



PROMOTING FOREIGN INVESTMENT THROUGH DECISIVE REFORM

**The EBC Report on the Japanese Business Environment
2003**

**The
European Business Community
in Japan**

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Promoting Foreign Investment
Through Decisive Reform

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2003

The
European Business Community
in Japan

European Business Community in Japan

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The European Business Community (EBC) is the trade policy arm of the 13 European National Chambers of Commerce and Business Associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents more than 3,000 local European companies and individuals who are members of their national chambers of commerce. Around 360 of the companies participate directly in the EBC's 26 industry committees and subcommittees, whose work aims to improve the local business environment in a wide variety of economic sectors.

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.

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

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2003

Editor and Principal Author: Casey Sedgman

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Message from the Chairman:

It is my great pleasure to introduce the EBC Report on the Japanese Business Environment 2003 “*Promoting Foreign Investment Through Decisive Reform*”, which tries this year to give a snapshot of the evolution of the business environment in Japan from a European perspective between 2002 and 2003.

A year ago, at the end of the presentation of the 2002 White Paper, a journalist made the ironic comment that nothing had changed from the previous report. This was precisely the point: there had been very little progress between 2001 and 2002 in the reform process!

This year, we have decided to slightly alter the presentation of the White Paper to better show the progress that has been made during the past 12 months, the things that have changed for the better... and unfortunately sometimes for the worse, as well as to highlight some new issues that European business circles have identified as inhibiting business development in the Japanese market.

In the past year, many things indeed have changed. The economic situation, although not yet in the Recovery Room, seems to be about to be able to leave the Emergency Room. 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. Foreign investors are playing their part of the game, showing that they are not all the blue-eyed vultures that some politicians are afraid of.

As a matter of fact, we believe that the future in Japan is on the brink of becoming brighter. The sincere willingness of Prime Minister Koizumi to encourage in the coming five years the doubling of foreign direct investment to this country, as he expressed during his speech to the Diet earlier this year, must be supported and we can't but call upon European firms to take their share of the new impetus this will create.

In this respect, the Japanese Administration has already taken some measures to help foreign investors find their way in the Japanese jungle of regulatory complexities and we would like here to express our gratitude to the METI and the JETRO for the creation of a One Stop Shop that will certainly help foreign companies to more easily establish their base in this market.

But, as we mentioned to Prime Minister Koizumi when the EBC met with him in January 2003 to talk about foreign investment, this is only one of the two necessary legs of the body for change. The other leg is the structural reform process. Without it, all the commendable efforts of the METI and the JETRO to promote foreign investment into Japan will be like a “fist stroke in the *Noren*” – a wasted effort.

Some people have criticized Prime Minister Koizumi for repeating in his recent speech at the Diet the word “Structural Reform Process” 30 times. Well, we hope that this will be enough to encourage the various administrations to go for it and very modestly, we would like to stress that we are more than ever supportive of the strong will of Prime Minister Koizumi and his Cabinet to pursue efforts to “make the structural reforms bud to become a strong tree”. Please see this 2003 EBC White Paper as our modest contribution to this huge 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 2003 White Paper, the fourth consecutive year of its publication. Entitled *"Promoting Foreign Investment Through Decisive Reform: the EBC Report on the Japanese Business Environment 2003"*, the report highlights the unresolved issues inhibiting European trade and investment in Japan.

The production of this report involved a massive undertaking to synthesize the views of hundreds of people from a wide range of professional backgrounds with the common desire to achieve a healthy, world-class, and stable business environment. This goal is all the more important given the current state of Japan's economy and the expressed desire of Prime Minister Koizumi and his government to double foreign direct investment as a key measure for economic recovery. This report, like the EBC itself, represents our diverse member companies, yet speaks with one voice on a variety of key trade 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 regulatory reform in the hope that it might shake-up Japan's overly bureaucratic and protectionist infrastructure. Achieving the ambitious goal of doubling foreign direct investment in five years will first require the creation of more appropriate conditions and greater regulatory transparency.

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 section at the end of this publication.

European firms have a long history in Japan and take an intimate interest in its recovery and continued development. Europe is now the largest source of foreign investment in the Japanese economy, a fact that has not gone unnoticed by the Japanese Government. 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

A large, solid gray rectangular block is positioned on the right side of the slide, partially overlapping the text 'Introduction'.

INTRODUCTION

Promoting foreign investment into Japan...

In his speech opening the regular session of the Diet, Prime Minister Koizumi stated the Government's goal of doubling foreign investment in Japan within the next five years.

The EBC welcomes this initiative. Experience has shown that foreign investment has had an extremely positive impact on economic development through the introduction of new capital, technology, managerial know-how, and opportunities for employment. Individual economies benefit from the economic stimulus of increased competition, productivity and innovation; companies benefit from the markets and resources of the global economy; and consumers benefit from increased access to innovative products and services at competitive prices.

As it stands, the level of foreign investment in Japan is remarkably low compared with other industrialized nations. The yearly intake of FDI into Japan compared to GDP averages barely 1% whereas the average in OECD member countries is closer to 20%.

The EBC has long argued that this situation will not change unless Japan clearly demonstrates to the rest of the world that it welcomes foreign investment and that it is willing to take decisive action to improve its economic situation and make it easier for foreign companies to both enter the Japanese market and pursue business opportunities once they have become established.

...Some encouraging signs...

There have been some encouraging signs that the Japanese Government is starting to address these issues.

For example, the EBC has noted a definite shift in attitude towards the role of foreign trade and investment in Japan. Japanese customers are seeking out innovative European products and services, local governments are actively promoting European investment, and Japanese companies are increasingly looking to European firms for financial and technical support. The EBC welcomes the fact that the Prime Minister himself has officially recognized the importance of increasing levels of foreign investment into Japan. European firms have also reported enthusiastic welcomes from the governors of a number of Prefectures and other high-ranking government officials. The EBC hopes that the recent establishment of the "one-stop-shop" for foreign investors within the JETRO organisation will help foster the Government's foreign investment initiative. The current Government's "reform" minded zeal will surely help in the promotion of Japan as an attractive location for overseas investors.

A number of changes in government policy over the past decade have also contributed to an increase in foreign investment. The liberalisation of large-scale retail outlets, telecommunications and financial services, for example, has resulted in substantial foreign investment in these sectors. Recent pressure on Japanese financial institutions to clean up their balance sheets has resulted in an influx of foreign capital and management know-how in corporate rehabilitation efforts and the disposal of non-performing loans.

The EBC welcomes the current Administration's ongoing pursuit of structural reforms and hopes that initiatives in areas such as regulatory reform (e.g. the creation of "special deregulation zones"), privatisation (e.g. postal insurance), and intellectual property protection will start to bear fruit.

INTRODUCTION

...But urgent need for further reform

Having said this, the EBC feels that foreign investment in Japan will never approach levels seen in other industrialised nations unless the Japanese Government makes more of an effort to create an environment conducive to the development of new business.

The EBC is disappointed that many long-standing issues have not been addressed:

- Plant quarantine regulations – The Japanese Government still does not make a practical distinction between harmful and non-harmful organisms, as is required under the GATT's Sanitary and Phyto-sanitary Chapter. Insects such as thrips, mites and aphids are not mentioned on the list of non-quarantined pests, even though they are widespread in Japan.
- Pricing and distribution for international airfares – Numerous restrictions continue to inhibit the development of direct sales to consumers, contrary to practice in nearly all countries worldwide.
- National assay for animal health in-vitro diagnostics – A number of in-vitro diagnostic products intended for animal use must still be assayed at a national laboratory. This requirement does not exist for in-vitro diagnostics intended for human use in Japan, even for those used to diagnose major infectious diseases such as Hepatitis and AIDS.

In other cases, reform has not achieved the desired effect:

- Liquor retail reform – Retail licensing has been deregulated with the elimination of minimum distance requirements and population controls, which took effect January 1 2001 and September 1 2003 respectively. Unfortunately, a number of regions have been designated "Urgent Adjustment Areas" under a temporary measure designed to protect existing retailers from deregulation, and no new licenses (or transfers of existing licenses) will be issued in these areas for at least one year.
- Triangular mergers – Revisions to the Corporate Revitalisation Law now allow for "triangular mergers" whereby foreign firms may use their own shares to acquire a Japanese company through a Japanese subsidiary. Unfortunately, such transfers do not qualify for capital gains tax-deferral, which limits the benefits of this reform.
- Food additives – Japan's food additives regulations remain out of step with the rest of the world. Of the 828 food additives authorized in Japan, only 294 have been approved by the Joint FAO/WHO Expert Committee on Food Additives (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. On December 19 2002 the Ministry of Health Labour and Welfare submitted a list of 46 substances to the Food and Sanitation Council for "priority" review, but none have been approved yet.
- Firewalls in the financial services industry – The EBC is disappointed that reforms enacted in 2002 allowing banks and securities firms to share common retail space in order to promote the sales of securities products to retail investors did not do more to rationalise existing regulations that impose artificial barriers between banks and securities firms. These reforms have resulted in a situation where firewalls are now stronger for wholesale than for retail activities, which defies the very reason firewalls were established in the first place – to protect individual investors.

INTRODUCTION

- Shipping terminal operations – Despite recent reforms aimed at liberalizing the licensing system for port operations, requirements such as minimum employment levels continue to hamper the development of a competitive market for port services in Japan. To date, no foreign firm operates its own terminals in Japan.
- Tax consolidation – The introduction of the new consolidated tax system remains woefully under-utilised because of the imposition of a 2% surtax and other restrictions such as a limitation on the carry-forward of pre-consolidated losses.

The EBC is disappointed that in many cases recent developments are likely to make the trade and investment situation worse:

- Telecommunication interconnection fees – Contrary to Telecommunications Council recommendations, revisions to interconnection fees were enacted in January 2003 resulting in an overall increase in interconnection charges for most carriers.
- Pricing reform in the health science sector – Reimbursement prices for medical products such as 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 sector to invest in new product development and introduce innovative new technology to Japan.
- Counterfeit goods on the Internet – The Internet has become very popular for buying and selling new and used brand-named products through auction and other sites. Unfortunately, the Internet has also become an easy way to dispose of counterfeit goods in Japan. It is estimated that over 80% of brand goods sold over the Internet are likely fake products.
- Factor-based tax – The Japanese Government has decided to introduce factor-based components such as capital and human resource costs into the Corporate Enterprise Tax. 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 system will also discourage further investment into the Japanese market by European firms as they will very likely be unable to credit factor-based taxes in Japan against tax in their home country.
- Food Safety Council – While the EBC supports the Japanese Government's desire to improve the regulatory environment governing food safety in Japan, the establishment of the new Food Safety Council has not been smooth. Animal health producers are now facing additional product approval delays until the Council gets up and running. Approvals for new food additives are facing similar delays.

These and other issues are discussed in more detail throughout this report. The EBC urges the Japanese Government to take decisive action to solve these problems, as foreign investment will not increase until more is done to remove obstacles inhibiting the development of new business.

