



Economic Integration: The New Reform Paradigm

**The EBC Report on the Japanese Business Environment
2008**

**The
European Business Council
in Japan**

Registered as the European (EU) Chamber of Commerce in Japan

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Chamber of Commerce in Japan)**

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The European Business Council (EBC) is the trade policy arm of the 18 European national chambers of commerce and business associations in Japan. Established in 1972, the EBC works to improve the trade and investment environment for European companies doing business in Japan.

The EBC currently represents some 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 29 industry committees, whose work aims to improve the local business environment in a wide variety of economic sectors.

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

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

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2008**

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Message from the Chairman

It is my pleasure to introduce the 2008 annual report of the European Business Council in Japan (EBC) on the Japanese business environment: *Economic Integration: The New Reform Paradigm*. This report presents the views of European business in Japan on developments over the past year and our recommendations for future economic reforms. It also builds on our 2007 report in further identifying how an EU-Japan Economic Integration Agreement (EIA) could strengthen the trade and investment relationship between Japan and the EU and vastly improve the business environment.

It is worth reminding ourselves at this time of global economic upheaval just how much is at stake for Japan and the European Union. Together they account for close to 40% of global GDP. Their importance to each other as trade partners is extremely significant.

As I write, the credit turmoil troubling most major economies has, so far, had comparatively little impact on Japan's banking industry. However, Japan's export-driven economy remains vulnerable to falling demand in foreign markets and domestic spending, far from being ready to take up the slack, is depressed. Even before the current crisis, Japan faced significant challenges. It suffers from the lowest stock of inward foreign direct investment (FDI), relative to GDP, of any OECD country. Its ageing population, combined with a declining birthrate and shrinking labour force, threaten to overwhelm the pension and healthcare systems and impose an unsustainable financial burden on employers and employees. It seems that Japan has reached an economic cross-roads.

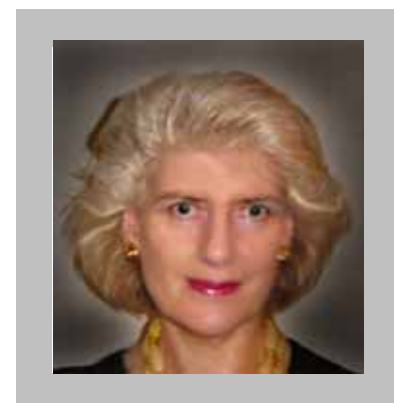
This situation presents an immediate and pressing challenge for the new Prime Minister, Mr. Aso. Special measures and stimulus packages offer only short-term solutions and risk compounding old problems. Unnecessary and outdated regulation, stifling bureaucracy, and vested interests continue to inhibit innovation, prohibit new business models and limit the growth of strong new companies in Japan. It is imperative that the focus of actions should be on addressing these issues and creating conditions that foster vibrant, robust, competitive businesses. This report points out numerous actions that the Government of Japan could take right now towards realising such conditions. The current crisis and the risk of further economic slowdown warrant an immediate and vigorous response.

Japan is in no way alone in needing economic reform. We in the EBC are especially aware of the many outstanding actions still essential to improving the business environment in the European Union, and the often slow progress there in meeting reform commitments. This is why the EBC believes that working together on an ambitious EU-Japan Economic Integration Agreement would enable both the EU and Japan to boost progress and learn from each other, while also crucially benefiting from improved trade, innovation and competitiveness.

Most importantly, the EU and Japan are ideal partners as we have much in common in terms of priorities and values. As societies with long traditions, we both emphasise a co-operative, inclusive and sensitive approach to solving socio-economic issues and share many of the same concerns and challenges at the global trade level. Both are strong believers in rules-based free trade, fair competition, as well as robust investment rules and environmental standards. When facing an emerging new world-order, it is our moral obligation to stand together to ensure that the values are not neglected, and contrarily, to set the rules for the game. This is no time for wavering. The global economic conditions provide every incentive to act now. We in the EBC stand ready to play our part. We offer the recommendations in this report as a guide for action and commend them to all those committed to building a brighter economic future for our countries.

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

Message from the Executive Director



The European Business Council in Japan (EBC) is pleased to present its 2008 annual report, *Economic Integration: The New Reform Paradigm*. This report presents the views of European business on market developments in Japan over the past year and makes recommendations to address issues that constrain business and investment.

For both the EU and Japan, sustaining the economic strength and competitiveness in the face of high commodity prices, fierce competition, falling demand in export markets and domestic slow-down remains a challenge. Creating economic conditions that allow business to flourish will be crucial. The EBC urges the new administration in Japan under Prime Minister Aso to rise to this challenge. A rigorous new approach is needed to promote growth and prosperity. Working with the European Union towards an ambitious EU-Japan Economic Integration Agreement (EIA) can help provide the necessary ideas and direction, as well as offer fresh opportunities to improve mutual trade and investment.

The EBC annual report offers recommendations on the immediate issues that the Government must address if it sincerely wishes to improve the conditions for doing business in Japan. It represents input from 29 sector-based committees, some 3000 companies and our key stakeholders, the European National Chambers of Commerce and other business organisations represented in Japan.

I would like to take this opportunity to emphasise the invaluable contribution of the members of the EBC committees to this report. Their generosity in sharing their professional experience and insights makes this publication a key source of information as well as inspiration for reform. As in previous years, I am also much indebted to the EBC's Policy Director, Jakob Edberg, for his tireless efforts and ever-expanding knowledge and understanding of the issues affecting European businesses in Japan.

On behalf of the EBC, I should like to thank the Delegation of the European Commission to Japan and the European national embassies in Tokyo for their expertise and support of EBC activities. Finally, I would add that the EBC is extremely proud to recognise the many EBC Members whose generous financial support for this publication is acknowledged in the sponsors and supporters sections at the end of the report.

Finally, may I emphasise the enormous potential value of this report. On the basis of first-hand observation and experience by European businesses in Japan, it identifies structural and regulatory reforms that, if implemented by the relevant authorities, would substantially improve the trade and investment environment. After years of slow progress, when the scope and pace of any economic reform has fallen far short of what was needed, the EBC in its report now proposes a fresh approach, whereby the EU and Japan should work together to boost trade and investment through development of an EU-Japan Economic Integration Agreement (EIA). At a time when both economies are under acute pressure, businesses struggling and public and private finances suffering, the EBC believes an EIA offers a positive way forward. We commend the report to our readers and trust that its recommendations will be a valuable source of ideas at this crucial time.

