals, but is concerned about the implementation period and other details concerning the construction of the model. The EBC feels that NTS costs should be eliminated immediately, and not over the 4 to 5 years suggests by the Council. The EBC does not support the Council recommendation to set a single averaged interconnection charge between NTT East and NTT West, as this violates the principle of cost causation and orientation. Finally, the EBC feels that more could be done to improve the cost model, for example by including common traffic, optimising costs, and extending depreciation periods to better reflect economic realities.

■ Strengthening competitive safeguards

Recommendation Japan should strengthen competitive safeguards against abuse of dominance by reinstating the obligation for NTT to notify and price on tariff in all market segments where it is dominant; requiring NTT to publish regulatory accounts horizontally across its different businesses and vertically between the network and retail parts of its horizontal business; and strengthening firewalls to prevent NTT from leveraging its dominant position in the local loop 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 – for example, 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 by cross-marketing new services to its customer base in areas where it is currently dominant. Aggressive action should 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 this proves inadequate, the local loop should be separated from the rest of NTT's business, to remove any ability for NTT to leverage its dominance.

■ **Spectrum**

Recommendation Inequalities in existing spectrum allocations between mobile operators should be addressed before further entry into the market is considered. Payment for spectrum usage should reflect the volume of spectrum used.

Current situation New issue. Current 3G spectrum allocations are unlikely to meet short-term growth requirements for 3G operators. Unfortunately, inequalities in the allocation of spectrum make it difficult for certain operators to re-deploy spectrum resources for 3G purposes. This issue should be addressed to ensure competitive neutrality and create a level playing field among competing operators.

With regards to spectrum usage fees, the EBC welcomes recent Japanese Government proposals to revise the calculation methodology with the goal of eliminating negative incentives and the unequal cost burden between users of spectrum in Japan. Under the current system, mobile operators pay the majority of total fees even though broadcasters use the majority volume of spectrum. The EBC feels that the best way to promote efficient and effective spectrum use is to base the spectrum fee formula on volume (amount of spectrum) and frequency (type of spectrum). This should be done in a clear and transparent manner that ensures full accountability for the collection and disbursement of funds. A transition phase may be required, but the ultimate goal should be to phase out the existing fee formula completely. Continuing to base any part of the spectrum fee on the number of radio transmitters would perpetuate negative incentives and inequalities that plague the current system.

■ **Institutional reform**

Recommendation The institutional structure of Japan’s telecommunications regulatory environment should be reformed to improve the quality, clarity and accountability of decision-making. 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; for example, by increasing the frequency and length of the public comment process. Over the medium term, the EBC recommends increased separation of the Ministry of Internal Affairs and Communications’ (MIAC) industry promotion and regulatory oversight functions.

Current situation No progress. The MIAC has wide-ranging statutory powers of intervention and control in the Japanese telecommunications sector. There are no clearly articulated criteria in the legislation governing the way in which these powers must be exercised. This introduces a high degree of uncertainty and unpredictability into the regulatory process. Most other countries require regulators to ensure that regulatory decisions promote the long-term interest of consumers and a competitive market environment. A similar provision is required in Japanese legislation to provide certainty and ensure that decisions are economically robust. Accountability could also be improved by strengthening the public consultation process. At present, important policy decisions are usually “pre-determined” before the public is given a chance to comment on new proposals. This leaves the impression that the consultation process is merely “window-dressing”, 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 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 welcomes the introduction of SDoC by the Japanese Government at the beginning of 2004, as has been introduced in Europe. However, the EBC is disappointed that this system will be 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 is studying 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 ITU and 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 that 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
Telekurs (Japan)

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, 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 is pleased to note that the Japanese Government introduced 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.

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 public sector procurement of foreign telecommunications equipment keeps pace with the private sector.

Health Science

Animal health
In-vitro diagnostics
Medical equipment
Pharmaceuticals

ANIMAL HEALTH

Summary of outstanding issues:

■ **Product approval process**

Recommendation The product approval process for animal health products should be improved by clarifying administrative responsibilities, eliminating duplicate procedures, and reducing administrative burden.

Current situation Worsened situation. Approval delays and high costs associated with the approval process for animal health products in Japan continue to inhibit the introduction of new products to the Japanese market. The creation of the Food Safety Council in July 2003 has made a bad situation worse, with increased confusion and approval delays. Interpretation of published guidelines by the New Product Deliberation Committee (chosakai) is inflexible, and Committee members frequently make requests to applicants that have no basis in science.

■ **National assay**

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

Current situation Limited progress. National assays are still required in Japan for biologicals (vaccines) and certain types of diagnostic products intended for use on animals. The Government is considering introducing a seed-lot system for vaccines, but no details or schedule for subsequent abolishment of the national assay has been released. There are currently no plans to eliminate the assay for diagnostic products, despite the fact that no such requirement exists for human use diagnostics in Japan, even for those used to diagnose major infectious diseases such as Hepatitis and AIDS. In Europe, most countries do not require manufacturers to submit control reports for vaccines, nor samples for examination, and thus consider the quality control laboratory of the manufacturer as an approved laboratory.

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

Recommendation Risk III and Risk IV ruminant raw materials from BSE-affected regions should be permitted if such materials comply with the requirements of the World Organisation for Animal Health or carry the European Directorate for Quality of Medicines certificate.

Current situation New issue. The Japanese Government has banned Risk III and Risk IV ruminant materials sourced from BSE affected countries, creating major supply problems for the producers of animal health products. 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
Boehringer Ingelheim Shionogi Vetmedica
Intervet
Merial Japan
Novartis Animal Health
Virbac Japan

Product approval process

In 1995 the Japanese Government committed itself to approving new products within 12 months of the initial application and has reconfirmed this target every year since with the issuance of the Drug Approval Guidelines (*seizo shishin*). This target is rarely achieved. Approval delays and high costs associated with the approval process for animal health products in Japan continue to inhibit the introduction of new products to the Japanese market. Despite recent trends to streamline procedures in other parts of the world, dossiers for new product applications still have to be amended with additional Japan-specific data, and delays due to administrative inefficiencies are not uncommon. Unfortunately, the establishment of the Food Safety Council has in many ways made this situation worse. The creation of this new entity has added another layer of regulation to an already cumbersome process with the result that new product approvals will take even longer and cost more than they do now. If this situation persists, it is likely that firms will simply stop developing products for the Japanese market. The EBC recommends immediate action on the following:

1. Additional local clinical trials for products that are already approved in the EU and the US should not be required;
2. Additional local clinical trials for human-use pharmaceuticals that are already widely used by veterinarians and for which efficacy is well documented in the veterinary literature should not be required;
3. Teratogenicity tests for companion animal products should be eliminated, so long as the products concerned are not intended for use on pregnant animals; and
4. Reports submitted for New Animal Drug Application and Animal Drug Importation Application should be accepted in English, accompanied by a written summary in Japanese, as is now possible in Japan for human drugs.