The EBC welcomes explicit reference made during the EU Japan Summit held in Athens in May 2003 to the need to further promote a mutual increase in FDI, and encourages both parties to develop a more structured framework to facilitate the establishment of a truly open environment for trade and investment.

Business Fundamentals

Human resources
Intellectual property
Retail
E-Commerce
Legal services
Tax

HUMAN RESOURCES

Summary of outstanding issues:

■ 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. Follow-on ordinances are expected in the fall.

■ Pensions

Recommendation

1. The defined-contribution 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.
2. Some progress. Social security agreements are being negotiated or have been concluded with France, the UK, Germany, the US, and South Korea.
3. No progress. Refunds on mandatory contributions to Japanese pension plans are capped at a max. 3 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.

■ Regulations governing temporary workers

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

Current situation Significant progress. Recent revisions to the Labour Standards Law have increased the number of job-categories for temporary (or dispatched) workers (including, for the first time, jobs in the manufacturing sector), eliminated the 3 year limit on temporary employment for 26 different job categories, and increased the allowable employment contract period from 1 year to 3 years for others.

Background:

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.

The EBC is disappointed that recent revisions to the Labour Standards Law did not do more to clarify the situation surrounding dismissals in Japan.

While the need for more flexibility was well recognized by an advisory-panel report submitted to the Ministry of Health and Welfare (MHLW) on 26th December 2002, revisions to the Labour Standards Law that passed the Diet on 26th June 2003 did nothing more than codify the right of companies to dismiss employees for justifiable reasons in line with accepted social customs. The new law provides no new criteria for what constitutes an “objectively justifiable reason”, nor further explanation of what is “socially fair”. It appears that the law does little more than fix the discrepancy between the Labour Standards Law (which until now has been silent on the subject of dismissals) and the Japanese Civil Code (which recognized 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. The EBC urges the Japanese Government to clearly state the rights and responsibilities of employers and their employees in restructuring and dismissal situations as it develops “follow-on” guidelines to recent Labour Standards Law revisions.

Promoting the development of human resources in Japan

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, 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. More emphasis should be placed on upgrading the skills of those already in the labour market, including Japanese workers and their spouses currently overseas. The EBC sees great potential in the development of a labour market for “returnees”, but only if these workers and their spouses are given the right incentives, including easy access to skill development while overseas and the ability to have these skills easily certified upon return to Japan. The EBC also supports an increase in academic and other links between the EU and Japan through exchanges, “twinnings”, internships and other means, as proposed in the EU-Japan Action Plan adopted at the EU-Japan Summit in 2001.

The EBC also notes that more could be done to encourage foreign investment by liberalizing Visa requirements for small-scale entrepreneurs in Japan.

EBC Human Resources Committee Member Companies

Action Japan
Baring Asset Management (Japan)
Bayer
Chanel
DaimlerChrysler Japan
Danfoss
Disco
Philippe Debroux, Soka University
Equant
France Telecom Japan
Gartmore Japan
Givaudan Japan
Global Expansion Network
JAC Japan
Nokia Japan
Oak Associates
Oakwood
Orrick, Herrington & Sutcliffe
Panache
PCA Life Insurance
Roche Diagnostics
Siemens-Asahi Medical Technologies
Zurich Insurance

INTELLECTUAL PROPERTY

Summary of outstanding issues:

■ **Border control**

Recommendation Procedures for seizing suspected counterfeit goods at the Japanese border should be subject to a more transparent judicial process. In order to alleviate Customs liability and workload, the burden of proof should be shared between the importer and the rights holder. Rights holders should be given the opportunity to make more use of civil proceedings to protect their intellectual property through increased information disclosure on the part of customs officials. Importers should be held more accountable for the authenticity of the goods being brought into the country.

Current situation Significant progress. Rights holders are now able to officially apply to the Japanese customs authority to have the importation of suspected counterfeit products suspended. Japanese Customs is also contemplating the implementation within 2004 of a new disclosure system allowing more sharing of information between rights holders and customs officials. However, as this will remain an administrative process it remains to be seen whether or not disclosure on the part of customs officials will be sufficient enough for rights holders to make more use of civil or criminal proceedings to protect their intellectual property.

■ **Fake goods on the Internet**

Recommendation The liability of Internet Service Providers (ISPs) should be more clearly defined with regards to requests for take-down and information disclosure on suspected infringements of intellectual property rights. ISPs should be obligated to take more stringent measures against repeat offenders.

Current situation Worsening situation. The Internet has become very popular for buying and selling new and used brand-named products through auction and other sites. Unfortunately, the Internet has also become an easy way to dispose of fake goods in Japan, a problem that continues to grow. No common policy has been developed amongst ISPs to help deal with this problem, a situation that the EBC finds deeply troubling. As well, ambiguities in the Law make it difficult for ISPs to provide personal information on particular listings, which has made it difficult for rights holders to trace suspected violations and pursue civil action. The EBC hopes that revisions to the ISP Liability Restriction Law under consideration by METI will address these issues.

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

Recommendation Japanese courts should take a more stringent approach to the interpretation of the similarity of designs under the Design and Unfair Competition Law.

Current situation No progress. Japanese courts continue to take a very narrow view in interpreting the similarity of designs under the design and unfair competition law, depriving the law of its primary purpose. Even minor changes prevent counterfeit goods from being accepted as dead copies. Offenders are taking advantage of this loophole to flood the market with cheap imitations at an increasing pace. Criteria used by the courts to define copyrights are also too restrictive to deal with unfair imitations that are not protected by trademark or design law. Effective protection from counterfeiting will not be achieved until the general attitude of the judiciary towards the interpretation of design, trademark, and unfair competition changes.

Background:

EBC Patents/Trademarks/License
Committee Member Companies

Laurent Dubois Foreign Law Office
Sonderhoff & Einsel

Strengthening the protection of intellectual property rights in Japan

Protection of intellectual property rights is becoming more and more important with the rapid development and incorporation of technology and software into the Japanese economy. In recognition of the increasing importance of intellectual property rights protection to the Japanese economy, the Japanese Government is making an effort to improve rights protection and enforce applicable laws. In 2002, the Japanese Government established the Intellectual Property Strategy Council, which has been working hard to develop a comprehensive government strategy on this issue, including policies designed to deal with threats to Japanese intellectual property rights holders from China and other developing markets.

The EBC strongly supports this government initiative, which is starting to show some tangible results. For example, revisions to the Customs and Tariff Law that came into effect on April 1st, 2003 will make it easier for companies to apply to customs authorities to have the importation of suspected counterfeit products suspended at the Japanese border. As well, the EBC appreciates the efforts that the police and customs authorities have been taking recently to crack-down on counterfeits (including the sale of such products over the Internet), as demonstrated by the marked increase in the number of criminal cases being pursued by the authorities.

Despite these positive developments, the EBC notes that counterfeits remain a very serious problem in Japan. It is estimated that almost all Italian brand goods distributed at Pachinko parlours are counterfeits. Over 80% of brand goods sold over the Internet through auction sites and other means are likely fake products. Numerous structural problems exist that prevent Japanese authorities from effectively dealing with this problem:

- Unlike in Europe, parallel imports are authorized in Japan. Because parallel imports are by their very nature insecure, foreign suppliers and Japanese importers often use this "open door" to flood the market with dubious products.
- Customs officials are prevented by law from disclosing the information necessary for rights holders to effectively pursue civil action against suspected abuses.
- 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.
- Discrepancies between the Customs and Tariff Law and the Trademark Law allow for the importation of counterfeit goods into Japan for "personal use" either by mail or by hand carry. This loophole is increasingly being abused by commercial importers, who import dubious products in small quantities to reduce the risk of detection. The EBC does not realistically expect this situation to change unless importers are forced to take more responsibility to control the authenticity of the goods that they bring into the country. Travellers are also authorized under this law to bring fake goods into Japan in small quantities, a practice that should not be tolerated.
- The liability of Internet Service Providers 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.
- Recourse to judicial means to combat the sale of counterfeit goods over the Internet is not always practical considering the numbers involved. It is also extremely time consuming for rights holders to continually monitor web sites for suspected violations.
- Despite recent improvement of the Patent and Trademark Law, damage awarded to the rights holders remains too low to reflect the impact of the infringement and to deter offenders from their 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. Only then will Japan be able to get rid of its image as a "heaven for counterfeits".

RETAIL

Summary of outstanding issues:

■ Large Store Location Law

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. Applications currently take upwards of 1 year to be processed. In many cases, local governments have imposed new conditions on applicants that negate the original purpose of the Large Scale Location Law, which replaced the Large Store Law in June 2000. In many cases, the procedure to open large-scale stores has become more complicated, not less. This increases the cost involved with opening new stores in Japan to the detriment of the Japanese economy.

■ Alcohol licensing

Recommendation 1. “Urgent Adjustment Areas” (*Kinkyu Chosei Chiiki*) should be abolished.
2. 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.
3. Recent liberalization 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 liberalized 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, and no new licenses (or transfers of existing licenses) will be issued in these areas for one year. As well, 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. 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 should be relaxed by adopting similar import procedures as exist in the EU. The validity period for import approval should be extended from 1 year to 5 years.

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 processing fee submitted for every tableware product, which increases the cost of importing these products into Japan. Import approval is officially valid for only one year.

Background:

EBC Retail Committee Member Companies

CARAN d'ACHE Japan
Carrefour Japan
Chanel
Club 8 Company
Copyrights Japan
Danfoss
Exel Japan
Henkel Japan
IKEA Japan
Land Development International
Nestle Japan

The business environment: An overview

New entrants into Japan's retail sector face major challenges. They must drive costs down to enhance customer value, develop a superior merchandizing scheme, optimize occupancy costs, withstand a rising competitive challenge from local retailers and overcome the chronically poor retail economics of the Japanese market.

One of the biggest challenges is no doubt to ensure viable long-term growth in Japan.

Deflationary pressures continue to weigh heavily on the minds of foreign investors.

The Japanese real estate market is not as efficient as those of many other developed countries so local operators have a clear advantage over global retailers in terms of information and the bidding process. Despite falling land prices, Japanese real estate remains very expensive, and retailers are often required to pay large up-front deposits.

Even after securing a location, large-scale retailers must navigate the licensing process set out by the new Large Store Location Law and it can take over eight months to secure permission to do business after filing an application. This law replaced the old Large Store Law in 2000 with the primary objective being to preserve living conditions for residents in surrounding districts as opposed to simply protecting smaller retailers, the main aim of the old law. The authority to implement the Large Store Location Law is now vested in local governments and not the national government as was the case with the old Large Store Law. While the EBC supports in principle the recent trend towards decentralization in Japan, the EBC also notes that local governments have taken advantage of their newfound authority to impose new conditions on new retailing businesses that defeat the original intent of the reform. It is imperative that the Large Store Location Law be applied in a fair and consistent manner and that the administrative burden placed on applicants seeking to open new stores be reduced in line with the original intent of the law.

Restrictions on opening retail stores of over 1000 m² have forced many foreign retailers to explore other options, such as acquiring existing Japanese retailers or developing smaller outlets.