Alison Murray
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Introduction



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INTRODUCTION

A new crisis for Japan, and an older challenge

During the time that this report has been in production, worldwide financial turmoil has focused attention on Japan's position in the global economy. Since the bursting of the bubble, now more than 15 years ago, Japan's domestic economy has proven stubbornly difficult to tease out of recession: attempts at monetary stimulus have led only to exceptionally low interest rates and in turn, to carry trade, lowering the value of the yen to levels many believed artificial. It was therefore no surprise to find that when the financial crisis hit this year, the unwinding of this carry trade caused the yen to surge rapidly. The effect has been to expose once again Japan's vulnerability in relying on its export industry to drive the economy forward. The global financial crisis should arguably have made Japan, a country that has this time largely steered clear of the speculation bubble, seem relatively robust. In fact, it has not: the rapid surge in the value of the yen and equally rapid deterioration of export markets have caused stocks to fall even more steeply here than in the US and Europe.

The core of the problem lies in Japan's inability to completely leave behind its once effective post-war growth model, characterised by central government guiding industry in the search for global market share and then redistributing the resulting export profits, while protecting domestic industry from competition.

It is important to note that Japan's inability to transform its economy is not due to a lack of will. The EBC can bear witness to many government-driven efforts to reform the current system, such as establishment of the Regulatory Reform Council, the Council for Fiscal and Economic Policies and the Japan Investment Council. The EBC has had the honour of being invited to take an active part in these efforts and used the occasions to argue strongly for reforms that would not only boost foreign companies, but crucially also help the many Japanese companies seeking to tap into foreign sources of capital, while also increasing levels of competition within the Japanese market and thus stimulating the economy as a whole.

Compared to a decade ago, progress has been remarkable. Prime Minister Koizumi took the lead in introducing wide ranging reforms including a new Corporation Law, which modernised legal structures and improved flexibility by making a wider choice of forms of legal presence available to firms in Japan. Mr Koizumi also broke with previous protectionist traditions by establishing a credible policy of non-intervention, which forced financial institutions to deal squarely with bad debts and non-performing loans. Streamlining of the multiple financial services regulators and the introduction of a no-action letter system also helped. Perhaps most dramatically, the Koizumi Government implemented a drastic cut in public spending on infrastructure projects that demonstrated a clear change of direction from the practice of previous governments of throwing money at projects as a way to stimulate the economy out of recession.

The governments under Mr Abe and Mr Fukuda followed suit, though arguably with less enthusiasm. The past year has witnessed further essential improvements, in line with long-standing EBC recommendations. At the end of 2007, the Council for Fiscal and Economic Policy, an advisory body to the Prime Minister, recommended the revision of firewall restrictions separating Banking, Securities, Asset Management, and Insurance businesses. Following a revision of the Financial Instruments Exchange Law and subsequent long consultations with the Financial Services Agency in which EBC members have taken an active part, we are waiting for the release of crucial guidelines as this Annual Report goes to press - if not too restrictive, these guidelines could pave the way for integrated financial services in Japan. Another notable development has been in the air transportation field where, finally, pricing restrictions on international air fares have been lifted and discussions on the internationalisation of Haneda airport are moving forward, although the exact terms on which foreign airlines will be allowed to operate from this attractive airport close to Tokyo remain to be settled. The EBC also welcomes the efforts undertaken to improve access to state-of-the-art healthcare, whereby the Government has convened expert groups with the explicit purpose of proposing policies to remedy the delay in introducing innovative drugs,

medical equipment, and medical diagnostics products into Japan. The EBC is contributing substantial and concrete policy proposals to this process, focusing on the need for Japan to take advantage of the clinical data already available to it rather than forcing manufacturers to conduct time-consuming duplicate tests if they wish to market products in Japan.

Yet, despite the patchwork of reforms to-date and the good intentions of the Government to go further, a quick look at the range of issues listed in this Report reveals that Japan is still a long way from achieving a more viable, comprehensive and long-term economic model.

A few examples serve to illustrate the extent of the challenge facing Japan.

- Notwithstanding the setting up of expert groups mentioned above, the much-needed overhaul of the healthcare system, crumbling under the pressure of demographic change and a resulting 3-4% increase every year in healthcare costs, has barely started. The only concrete Government action so far has been to increase contribution fees, reduce users' cover under the National Public Health Insurance Scheme and cut reimbursement prices for pharmaceutical, medical diagnostic and medical equipment products. Attempts to modernise certification systems through the introduction of Good Clinical Practices (GCP), Good Manufacturing Practices (GMP), and the Quality Management System (QMS) have, despite good intentions, resulted in duplication of work, since a cautious regulator has seen to it that these concepts have not replaced, but in many cases simply been added to the old prescriptive rules.
- Progress in the area of investment promotion has also been slight. The crown-jewel of the Government's promotion policies, the so-called Triangular Merger Scheme, allowing Japanese branches of foreign companies to use mother company stocks as consideration when merging with or acquiring Japanese companies, has been a disappointment. Last-minute manoeuvring on the part of domestic industry groups, in collaboration with politicians and the Ministry of Economy, Trade and Industry (METI) before the law passed Parliament have resulted in the new rules failing to offer predictability as to whether a transaction will be tax deferrable or not. Consequently, the scheme has been used only once so far – and that was for a squeeze-out rather than a foreign investment per se. This extremely low rate of use is all the more remarkable as the scheme has been available for 18 months since May 2007.
- In the field of food regulations, progress has been equally disappointing. Only 294 of the 828 food additives authorised in Japan are accepted as being safe by the WHO/FAO, while, on the other hand, over 600 substances accepted as being safe by the WHO/FAO are not allowed in Japan. Trying to remedy this situation, in December 2002, the Ministry of Health, Labour and Welfare (MLHW) identified a list of 46 food additives which, in their own words, “have been proven safe and are widely used in the world” and which could therefore be given fast-track approval. Since then, only 14 out of these additives have been formally approved. It is difficult to understand why it takes so much time for the Ministry to accept additives which it has already acknowledged to be safe.

These are just some of the examples to be found in this Report, showing how difficult it is proving for Japan to break with the bureaucratic control of the post-war growth model, even though the barriers initially set up to protect domestic industry from competition are now hurting the economy at large. Japan's political leadership has clearly grasped the importance of resolving these issues, but reaching the right collective decisions has been, and still is, proving to be extraordinarily difficult. Prime Minister Koizumi managed to move the political consensus in a more reform-friendly direction, but was not able to secure implementation. The following two Prime Ministers (Mr Abe and Mr Fukuda) both lost momentum soon after taking office. The political dead-lock caused by split majorities in the upper and lower houses of Parliament over the past year has only exacerbated the situation. Ministries and other government agencies remain largely unchallenged in their control over respective industry sectors, ensuring that policies do not undermine their own powers or the interests of their closest, often ailing, industry allies.

The only positive performance indicator for the Japanese economy has come from strong exports, sustained by the low value of the yen over the past few years. The sight of this export-driven recovery and the apparent durability of old structures have suggested to some that there might yet be life in the post-war growth model, delaying further the reforms that ultimately have to be made. Yet given the current financial turmoil, such old solutions must, inevitably, soon breathe their last breath. Japan will not be able to export away the need for structural reforms but needs finally to face the challenge of finding a new economic model, which can generate growth even in a highly globalised economy, without compromising the very values underpinning Japanese society.