Risk assessment guidelines for antibiotic use in livestock

The Japanese Government is currently developing a new set of risk assessment guidelines concerning the use of antibiotics in livestock. The EBC supports this initiative. Antibiotics have been used in the livestock industry in Japan for more than half a century, contributing to the development of the livestock industry and the development of a steady food supply. It is important, however, that effective risk assessment guidelines are established that mitigate the risk of anti-bacterial resistance, while recognising the fact that zero-risk is not achievable. The EBC urges the Japanese Government to establish guidelines that reflect both the risks and benefits of anti-biotic use based on scientific evidence, including overseas data.

Revisions to the Pharmaceutical Affairs Law

Revisions to the Pharmaceutical Affairs Law will come into effect in April 2005 that are likely to have far-reaching consequences on the management of animal health businesses in Japan. A great deal of confusion persists in the industry regarding apparent requirements to employ extra pharmacists for quality control functions. The EBC urges the Japanese Government to clarify these concerns. The EBC recommends more focus on ability to “do the job” than on specific qualifications and asks that personnel with experience and qualification in related fields such as veterinary medicine or the natural sciences also be allowed to fulfil these functions.

Brand-specific listing

Brand-specific (as opposed to compound) listing for antibiotic and other feed additives should be introduced in Japan as has been done in Europe. The current system does not adequately recognise the significant expense, time, and sophisticated intellectual property involved in product development. Brand-specific listing would help clarify manufacturer responsibility vis-à-vis requests for the submission of safety data, not only for new products, but also re-evaluations of existing products and other studies such as the Japanese Government’s on-going investigation into resistance development in humans.



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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 should better reflect the clinical value of diagnostic equipment and reagents based on differences in quality (accuracy, specificity, laboratory certification), speed (emergency response, point of care), and contribution to comprehensive patient care (risk management, qualitative indications). Future price revisions should take into account the special role diagnostics play 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 Worsening situation. 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.). 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. 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.

■ 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 Changes expected. Japan will soon introduce a third-party/self-certification system based on risk classifications as a result of revisions to the Pharmaceutical Affairs Law to be implemented in April 2005. This will bring Japan's product approval system closer to international best practice. However, a number of problems still remain, including risk classifications methodologies and data requirements that are unique to Japan.

■ 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

Bayer Medical
Dade Behring
Nihon Schering
Ortho-Clinical Diagnostics
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 length of hospital stay, monitoring drug treatment, and managing medical risks.

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. 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.

The EBC is also concerned that patients, as well as doctors, nurses, hospital management staff and others involved in medical services, are starting to lose sight of the special characteristics of medical diagnostics.

Medical diagnostics have become a favourite target of cost cutting following the introduction of 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.

Instead of a single-minded focus on cutting medical diagnostic costs, the EBC feels that there is a pressing need to review the costs and benefits of medical diagnostics vis-à-vis patient quality of life, physician support, risk management, hospital management, and underlying health economics. Appropriate use of modern medical diagnostics would result in better quality care, and the EBC urges further reforms to the medical system so that medical diagnostics are better utilised.

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 promote 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. Preparations continue for the implementation of this Law in April 2005. The EBC welcomes this development, but notes that a number of important issues remain, including rising application fees, differences in risk classification methodologies between Japan and the Global Harmonisation Task Force (GHTF), Japan-specific application data requirements, and the speed at which products will be approved once this new system has been implemented.

MEDICAL EQUIPMENT

Summary of outstanding issues:

■ Reimbursement prices

Recommendation The reimbursement price for medical equipment set by the Japanese Government should better reflect the economic and clinical benefits of individual treatments. Additional consideration should be given to the cost of maintaining and operating medical equipment once it has been purchased.

Current situation No progress. The high cost of advanced medical equipment is often singled out as one of the main culprits underlying Japan's rising health care costs even though medical equipment represents only a small percentage of Japan's total health care expenditure. The reimbursement prices should consider the running cost of medical devices with a focus on equipment maintenance and quality assurance.

■ Product approval process

Recommendation Further reforms are needed to decrease the time and cost associated with introducing new medical equipment into the Japanese market. The Japanese Government should set and then honour a target for approving medical equipment within a certain time frame as it has done for other products such as in-vitro diagnostics.

Current situation Limited progress. The time and cost associated with bringing new products to the Japanese market is having a serious adverse effect on the type and quality of treatments being made available to Japanese patients. The EBC is worried that the burden on producers will increase as a result of changes to the Pharmaceutical Affairs Law in July 2002 that come into effect in April 2005.

■ 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 a Mutual Recognition Agreement recently signed between the EU and Japan did not include medical devices.

■ Structural reform in the medical sector

Recommendation Private companies should be allowed to own and/or operate hospitals in Japan, as is allowed in most countries of Europe.

Current situation Some progress. Stock companies will be able to own and operate medical facilities in "Special Deregulation Zones" as part of deregulation measures announced earlier this year. However, such facilities will only be allowed to provide medical services for a limited range of procedures and must be approved by the local authorities.

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
Fresenius Medical Care Japan
Gambro
Laerdal Medical Japan
Macopharma Japan
Nippon BXI
Oxford Instruments
Philips Medical Systems
Porges
Radiometer
Sata
Siemens-Asahi Medical Technologies
Smiths Medical Japan
Sorin Biomedica Japan
TUV Product Service Japan

Healthcare reform

Healthcare reform continues unabated in Japan. 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 policy responses to rising health care costs and a rapidly aging society seem to be based less on clear long-term healthcare goals, and more on short-term measures designed to reduce costs by any means available. Insurance coverage for numerous types of patient treatments has been reduced considerably, which has eliminated the main incentive for companies to develop innovative new treatments to help keep pace with the healthcare demands of the 21st century.