Entrance into the Japanese market through M&A and/or strategic alliances has become easier due to slumping stock prices in the Japanese retail sector, an increasing acceptance in Japan of foreign intervention to help with corporate restructuring, and greater flexibility in structuring transactions as a result of recent changes to the Japanese Commercial Code and civil rehabilitation laws. The development of other policy initiatives such as the creation of the Industrial Revitalization Corporation has also helped.

Liquor licensing

The EBC welcomes new legislation that came into effect on September 1 2003 that further liberalizes the liquor licensing system for retailers in Japan, a process that started in 2001. Outdated regulations and procedures such as the lottery system and restrictions based on distance and population have been abolished. Unfortunately, a new law was enacted in August 2003 that was designed to provide temporary relief to incumbent retailers from the effects of ongoing liberalization. For one year, the director of the local tax office can designate their jurisdiction as an "Urgent Adjustment Area" if supply exceeds demand and sales volumes for 2002 dropped more than 10% of the average of FY99-01 for over 50% of incumbent retailers. 933 out of a total of 3383 areas have been designated as such. If this law is renewed and "Urgent Adjustment Areas" reviewed every year, foreign firms will be taking a big risk in investing in Japan.

The EBC is also concerned with the implementation of the new liquor licensing regulations. Recipients that hold a large scale store liquor license, which does not allow for the sale of Japanese sake, *shochu* or beer, will not be able to apply for a new-type license that allows for a wider scope of alcohol sales until their previous license expires (3 year term).

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. A high level of distrust in the security of Internet and electronic transactions persists, as seen in the shy development of online transactions through open e-marketplaces as well as through adverse public reaction to initiatives such as the introduction of the “Juki-Net” electronic national residency database. The Japanese Government appears to recognize these problems and is starting to address the issues involved, such as protecting the use of personal information.

■ 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 service 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

Barclay Capital (Japan)
BT Japan
Coface Japan
France Telecom Japan
Haarman, Hemmelrath & Partner

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, nearly doubling to 2.7 million yen in 2002 from the previous year according to statistics prepared by the Electronic Commerce Promotion Council of Japan. 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. The market for business-to-business electronic commerce (B2B) transactions topped 46 trillion yen in 2002, representing a year-on-year growth of 36%, and is expected to grow to 126 trillion yen by the year 2007.

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.

In the B2B market, 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 this area, 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 appears to recognise 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:

■ Freedom of association

Recommendation Japanese lawyers (*bengoshi*) and foreign lawyers (*gaiben*) who choose to work together to better serve their clients should be able to organise and manage their business without restriction. The current *tokutei kyodo jigyo* system should be replaced by a system that allows for full partnership between *bengoshi* and *gaiben*.

Current situation Significant progress. Progressive legislation was passed by the Diet in July 2003 which, when implemented, will lift restrictions on the form of association through which *bengoshi* and *gaiben* may choose to operate. Inexplicably though, and contrary to the forward looking spirit of the new law, certain Nichibenren regulations will have to be satisfied for *bengoshi* and *gaiben* to share the same business name. It is crucial to international business interests in Japan and for the promotion of much needed FDI that this ground-breaking legislation is quickly brought into force and the potential two year implementation period is kept as short as possible.

■ Equal treatment

Recommendation Foreign lawyers and *bengoshi* should be able to employ lawyers (wherever qualified, and including *bengoshi*) on an equal and fair footing provided the interests of clients are served and protected.

Current situation Progress. The new legislation will remove prohibitions preventing *bengoshi* from being employed by foreign law firms in Japan. It has however been suggested that as a consequence of restrictions on foreign law firms in Japan advising on Japanese law, a *bengoshi* employed by a *gaiben* would not be able to give advice in the name of the foreign firm unless there is a *bengoshi* partner in that firm. The EBC rejects such an interpretation as it defeats the clear objective of the new provisions and would in effect render *bengoshi* unemployable.

■ Incorporated law firms

Recommendation The benefits of fairly recent legislation enabling only *bengoshi* to incorporate their law offices should also be made available to foreign lawyers. There is no justification for restrictions limiting the freedom of *bengoshi* and foreign lawyers who choose to collaborate in choosing the firm name or style under which they operate an integrated legal service.

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

■ **Dispute resolution**

Current situation The recently published Report of the Alternative Dispute Resolution (ADR) Study Group of the Judicial System Reform Promotion Headquarters has proved a very valuable first step in a process which will hopefully result in the introduction of an ADR basic law which will best promote and facilitate the use of ADR in Japan. This will be much welcomed by international business which benefits from the expeditious resolution of civil disputes.

Commentary Experienced commentators on ADR have cautioned against a restrictive and overly bureaucratic approach in developing dispute resolution in Japan. They have urged the Japanese Government to ensure that all persons and organisations may work freely in arbitration, mediation, and other forms of alternative dispute resolution and dispute avoidance whether or not they are admitted as lawyers or otherwise registered or licensed by the government.

■ **Qualifying as a *gaiben***

Recommendation The procedure for becoming a *gaiben* should be streamlined and should more readily reflect a mutual recognition of legal qualifications gained in different jurisdictions. The requirement for a *gaiben* to have a minimum of three years experience before being licensed in Japan should be eliminated. Furthermore, all post-qualification experience should be considered of equal value, regardless of which country it was gained in.

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 in Japan and which fully recognises their post qualification experience when applying 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* 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.

TAX

Summary of outstanding issues:

■ **Accountability**

- | | |
|--------------------------|--|
| <i>Recommendation</i> | <ol style="list-style-type: none"> 1. The National Tax Agency should provide all rulings and clarifications in writing as a matter of standard practice, and not only for requests received under the formal <i>Kaito Bunsho</i> system. This should include requests for prior clearance for specific transactions. 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. |
| <i>Current situation</i> | <ol style="list-style-type: none"> 1. <u>No progress</u>. A lack of clear and binding guidance regarding specific tax situations continues to be a persistent problem for European firms doing business in Japan. Firms report numerous cases of arbitrary and inconsistent treatment from tax authorities in Japan. It is still uncommon for clarifications on specific transactions to be issued in writing. With the exception of responses issued under the formal <i>Kaito Bunsho</i> system, no record of any specific guidance is made available to the public. This makes business planning difficult and inhibits firms from seeking effective redress when there is a dispute with a particular ruling. 2. <u>No progress</u>. Disputes between taxpayers and the Japanese tax authorities continue to be published regularly in the media, a tendency that appears to be increasing. This discourages much needed foreign direct investment. The EBC views any “leaking” of information protected by Japanese taxpayer confidentiality laws with extreme concern. |

■ **Consolidated taxation**

- | | |
|-----------------------|--|
| <i>Recommendation</i> | <ol style="list-style-type: none"> 1. The 2% surtax levied on companies electing to use the consolidated tax system should be abolished. No such tax exists in Europe. 2. The requirement that only 100% subsidiaries may be consolidated is too restrictive and should be replaced by a 50% threshold. 3. The expiry of pre-consolidation period losses of companies when they enter the consolidated group should be eliminated. 4. The obligatory taxable revaluation of assets of companies entering the consolidated group should be eliminated. 5. The obligatory integration of all 100% subsidiaries if a group wishes a consolidation should be eliminated. 6. Local taxes should be included in the consolidation. The taxation system related to Corporate Inhabitant Tax (<i>hojin-jumin-zei</i>) and the Corporate Enterprise Tax (<i>hojin-jigyo-zei</i>) should be simplified as much as possible in order to reduce administrative burden in the preparation of related local tax returns. |
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Summary of outstanding issues cont'd:

EBC Tax Committee Member Companies

Aventis Pharma
BASF Japan
Bayer
British American Tobacco Japan
Chanel
Ciba Specialty Chemicals
DaimlerChrysler Japan
Dalpayrat Foreign Law Office
Haarmann, Hemmelrath & Partner
Henkel Japan
KPMG Peat Marwick
Loyens & Volkmaars
Mazars Japan
Nippon Boehringer Ingelheim
Novartis Pharma
Orrick, Herrington & Sutcliffe
Philips Japan
PricewaterhouseCoopers
Sonderhoff & Einsel
Telekurs (Japan)

Current situation No progress. It is not likely that the consolidated tax system in Japan introduced in 2002 will be fully or actively utilized among the Japanese corporate taxpayers in Japan unless the issues outlined above are addressed.

■ Factor-based tax

Recommendation The factor-based criteria should be eliminated from the Corporate Enterprise Tax.

Current situation No progress. Criteria other than profits such as capital and employee expenses will become part of the Corporate Enterprise Tax effective April 2004. Such taxes discourage foreign direct 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 parent companies to obtain a full foreign tax credit on Japanese income.

■ Loss carry forward

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

Current situation No 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.

■ Corporate reorganisation

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 tax-deferred in all cases.
2. Laws and rules 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 Revitalization allows cross-border "triangular" mergers if a company is in distress and if the company's revitalization plan is approved by the Japanese Government. However, the Law fails to address taxation and thus the rules for qualified tax-neutral mergers are not applicable.

■ 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. In order to account for the effect of Selling, General & Administration (SG&A) expenses to sales ratio on gross margin levels there should be greater flexibility in the use of SG&A adjustments, whether from actual functions and risks, or from intensity of the functions performed.</p> <p>4. Less weight should be placed on special characteristics of the Japanese market.</p>
<i>Current situation</i>	<p><u>No 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 Japanese tax authorities focus heavily on the gross profit margins of individual products or groups of products. This focus penalises companies with ratios to sales of SG&A costs that are lower than the ratios of comparable companies. These differences arise either from differences in intensity of function, or from differences in the actual functions and risks between the taxpayer and the comparable companies. Such differences should be recognised in making any transfer pricing adjustments.</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>Stock-option tax benefits should be extended to all stocks, irrespective of where issued.</p>
<i>Current situation</i>	<p><u>Significant progress.</u> The EBC welcomes a recent ruling by the Tokyo Court of Appeals requiring income from stock options issued by foreign companies to be treated the same as income from stock options issued by Japanese firms.</p>
<p>■ R&D and IT tax incentives</p>	
<i>Current situation</i>	<p><u>New issue.</u> A 10%-12% tax credit will be available for qualified R&D expenditures (and not only on the increase in R&D spending, as it used to be in the past), which is welcomed by the EBC. However, enterprises that have R&D facilities in Japan but account for these expenses outside of Japan will not qualify for this tax credit.</p>

Financial Services

**Asset management
Banking
Insurance**

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.

■ **Offshore funds**

Recommendation The EBC urges reforms to regulations governing the sales and promotion of offshore products (including “alternative” investments such as hedge funds and structured products) to make it easier for asset managers to promote and distribute products managed by group affiliates to professional institutional investors in Japan. Japan Investment Trust Association rules should be amended to allow onshore feeder funds to invest wholly in a single offshore vehicle. In addition, tax rates on income and capital gains should be harmonised between onshore and offshore investment products.