This is why an EU-Japan Economic Integration Agreement would be so very valuable.

Rather than simply identifying where the Government is failing to boost trade and investment, we try in this Report to build on the approach made last year, in suggesting how economic integration between the European Union and Japan could solve the issues industry is facing. The EBC firmly believes that working towards a bilateral agreement would provide both Japan and the EU with a unique opportunity to not only address longstanding trade issues, but more importantly, also lay the foundations for growth in both economies.

What could make the EU and Japan good partners in such an enterprise? Firstly, the sheer size of their combined economies - the EU and Japan account for around 40% of global GDP means that each offers huge potential to the other. Secondly, they have much in common in terms of priorities and values, emphasising a co-operative, inclusive and sensitive approach to solving socio-economic issues. Finally, the EU and Japan share many of the same concerns and challenges at the global trade level. Both are strong believers in rules-based free trade. Both would like to see the World Trade Organisation (WTO) take on wider responsibilities to guarantee fair competition, procurement and investment rules and environmental standards at the global level. However, international political realities do not permit such issues to be included in WTO negotiations in the foreseeable future. So an ambitious EU-Japan Agreement addressing these issues should present no danger to the multilateral system, but complement it and provide an example of a way forward for the benefit of all. Yet at this stage, the economic and trade relationship between the EU and Japan suffers from endless wrangling over differences in respective rules and regulations and very little vision of a way forward for anyone. It is time to change this.

Why an EU-Japan Economic Integration Agreement?

The Economic Integration Agreement envisaged by the EBC would entail Japan and the European Union working together towards the abolition of obstacles to mutual trade. The experience of Member States in establishing the EU's Single Market testifies to the real benefits that can be gained from this. It also testifies to the challenges involved. Yet realising what was at stake, the Member States invested hugely in making the Single Market a success. Years of work by numerous committees and expert groups from across the Member States, addressing a host of different issues, led to balanced agreements that without compromising efficiency, proved sensitive to the technical, social and cultural concerns of all parties. The result is a body of singularly robust rules and regulations establishing a Single Market characterised by the free movement of goods, people, services and capital. These rules and regulations have been adopted and supported by the now 27 Member States, boosting trade within the EU. Why, then, not use them as a model to inspire – and even give substance to – a body of rules and regulations to boost trade between the EU and Japan?

This is not to suggest that the EU and Japan should embark on precisely the same extensive programme of integration that has been achieved by EU Member States. The EBC recommends working towards an Agreement with a specific focus on achieving closer cooperation in the economic arena, based around the concepts of a free market for goods, people, services and capital. This has the potential to boost trade and investment between the two economic giants. It would offer consumers a wider choice of quality goods and services, in many cases at lower prices, as well as the opportunity to move across borders for work without foregoing welfare protection. It would deliver benefits for business in terms of a single set of rules and unified certification schemes, especially

valuable to small and medium-sized enterprises, which might otherwise be deterred from entering new markets by the costs and difficulties involved. It seems to us an Agreement worth working for.

To be clear about the EBC's vision for an EU-Japan Economic Integration Agreement, the following summarises the scope of issues we believe it should cover, in order to ensure free movement of goods, people, services and capital.

Free movement of goods between the EU and Japan

The economic success of the EU has demonstrated the benefits of easing barriers to cross-border trade. To extend such benefits to the EU-Japan relationship, the EBC believes a first step should be mutual acceptance of standards and certification schemes in product areas such as Construction Materials, Medical Equipment, Medical Diagnostics, Animal Health and Vaccines, as well as all products sold on retail markets where certification schemes exist.

- Both European Union standards (EN) and Japan Agricultural Standards (JAS)/Japan Industrial Standards (JIS) are scientifically-based and highly sensitive to issues of human and environmental safety. In many product areas, standards exist in both the EU and Japanese systems and are basically the same. These facts should make it relatively easy for each side to agree on direct and unconditional acceptance of the other's standards.
- Certain other product areas are covered by EN standards but not JIS/JAS - Medical Devices and Medical Diagnostics being prime examples. Yet here Japan employs a policy of certification per product (or what would be called "market authorisation" in the EU context) based on the same requirements as the EN standards, as set out under Good Clinical Practice (GCP), Quality Management System (QMS) and Good Manufacturing Practice (GMP) regulations. Furthermore, both the EU and Japanese approaches are built on ISO requirements. Given their common foundations, it should be possible to establish mutual acceptance of GCP, QMS and GMP from both regions with a view to establishing, in the longer-term, mutual acceptance of all products authorised for the market.

It will also be important for Japan and the European Union to agree on systems for ensuring human and environmental safety where this is not linked to specific product certifications or standards - for example, the negative list of unapproved food ingredients used in the European Union and positive list of approved food ingredients in Japan, and positive lists used in both regions concerning residues in food. Here, mutual acceptance of each party's lists may be difficult to achieve and so the most practical approach might be to create a set of common standards in these fields. The potential benefits of mutual acceptance and common standards cannot be over-stated in terms of accelerating the introduction of innovative goods to market, boosting competition, lowering costs for consumers and producers, and increasing trade.

Nevertheless, an EU-Japan Economic Integration Agreement would need to focus on more than this. It should also aim to develop common approaches to customs duties and import/export taxes. European exporters still encounter prohibitive tariffs in Japan for food products, industrial materials, liquor, leather and forestry products, while Japanese firms report problems importing into Europe. The EBC believes that, in the end, the fundamental principle should be no discrimination on grounds of origin between the EU and Japan.

Free movement of services between the EU and Japan

EU companies have the right to establish themselves in other Member States, and to provide services on the territory of a Member State in which they are not established. To reinforce these rights, specific legislation has been enacted in fields such as financial services, telecommunications, broadcasting and the recognition of

professional qualifications, while a general Services Directive aims to eliminate remaining discriminatory barriers, cut red tape and modernise and simplify legal and administrative frameworks, with a view to improving the competitiveness not just of service enterprises, but also of European industry as a whole.

The EBC believes that such benefits could be extended across the EU-Japan trade relationship and suggests that work should focus particularly on establishing common competition rules and common standards for service providers in the financial, legal, telecom and construction sectors.

Of course, establishing common rules for competition would be crucial to boosting the EU-Japan trade relationship in many other services sectors as well. For example, the EBC has expressed serious concerns about the so-called privatisation of Japan Post, which seems to be enjoying special treatment from the government (still its only stockholder) in order to shore up future profitability: these concerns are raised in detail by a number of EBC sector committees in the pages of this Report.