The EBC is also disappointed that the high cost of advanced medical equipment continues to be singled out as one of the main culprits underlying Japan's rising health care costs. Medical equipment represents only a small percentage of Japan's total health care expenditure. The cost of this small investment stands in no relation to the enormous potential medical devices have to improve the quality of patient care and reduce the amount spent on hospitalisation and pharmaceuticals.

Insurance coverage

It is necessary in Japan for producers of medical equipment to file medical insurance coverage applications so that medical institutions using these devices can recover the treatment cost. The EBC is very concerned that the reimbursement price set by the Japanese Government does 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. The EBC feels that 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. The main problem, however, is a short-sighted desire to reduce costs by drastically reducing reimbursement prices. Foreign treatments have been particularly hard-hit as a result of foreign reference pricing. The EBC recommends that the Ministry of Health Labour and Welfare establish clearer categories for establishing reimbursement prices that better reflect the benefit of individual products.

Regulatory environment governing product approvals

The EBC has long advocated reforms to the approval and monitoring process for medical treatments in Japan with the goal of reducing the time and costs associated with introducing innovative new treatments to the Japanese health care system. Outstanding issues include:

- Vague classification criteria for many insurance categories (e.g. for the A1 and A2 categories);
- Discrepancies between categories prescribed by the laws and the actual price determined by investigating officers at local inspection offices;
- Limited use of ISO standards; and
- The time needed to have a new treatment approved for sale.

While the EBC welcomes promises to introduce 3rd party testing for low risk products and allow manufacturing to be subcontracted, the EBC is concerned that other reforms expected to be implemented in April 2005 will lead to an increase in the regulatory burden on producers, not a decrease as the EBC has long advocated. Application fees are expected to rise, and producers are bracing themselves for more stringent personnel requirements in the application process. Costs are also likely to rise as a result of new EMC compliance regulations, the introduction of mandatory bar-coding, and filing requirements associated with the new product approval process. It is likely that this will affect new technologies to a much greater extent than older products.

Structural reform in the medical sector

The EBC supports recent efforts by the Koizumi Cabinet to deregulate regulations governing the ownership of medical facilities. The EBC feels that allowing stock companies to own medical facilities will lead to an increase in management efficiency and help the Japanese Government control medical expenditures.

PHARMACEUTICALS

Summary of outstanding issues:

■ **Pharmaceutical pricing reform**

Recommendation EFPIA Japan urges the Japanese government to be more committed to its decision to give significant price premiums on innovative new drugs.

Current situation Limited progress. From April 1st this year, there was a price cut of an average of 4.2% on all pharmaceuticals in Japan. At the same time, changes were made in the pricing rules to address issues under debate since last year. The revision provides greater rewards for effective drugs, both new and existing. On the other hand, issues concerning foreign price adjustment still remain unresolved, and are likely to be discussed for the next revision. EFPIA Japan requests that arbitrary or unreasonable changes should not be made in the foreign price adjustment rule.

■ **Product evaluation and approval process**

Recommendation EFPIA Japan anticipates that the new agency, the Pharmaceutical Medicine and Device Agency (PMDA), will streamline the drug evaluation and approval process, increase the quality of the review system, and provide improved service reflecting the fees that are requested of pharmaceutical companies.

Current situation Some progress. The PMDA was established in April 2004 on schedule. As it has been only a few months since the establishment, it is difficult to assess their performance. They seem to be committed to recruiting new reviewers, but at present, the absolute number of the personnel is falling below the anticipated number. EFPIA Japan expects the PMDA to recruit an adequate number of quality staff.

In their new consultation programme, we expect the results of New Drug Application (NDA) review to be more consistent with the outcome of the consultation. We believe that the unification of the Organisation for Pharmaceutical Safety and Research (KIKO) and the Pharmaceutical and Medical Devices Evaluation Centre should enable this.

EFPIA Japan also anticipates that the PMDA will play a major role in Drug Safety Monitoring, for example through intensive and regular monitoring in key hospitals.

■ **Intellectual property protection**

Recommendation EFPIA Japan urges the Japanese government to legislate eight-year data protection in response to the proposal submitted by the Federation of Pharmaceutical Manufacturers' Associations of Japan (FPMAJ).

Current situation Significant progress. In April 2004, the industry submitted their single-voice request to the Ministry of Health, Labour and Welfare (MHLW) to provide eight-year regulatory data protection. EFPIA Japan supports this move and anticipates that the MHLW will take appropriate action immediately.

Background:

Overview

On 30 April, the MHLW reported on the progress of the Action Plan proposed in their "Vision" statement for the pharmaceutical industry. Implementation of the "Vision" is critical, as fostering the pharmaceutical industry is vital for the promotion of public health, improvement of medical care, and enhancement of treatment efficiency. This environment exists now in the US, and following the G10 report, Europe is now moving to this direction. High performance by the recently established PMDA is a key to quicker launch of innovative new medicines. However, reducing review time in itself is not enough to allow patients' faster access to new medicines. We need a system that will allow a submission for a new drug in Japan simultaneously with Europe and the US. EFPIA Japan believes that commitment to global harmonisation is vital to be internationally competitive.

Pharmaceutical pricing reform

The MHLW makes a biennial drug price revision. Through price revision, issues around excessive *Yakkasa* (drug price margins) and the large proportion of pharmaceutical spending in the overall healthcare expenditure were settled. For the sake of budgetary control, however, an additional price cut was made in long-listed drugs. This goes against the principle of price revision, which is to reflect the current market value in the reimbursement price.

The pricing rules were revised twice since its establishment in 2000, and the revision provides better premiums for effective new drugs. However, we do not see any significant application of the new rules. Furthermore, changes in the foreign price adjustment rule are being proposed at every revision. EFPIA Japan anticipates that new drugs are priced under fair rules in order to allow Japanese patients' early access to new medicines, in line with patients in the rest of the world, and to ensure a stable supply of medicines.