Current situation Worsening situation. Regulations governing the sales, marketing, and service of offshore funds continue to make it difficult for asset management firms to promote the products of offshore affiliates to investors in Japan. In fact, the situation surrounding the sale of offshore products is likely to worsen with the implementation of new tax rules that further discriminate against unregistered offshore products. This will further reduce investment options open to Japanese consumers, which is exactly the opposite of what the Japanese Government should be trying to achieve.

■ **NAV calculations**

Recommendation Net Asset Values (NAVs) should be calculated independently of the asset management company for consumer protection purposes.

Current situation No progress. All investment trust NAVs are calculated twice in Japan, once by the trust bank and again by the fund manager. The duplication of NAV calculations represents a significant additional cost that is eventually passed on to consumers.

■ **Affiliated dealing**

Recommendation Asset managers in Japan should be able to place orders to buy or sell Japanese securities on behalf of group affiliates.

Current situation Some progress. The Financial Services Agency (FSA) has indicated orally that asset management firms in Japan may place orders on behalf of group affiliates so long as a certain amount of order-placing discretion is delegated by the group affiliate. The EBC is seeking to clarify this position through a “no-action letter” and urges the FSA to respond to this request as soon as possible.

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 would welcome an 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 asset managers may deal in are much more restrictive than 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. 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
Commerz International Capital Management
Credit Agricole Asset Management
Credit Lyonnais International Asset Management
Credit Suisse Asset Management
Gartmore
HSBC Asset Management
ING Mutual Funds Management
Meiji Dresdner Asset Management
Pictet Asset Management
PCA Asset Management
Schroder Investment Management
SG Yamaichi Asset Management
UBS Global Asset Management
West LB Asset Management

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 some 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, nor at establishment of an integrated financial industry in Japan.

■ Regulatory burden

Recommendation 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 Limited progress. While the FSA/SESC has continued to step-up its supervisory and inspection functions by adding staff and gaining experience as a regulator, other organizations such as stock exchanges and the Japan Securities Dealers Association (JSDA) have also increased their own monitoring of financial organisations leading to duplications of functions and heavy reporting requirements.

■ Regulatory clarity

Recommendation Rules and regulations should be applied more consistently. The FSA should increase the comment period for the collection of opinions under the public comment system, genuinely encourage the use of the “no-action letter” system, and shorten the period for replying to requests for clarification received under this system.

Current situation Limited progress. While the FSA has shown an increased willingness to engage in a dialogue with industry, questions over consistency and transparency of the interpretation of rules by the FSA/SESC remain a major concern.

■ 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 New issue. 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. This is particularly crucial with regards to audits from the tax authorities and the FSA.

Background:

The need for further reform

The EBC recognizes the efforts of the Japanese Government in the past years to revitalise the financial sector and encourages further action without retreating from the underlying principles of financial sector reforms. The EBC feels that the revitalisation of the financial sector is one of the most important issues that the Japanese Government currently faces, as the existence of reliable and competent financial intermediaries is vital to the whole economy.

The EBC supports moves such as the Bank of Japan's decision to buy shares held by Japanese banks, the establishment of the Industrial Revitalization Corporation of Japan, and numerous other reform measures designed to promote the establishment of more efficient financial markets in Japan. Japanese banks appear to be taking a harder line in disposing of non-performing loans as a result of pressure from the Japanese Government.

Having said this, problems in the financial sector continue to be exposed, most recently with the recapitalisation of the Resona banking group in May 2003. 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.

Firewalls

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. The EBC is disappointed that reforms enacted in 2002 allowing banks and securities firms to share common retail space in order to promote the sales of securities products to retail investors did not do more to rationalise existing regulations that impose artificial barriers between banks and securities firms. The EBC renews its request that Article 65, which prohibits banks from conducting securities business and vice-versa, be abolished. The EBC feels strongly that only through such liberalisation 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, industry and institutional investors.

Improving the regulatory environment

The EBC urges the Financial Services Agency (FSA) to continue working towards securing transparency and fairness in the application of laws and regulations. At the same time, more effort is needed to reduce regulatory burden in the Japanese financial services sector by streamlining regulatory processes, reducing reporting requirements and eliminating duplicated regulatory functions. The EBC feels that the Japanese Government should either establish a super-regulator model (along the lines of the UK FSA) and absorb the regulatory functions of industry associations within the FSA or improve coordination to avoid wasteful duplication of supervision, inspections and reporting.

At the same time, 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 establishment and the recent introduction of a Japanese-style "no-action letter" system, the EBC questions whether these two mechanisms are being utilized 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 two years ago. The small number of issues being addressed by the system may indicate that it is not been 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
Banca Intesa
Barclays Bank
Barclays Capital Japan
BNP Paribas
BNP Paribas Securities (Japan)
Commerzbank
Credit Agricole Indosuez Securities
Credit Lyonnais Securities
Credit Lyonnais
Deutsche Securities
Dresdner Bank
Dresdner Kleinwort Wasserstein
HSBC
HSBC Securities Japan
ING Bank
ING Securities (Japan)
Orrick, Herrington & Sutcliffe
Sanpaolo-IMI Bank
Société Générale Securities
Standard Chartered Bank
Swedbank
West LB SecuritiesPacific

INSURANCE

Summary of outstanding issues:

■ **Product approval**

Recommendation All remaining 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 stresses 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.

■ **Policyholder protection fund**

Recommendation The Japanese Government should explore ways to alleviate the very 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.

■ **Insurance sales through financial institutions**

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

Current situation Some progress. Financial institutions such as banks and securities firms are now allowed to distribute certain product classes following reforms liberalising bank sales in April 2001 and October 2002. Other products are likely to be added, but no clear schedule has been set by the FSA.

■ **Reserving methodologies for variable annuities**

Recommendation Reserving methodology for premium and contingency reserves should be changed to reflect more accurately the unique characteristics of variable annuity products.

Current situation New issue. Reserve requirements for variable annuities in Japan require insurance companies to hold a larger share of premium reserves relative to account value than in other countries, which has the effect of making variable annuity products more costly, both for insurance companies and for consumers. The FSA has asked the Institute of Actuaries of Japan to review reserve requirements for all products affected by market fluctuations and the EBC hopes that for variable annuities this will lead to changes that will reduce capital strain for premium reserves in the short run, while ensuring adequate contingency reserves over a longer term.

Background:

EBC Insurance Committee Member Companies

Allianz
Aoba Life
Aon
AXA Life
AXA Non-Life
Coface
Credit Suisse Life
GeneralCologne Re
Gerling-Konzern Allgemeine
Hartford Life
ING Life
Jardine Lloyd Thompson
Lloyd's
Manulife
Marsh
PCA Life
SCOR
Skandia Life
Swiss Re
Watson Wyatt
Zurich

Regulatory reform and macro-supervision

The EBC supports the Japanese Government's long-term goal as set out in its regulatory reform program to continue moving away from the micro supervision of policies and pricing to macro-level supervision of solvency ratios, capital adequacy, and appropriate, modern accounting practices. This will only be possible if the Japanese Government adopts an open regime that clearly defines what is and is not allowed, and enables all participants the freedom to innovate without the uncertainty of possible adverse interpretation. Micro-level steering favoured by the Japanese authorities should be discontinued and supervision refocused on macro-level monitoring of critical financial data such as solvency ratios and capital adequacy. This will enable the development of innovative new products, while ensuring that insurance companies are able to meet their obligations to policyholders.

Distribution

The EBC is pleased that the FSA has started to deregulate the distribution of insurance products through banks and other financial institutions and urges the FSA to expand the scope of this reform to include product classes that were not included in the first two rounds of deregulation in April 2001 and October 2002. Eventually, financial institutions should be allowed to distribute all product classes without restrictions.

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.

Policyholder protection fund

Policyholder protection funds have been established in Japan to protect consumers in the event an insurance company becomes unable to meet its financial obligations. The current pre-funded system is a substantial financial burden to insurance firms in both the life and non-life sectors. 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. The EBC urges the Japanese Government to start immediately on a promised review of the current policyholder protection fund system. 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. Having said this, the EBC continues to stress that the best way to ensure consumer protection is to promote more prudent macro-level supervision.

Creating a level playing field in the Japanese insurance sector

The EBC believes that the post office's *Kampo* life insurance business and the insurance business of cooperative societies (*kyosai*) should be subject to the same capital, solvency margin, and policyholder protection funding requirements as private insurers in order to create a level playing field in the life-insurance market. Since *Kampo* and *kyosai* provide the same services as their private-sector competitors, all should be subject to the same legal and regulatory requirements. The EBC supports the eventual privatisation of *Kampo*. It is imperative that the newly created Postal Public Corporation does not abuse the preferential treatment it continues to receive from the Japanese Government to unfairly expand its business.

Reporting duties

The five-day limit on the reporting duties of shareholders of insurers under the Insurance Business Law is too short for foreign shareholders and should be reasonably extended.

Transportation & Communications

Airlines
Shipping
Telecommunications
Telecommunications equipment

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. 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. This is contrary to practice in nearly all countries worldwide and is detrimental to the consumer.

■ 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 over the next five years.

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 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 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.

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 New issue. The Japan Foreign Steamship Association, which includes 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 make decisions about where to trans-ship large cargo volumes, e.g. in Japan or increasingly in Korea or China. Foreign shipping lines 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.

■ Terminal operations

Recommendation The Japanese Government should support the establishment of new, competitive terminal operations, including those owned by shipping lines themselves. 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 process applications within two months of receipt, requirements such as minimum employment levels continue to hamper 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.

Current situation No progress. The Japan Harbour Transport Association (JHTA) still wields enormous discretionary power in determining how the Japanese waterfront is run. 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 bids for waterfront services.

Background:

EBC Shipping Committee Member Companies

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

Overview

The global shipping sector is a vital component of Japan's business infrastructure. The costs associated with shipping goods around the world have an immediate impact on the competitiveness of other important parts of the Japanese economy.

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.

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.

TELECOMMUNICATIONS

Summary of outstanding issues:

■ Regulatory independence

Recommendation A regulatory authority independent from the Ministry of Public Management, Home Affairs, Posts and Telecommunications (MPHPT) should be established as a way to overcome the inherent conflict of interest of having industry development functions and competition promotion objectives within one single Ministry. This is standard in all major countries – Japan is a rare exception.

Current situation No progress. The existing Disputes Resolution Commission (DRC) within the MPHPT is designed for inter-carrier disputes, as opposed to regulatory separation. The fact that five carriers have decided to open a court case against the MPHPT is an indication of the perceived lack of effectiveness of the DRC scheme.

■ Dominant carrier controls

Recommendation The EBC urges the Japanese Government to undertake a competitive review of all services provided by the NTT Group companies, to designate where those companies have significant *market power* in their respective market segments, and introduce in the revised Telecommunications Business Law (TBL) provisions for NTT to notify tariffs and maintain regulatory accounts in respect of all designated services.

Current situation Potentially worsening situation. The EBC is concerned that recent revisions to the TBL could make the current situation worse if it results in removing necessary controls on the ability of the NTT Group companies to abuse their market dominance and prevent the development of effective competition.