Procurement

Host Government procurement policy is a particular concern for many companies seeking to market their goods and services overseas. Both Japan and the EU are party to the plurilateral WTO agreement on government procurement (APG) and have implemented WTO-plus provisions aiming to open up as much of this business as possible. Nevertheless, participation of European companies in public works in Japan remains very low, in part because, while transparent procurement procedures are in place, they are often simply not used, and also because contracts are frequently so sub-divided that none meets the threshold to be covered by the WTO agreement. The EBC therefore considers that an EU-Japan Economic Integration Agreement should seek to secure reciprocal market access with binding rules and simplified, yet more effective, compliance measures than those of the WTO APG, guaranteeing equal treatment of foreign and domestic suppliers; transparency of information on and notice of government procurement opportunities; relevant brand neutral specifications; the process for bid evaluation; the award challenge procedure; and concrete enforcement mechanisms.

Free movement of people between the EU and Japan

Any attempt at achieving greater economic integration between the EU and Japan will depend on the ability to make it easier for people to move between the two territories. This will entail substantial revision - and in some cases abolition - of current visa and work permits for EU citizens in Japan and Japanese citizens in Europe. There is also a case for facilitating participation in respective education and academic programmes, such as the EU's Erasmus programme. An EU-Japan Agreement should additionally ease obstacles in the form of national social security procedures, and eliminate the need for individually brokered arrangements between each Member State and Japan on issues such as reimbursement of compulsory state pension contributions.

Free movement of capital between the EU and Japan

There are strong arguments for working towards the long-term goal of free movement of capital between the European Union and Japan. It would serve to facilitate trade across borders and workers' mobility. It would also support the cross-border activities of financial services companies, offer consumers a wider choice of financial products to choose from, make it easier and cheaper for companies to borrow money, and so bring down the cost of capital, goods and services for everybody. As a realistic first step, an EU-Japan Economic Integration Agreement should focus on enabling financial services firms to integrate their services and operations between the territories. This will depend on establishing mutually accepted principles governing the financial services industry and mutual acceptance of the home regulator as the core regulator. The respective industries in the EU and Japan will also need to be granted the right to invest and to establish financial institutions in each other's territory and guarantees that they can operate free of any discrimination.

Furthermore, an Economic Integration Agreement should seek to eliminate double taxation between the EU and Japan and withholding tax on dividends, royalties and interest. It should also enable employers' and employees' contributions to social security systems within the EU and Japan to be tax deductible on a mutual basis, and establish joint guidelines on interpretation and harmonisation of documentary requirements for transfer pricing assessments.

How this report is organised

This Report consists of 33 chapters covering a wide range of sectors and business areas. Each chapter addresses the concerns of a specific EBC sector committee and derives from the collective first-hand experiences of committee members doing business on the ground in Japan. Chapters consist of a series of recommendations for further regulatory reform with a section on prospects for economic integration, highlighting the priorities of each sector of the industry.

We trust this Report will prove to be a positive contribution to the thinking of the Government and all other authorities in Japan and in the EU seeking to improve the environment for business and investment in Japan.

Business Fundamentals

Human resources
Intellectual property
Retail & wholesale
Legal services
Tax

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HUMAN RESOURCES

Introduction

Economic globalisation and current demographic trends in Japan, including an acute shortage of skilled labour, an ageing population, and a declining birth rate, present significant challenges for domestic and foreign-owned businesses and for the long-term vitality of the Japanese economy. Companies are forced to streamline their management, improve working conditions, enhance operational efficiency and find new sources of labour from abroad. In the light of these challenges, it is critical that labour regulations and human resource management facilitate international commercial transactions and provide the best means of acquiring and retaining a highly skilled competitive workforce. In order to meet the evolving demands of today's fast-paced global economy, the Government of Japan must deregulate obstructive regulations on immigration, pension schemes, and employment tenure in line with international standards and practices.

Challenges for EU-Japan Economic Integration

Immigration policies in Japan have yet to enable efficient, cost-effective transfer and employment of foreign staff. For Japanese companies and foreign-owned businesses relying to a significant extent on foreign expertise, the full mobility of foreign labour in and out of the country is crucial to their success.

Japan is the only advanced industrial nation to regulate the movement of foreign residents through a dual visa and re-entry permit system. In addition to a standard visa system, the Immigration Bureau under the Ministry of Justice administers a unique re-entry permit system that requires all foreign residents, including permanent residents, to acquire special permission if they wish to leave the country without losing their residency status. In 1999, a revision of the Immigration Control and Refugee Recognition Act enabled an extension of the maximum period during which re-entry is permitted, from one year to three years. The revision made it easier for foreign residents to enter and leave Japan, but only after a multiple re-entry permit has been obtained and as long as the visa remains valid. Restrictions on work permits also pose a challenge for businesses wanting to employ foreign staff. Under the current system, work visas for special skilled workers that do not have a university degree are only granted if proof of ten years' work experience can be demonstrated.

Revisions to labour laws over the past years have been successful in granting greater flexibility in terms of working hours, compensation, pension schemes and contracts, while continuously supporting the long-term employment system. The Labour Standard Law was amended in June 2003 to permit employee dismissals only if the employer meets stringent criteria for economic hardship. This amendment, however, did not set out specific criteria for determining reasonable compensation for severance.

Japan's Defined Contribution Pension Law of 2001 enabled employers to offer more flexible and attractive pension schemes to employees, however, there are yet to be amendments that would enable expanding refunds of mandatory Japanese pension fund contributions for expatriate workers leaving Japan. Refunds for pension payments are covered by social security agreements currently in the process of being concluded with Belgium, France, the UK and Germany. A comprehensive Economic Integration Agreement between the EU and Japan should streamline the process of brokering multiple individual agreements on social security pension reimbursement. The EU and Japan should also revise all visa and work permit requirements between the EU and Japan with a view to creating a single labour market extending to both regions in the long-term.

Key Issues and Recommendations

■ Immigration and re- entry permits

Yearly status report: limited progress. The Council for Regulatory Reform of Japan recommended that the re-entry permit system be reformed before the end of fiscal year 2007, but the system remains unchanged. The process for applying and renewing such permits remains bureaucratic and time-consuming, with cost implications for both applicants and employers. Furthermore a re-entry permit does not appear to provide additional benefits to the Government of Japan for controlling immigration, as foreigners possessing a visa have already been screened and found eligible to stay in the country. Immigration officials are able to monitor the exit and entry of foreigners through their visa, which can be cancelled at any time should the holder be found to engage in activities other than those permitted under the terms of the visa. The Ministry of Justice is planning to submit a new “resident ledger” law at the next ordinary session of the Diet, merging parts of the Immigration Control Act and the Alien Registration Law. The plan is to issue a resident card at the port of entry when the foreigner first arrives in Japan, instead of later, after he/she registers at a local municipal office, as currently is the case. If the Government of Japan wants to maintain the re-entry permit system, linking the permit to the new resident card would substantially facilitate the process.

Recommendation:

- The Government of Japan should abolish the re-entry permit system. At the very least, re-entry permits should be granted at the time of issuance of the new residence card.