Product evaluation and approval process

Under the Pharmaceutical Affairs Law revision, a new licensing system will be implemented in April 2005. The license, which is currently given for import and manufacturing, will, from April next year, be granted for wholesale and retail, and will be applied to all pharmaceutical products, both existing and new. In addition, the revision requires a new system that guarantees the quality of products for which licenses are held.

Furthermore, in order to improve the clinical trial environment in Japan, the MHLW together with the Ministry of Education organised a working party and developed a three-year plan for clinical trial promotion. Under the plan, a large-scale clinical trial network was established, and more than 550 medical institutions participate in this nationwide network, in which the Japan Medical Association (JMA) is taking the initiative. EFPIA Japan supports these moves to improve the clinical trial environment.

Intellectual property protection

The Intellectual Property Policy Headquarters, which was established within the Cabinet in 2003 to improve the international competitiveness of Japanese industry, published an action plan for 2004. The action plan includes items directly affecting the pharmaceutical industry, such as regulatory data protection, remuneration for employees' invention, and patent protection for medical activities.

In Europe, new pharmaceutical legislation, which includes harmonised data protection with an 8+2+1-year system, was finally approved in March 2004. Under the new scheme, eight years of data protection and ten/eleven years of marketing protection are provided throughout the member states. In Japan, as a result of heated discussion between the innovative industry and the generic industry, the FPMAJ, which represents both of the industries, sent a request for eight-year data protection to the MHLW in April this year. EFPIA Japan supports this move in principle.

With the aim of mitigating any adverse impact of the recent court decisions to award extraordinary heavy compensation to inventors, a bill was submitted to the Diet and was passed in May this year. EFPIA Japan opposes the bill, and last October, we submitted a position paper requesting complete abolition of the relevant provisions in the Patent Law. EFPIA Japan continues to monitor the move carefully.

EFPIA Japan Member Companies

Actelion Pharmaceuticals Japan Ltd.
Amersham plc
AstraZeneca K.K.
Aventis Pasteur K.K.
Aventis Pharma Ltd.
Bayer Yakuhin Ltd.
Bracco-Eisai Co., Ltd.
Chugai Pharmaceutical Co., Ltd.
Fournier Japan
Fresenius Medical Care Japan K.K.
GALDERMA K.K.
GlaxoSmithKline K.K.
Guerbet
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.
Sanofi-Synthelabo K.K.
Schwarz Pharma Japan K.K.
Sero Japan Co., Ltd.
Solvay Seiyaku K.K.
UCB Japan Co., Ltd.
ZLB Behring K.K.

Consumer Goods

Cosmetics
Cut flowers
Food
Liquor

COSMETICS

Summary of outstanding issues:

■ **Regulatory reform of quasi-drugs**

- Recommendation* The EBC strongly urges the Ministry of Health Labour and Welfare (MHLW) to:
1. Publish a nomenclature list, specifications, doses, product category, and related claims to increase transparency of accepted ingredients;
 2. Ease regulations concerning the approval of new active ingredients, and allow use of additives based on self-responsibility of the manufacturer;
 3. Reduce standard administrative processing times associated with new quasi-drug approvals, and reduce standard processing times for changes to already approved products;
 4. Ease regulations concerning applications for the approval of new marketing claims; and
 5. Move to full labelling in the same spirit as recent regulatory reform for cosmetics.

Current situation Regulation of the quasi-drug category remains obscure. Many strict regulations unique to Japan governing the approval of new active ingredients still exist. When a new cosmetics ingredient is contained in a quasi-drug, the ingredient must be approved as a quasi-drug additive. There appear to be limits, however, on how many new additives will be approved, especially for cosmetics with medical properties. On a positive note, the EBC applauds recent progress in discussions between industry and relevant authorities with regards to full ingredient labelling.

■ **Regulatory reform of cosmetics**

- Recommendation*
1. The MHLW should liaise with EC regulators and their scientific advisory committee (SCCNFP) in order to harmonise Positive and Negative Lists.
 2. The MHLW should join with its European counterparts to establish mutually acceptable safety standards for the positive list.
 3. Permissible product marketing claims should be harmonised with European standards and further liberalised to support product innovation and distribution on a global basis.

Current situation Harmonisation with the EU of the current Positive and Negative List remains insufficient. The EBC urges the Japanese Government to establish mutually acceptable safety standards with the EU for ingredients listed in the Positive List and the Negative List, and to harmonise the contents of these lists. With regards to safety standards, the EBC feels that it is necessary for Japan to consider recent trends in Europe, including the elimination of animal testing.

Regulations concerning allowable marketing claims continue to prevent effective product differentiation.

Background:

EBC Cosmetics Committee Member Companies

Beaute Prestige International
Chanel
Charles Raith Japan
Clarins
Elle International
Estee Lauder Group of Companies
Henkel Japan
LVMH
Nihon Coletica
Nihon L'Oreal
Nippon Lever
Nivea Kao
Pierre Fabre Japon
PUIG Japan
Wella Japan
Yves Saint Laurent Parfums

More reform in the cosmetics regulatory environment

More progress has been achieved this year in cosmetics deregulation with new rules governing the use of medicinal ingredients in cosmetic products. However, differences remain between the EU and Japan in the regulation of cosmetics. In particular, the EBC recommends further improvements in the following two areas.

First, too many differences still exist between the EU and Japan's respective positive and negative lists. As a result, European makers are often forced to reformulate their products specifically for the Japanese market. With regards to the positive list, there is a pressing need for further harmonisation of Japan's list of active ingredients with preservatives, UV absorbent materials, and tar pigments commonly used in Europe. In order to achieve this goal, responsible authorities will need to establish common safety evaluation standards and increase mutual recognition of safety data. The EBC urges the Japanese Government to increase its understanding of the European system, and bring cosmetics regulations in line with European regulations as soon as possible.

Second, allowable marketing claims are too standardised. Fifty-five marketing claims are now allowed following expansion of this list in 2001. However, most claims allowed are too general to allow for significant product differentiation. In Europe, performance claims are based on verifiable data, which is the responsibility of the manufacturer. The EBC feels that it would be appropriate to introduce such a system into Japan. By improving allowable marketing claims, the EBC hopes that an environment conducive to greater product differentiation can be introduced into the Japanese market.