■ Interconnection

Recommendation Japan should revise the application of the long-run incremental costing (LRIC) model currently in use to calculate interconnection rates for fixed line, with the goal of a mandatory reduction to reach international benchmark standards.

Current situation Worsened situation. Contrary to the 2002 Telecommunications Council recommendations, an increase of interconnection fees was enacted in January 2003, under which local interconnection will *decrease* by 3% but single tandem interconnection will *increase* by 12%, resulting in an overall *increase* in interconnection costs for most carriers.

■ Over-regulation of non-dominant service providers

Recommendation Over-regulation of non-dominant carriers should be further relaxed. Non-dominant carriers should not be forced to file and price on tariff and licensing requirements under the Type I/ Type II regimes should be simplified considerably.

Current situation Substantial progress. Recent revisions to the Telecommunications Business Law (TBL) will simplify licensing requirements substantially. The EBC is disappointed, however, that prescriptive tariff filing and regulatory accounting obligations on non-dominant operators will be maintained in some service areas.

Background:

EBC Telecommunications Carriers Committee Member Companies

BT Japan
Cable & Wireless
Deutsche Telekom
Equant
France Telecom Japan
France Telecom Long Distance
T-Systems Japan
Vodafone-Japan

The last twelve months

2001/2002 witnessed the explosion of broadband services in Japan, and in 2002/2003 IP broadband entered the voice arena. In less than two years, Japan has accomplished a remarkable catch-up in broadband and Internet penetration and has become one of the leading countries in the world. However, the unprecedented success of IP-based telephony is leading to a gradual erosion of switched voice traffic among traditional voice services providers, with monthly minutes of traffic declining by over 15% between 2001 and 2002.

Legislation revising the Telecommunications Business Law (TBL) recently passed the Diet, which included provisions abolishing the distinction between Type I and Type II carriers, the permission system for entry and exit, tariff regulations for non-dominant carriers, and ex-ante regulations with regard to interconnection. It appears that changes to the TBL will likely result in significant relaxation of regulatory requirements for many telecommunications firms.

Finally, it is worth noting that, for the first time in Japanese history, a group of Japanese and foreign carriers opened a court case against their own regulator, the MPHPT, following the decision to raise interconnections charges. The court case establishes a new style of dispute resolution where current models are felt to be ineffective.

The new TBL: One step forward - two steps backward?

Alternative providers welcome a reduction in the regulatory burden associated with doing business in the Japanese market. However, the EBC is very concerned that the new laws and follow-on ordinances will not do enough to regulate the market power enjoyed by the NTT Group companies in most market segments, finally resulting in less competition.

The EBC recommends that the Japanese Government move swiftly to address these concerns by introducing measures to reinforce competition-based controls. Key issues remain:

- 1) Definition of dominance – It is common practice in competition policy to define product and service markets in order to identify dominant operators. It has yet to be made clear how the new TBL will define *dominance* in a specific market segment, and whether the notion of *market power* – i.e. the ability of an operator to exert influence and manipulate a market, unconstrained by competitive forces – will be considered. Japan needs a methodology included in the telecommunications legislation to determine significant market power and appropriate remedies.
- 2) NTT Group firewalls, accounting separation and tariff control – As the Japanese Government removes restrictions on carriers, every effort must be taken to ensure that the dominant carrier does not use its control of monopoly services to enter into a competitive service on unfair terms. Standard preventative measures include obligations to establish separate line-of business subsidiaries, with separate ownership, management and accounts; non-discriminatory provision for the supply of services to unaffiliated parties; prohibitions on cross-subsidisation and a continuation of tariff filing for all market segments where the carriers is recognised to be dominant.
- 3) Interconnection fees – Current interconnection charges in Japan are up to 50% above comparable rates elsewhere in OECD countries, even allowing for local factors in Japan such as higher construction costs. High interconnection charges will continue to smother competition unless they are amended.
- 4) Regulatory independence – A perceived lack of transparency and independence of the regulatory process has forced operators to rely on judicial (rather than regulatory) solutions.

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 one accredited testing body has been recognized. (TELEFICATION B.V. in the Netherlands was registered by the Japanese Government as the first accredited body in EU on Feb.14, 2003)

■ Suppliers Declaration of Conformance (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 intention of the Japanese Government to introduce a system based on Supplier's Declaration of Conformance at the end of 2003, 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.

■ Spectrum allocation

Recommendation The EBC urges the Japanese Government to harmonise spectrum allocation with European standards for additional IMT-2000 bands beyond current allocations in the 1920-1980 MHz and 2110-2170 MHz range, especially for the 2.5 GHz band already identified for IMT-2000, as well as for future allocations for systems beyond IMT-2000.

Current situation No progress. The current allocation of spectrum for mobile and fixed services differs substantially between Japan and other regions of the world. This may continue to be a major barrier to interoperability with other regions and countries if no measures are taken to address this problem.

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 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 Public Management, Home Affairs, Posts and Telecommunications (MPHPT) policy committees as an official participant.

The Communications and Information Network Association of Japan (CIAJ) has been studying the introduction of Supplier's Declaration of Conformance to supplement the use of 3rd party designated testing bodies in Japan and the EBC is pleased to note that the Japanese Government plans to introduce such a system at the end of 2003. Such a system has been introduced in Europe, which has made it easier for manufacturers to quickly introduce new products in the rapidly developing telecommunications market. The EBC feels that the Japanese SDoC system should be as broad-based as possible, covering all wired terminal equipment and specified radio equipment, and not be limited to wired products as is currently being prepared by the MPHPT.

The EBC urges the EU and Japan to cooperate even further on the harmonisation of mobile telecommunications standards, especially for 3G wireless technologies and beyond. One area that deserves more attention is the further harmonisation of spectrum allocation, particularly for the 2.5 GHz band already identified for IMT-2000 allocation in Japan. Continued divergence in the allocation of spectrums will have a negative impact on equipment interoperability to the detriment of consumers and producers throughout the world.

Issues concerning the global circulation of IMT-2000 handsets also need to be studied carefully. The expansion of 3G wireless service around the world will likely lead to an increasing global demand for terminals based on the IMT-2000 standard. The EBC supports harmonisation of technical requirements concerning terminal interoperability and emission limits, but emphasises that circulation should be industry led based on the previous success of the GSM deployment model, with minimum involvement of the International Telecommunications Union (ITU). The EBC supports a recent change to Japanese regulation making possible now for mobile users to bring his/her own IMT-2000 WCDMA handsets from Europe into Japan without having to fulfil any additional approval procedures.

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:

■ **Expediting the product approval process**

Recommendation The EBC urges more efficiency in the product approval process for new animal health products. The role of the Food Safety Council should be clarified immediately so that all applications may be processed in an expedient manner.

Current situation Worsening situation. The creation of the Food Safety Council in July 2003 has thrown the product approval process for new animal health products into turmoil. More than 20 applications are now blocked because relevant procedures have not yet been established.

■ **National assay for vaccines**

Recommendation The mandatory 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 No progress. Every production batch still must be submitted to the National Veterinary Assay Laboratory for release testing, a process that can last up to 100 days for some vaccines. Most European countries do not require manufacturers to submit control reports, nor samples for examination for most vaccines, and thus consider the quality control laboratory of the manufacturer as an approved laboratory.

■ **National assay for in-vitro diagnostics**

Recommendation The national assay requirement for all veterinary in-vitro diagnostics should be eliminated immediately.

Current situation No progress. This requirement does not exist for in-vitro diagnostics intended for human use in Japan, even for those used to diagnose major infectious diseases such as Hepatitis and AIDS.

■ **Brand specific listing**

Recommendation Brand specific (as opposed to compound) listing for antibiotic and other feed additives should be introduced in Japan as has been done in Europe.

Current situation No progress. The current system does not adequately recognize the significant expense, time, and sophisticated intellectual property involved in product development. Brand-specific listing would help clarify 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.

■ **Filing procedures for new animal drug applications**

Recommendation The Ministry of Agriculture, Forestry and Fisheries (MAFF) should accept reports submitted for New Animal Drug Application and Animal Drug Importation Application in English, accompanied by a written summary in Japanese, as is now possible in Japan for human drugs.

Current situation No progress. MAFF still requires all reports to be written in Japanese.

Background:

EBC Animal Health Committee Member Companies

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

The animal health industry

Animal health products make an important contribution to quality of life by keeping pets healthy, promoting the efficient production of livestock, and guaranteeing maximum food safety. Animal health products are the result of intensive research and technological innovation with special emphasis on safety, quality, and product efficacy. A large amount of time, effort, and money goes into the development of new products. Given this situation, it is important that the regulatory environment surrounding new product approval does not add unnecessary delay and costs to the introduction of such innovative products to the market.

Regulatory reform: Modest progress...

The EBC welcomes decisions taken recently by the Japanese Government to eliminate the acute toxicity animal test for mycelial (feed grade) products, relax the requirement for antibiotic feed additives to be assayed by a national testing institution, and introduce over the next 3 years a residue control system based on Maximum Residue Limits (MRL). Since June, companies have been able to apply to have their production facilities accredited by the Japanese Government, which will eliminate the need for antibiotic feed additives produced at accredited facilities to be assayed by the National Veterinary Assay Laboratory. As part of the introduction of the new residue control system, the Japanese Government has reportedly decided to synchronise the review process for both product approval and MRL. This would bring Japan more in line with international best practice and facilitate the harmonisation of animal drug reviews currently being pursued under the auspices of the VICH (International Cooperation on Harmonisation of Technical Requirements for Registration of Veterinary Products).

...but urgent need for further reform

Despite these improvements, 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. Additional trials for products that are approved in the EU, US, and other parts of the world should be reduced to a minimum and duplications avoided. Applications for human pharmaceuticals that are already widely used by veterinarians and for which efficacy is well documented in the veterinary literature should be possible with a minimal program of local clinical trials.

Unfortunately, with the recent establishment of the Food Safety Council this situation is likely to become worse before getting better. The creation of this new entity will add 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. All applications are currently blocked, even products that were nearing the end of the approval process. In 1995 the Japanese Government committed itself to approving new products within 12 months of initial application and has reconfirmed this target every year since with the issuance of the Drug Approval Guidelines (*seizo shishin*). The EBC requests that the Japanese Government honour this commitment.

National assay for vaccines and in-vitro diagnostics

The EBC also encourages the Japanese Government to continue moving away from the use of the national assay to test the production quality of animal health products given the introduction of Good Manufacturing Practice (GMP) and an increasing global trend towards the use of self-declaration regulatory mechanisms for product conformance and quality assurance. The national assay invariably adds to the cost and time needed to bring products to the market in Japan, costs that are eventually passed on to the consumer in the form of higher prices and restricted choice. The EBC welcomes the decision of the Japanese Government to eliminate the need for a national assay for antibiotic feed additives, and hopes that a similar system will be introduced for vaccines and in-vitro diagnostics as well. The EBC notes that no national assay requirement exists for human health related in-vitro diagnostic products in Japan.