■ Pensions

Yearly status report: limited progress. Social security agreements are being negotiated or have been concluded with Belgium, France, the UK and Germany, as well as the US and South Korea, but refunds of mandatory contributions to Japanese pension plans remain capped at a maximum of three years, or approximately 1.5 million yen in the case of departing expatriates.

Recommendation:

- Japan’s Defined Contribution Pension Law of 2001 should be improved by increasing tax-exempt contribution levels, allowing matching contributions and permitting plan-holders to borrow against their pension reserves.
- Mandatory contributions to the Japanese public pension system should be remitted in full to departing expatriates and their employers.
- Contributions made to foreign-based pension plans should be subject to the same tax relief as contributions made to pension plans in Japan.
- The Government of Japan should conclude social security agreements with all EU Member States under a comprehensive EU-Japan Economic Integration Agreement.

■ Dismissals of employees

Yearly status report: limited progress. Although the revision to the Labour Law permitted employee dismissals, it did not address the issue of severance payments, an area where standard practice urgently needs to be codified in law in order to avoid uncertainties and the risk of unnecessarily costly settlements. For operational efficiency and to maintain a high standard of working conditions for employees, companies need a clear mandate on the hiring and dismissal of employees.

Recommendation:

- Regulations governing employee dismissals should be further clarified to enhance management flexibility and operational efficiency. Specific rules defining acceptable grounds for dismissal based on economic reasons should be introduced, along with clear guidance on what would constitute an appropriate severance payment.

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INTELLECTUAL PROPERTY

Introduction

Japan remains the world's most attractive market for luxury products as it still accounts for 29% of worldwide consumption of luxury goods and is worth around Euro 14.3 billion. Given the sheer size of the market, Japan is among the principal targets for the trade in counterfeit goods. Most of the counterfeit goods entering and circulating in Japan are sold through Internet auction websites. More than 20% of well-known foreign brand goods sold on the Internet and mobile phone auction sites are fake. Yahoo!Japan, Rakuten and DeNA are the principal auction site operators in Japan and play a significant role in the fight against counterfeits. In the last few years, the Japanese authorities have also started to more pro-actively counteract violations of intellectual property rights. However, notwithstanding important legal improvements and encouraging results following intensified surveillance over the past years, crucial issues remain unresolved. Though we have recently witnessed a somewhat lower frequency of interventions, the EBC believes that the Japanese authorities are seriously looking for solutions to deal with outstanding issues.

Challenges for EU-Japan Economic Integration

Since the launch of the Intellectual Property Strategy Council's 10-year action plan, adopted in 2002, Japanese authorities have shown a significant interest in intellectual property rights protection, issuing some 40 new initiatives, including new laws and revisions of existing laws. The 2003 reform of the Customs and Tariff Law was part of this reform policy; improving cooperation between the customs services and companies holding infringed intellectual property rights. In 2004, such companies were given the right to receive information concerning the importers of alleged counterfeit goods from the customs services. Moreover, in 2005, the first High Court of Intellectual Property was established as a specialised branch of the Tokyo Court of Appeal. In 2006, the prohibition of importation was extended to goods that are similar to famous-name brands. Reform of the Trademark Law increased the fine applicable to importers of counterfeit goods for commercial purposes to 300 million yen for legal entities and from 5 million to 10 million yen for individuals.

Reform of the rules for applying the Act on Specified Commercial Transactions also resulted in significant improvements. This measure strengthens control of the identity of vendors on Internet auction sites, compelling vendors to furnish their complete identity data when selling twenty or more luxury brand goods. In the event that they do not comply with this obligation, the Ministry of Economy, Trade and Industry (METI) may request banning of the vendor from the auction website. As a consequence, auction site operators have strengthened their control of vendors to the extent that they are now able to provide intellectual property rights-holders with information collected on counterfeiters. The measures taken by the operators against repeat counterfeiters have also been strengthened considerably. Such regulatory revision represents an important achievement in the fight against counterfeits and gives substance to the authorities' guidelines for stopping the spread of counterfeit product sales in the Japanese market.

Despite significant improvements, however, crucial issues remain unresolved as Japanese regulations prove still inefficient in the enforcement of trademark violations. This is demonstrated by the persistent acceptance of parallel imports, which implies inadequate border control of importation and facilitates the entrance of fake goods into Japanese territory. The Japanese police and prosecutors face, moreover, tremendous difficulties in proving that the counterfeiter is aware of distributing goods that are fake, which, currently, is a prerequisite for taking action. This difficulty in proving awareness allows some importers to continue importing counterfeits unpunished.

Key Issues and Recommendations

■ Fake Goods on the Internet

Yearly status report: progress. The Internet remains the principal instrument for purchasing fake goods in Japan, as more than 20% of well-known foreign brand goods being sold on Internet and mobile auction sites are counterfeit products. Auction site operators have taken action to counter this new type of sale, by strengthening measures against repeat counterfeiters. However, enforcement of the Act on Specified Commercial Transactions is not sufficiently systematic as it is not really applicable to goods sold on mobile auction sites and does not include restrictions on clothing, which represents a significant proportion of the counterfeit goods distributed in Japan.

Recommendation:

- Auction operators and vendors on the Internet should be rigorously controlled and punished if found guilty of not fulfilling their obligations.
- The Act on Specified Commercial Transactions should be more systematically enforced, and extended to cover goods sold through auctions on mobile websites.

■ Border Control

Yearly status report: some progress. Despite revisions of the Trademark Law and stepped-up efforts by customs authorities to improve the appraisal process, Japan has not yet been able to curb imports of counterfeit goods. Customs services still invite intellectual property rights-holders to visit their offices to see suspicious goods rather than send pictures to rights-holders by e-mail, thereby delaying procedures. Parallel importation remains legal and civil and criminal sanctions of the Customs Law are insufficient.

Recommendation:

- Cooperation between customs services and rights-holders should be simplified by sending pictures of goods by e-mail whenever possible, and rights-holders should have the right to intervene through judicial means in procedures for seizing suspected counterfeit goods at the Japanese border.
- The Customs Law should be revised to make it an offence for individuals or legal entities to attempt or act with intent to import counterfeit goods; moreover, applicable sanctions should be strengthened.

■ Imports for Personal Use

Yearly status report: no progress. The import of counterfeit goods for “personal use” is still legal in Japan, a loop-hole used by persons wishing to import fake products in small quantities for commercial purposes without legal risk. In the past couple of years, upon discovering a suspicious product, the Customs authorities have adopted the practice of sending a letter to the recipient of the package requiring confirmation of authenticity and purpose. Some 90% of recipients decide to abandon the counterfeit goods ordered upon receiving such a letter, but the efficiency of the system is gradually being eroded as importers are becoming increasingly aware of the non-binding nature of these letters.