While these two issues are of particular importance, the EBC notes that elimination of the approval system for general cosmetic products in 2001 has resulted in an increase in parallel imports by businesses without proper quality control systems. To the consumer, this development is undesirable. The EBC hopes that such abuse will stop once the "manufacturing/sales business" system is introduced as part of upcoming revisions to the Pharmaceutical Affairs Law.

The necessity of regulatory reform for Quasi-Drugs

The Japanese Quasi-Drug category consists of a wide range of products including medicated cosmetics such as whiteners, body deodorants, hair growers, depilatories, hair dyes, medicated dentifrice, bath preparations etc. which are subject to far more restrictions than other Cosmetics even though they are treated as Cosmetics in Europe and the United States. The EBC is not opposed to the existence of a Quasi-Drug category in principle. However, the EBC has long advocated reforms to the Quasi-Drug categories to address the following concerns:

1. Lack of transparency and lack of public disclosure regarding active ingredients (ingredient name, specifications, quantity, product categories etc.);
2. Cost and time needed to obtain approval for a new active ingredient in the Quasi-Drug category; and
3. Restrictions on the use of new cosmetic ingredients contained in Quasi-Drugs.

Given that the Japanese market for Quasi-Drugs has been expanding recently, especially for medicated cosmetics, the EBC asks that these issues be addressed as soon as possible. With regards to the use of cosmetics ingredients in Quasi-Drugs, the EBC feels that the use of these substances should be the responsibility of the manufacturer. Formal approval of cosmetics ingredients used in Quasi-Drugs should not be required as most of these substances are already in common use.

Recent developments in EU cosmetics regulation

The 7th round of amendments to EU Council Directive 76/778EEC will result in new requirements for cosmetics, including the elimination of animal testing, increased protection for consumers that suffer from allergies, and new best-before labelling requirements. The EBC urges the Japanese Government to engage in an active dialogue with the EU concerning the design and implementation of these new rules. The EBC strongly hopes that further harmonisation based on the principle of mutual recognition can be achieved on an incremental basis in the near future.

CUT FLOWERS

Summary of outstanding issues:

■ Plant quarantine regulations

Recommendation The Japanese list of non-quarantine organisms should be extended 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) that currently account for 80-90% of all shipment rejections and to accelerate the process to abolish zero tolerance for all organisms common in Japan.

Current situation No progress. Whereas other countries have brought their plant quarantine regulations in line with the letter (or at least the spirit) of the GATT's Sanitary and Phytosanitary chapter, Japan remains an exception. International negotiations have dragged on for years without any tangible results. Japan is using plant quarantine regulations to limit imports of cut flowers. The Japanese Government has initiated a review of its Pest Risk Analysis, but it remains uncertain whether this will lead to any improvements.

■ Fumigation costs

Recommendation Further competition in the provision of fumigation services should be encouraged 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. In March 2001, the Japan Fair Trade Commission (JFTC) started an investigation into alleged unfair trading practices between the two incumbent suppliers of fumigation services at Narita Airport. After a lengthy investigation and hearing process, the JFTC issued a final decision in December 2003 calling for the elimination of price fixing and other collusive practices (such as the sharing of orders) between the two companies involved. The EBC had hoped that the JFTC's intervention would lead to lower prices for fumigation services at Narita airport, but this does not appear to have occurred.

■ Inspection and handling facilities

Recommendation Further improvements are necessary at bonded warehouses and dispatch areas, especially at Narita where the largest volumes of imports are handled. Inspection capacity should be increased during peak seasons and inspection made available from 06:00 hrs, a request that the EBC originally made 6 years ago.

Current situation Some progress. Inspection capacity has improved over the last few years, and processing fees charged for holidays and overtime have come down. There have also been improvements to warehousing facilities, with cooler temperature-controlled warehouses now available from June through to September. Costs for these services have also dropped. The EBC notes, however, that there is still room for improvement – the facilities at most international airports in Japan are still inadequate for handling large volumes of cut flowers and other perishables.

Background:

The market for cut flowers in Japan

The market for cut flowers in Japan is one of the largest in the world. While the EBC feels there is great potential in the cut flower market geared towards personal consumption, this situation will not improve significantly until mass-market products can be supplied at prices below present levels.

Japanese growers have not yet achieved the economies of scale that have long been a feature of the industry in, for example, the Netherlands. European producers, for their part, have been unable to make use of this comparative advantage due to a number of trade barriers preventing the importation of large volumes of flowers at low prices. As a result, the overall share of imports in Japan's cut flower market stands at a mere 7-8%.

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 supposed to be applied only to organisms, which 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. In practice, this revision has so far not had an effect on cut flower imports, as the Japanese Government still does not make a practical distinction between harmful and non-harmful organisms. Insects such as thrips, mites and aphids, for example, are not mentioned on the list of non-quarantine pests, even though they are widespread in Japan. The Japanese Government has so far refused EU requests to increase the number of non-quarantine pests. Only recently has the Japanese Government indicated that tolerance levels for some organisms may be introduced, and tests are currently being conducted at pre-inspection facilities in the Netherlands. The EBC requests that tolerance levels be introduced as soon as possible.

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. This adds unnecessary cost to businesses importing cut flowers into Japan.

The EBC applauds 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.

Other issues

Under Japanese law, perishables have to be inspected at the first point of entry. By using sealed containers perishables can be transported by plane to another airport where plant quarantine inspection is carried out. Transporting sealed containers by road, however, is not permitted. This should be made possible.

Finally, the EBC encourages the Japanese Government to eliminate import duties of 3.0% on greens and leaves, which further increase the cost of importing cut flowers into Japan.

FOOD

Outstanding issues:

■ **Food safety, quality, choice & value**

Background A considerable number of high quality food items cannot be imported into Japan or are unnecessarily expensive. This is due to overly restrictive and cumbersome regulations as well as punitive duty rates. The loser is the Japanese consumer. Food safety has become a dominant issue in Japan. The emergence of BSE from September 2001 and bird flu more recently, in combination with isolated examples of fraud and mismanagement by local companies have led to a state of paranoia regarding food in Japan. Unfortunately, well-meaning food producers and importers, both Japanese and foreign, have suffered from the fallout.