IN-VITRO DIAGNOSTICS

Summary of outstanding issues:

■ Reimbursement pricing

Recommendation The EBC urges the Japanese Government to ensure that decision-making on changes to reimbursement pricing is more transparent. Prices of medical diagnostics should better reflect the clinical value of diagnostic equipment and reagents driven by quality (accuracy, specificity, laboratory certification), speed (emergency response, point of care), and contribution to comprehensive patient care (risk management, qualitative indications).

Current situation Worsening situation. No information has been made public regarding the decision-making process (how decisions will be made, what the basis for price cuts will be, etc.) for upcoming revisions to reimbursement prices, which take place every two years. Repeated cuts to reimbursement prices in the last 10 years have reduced pricing levels below that of comparable overseas markets. All test items are reimbursed at the same price regardless of the economic or clinical advantages of individual products, including new products utilizing innovative technologies. This has severely 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. Requirements for application data that is 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 a risk-based classification system should be introduced based on global standards.

Current situation Some progress. While the speed of product approval has improved, many outstanding issues remain. Unique product approval and reimbursement price registration requirements prevent timely introduction of new products into Japan. While the Japanese Government promised to introduce a risk-based classification system, further reform is necessary to improve overall efficiency of the system.

■ Diagnosis Procedure Combination (DPC)

Recommendation The Japanese Government should establish guidelines for 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. The EBC is worried that with the introduction of DPC in 82 special function hospitals too much emphasis will be placed on cutting short-term costs over the effective use of medical diagnostics. The EBC feels that it is the Japanese Government's responsibility to promote the effective use of medical diagnostics in patient treatment and urges the Authorities to establish a set of appropriate treatment guidelines in consultation with the medical community.

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

The Japanese Government sets the price (reimbursement point) at which medical institutions can apply to the National Insurance System to recover treatment costs. In order to reduce medical expenditures, the reimbursement price for medical diagnostics was cut in April 2002 by an average of 13%, the largest cut in history and two times more than price cuts made during the previous reimbursement price review. Pharmaceutical products and special medical materials/devices, on the other hand, were only cut 1.3% and 0.1% respectively. As a result of repeated price cuts (2003 average price is only 67% of that of 1998), 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 introduction in April 2003 of Diagnosis Procedure Combination (DCP), a type of reimbursement mechanism whereby reimbursement is based on sickness type and not actual treatment costs, to a select number of special function hospitals is likely to further impact the introduction of new diagnostic products into the Japanese healthcare system. The EBC is worried that DCP will place too much focus on restraining short-term medical costs to the detriment of patient quality of life. It is also likely that in the long run such a system will result in higher total medical expenditures, not less.

The clinical value of medical diagnostic products varies considerably depending on how testing is conducted. Regardless of the variety of testing procedures such as testing result reports with additional information/comment by in-hospital medical technologists with direct access to patient information, point-of-care testing, emergency testing and sending-out (outsourcing) testing at external commercial laboratories, under the current reimbursement system all the diagnostic tests are reimbursed at the same price if they are the same assay.

As a result, medical diagnostics have been unable to fulfil their proper and important role in the deliverance 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 overall quality of healthcare in Japan.

Product approval

For years the EBC requested that a product approval system based on risk classifications be introduced in Japan, with lower risk products subject to a simple notification procedure. The Office of the Trade Ombudsman (OTO) ruled in 1995 and again in 2001 that the Japanese Government should introduce a notification system for low-risk products as soon as possible. Last year, the Ministry of Health Labour and Welfare decided to revise the Pharmaceutical Affairs Law (PAL) introducing such a system into Japan. The EBC welcomes this. The EBC urges the Japanese Government to fully adhere to the spirit of the OTO ruling when developing follow-on ordinances to the PAL revisions.

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 the medical devices with focus on actual 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 is going to increase as a result of changes to the Pharmaceutical Affairs Law in July 2002.

■ 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.

Background:

EBC Medical Equipment Committee Member Companies

Agfa-Gevaert Japan
B.Braun Aesculap Japan
Centerpulse Japan
Dornier MedTech Japan
Draeger Medical Japan
Edap Technomed
ELA Medical Japan
Elekta
Fresenius Medical Care Japan
Gambro
Jostra Bentley
Laerdal Medical Japan
Nippon BXI
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. Unfortunately, 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. Unfortunately, the high cost of advanced medical equipment has often been singled out as one of the main culprits underlying Japan's rising health care costs. The EBC would like to point out that 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; 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 as a result of changes to the Pharmaceutical Affairs Law in July 2002 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.

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 ensure that decision-making on pricing is more transparent and to be more committed to its decision to give significant price premiums on innovative new drugs.

Current situation Limited progress. In the pricing rules for new drugs, the requirements for price premiums and the premium rate for “innovativeness” and “usefulness” were revised last year. On the other hand, the Drug Price Organisation raised issues concerning the present pricing rules, and they are currently under discussion in the Drug Expert Committee of the *Chuikyo*. The ongoing discussion includes transfer prices and validity of foreign reference prices for drugs of foreign origin. EFPIA Japan expects that these issues be thoroughly discussed in the light of enhancement of competitiveness among research-based pharmaceutical companies. We would again like to stress the need for an appropriate reward for innovation and urge that a new pricing system for rewarding innovative new drugs be established. We also encourage the Ministry of Health, Labour and Welfare (MHLW) to establish a medium to long-term policy about the drug pricing system and anticipate that drug price revision be carried out based on an established policy.

■ **Product evaluation and approval process**

Recommendation EFPIA Japan anticipates that the consolidation of the Drug Organisation and the Evaluation Centre into an independent administrative agency will streamline the drug evaluation and approval process, increase the quality of the review system, and provide improved service reflecting the fees that will be requested of pharmaceutical companies.

Current situation Significant progress. The MHLW has finalised its plans for the establishment of the new drug evaluation agency and has applied for a budget allocation in 2004. The new agency should be held accountable for its performance and achievement with regards to the medium-term target to be set by the authorities. EFPIA Japan encourages the agency to introduce a transparent, open communication policy in terms of its performance; e.g., that the agency produces an annual report. We also urge the agency to clarify criteria for its budget sources in order to distinguish between government responsibilities and industry services, given the fact that the new agency has been given permission to increase user fees for New Drug Applications (NDAs) and supplemental NDAs (sNDAs) and contributions for safety administration based upon the sales of individual companies.

■ **Intellectual property protection**

Recommendation EFPIA Japan urges Japan to provide a level of protection for new drug application data equal to the level of protection currently provided for in Europe.

Current situation Some progress. Ten-year regulatory data protection is now under discussion in the Intellectual Property Policy Headquarters. EFPIA Japan supports this move and would again like to state the need for protection of new drug application data.

Background:

Supporting the development of the pharmaceutical industry in Japan

On 30 May, the MHLW reported progress on the Action Plan proposed last year in its “Vision” statement for the pharmaceutical industry. EFPIA Japan congratulates the MHLW for the progress that has already been made in some areas in just one year. It is, however, a long-term vision and much still needs to be done to implement all actions in full. For example, EFPIA Japan appreciates the support for clinical trials, including the tax incentives for R&D, but sees some imbalance in the budget allocation between basic research and clinical trials. We also believe that commitment to global harmonisation is vital to be internationally competitive.

Pharmaceutical pricing reform

The MHLW makes revisions to drug prices every two years. Although there had been concerns about excessive *Yakkasa* (drug price margins) and the large proportion of pharmaceutical costs in the overall healthcare spending, significant improvements were made through healthcare reform and drug price revision, and major issues have been resolved.

On the occasion of budget compilation for the coming year, however, it is repeatedly being discussed how drug prices should be reduced from the perspective of fiscal control. Such price cuts without policy will ravage the pharmaceutical market in Japan, and apparently contradict with the “Vision” statement for the pharmaceutical industry, which was developed by the MHLW last year with the aim of improving the international competitiveness of the industry.

Product evaluation and approval process

With the aim of streamlining the consultation and review process, the Organisation for Pharmaceutical Safety and Research and the Pharmaceutical and Medical Devices Evaluation Centre will be merged, and the Independent Administration Agency for Consultation, Registration Review, and General Safety Management will be established and begin operations in April 2004. The Agency is also expected to strengthen overall safety management of marketed drugs, especially through expansion of its activities in epidemiological research. EFPIA Japan believes that this will enable the Agency to design comprehensive studies that the average pharmaceutical organisation may have difficulty conducting independently.

Intellectual property protection

Intellectual property rights such as pharmaceutical patents should be protected and respected. EFPIA Japan is disappointed that generic drug manufacturers are still allowed to start developing products before patent expiry. Respect for intellectual property rights and brand names should be extended to the pricing mechanism as well.

The Basic Law on Intellectual Property, which aims to intensify the international competitiveness of Japanese industry, was put into force in March this year. Under the Law, the Intellectual Property Policy Headquarters was established within the Cabinet to develop, implement, and coordinate action plans, which include those directly affecting the pharmaceutical industry, such as regulatory data protection, patent protection of medical activities, and abolition or revision of the employee invention provision in the Japanese Patent Law.

EFPIA Japan supports these plans to provide incentives for R&D activities in the pharmaceutical industry in order to launch more medicines for patients.

Amongst those plans, EFPIA Japan views securing a 10 year data protection period in Japan to be of paramount importance. The cost of developing innovative new drugs and obtaining regulatory approval is substantial. Pharmaceutical companies spend on average 10 years and several billion yen to bring a new drug to market. Data submitted along with new drug applications to the MHLW are therefore valuable intellectual property. The TRIPs Agreement, an international agreement on intellectual property protection, requires the signatory states to provide protection to such data.

In Europe, there is a proposal for providing 10-year data protection across the EU, as well as an additional year of data protection for important new indications under certain conditions.

EFPIA Japan Member Companies

Actelion Pharmaceuticals Japan
Amersham
AstraZeneca
Aventis Behring Japan
Aventis Pasteur
Aventis Pharma
Bayer Yakuhin
Bracco-Eisai
Chugai Pharmaceutical
Fournier Japan
Fresenius Medical Care Japan
GALDERMA
GlaxoSmithKline
Guerbet
Janssen Pharmaceutical
Leo Pharmaceutical Products
Lundbeck Japan
Merck
Nihon Schering
Nihon Servier
Nippon Boehringer Ingelheim
Nippon Organon
Novartis Pharma
Novo Nordisk Pharma
Sanofi-Synthelabo
Schwarz Pharma Japan
Serono Japan
Solvay Seiyaku
UCB Japan

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. Increase transparency for accepted ingredients and publish a nomenclature list, specifications, doses, product category, and related claims;
2. Ease restrictions on the registration of new actives and allow the use of new cosmetics ingredients; and
3. Move to full labelling in the same spirit as recent regulatory reform for cosmetics.

Current situation No progress. The regulation of the quasi-drug category remains obscure, the number of the new active ingredients that may be used for each product category is extremely limited, and it is difficult to get a new active ingredient approved. What is worse, the system has changed after the deregulation of cosmetics in 2001 to prohibit new cosmetic ingredients from being used in quasi-drugs in which the expansion of the usage in medicated cosmetics is restricted.