Recommendation:

- The Trademark Law should be revised so as to prohibit the importation of counterfeit goods regardless of whether they are meant for personal or commercial use, as this is the only way to ensure that no such products are imported

■ Designs

Yearly status report: no progress. Procedures for applying for protection of intellectual property rights in respect of designs remain too complex and expensive, effectively denying to foreign companies the benefit of protection enjoyed in Europe and most other markets.

Recommendation:

- Application fees should be reduced and examination procedures eliminated or substantially alleviated.
- A more stringent approach should be taken by Japanese courts when interpreting the similarity of design.

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RETAIL & WHOLESale

Introduction

The Japanese retail market is one of the largest and most vibrant in the world. However, unlike in many markets, non-franchised outlets of overseas retail chains are rare. Successful entries into Japan by European retailers have been few and the failures have been given considerable coverage by the local and international media. This has led to a perception, sometimes unfair, that Japan is simply 'too difficult': competition is intense, costs are high, the threat of a rise in consumption tax is real, and regulatory requirements and enforcement are opaque. Many retailers looking to expand internationally pass over Japan in favour of other markets that provide examples of non-local retail success. Nevertheless, a number of European retailers that have made careful studies of the Japanese market have elected to 'set up shop'. It is important that they be allowed the opportunity to succeed. Their success benefits the Japanese consumer by offering them greater choice. Success of European retailers in Japan also benefits Japanese retailers and wholesalers by providing new opportunities to compete and to further strengthen their global competitive edge.

Challenges for EU-Japan Economic Integration

Little has changed for the better in recent years for foreign retail and wholesale companies wishing to invest in the Japanese market. Although Japan is the second largest retail market in the world, very few non-Japanese retailers are active in the Japanese market. Despite a marked expansion of foreign retail activity in the specialty retail channel (albeit with many outlets operating via franchises or under licence to Japanese companies), it has proved difficult for foreign retailers to take advantage of global-scale logistics when entering the Japanese market. The process for developing and opening new retail outlets has remained fraught with restrictions, inefficiencies and delays. Opportunities to streamline the new Large Store Location Law of 2000 - intended to improve efficiency by decentralising control and decreasing administration - with the Building Permit and Environmental Impact Assessment procedures were not taken. Instead the new law led to individual local governments imposing their own procedures and, in some cases, new licence conditions, thus increasing costs and delays. The effect, combined with restrictions on opening retail stores above 10,000 m², has been to discourage foreign retailers further by making the costs to enter and establish operations in Japan even higher. The Government took note of the EBC's concerns and introduced crucial exemptions to the new restrictions for large-scale retailing before the revisions to the City Planning Law were passed in the Diet in early 2006. Arguably more important than restriction on large-scale retailing per se is the local interpretation of construction, safety and environmental regulations. This adds to investment costs and increases uncertainty and risk, effectively undermining any learning curve benefits for retailers attempting to expand operations in Japan.

Importing, certifying and labelling various consumer products continue to be overly costly and complex, due to Japan insisting on additional product testing against specifically Japanese standards, even where products are already covered by international and European standards. The EBC can see no reason why products already certified for the European market have to undergo testing and certification anew if they are to be sold on the Japanese market. As standards for most retail products are similar, the EU and Japan should swiftly move to establish mutual acceptance of standards and certification.

Key Issues and Recommendations

■ Large-scale retailing

Yearly status report: limited progress. While progress has been made in clarifying many of the provisions in the Large-scale Location Law, a lack of transparency and unequal regional implementation limit the entry of foreign retailers into the market. Local interpretation of construction, safety and environmental regulations is inconsistent. This adds to investment costs and increases uncertainty and risk, effectively undermining any learning curve benefits for retailers attempting to expand operations in Japan. The conspicuous rarity of foreign-owned and -operated large-scale retailers in Japan bears witness to the impact this has on investment. The discussion on new restrictions on large-scale retailing is, however, continuing. The EBC urges the Government of Japan to exercise caution and not introduce any further restrictions as it will only exacerbate the situation at the regional level, leaving the countryside with no global retailers, limited selection, reduced competition and, in the long-run, lowered economic activity.

Recommendation:

- Regulations governing applications for and implementation of business licences for large-scale retail facilities should be made more transparent and consistent. The Government should ensure that the exemption of larger cities (more than one million inhabitants) from new restrictions on new large-scale retailing is continuously respected under the revised City Planning Law.

■ Prohibitive import, certification and labelling rules

Yearly status report: limited progress. Reluctance to accept EN and ISO standards or CE marking of products exported to Japan delays the introduction of new products to the market and increases import costs. While accepting the need to safeguard consumer health and safety, the EBC urges the Governments of Japan and the European Union to mutually recognise standards and products.

Recommendation:

- Japan and the EU should mutually accept regulations governing the application process for importing and selling/using products with particular consideration for consumer safety and health, so that products certified for one market are automatically accepted in the other market.

■ Labelling of household products

Yearly status report: some progress. The Household Product Quality Law and accompanying voluntary labelling guidelines (“*hyojikitei*”) prescribe in extreme detail how household products should be labelled when sold in Japan. Local governments inspect retailers regularly and issue warnings when finding violations. The legal backing of the guidelines is weak and the legality of issuing public warnings therefore questionable. The combination of legal uncertainty and detailed rules cause considerable problems for retailers sourcing on a global basis. A particular problem is the rule stating that all measurements have to be stated in millimetres and not centimetres, in contrast to general practice in the industry. If forced to comply with all rules, manufacturers would have to alter their global production system, adding unacceptable costs for customers. METI is adopting a flexible interpretation currently, but to solve the problem, clarifying guidelines should be issued.

Recommendation:

- METI should issue clarifying orders to provide retailers with alternatives for providing Japanese consumers with globally sourced household products while taking full responsibility for the quality and safety of the products.

■ Liquor

Yearly status report: no progress. Since 2001, deregulation has gradually liberalised liquor licensing in the retail sector in Japan. The withdrawal of the interim measure establishing “Urgent Adjustment Areas” in September 2006 was a significant step towards complete liberalisation. The EBC applauds the progress made and asks the Government to apply the same measures to the wholesale market, where the lack of liberalisation is becoming an issue of increasing concern.

Recommendation:

- Wholesale liquor licensing should be deregulated.

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LEGAL SERVICES

Introduction

Foreign lawyers in Japan have provided a valuable service in introducing new corporate and financing techniques to Japan. They play a crucial role in the integration of both economies by providing assistance in interfacing between European and Japanese firms on cross-border investment, in advising financial institutions investing or lending abroad, and in assisting Japanese companies wishing to access the European capital markets. Lawyers are, however, restricted in exercising their profession, as legal qualifications are currently not recognised across jurisdictions and/or their activities are circumscribed by local rules.

Challenges for EU-Japan Economic Integration

The past few years have witnessed a number of positive changes in the regulation of the legal profession in Japan, particularly as a result of the 2005 Foreign Lawyers Law, which lifted some restrictions on the form of association through which Japanese lawyers and foreign lawyers may operate. However, significant regulatory impediments to competition still remain, preventing firms of *bengoshi* and *gaiben* already collaborating together from incorporating their firms; restricting the advice foreign lawyers can give on third-country law; and preventing a foreign firm operating in Japan from benefiting from limited liability status recognised in its home market.