Food safety has been high on the agenda of the EU for many years. The European Food Safety Authority was set up in 2002 and member states have set up their own national food safety authorities. The Japanese Government set up a Food Safety Commission in 2003. Unfortunately, this has not resulted in any substantive change to policy in areas of primary concern to European food producers and importers.

Though there have been indications of a more reasonable approach to food imports, the facts indicate that little progress has been made. For example, it has proved hard to convince authorities that European or American standards for the use of additives should be accepted.

The mission of the Food Committee of the EBC is for all high quality foods readily available in Europe to be accessible in Japan at reasonable prices. How can Japanese consumers have greater safety, quality, choice and value in relation to food? Some recommendations, most dating back several years, can be seen below.

■ **Food additives**

Recommendation Japan's food additives list should be modernised to conform with international standards set out by such bodies as the Joint FAO/WHO Expert Committee on Food Additives (JECFA). As a first step, all 46 substances recommended by the MHLW in Dec 2002 for priority review should be approved in the shortest possible time frame. As well, standards of use for common preservatives such as sorbic acid, potassium sorbate and sulphur dioxide should be reviewed so as not to penalise imported food.

Current situation No progress. Japan's food additives list remains out of step with the rest of the industrialised world. Of the over 800 food additives authorized in Japan, only 294 are accepted by JECFA. Over 600 other substances accepted by JECFA as being safe are not allowed in Japan, including many additives in common use around the world. This has long acted as a major barrier to the importation of European foods into Japan. In recognition of this problem, the MHLW has re-evaluated its food additive policy, and is for the first time reviewing substances accepted by JECFA and approved for use in the EU and the US without waiting for companies to apply for approval.

Current situation cont'd On December 19 2002 the MHLW submitted a list of 46 “priority” substances to the Food and Sanitation Council to be reviewed for possible acceptance in Japan. As we write this, none of these substances has been approved, nearly two years from the MHLW’s initial announcement. A speeding up of this process is requested. The EBC also asks that standards of use for additives already approved in Japan be modified so that they do not discriminate against the importation of European food products. The current regulations are so complex that the authorities themselves are sometimes unable to decide what is legal and what is not. Also, European foods containing far lower levels of common preservatives such as sorbic acid, potassium sorbate and sulphur dioxide than many Japanese foods are not allowed to be imported. This situation must also be addressed.

■ **Import duties**

Recommendation Food tariff rates should be reduced, especially for raw materials used by Japanese food manufacturers such as chocolate, bread improvers, mixes, icings, and glazes.

Current situation No progress. In a number of food categories, Japan’s import duty rates are significantly higher than those of its major trading partners. Since most European foods are unique and do not threaten Japanese food companies, no benefits can be seen from such a policy. Furthermore, many of these imported foods are ingredients used by Japanese food manufacturers, raising their costs and forcing some companies to move production to China.

■ **Phytosanitary border control**

Recommendation The Japanese list of non-quarantined organisms should be extended to include all non-harmful organisms found in fruits and vegetables.

Current situation No progress. The Japanese Government still does not make a practical distinction between harmful and non-harmful organisms, as required by the SPS chapter of the GATT Uruguay Round Agreement. Many insects are not mentioned in Japan’s non-quarantine list, even though they are widespread in Japan.

■ **Meat**

Recommendation Restrictions on imports of meat (specifically beef, lamb and pork) and meat products (such as non-heat, dry cured ham, shoulder and loin) from the EU should be reviewed, taking into account the control, surveillance and tracing systems that have been established in Europe and scientific evidence concerning transmission risk (e.g. animal age).

Current situation The EU operates stringent controls and surveillance on Specified Risk Material (SRM) relating to spongiform encephalopathies in all animal species. Tracing systems in the EU are more developed than anywhere else in the world. Despite these controls, Japan maintains stringent restrictions on the import of European beef and lamb, even though there is no scientific evidence that Scrapie, the ovine form of BSE, has any effect whatsoever on humans.

Processed pork products have also been subject to import restrictions following outbreaks of Classical Swine Fever, despite the scientific fact that the virus causing this disease dies during processing.

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. Recently established "Urgent Adjustment Areas" (*Kinkyu Chosei Chiiki*) should be abolished.

Current situation Some progress. The Japanese Government has commenced deregulating the retail environment through the elimination of minimum distance requirements between retail licensees and population controls, which took effect January 1, 2001 and September 1, 2003 respectively. Unfortunately, an increasing number of regions are being designated "Urgent Adjustment Areas" under a supposedly temporary measure designed to protect existing liquor retailers from deregulation, and no new licenses (or transfers of existing licenses) are issued in these areas for renewable periods of one year.

Furthermore, firms that already hold 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 or importer of liquor products.

■ Tariffs

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

Current situation No progress. While 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, tariffs still remain a major obstacle to importing European liquor products.

Background:

EBC Liquor Committee Member Companies

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

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 80% 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 50% and on the whole the prospects for wine imports in Japan remain very positive. Consumer interest in wine has increased dramatically and 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 for imported wine. The only caveat is that in the current deflationary environment there is strong downward pressure on the shelf price of wines with most demand increasingly coming in the under 1,000 yen per bottle range.

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 domestic whisky, 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.

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 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 take full account of the views of automobile importers in formulating its environmental policies.

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 will be implemented in such a manner that these policies do not put a disproportionate burden on importers. In particular, 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 Japon
DaimlerChrysler Japan
Fiat Auto Japan
Ford Japan
General Motors Japan
Jaguar Japan
Land Rover Japan
Nicole Automobiles
PAG Import
Peugeot Japan
Porsche Japan
Renault Japon
Volkswagen Group Japan
Volvo Nippon

Overview

Japan is the by far 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 244,000 units in 2003, imports were still well below the peak. This represents just under 6% 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 its 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. The Central Environment Council is currently reviewing Japan's future long-term emission requirements. Foreign automakers argue that it would be premature for Japan to adopt more stringent standards when the technology is not commercially available to comply with those already adopted.

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:

■ 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 issues affecting the industry. The next meeting is scheduled for 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 annual congress/paper presentation scheduled for May 2005 in Yokohama.