■ Regulatory reform of cosmetics

Recommendation

1. The MHLW should liaise with EC regulators and their scientific advisory committee (SCCNFP) in order to harmonise the current Positive and Negative Lists.
2. The MHLW should join with its European counterparts to establish mutually acceptable safety standards for the acceptance of new ingredients both to the Positive List and to Quasi-Drug categories.
3. Permissible product marketing claims should be further liberalised to support product innovation allowed under the new laws and harmonised with current European standards.
4. The laws should be implemented and enforced in a consistent manner for all parties involved and should not provide loopholes for non-law abiding importers.
5. As for recycling marks, the same effort of harmonization is asked of the Ministry of Economy Trade and Industry when meeting with their European and American counterparts.

Current situation Limited progress. Harmonisation with the EU of the current Positive and Negative List remains insufficient. The EBC strongly requests that the Japanese Government establish mutually acceptable safety standards for the ingredients listed in the Positive List and the Negative List and to harmonise allowable product marketing claims with current European standards.

Background:

EBC Cosmetics Committee Member Companies

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

A new regulatory environment for Cosmetics

In April 2001, new laws came into effect introducing a regulatory framework for cosmetics similar to that currently employed in Europe. The use of ingredients has been deregulated, product safety has become the responsibility of manufacturers/importers, a limited Positive and Negative List system has been established, and full ingredient labelling in Japanese is now required on all product containers. The EBC supports the spirit of these reforms. Having said this, two areas require further consideration.

The first area concerns poor harmonisation between European and Japanese regulations on the contents of the Positive and Negative Lists. As a result, European cosmetics manufacturers continue to reformulate products specifically for the Japanese market. Even though the categories of the Positive List (preservatives, UV-absorbents and coal-tar colours) are the same between Japan and Europe, the contents differ substantially and further harmonisation of the safety evaluation standards is required.

The second area concerns allowable marketing claims. Even though allowable marketing claims have been expanded to 55 under the new laws, they are still too general and reflect poorly on product innovation allowed under the law, resulting in low product differentiation. The EBC feels that product-marketing claims should be the responsibility of individual manufacturers based on sufficient product substantiation data as in EU countries, and urges further liberalisation in this area.

In addition, the EBC urges the MHLW to strengthen the regulations against illegal activities of non-law-abiding importers.

The necessity of regulatory reform for Quasi-Drugs

In Japan, the Quasi-Drug category consists of a wide range of products including medicated cosmetics (such as whitenings), 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. Costly and time-consuming system to obtain approval for a new active ingredient in the Quasi-Drug category; and
3. Restrictions in quantity of new cosmetic ingredients that may be used in Quasi-Drugs.

Given that the Japanese market for Quasi-Drugs, especially medicated cosmetics, has been expanding recently, the EBC asks that these three points be addressed as soon as possible for the benefit of consumers.

Revisions to the Pharmaceutical Affairs Law and its effect on Cosmetics/Quasi-Drugs

The EBC has large expectations for recent revisions to the Pharmaceutical Affairs Law designed to improve quality assurance and product safety. At the same time, the EBC urges the relevant authorities to ensure that the introduction of this new system does not function as an even greater restriction on product development than exists in the present environment for Cosmetics and Quasi-Drugs (excluding newly re-categorized Quasi-Drugs).

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.

■ Fumigation costs

Recommendation Further competition in the provision of fumigation services should be encouraged to help reduce fumigation costs. The EBC urges prompt action on the part of the Japan Fair Trade Commission (JFTC) to fully implement recommendations contained in a ruling issued in August 2001 that concluded that fumigation and warehouse service providers at Narita Airport colluded to set prices and distribute work in contravention of Section 3 of the Antimonopoly Act (unreasonable restraint of trade).

Current situation No progress. One of the affected parties has challenged the JFTC decision, and the process is now stalled in administrative hearings. Prices for fumigations services have not declined.

■ 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 5 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. Having said this, the EBC notes that there is still much room for improvement – the facilities at most international airports in Japan are inadequate for handling large volumes of cut flowers and other perishables.

The market for cut flowers in Japan

The market for cut flowers in Japan is one of the largest in the world. Annual consumption stands at approximately 800 billion yen per year but has been stagnating over the past few years, in part as a result of persistent non-tariff barriers to trade in the sector. 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.

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, on the basis of the Sanitary and Phytosanitary chapter of the GATT Uruguay Round Agreement, are considered to be harmful. 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

Summary of outstanding issues:

■ Food additives

Recommendation Japan's food additives list should be modernized 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 currently under review by the Food and Sanitation Council should be approved immediately. As well, standards of use for common preservatives such as sorbic acid, potassium sorbate and sulphur dioxide should be made simpler and more effective.

Current situation Limited progress. Many substances in common use around the world and recognized as being safe by international food safety bodies such as JECFA are not allowed in Japan. Other substances approved by Japan have been approved with standards of usage that differ substantially from accepted international practice. On December 19, 2002 the Ministry of Health Labour and Welfare (MHLW) submitted a list of 46 substances to the Food and Sanitation Council for "priority" review, but none have been approved yet. A number of substances proposed by the EBC for inclusion on this list of "priorities" were ignored.

■ Import duties

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

Current situation No progress. Import duties for many food categories remain well above those of Japan's main trading partners.

■ Organic food regulation

Recommendation All remaining applications from European organic food certification and testing bodies for accreditation in Japan should be processed as quickly as possible. All European organic food certification and testing bodies accredited in Japan should automatically be authorised to certify organic livestock products as well.

Current situation Limited progress. Demand for high-quality organic food continues to grow in Japan. While European producers are very strong in this field, only a small number of European organic food certification and testing bodies have received accreditation in Japan.

■ 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.

Background:

EBC Food Committee Member Companies

Arcane
Arla Foods Ingredients (Japan)
CMA
Danisco Japan
Japan Europe Trading Company
Nestle Japan
PURAC Japan
Puratos Japan
Roquette Japan
Strobbe Trading International
Sweden Food & Forestry
Tozai Group

The regulation of food additives in Japan

Japan's food additives list remains out of step with the rest of the industrialised world. Of the 828 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. More importantly, this situation continues to undermine the credibility of Japan's food regulations with producers, importers and Japanese consumers.

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. Ferro-cyanide, an anti-caking agent, was approved in July 2002. On December 19 2002 the MHLW submitted a list of another 46 "priority" substances to the Food and Sanitation Council to be reviewed for possible acceptance in Japan. The MHLW has started collecting information on the first group of substances in this list (polysorbates, calcium stearate, dimagnesium phosphate, hydroxypropylcellulose, and modified starches) and has submitted an approval dossier for the polysorbate group to the Food Safety Committee on October 8 2003.

While the EBC welcomes the recent change in Government policy towards the approval of food additives in Japan, the EBC feels that the approval rate for the 46 priority substances is far too slow. These substances should be approved immediately without further delay. All 46 of these substances are in common use throughout the world and have been approved by JECFA and are approved for use in both the EU and the US.

Furthermore, the stearates group, listed after polysorbates in "group 1" of the 46 substances, should be broadened to include the whole range of salts of fatty acids. JECFA considers salts of fatty acids as one group, which includes calcium, potassium or sodium salts of myristic, oleic, palmitic, stearic, acids or mixtures of these acids from edible fats and oils. JECFA calculates the total content of salts of fatty acids as sodium oleate, and the EBC recommends that Japan follow this approach.

Unfortunately, several additives proposed by the EBC were not considered for inclusion on the MHLW's list of priorities. The EBC requests that the following substances be reconsidered for priority approval in Japan: hydroxypropylmethylcellulose, acetaldehyde, iodised salt, synthetic taurine, glucuronolactone, nicotinamide adenine dinucleotide (NADH), potassium aluminium silicate, glutaraldehyde, metatarsic acid and synthetic caffeine.

As part of the modernization of Japan's food additives list, 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 are sometimes unable to decide what is legal and what is not. This puts food importers in a very difficult position. The EBC is particularly concerned with the standards of use for common preservatives such as sorbic acid, potassium sorbate and sulphur dioxide. The allowable limit for sulphur dioxide in the "other foods" category is <0.03g/kg, a level that effectively prevents the importation of a large number of European products. No "other foods" category exists for sorbic acid/potassium sorbate, which prevents products such as pralines from being imported, as no category exists for chocolate confectionary. The EBC urges the Japanese Government to increase the limit for the sulphur dioxide "other foods" category to <0.3g/kg and introduce an "other foods" category for sorbic acid/potassium sorbate with a limit of <0.5g/kg. This is largely in line with existing regulations, but would allow foreign foods to be imported into Japan more easily while at the same time maintaining a very conservative and safe position for Japanese consumers.

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 continue reducing the number of licenses required to do business. 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, a number of regions have been designated "Urgent Adjustment Areas" under a temporary measure designed to protect existing liquor retailers from deregulation, and no new licenses (or transfers of existing licenses) will be issued in these areas for one year. As well, 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. 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
Jardine Wines & Spirits
Maxxium Japan
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 with approximately 100 million cases (900 million litres) sold per year. *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 reducing 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

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.

Japan has committed to adopt 30 UN/ECE regulations by the end of Fiscal 2003 but has given no undertakings beyond that date.

■ **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.

Background:

EBC Automobile Committee Members

ACEA
Audi Japan
BMW Japan
Citroen Japan
DaimlerChrysler Japan
Fiat Auto Japan
Ford Japan
General Motors Asia Pacific (Japan)
Jaguar Japan
Land Rover Japan
Nicole Automobiles
PAG Import
Peugeot Japan
Porsche Japan
Renault Japan
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 257,000 units in 2002, imports were still well below the peak. This represents about 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

Diesel technology plays an essential part in reducing CO2 emissions in the EU. Japan has, however, adopted very demanding diesel emission standards, particularly for NOX. For passenger cars to meet these requirements in the prescribed time-frame would require significant technological progress so that the diesel engine can offer an economically viable solution for the Japanese market.

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.

AUTOMOTIVE COMPONENTS

Summary of outstanding issues:

■ Promoting information exchange

Recommendation The EBC strongly supports the continuation of face-to-face meetings in Europe 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 April 19 – 23, 2004 in Gothenburg, Sweden, and the EBC encourages top-level Japanese industry participation.

■ Internationalisation of the automobile industry

Recommendation The EBC urges the Japanese automobile industry to build on recent trends in the global market by focusing more on the technical, commercial and logistical aspects of automobile production. Procurement of car components and systems should ultimately be based on merit.

Current situation Limited progress. The Japanese automobile manufacturing sector continues to evolve with the changing circumstances of the global and domestic market. 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. 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. Unfortunately, despite the globalisation of the industry, European automotive component and system manufacturers continue to face hurdles in promoting European technical expertise to Japanese automobile manufacturers due to continued reluctance on the part of Japanese manufacturers to outsource product development on a global basis and procure from non-traditional sources. As a result, European market share in the Japanese car parts sector remains small.