Discriminatory regulations impact individuals as well as firms, requiring foreign employees to gain experience outside Japan before they can be licensed as a *gaiben* in Japan, and restricting Japanese lawyers from giving advice in the name of a foreign employer unless one of the firm's partners is also a Japanese lawyer. So long as these regulatory impediments continue, Japanese consumers will be deprived of choice in the crucial field of legal advice, while foreign firms will be unfairly deprived of potential customers. In addition, the EBC Legal Services Committee has, over the recent past, detected a hardening and less helpful attitude on the part of the authorities towards *gaiben* applications, resulting in undue delay in the approval of applications. The lack of transparency in the method of selection of members of a committee to consider aspects of the law relating to *gaiben*, and the absence of *gaiben* representatives on the committee, serves only to reinforce *gaiben* suspicions in this regard.

Mutual acceptance of legal qualifications, acceptance of vehicles through which lawyers can operate, and acceptance of engagement in a wider scope of activities as permitted by home jurisdiction rules should be included in an EU-Japan Economic Integration Agreement, and would address a number of the concerns set out on the following page.

Key Issues and Recommendations

■ Recognition and approval as foreign lawyer in Japan

Yearly status report: no progress. In order to become registered as a foreign lawyer (*gaiben*) in Japan, three years of professional experience in the foreign lawyer's home law is required, out of which two have to be obtained outside Japan. This rule is in stark contrast to the rules governing Japanese lawyers (*bengoshi*) who are not required to have any post-qualification experience before being recognised. The EBC believes that this practice is not only discriminatory, but also makes little sense as the lawyers are already acknowledged by their jurisdiction of qualification. If there should be such a rule, what is important is the experience in home jurisdiction law, not where it is practiced. The procedure for admitting foreign lawyers as *gaiben* also imposes undue costs on foreign firms and individuals. Currently a foreign lawyer can only apply after he has obtained an alien registration card and leased residential premises in Japan. This means that the application cannot be handled before an inter-company transferee arrives in Japan. It is often several months before the application is approved. The foreign lawyer is in the meantime unable to advise clients, representing an unnecessary business interruption and burdensome costs.

Recommendation:

The rule requiring a specific number of post-qualification years of experience should be abolished. At the very least, experience in home jurisdiction law should be recognised regardless of where it has been practised.

- The rules for registration as *gaiben* should be simplified by allowing firms to be registered, rather than the individual lawyers who are members of the firms. Once a firm has been approved, there should be an accelerated procedure for registering new lawyers coming to Japan. Moreover, at the very least, the application procedure for *gaiben* recognition should be allowed to start before the foreign lawyer resides in Japan.

■ Branches

Yearly status report: no progress. Under the current rules, it is not possible for a *gaiben* law firm, or a joint enterprise between *gaiben* and *bengoshi*, to open more than one office in Japan. Such a possibility is open to *bengoshi*, who may do so through a *bengoshi* corporation or *hojin*: however such a structure is not available to *gaiben*. The EBC does not understand why the restriction on branches is necessary, or, if the addition of branches is to be addressed through a *hojin*, why the *hojin* mechanism is not available to *gaiben*.

Recommendation:

- It should be possible for *gaiben* firms to open branches, and the current discriminatory *bengoshi hojin* restrictions should be removed by allowing *gaiben* firms and joint enterprises to establish *bengoshi hojin*.

■ Limited liability

Yearly status report: no progress. Under current rules, limited liability status is not available to lawyers in Japan. This is consistent with the traditional position of lawyers in Japan, as court lawyers, rather than as handlers of complicated international commercial transactions and conductors of due diligence activities involving potential liabilities in the trillions of yen. In many fields, professionals in Europe and other countries have been able to operate under a regime of limited liability, subject to financial disclosure, particularly with regard to the enormous potential liabilities for firms engaged in the financial markets. In Europe it has been considered unfair to exclude lawyers from the ability to participate in the use of such structures. However in Japan, firms have to operate through individuals and their representatives in Japan are not permitted to have the benefit of limited liability, which exposes all law firms in Japan to an inequitable level of risk.

Recommendation:

- A limited liability structure should be made available in Japan for both foreign and domestic law firms.

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TAX

Introduction

A vital and robust economy is impacted by rules and regulations in the tax regime. The Government of Japan deserves credit for undertaking far-reaching tax reforms in recent years; however further measures are needed to create a tax system compatible with the globalisation of corporations and increased capital mobility. European firms continue to encounter inconsistent and arbitrary treatment from tax authorities and regulations that impede market access and growth. Discrepancies in the interpretation of common tax concepts found in European and Japanese tax laws, a deviation in the progress of tax treaty re-negotiations between Japan and European countries, inconsistent interpretation of OECD-based transfer pricing policies, and a lack of clarity in the rules pertaining to capital gains from cross-border mergers must be addressed.

Challenges for EU-Japan Economic Integration

New concepts of fundamental importance have been introduced to the corporate tax regime in Japan. The most notable of these has been the introduction of tax qualified corporate reorganisations and preferential withholding tax rates on dividends and capital gains (to stimulate the financial markets), both cornerstones of the Koizumi reform policies. Equally important is the system of consolidated taxation introduced in 2001. These reforms and the extension of the tax loss carry-forward period by two years were a crucial part of the economic restructuring process.

The introduction of the *Bunsho Kaito* (written reply system) has somewhat enhanced transparency and accountability, especially after the system was improved in 2004, entitling tax payers to written clarification of specific individual transactions. Another area where progress can be seen is the protection of confidentiality. Press reports on tax audits and about disputes between tax payers and tax authorities are less common now than five years ago. Moreover, information regarding amended corporate tax returns, usually filed in the course of tax audits, is no longer made public.

It is difficult to claim, however, that the Government of Japan has done enough to create a tax environment that is sufficiently supportive of businesses. Tax deferral rules for cross-border mergers through the so-called triangular merger scheme are unnecessarily complex. The “business continuity test” especially imposes an insurmountable burden to market entrants. While the introduction of consolidated taxes was crucial, the qualifying conditions need to be relaxed if the system is to fulfil its potential.

The EU and Japan should, within an Economic Integration Agreement (EIA), eliminate all double taxation, withholding tax on dividends, royalties and interest, such as provided for in the treaties concluded between Japan and the UK, France and the US. An EU-Japan EIA should, furthermore, enable employer’s and employee’s contributions to social security systems within the EU and Japan to be tax deductible on a mutual basis. A bilateral agreement should also establish joint guidelines on interpretation and harmonise documentary requirements between the EU and Japan for transfer pricing assessments.