■ Internationalisation 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. This would complement industry trends towards global purchasing, cost-effectiveness, and single platform development.

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. 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 that specifications differ between domestic and overseas production, even within the same company.

Background:

EBC Automotive Components Committee Member Companies

A. Raymond Japan
BASF Japan
Behr Japan
BOSCH Automotive Systems
Central Saint-Gobain
DuPont Shinto Automotive Systems
Faurecia Japan
Henkel Japan
HP Pelzer Japan
Knorr-Bremse Commercial Vehicle Systems
Nihon Inalfa
Osram
Sachs Automotive Japan
Seric
Siemens VDO Automotive

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 the 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 firms are not tied to specific European automobile manufacturers, and have products proven to the rest of the auto 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 would like to encourage 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 public in general.

Current Situation Despite the fact that 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 its worldwide average.

■ 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 a great opportunity to significantly enlarge the scope of cooperation between Japan and Europe. The EBC encourages METI and other government affiliated institutions to openly promote and fund collaboration with European companies in a similar fashion as they do 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 7E7 project and the decision by ANA to become the launching customer will 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 in areas such as airframe, propulsion, components, air traffic management, and navigation systems.

Background:

EBC Committee of Aeronautics, Space and Defence Member Companies

AgustaWestland
Airbus Japan
Alcatel Japan
Arianespace
BAE Systems International
Barco
Eurocopter Service Japan
Rolls-Royce International
Thales Avionics Japan
Thales International Japan
Turbomeca Japan

The Japanese market for commercial aircraft

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. Japan Airlines (JAL), for example, has sourced exclusively from what is now a single US supplier. All-Nippon Airways (ANA) is also moving in this direction.

JAL is now operating European aircraft following its merger with Japan Air System (JAS). The EBC hopes that this will improve JAL's 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 and other airlines to consider European commercial aircraft for future fleet renewal or modifications.

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 been as successful as expected.

Japanese companies still rely heavily on defence contracts, which accounts for over 60% of their total aerospace turnover, and on partnerships with Boeing for commercial contracts.

The EBC wishes to point out that as far as 30 to 50 seat aircraft are concerned, European success is without equivalent anywhere else in the world (e.g. ATR, BAE, Casa, Dornier, Fokker, SAAB, Shorts). The EBC is convinced that cooperation with European manufacturers in this field could be of mutual benefit to Japanese and European industries.

Co-operation in commercial aircraft development

Pro-active 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 business opportunities and further develop their technological base. Japan would also benefit from co-operation in the quickly evolving fields of air traffic management and ground-based products that will certainly help to enhance the safety of Japanese airspace.

The cooperation between Kawasaki Heavy Industry (KHI) and Eurocopter on the BK117 helicopter, for example, is an encouraging example of successful cooperation.

However, the approval by METI's Aircraft Industry Council of the 7E7 as a national project has an impact on the scope of potential work of Japanese industrial concerns with European firms. The contractual agreement that will regulate participation in this new program needs to be carefully drafted to prevent repeating a situation in the past where Japanese companies were implicitly excluded of any meaningful collaboration with European companies in new product and technology development.

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 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 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 to introduce more Japan-Europe cooperation.

Current situation Close relations have long been maintained between Japan's and Europe's 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 the increasing cooperative initiatives between Japan's and Europe's 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 other reasons this cooperation must be comprehensive and systematic: timid, half-boiled measures will not work. The EBC also strongly supports discussions by Japanese and European companies of 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 an independent access to space without a large and supportive government market. In an unprecedented initiative, Japan and Europe's major space authorities have been studying a possible agreement to back up each other's governmental launch missions based on the principle of reciprocity. 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. Also, Japan's and Europe's 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 Service Japan
Rolls-Royce International
Snecma
Thales Avionics Japan
Thales International Japan

Japan and the space sector

Japan is one of the leading nations in the field of space. Its own heavy-lift H-IIA launchers give it an independent access to space. A lighter launcher, the Galaxy Express, is now under development. Japan also builds state-of-the-art technological and scientific satellites at the rate of one or two per year, but due to unexpected extra budget expenditures for analysis and recovery following the failure of the H-IIA last November, 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 be opened to international competition in 1990. Most of the responsibility for the H-IIA launcher, on the other hand, is being transferred to the private sector in the midst of a market depression.

These circumstances have been made worse by stringent budgetary constraints that may be the root cause of recent launcher and satellite failures. 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 more efforts by European makers to provide information about their satellites, and to better recognition worldwide of the fact that European-made satellites have an excellent track record, with particularly high quality and reliability. Another factor is opaque and unreliable U.S. export control policies.

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 Europe's and Japan's space authorities and agencies. Europe's and Japan's space industries have steadily grown more confident that they can co-operate, 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), and has decided to help develop the smaller Galaxy Express launcher. But 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 taking shape. In the commercial arena Arianespace, MHI and Boeing Launch Services agreed to make it easier for customers to shift their satellites within this group in case of technical problems with one of the group member's 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. Defence equipment should be chosen 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 EBC urges the Japanese Government to ease regulations concerning the transfer of information for European companies looking to co-operate on product development in Japan. This will give Japanese industry and governmental agencies access to new technologies and processes, including much needed real-world operational experience. In the present world, the EBC believes strongly that partner diversification is not only beneficial, but in fact crucial to the efficient provision of Japanese defence.

Current situation 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 constitution and modification 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 as yet no conclusion has been reached. 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.

Background:

**EBC Committee of
Aeronautics, Space and Defence
Member Companies**

AgustaWestland
Airbus Japan
Alcatel Japan
Arianespace
BAE Systems International
Barco
Eurocopter Service Japan
Rolls-Royce International
Thales Avionics Japan
Thales International Japan
Turboomeca Japan

The Japanese defence market

The market for defence equipment in Japan is the second largest in the world by monetary value. Japan's current five-year defence build-up plan includes an arms procurement budget of around 4.5 trillion yen, of which an estimated 75% will be spent on weapons systems developed and built locally. Products built under license from US manufacturers or directly imported from the US make up most of the remaining 25% of Japan's defence hardware market, with imports or licensed production originating in Europe still accounting for only a few percent. 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 or attend demonstrations of European equipment. The defence establishment remains relatively uninformed about European products, and this lack of exposure leads to narrow views on defence and procurement policy. This situation has been exacerbated by restrictive information transfer practices limiting the opportunity for EU/Japan industrial co-operation in the development and adaptation of defence equipment. 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 completely 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, state-of-the-art defence equipment, and would enable the Japanese Government to obtain higher value within their existing 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:

■ **Structural reform**

Recommendation The EBC urges the Japanese Government to promote structural reform in the Japanese construction sector through further deregulation, industry consolidation, financial restructuring, and encouragement of competitive bidding in public works projects.