Background:

EBC Automotive Components Committee Member Companies

A. Raymond Japan
BASF Japan
Behr Japan
BOSCH Automotive Systems
Delphi Automotive Systems Japan
Faurecia Japon
Freudenberg
Herberts Shinto Automotive Systems
HP Pelzer Japan
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.

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 have to 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 established a global network of clients. European car parts producers have a reputation for product innovation, technical expertise, efficiency, quality and personal attention that Japanese automobile manufacturers have come to expect from their suppliers.

Promoting mutual understanding

The EBC hopes that annual meetings between the European car parts industry and Japanese carmakers will continue, and that one day these meetings take place in Japan to broaden European understanding of Japanese manufacturer expectations.

For its part, the European automotive components industry will also work hard to increase mutual understanding with Japanese firms, with the goal of increasing product development and manufacturing relationships with Japanese operations in both Europe and Japan.

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.

Current Situation Worsening situation. The recent decision of All-Nippon Airways (ANA) to revert to a single source is a clear step backwards in the worldwide industry strategy of promoting competition. 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. And, unfortunately, there are no signs of any substantial improvement in the future.

■ Promoting industrial co-operation

Recommendation The EBC is looking to increase Japanese industrial involvement in the development of European commercial aircraft, components and navigation systems. Given the difficult political and strategic environment surrounding industrial co-operation on large-scale projects, the EBC recommends that co-operation starts on a smaller scale to encourage working relationships and promote mutual trust and understanding.

Current Situation Limited progress. Co-operation in commercial aircraft development is still heavily biased in favour of North America. The recent announcement of government funding for the 7E7 project will limit the potential of future collaboration. 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. We encourage Japanese institutions and firms to actively pursue the opportunities ahead.

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 market for commercial aircraft

The Japanese market for large commercial aircraft and helicopters is one of the largest in the world and has been historically dominated by the United States. As such, Japan Airlines (JAL) has found itself with an extensive commercial aircraft fleet from a single source supplier. Its merger with Japan Air System (JAS) has brought challenges, but also an excellent opportunity to rationalise its fleet around the world's best available aircraft.

On the other hand, All Nippon Airways (ANA) has recently decided to walk the reverse path, returning to a single source supplier system after ten years of experience with a triple system, a situation that runs contrary to common industry standards of promoting competition among suppliers. The EBC is disappointed by this turn of events, and would like to encourage JAL, ANA and other airlines and companies in a similar situation to secure double sources for the benefit of their customers, shareholders, and public in general.

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.

The industry still relies heavily on defence contracts, which accounts for over 60% of their total aerospace turnover, and on partnerships with Boeing for commercial contracts. The recently announced decisions of METI to fund the 7E7 project, although still in very early stages of conceptual design, and the effort of developing an indigenous 30- to 50-seater is seen with mixed feelings from Europe. The EBC is disappointed to see that the Japanese institutions do not seriously promote co-operation with Europe.

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.

However, the potential approval by METI's Aircraft Industry Council of the 7E7 as a national project will certainly have 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. It seems the past might repeat itself.

The EBC is mildly encouraged on one hand by the progress achieved to date, but at the same time remains cautious to the challenges ahead. The EBC would like to encourage METI and Japanese institutions to walk-the-talk and openly promote and fund collaboration with European companies in a similar fashion as they openly finance the collaboration with American firms.

SPACE

Summary of outstanding issues:

■ Satellites and ground segment

Recommendation The EBC supports ongoing co-operation between Japan and Europe and welcomes increased interest shown recently for new developments and a new scale of Japan-Europe co-operation. First of all, we particularly encourage the development of ever closer ties between the new Japan Aerospace Exploration Agency (JAXA) and Europe's space agencies. We also encourage agencies on both sides to discuss their respective plans in new application areas from the earliest stage possible, in order to enable the introduction of more Europe-Japan co-operation before it is too late.

Current situation Close relations have long been maintained between Japan's three former aerospace agencies NASDA, ISAS and NAL, and Europe's space agencies (ESA and the member countries' national space agencies). New interest has been shown recently on both sides for expanded co-operation and more discussions have been taking place. Although there have been a few exploratory moves by some companies, concrete co-operation in satellite and ground station development remains very limited. Industrial co-operation in new application areas is only possible when promoted by the space agencies.

■ Launchers

Recommendation The EBC supports the increasing co-operative initiatives between Europe's and Japan's space authorities, and strongly hopes that the current and future discussions will bring about a balanced, fruitful and active mutual co-operation between their respective heavy-lift launchers. The EBC also supports several renewed attempts by companies on both sides at discussing commercial and industrial co-operation in the field of launchers and space transportation in general.

Current situation Europe and Japan 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, Europe and Japan's major space authorities have decided to study a possible system to back up each other's governmental launch missions based on a reciprocity principle. This will address both the problem of major government mission delays in case of technical delays due to 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, Europe's and Japan's space industries are coming closer together to try co-operating on a commercial and 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 satellites at the rate of one or two per year. 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 American pressure forced the opening to international competition of much of the government market in 1990. Much of the responsibility for the H-IIA launcher, on the other hand, is being transferred to the private sector in the midst of a severe market depression.

These circumstances are made even worse by stringent budgetary constraints, which have forced the merger of NASDA, ISAS and NAL into the new space agency JAXA.

Space activities often suffer from low interest among the Japanese public, but this public supports international co-operation 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 have not yet sold satellites in Japan, but Japanese customers are showing increasing interest because of the high quality of European satellites and unreliable US export control policies.

Japan often uses international co-operation to reach technological and industrial excellence through contacts with advanced partners. However, co-operation in satellite development remains heavily biased towards the US, particularly for programs close to national security. 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, however, may be at hand following recent meetings between Europe's and Japan's space authorities and agencies. Europe's and Japan's space industries, on the other hand, 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 trustful relations have also been maintained with Japan's industry and space authorities.

Japan develops, builds, maintains and operates advanced satellite launchers. To maintain independent access to space in the face of severe budgetary constraints and a very limited government satellite market, the Japanese Government transferred the main responsibilities of the current H-IIA launchers to Mitsubishi Heavy Industries and decided to develop the smaller Galaxy Express launcher. But the current satellite market trough makes it difficult to introduce yet more launchers into an already overcrowded and fragile commercial launch market. The home government satellite launch market will remain essential for the foreseeable future.

Cooperation between the Ariane 5 and H-IIA launchers is taking shape. In the commercial area, Arianespace, Mitsubishi Heavy Industries (MHI) and Boeing Launch Services agreed to make it easier for customers to shift launchers within this group in case of technical problems with one of the group member's launchers. Europe's and Japan's space authorities are also studying a similar but bilateral scheme between Arianespace's Ariane 5 and MHI's H-IIA for the mutual backup of government missions.

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 historically 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 Some progress. During the past year there were encouraging signs that Japan is now prepared to select a European solution, especially when it uniquely meets a requirement or provides best value for the taxpayers' money. The EBC is working to increase the presence of European companies in Japan by building on the welcome progress of the last year. However, the lack of transparency in the procurement process and insufficient balanced assessment of European equipment continue to limit the effectiveness and scope of many areas of the defence procurement process. 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.

Current situation Little progress. Japan prohibits co-development involving the exchange of defence related information with all countries except the US. Since specifications for military equipment also fall within the scope of this prohibition, it is very difficult for European companies to participate in co-operative ventures with the Japanese defence industry.

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 locally built and developed weapons systems. 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. However, there are indications that the situation is now gradually improving for European firms.

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 interoperational problems.

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 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 and private finance initiatives.

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 The ceiling price system (*yotei kaku*) for public tenders should be abolished and requirements for bid participation should be relaxed. The EBC also urges more transparency in the screening process. 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.

Current situation No progress. European firms have traditionally found it much easier to supply innovative materials, designs, and techniques to the private sector than to the public sector in Japan. Reasons for this include difficulties procuring information on tender offers from commissioning entities, fragmented qualifying procedures, close ties between commissioning entities and incumbent firms, selectively disclosed specifications, specifications that favour traditional suppliers, and lack of process transparency – from securing bid qualifications through to the evaluation and awarding of contracts. The EBC does not realistically 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. Recently introduced regulations governing formaldehyde emissions highlight the seriousness of this problem. There is at present no testing body within the European Union accredited to perform testing of JAS/JIS standards in this area. While the Japanese Government has 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”, the underlying structural barriers remain.

Background:

EBC Construction Committee Member Companies

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

The business environment: an overview

The Japanese construction market is becoming increasingly unattractive to European firms involved in the sector. The numerous obstacles European firms have traditionally faced doing business in Japan have simply been compounded by continued economic stagnation and problems that continue to plague the industry in general.

There are too many firms chasing too little work in Japan. Investment in construction has decreased by almost 30% since the peak in 1990, but the number of firms has increased. Of the approximately 570,000 firms involved in the sector, including 70,000 general contractors, only 6,000 are capitalised at over 100 million yen. The construction sector employs over 10% of the Japanese workforce – an increase of 10% more from 1990 and an unusually high percentage by OECD standards.

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.

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.

Performance standards

Although changes to the Building Code in June 2000 allow materials receiving approval on the basis of performance standards to be admitted to Japan, and although it is now theoretically possible to test these materials in their country of origin (provided the testing centre is approved by the Japanese Government), there is little evidence of increased use of innovative materials and components from overseas. The EBC feels that this is largely due to bureaucratic resistance to innovation or change and, in the case of public works, the fear of sanctions by the Board of Audit, as even the smallest change from established practice is subjected to question and close examination. The EBC urges the Japanese Government to work towards encouraging the use of innovative construction technologies, materials, and techniques and to further promote efficiency in the product approval process.

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 Limited progress. Arbitrary tariff classifications and revisions continue to make things difficult for European suppliers of industrial materials in Japan. 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 subjected 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

Background

High tariff rates on imported industrial materials significantly increase commodity procurement costs and seriously affect the competitiveness of Japanese industry. This adds to the problems Japanese firms continue to face in important sectors such as steel, glass and machining, which are struggling to remain competitive in an increasingly international market. 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. High tariff rates remain the key factor inhibiting European access to the Japanese market for industrial materials. 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 struggling for survival. 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 and production costs that are acknowledged to be the highest in the world. This has led to a situation where Japanese nickel producers now export 32% 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. The EBC feels that these fears are unfounded. 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.

Fused aluminium oxide

Fused aluminium oxide, also called artificial corundum, is used in the abrasive industry for grinding wheels, sand paper, or loose grain applications like grinding and polishing of glass, electric components, and refractory products. Imported corundum 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. This increases the price for imported corundum and effectively penalises the Japanese end-user.

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. Unfortunately, the regulatory regime governing environmental protection and environment-related businesses is not as highly developed in Japan as it is in Europe. One can compare the present situation in Japan with the situation that existed twenty years ago in certain countries in Europe.

■ **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 is pleased to note that the EU and Japan are planning to place more emphasis on public procurement issues in their bilateral relations, and the EBC hopes that both parties will take this opportunity to share 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
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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

Having said this, the EBC is encouraged by a number of recent developments that bode well for the future of the 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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