Current situation Limited progress. Opportunities for European firms to participate in the construction market in Japan will not increase until the economic situation improves and a serious attempt is made to address the numerous structural deficiencies in the Japanese construction industry.

■ **Public procurement**

Recommendation Procuring entities should place more emphasis on obtaining “value-for-money” through the establishment of effective quality/performance management systems.

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 notes recent efforts on the part of procuring entities in Japan to improve disclosure of information on public works projects, but this has not resulted any substantial change to the procurement process in Japan. Little effort is made to ensure “value-for-money” and quality control measures are in many cases non-existent. The EBC does not expect this situation to improve substantially until the symbiotic relationship between politicians, bureaucrats, and the construction industry erodes.

■ **Mutual recognition of standards**

Recommendation Mutual recognition of JAS/JIS and ECN standards and conformance assessment practices should be encouraged. In the meantime, the Ministry of Land Infrastructure and Transportation (MLIT) should streamline the procedures for accrediting foreign testing bodies to certify JAS/JIS standards.

Current situation Limited progress. Despite changes to the Building Code in June 2000 that allow products to be tested in their country of origin on the basis of Japanese performance standards (provided the testing centre is approved by the Japanese Government), few European testing organisations have been accredited and there is little evidence of increased use of innovative materials and components from overseas. Regulations governing formaldehyde emissions introduced in 2003 highlight the seriousness of this problem. While the Japanese Government agreed to accept testing results from foreign testing organisations for formaldehyde emissions on the condition that they enter a co-operation agreement with a designated “Performance Evaluation Organisation”, only one European organisation has been accredited.

Background:

EBC Construction Committee Member Companies

Bovis Lend Lease Japan
Clestra Hauserman
Currie & Brown (Japan)
Forbo Linoleum Japan
Saint-Gobain Hanglas (Japan)
Schindler Elevator
S'International Architects

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. Productivity is in decline. All firms, even ones that are well-run, have suffered as a result.

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. Facing fiscal constraints itself, the Government has become increasingly interested in the cost effectiveness of the projects that it funds. In the case of public works, however, the official policy of sharing work among the many small and medium-sized contractors and “political intervention” continue, holding back changes and improvements to productivity.

There has been little new foreign investment in the Japanese construction sector, despite the current Government’s stated policy of doubling levels of FDI by the year 2008. While a number of European firms have established successful businesses in niche areas of the market, these examples have been limited in both scope and scale.

Regulatory burden

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 taken away by over-regulation and complicated procedures to obtain the necessary approvals.

For example, in Japan, especially for new building projects, it is almost impossible to sell building supplies directly to end-users. To be a direct subcontractor of a general contractor (*zenecon*) in Japan, a company needs to hold a permit (*kensetsu koji kyokasho*). To obtain this permit, a company must have a Residing Managing Director who has been a registered director for more than 5 years in the same company or in another company in the same field. Foreign firms often have trouble fulfilling this requirement. 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 involved in doing business in the Japanese market.

The EBC sees much potential in PFI/PPP schemes designed to involve the private sector in the provision of public services, but this potential will likely remain largely unfulfilled until procuring entities place more of an emphasis on “value-for-money”. European firms often find that bidding for projects is more trouble than it is worth given the complexity of the bidding process, lack of transparency, and lack of clear bidding criteria concerning performance requirements and quality control.

At the very least, the ceiling price system (*yotei kakaku*) for public tenders should be abolished and requirements for bid participation should be relaxed. Requirements peculiar to the construction of public works such as the requirement for site representatives for all projects over 5 million yen, the requirement for some component suppliers (such as elevator manufacturers) to maintain local production facilities, and burdensome inspection requirements not experienced in private sector projects should be eliminated.

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 users access to high quality products at market-based prices.

Current situation No progress. Tariffs are by far the largest barrier to trade in industrial materials with Japan. Most common industrial materials are sold worldwide under transparent prices and even the smallest tariff-induced price differential makes it difficult for European producers to compete. Japanese consumers of industrial materials in industries such as stainless steel, electronic components, battery production, automobiles, and ceramics face increasingly stiff international competition and would benefit from cheaper commodity procurement. Japan applies tariffs selectively with no other purpose than to support a small number of local companies. This greatly distorts competition in Japan and in export markets abroad.

■ Discriminatory treatment

Recommendation The EBC urges the Japanese Government to remove any barriers to trade that discriminate against European producers, such as the Generalised System of Preferences (GSP).

Current situation No progress. Many types of industrial raw materials are subject to discriminatory treatment under the Generalised System of Preferences, whereby imports from certain countries are exempted from paying Japanese duty while imports from other countries are not. European producers do not enjoy this exemption.

■ 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 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 ASA Materials
Eramet Japan
Falconbridge (Japan)
Lafarge Aluminates 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. This adds to the problems Japanese firms continue to face in important sectors such as steel, glass 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 market-based 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 reduce tariff rates on imported industrial materials and remove all forms of discrimination against European products.

Nickel

Japan is the only developed country in the world to apply duties on processed nickel products such as nickel metal (used in, for example, high nickel alloys), ferro-nickel (primarily used in the stainless steel industry) and nickel hydrides (used in batteries for cell phones and hybrid cars). This significantly increases 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 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.

This is also unfair to European producers who are forced to compete with Japanese producers who are protected at home. Since Europe does not impose import duties on processed nickel products, for some 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 recently decided to decrease import duties on nickel 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 thought of 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 The regulatory regime governing environmental protection and the environmental business should be further strengthened, 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 environment 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 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
TÜV 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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