Key Issues and Recommendations

■ **Accountability and confidentiality**

Yearly status report: progress. Taxpayers may now seek written clarification of specific transactions as a result of changes made to the *Bunsho Kaito* system under the 2008 tax reforms. According to the new guidelines, advance inquiries can be sought for certain types of transactions without the inquirer being obliged to complete the transaction after receiving the ruling. The new rules have also made it possible for the inquirer to request a 180-day delay to publication of the ruling, an improvement from the previous 120-day limit. Despite this improvement, an overall lack of transparency and systematic accountability continues to impede the development of business in Japan. European firms continue to report cases of arbitrary and inconsistent treatment from the tax authorities. The EBC views any "leaking" of information protected by Japanese taxpayer confidentiality laws with extreme concern.

Recommendation:

- The National Tax Agency (NTA) should allow the inquirer seeking an advance ruling to request a substantially longer delay in the publication of the ruling.
- Anti-abuse provisions, giving the tax authority the right to deny advance rulings, should be made more specific to avoid arbitrary denials.
-

■ **M&A and corporate restructuring**

Yearly status report: progress. The tax treatment of triangular mergers, made possible through changes to the Company Law in May 2007, is in practical terms a barrier to market entrants with no established business in Japan if they want to use their shares to acquire a Japanese company. Current rules do not, in principle, allow for a tax deferral if the transaction is carried out using a Japanese special purpose company, although the definition of the latter is subject to debate. If the Government is committed to promoting investment to Japan, non-discriminatory treatment of foreign shares as currency in mergers with Japanese companies is the most important policy step to take. Limitations on the utilisation of tax loss carry-forwards after the acquisition of more than 50% of the shares of a company have been introduced. The EBC recommends that the new rules be applied narrowly and further clarified.

Recommendation:

- Current rules should be revised so as to permit a deferral of capital gains for shareholders receiving shares from a foreign company with no previous operations in Japan under the triangular merger scheme and other reorganisation schemes.
- Rules and regulations underpinning the corporate reorganisation laws should be further clarified to reduce the discretion that the tax authorities retain in defining key concepts. Key terms such as "business continuity test" should be defined precisely to make the rules more transparent.
- Taxpayers should be able to obtain public or private letter rulings on whether or not an intended reorganisation complies with the conditions for a tax-qualified reorganisation.

■ **Consolidated taxation**

Yearly status report: no progress. Current restrictions on tax consolidation limit the consolidated tax system from being fully or actively utilised among corporate taxpayers in Japan.

Recommendation:

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

■ **Transfer pricing**

Yearly status report: limited progress. The Japanese tax authorities continue to base transfer pricing assessments on secret comparables, which makes it difficult for the taxpayer to confirm product and functional similarities. Moreover, the use of secret comparables for audit assessments is inconsistent with the transfer pricing methodology of Advanced Price Agreements (APA), in which company-level profitability of public companies is commonly used as a reference point.

Recommendation:

- Establish joint EU-Japan guidelines on interpretation and harmonise documentary requirements between the EU and Japan for transfer pricing assessment.
- 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. Furthermore, there should be consistency between the transfer pricing methodology for audit assessments and that used for APAs.

■ **Tax treaties**

Yearly status report: some progress. Japan is currently re-negotiating tax treaties with The Netherlands and Germany.

Recommendation:

- The EBC encourages the Government of Japan to review current tax treaties with EU Member States and particularly welcomes treaties that include the exemption of withholding tax on royalties and qualified dividends and interest, such as the revised Japan-UK and Japan-France tax treaties.

■ **Factor-based taxation**

Yearly status report: no progress. Criteria other than profits, such as capital, employee expenses, etc., are part of the Corporate Enterprise Tax applicable to firms with share capital over 100 million yen. Such a tax discourages foreign investment and defies global trends that are moving away from the use of criteria contravening the principle to tax in accordance with the ability to pay.

Recommendation:

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

■ **Financial markets**

Yearly status report: some progress. Japanese investment management companies acting as discretionary advisors to offshore hedge or private equity funds residing in countries that have not concluded any tax treaty with Japan are exposed to the risk of being treated as a permanent establishment in Japan of the offshore fund. Though the 2008 tax reform made clear that independent agents should not be treated as permanent establishments in Japan, laws and regulations do not provide a specific definition of the former. Only a subsequent notification by the Financial Services Agency, coordinated with the National Tax Agency, sets out such conditions.

Recommendation:

- In addition to FSA circulars, tax laws and regulations should provide a definition of who qualifies as an independent agent.

■ **Reduction of corporate tax rates**

Yearly status report: no progress. The effective corporate tax rate for companies based in Tokyo with a share capital of 100 million yen and less is 42% (40.7% where the factor based tax applies, thus imposing an additional 0.48% on salaries, rents, interests, etc and 0.2% on equity). Currently, the introduction of a participation exemption for foreign dividends is being discussed. The EBC would welcome this exemption, which shows clearly that the effective corporate tax rate is too high when compared with international levels.

Recommendation:

- The Government of Japan should reduce the effective tax rate from the current top international bracket to an average international level.

Financial Services

Asset management
Banking
Insurance

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ASSET MANAGEMENT

Introduction

Professional management of pooled assets is becoming increasingly important in Japan, as the financial basis of the social security system steadily weakens. With the birth-rate at its lowest level ever and the post-war baby-boom generation starting to retire, even a sustained economic upturn with a potentially increased tax base would be unlikely to reverse the trend of decreasing revenues. According to the Bank of Japan, Japan's combined household and pension financial assets amounted in March 2008 to approximately 1790 trillion yen - that is nearly three and a half times the country's total GDP. Of this total amount, household assets accounted for 1490 trillion yen, and pension funds for the rest. The proportion of Japan's financial assets managed by investment management firms was relatively low compared to other major economies, at 8.4% of the total (worth 151 trillion yen), while another 12% was managed by life insurance companies (209 trillion yen). The reasons for the relatively low level of penetration by investment management firms are plain. Active asset management in Japan only really took off when pension reforms were introduced in 2004, spurring a rise in the number of investment management firms and new contracts. Since then, assets under discretionary management have more than doubled, with Japanese pension funds accounting for a significant part of this growth. By providing professional advice and innovative services in an increasingly complex market, global professional asset management companies are proving they can contribute to the more effective allocation of resources in the economy at large.

Challenges for EU-Japan Economic Integration

Despite considerable recent growth in the asset management industry in Japan, the Government of Japan continues to unduly restrain the operation of asset management companies. Rules governing the types of securities that asset managers may deal in are much more restrictive than in other jurisdictions. Moreover, the approach to registration remains inconsistent, with a variety of bodies issuing regulations and thereby driving up compliance costs. The creation of a new Financial Instruments and Exchange Law (FIEL) did not result in consolidation of the Investment Trust and the Investment Advisory Service Law, although it relaxed the scope of ancillary business, which asset management companies may conduct and made it easier to obtain a sub-licence after the law was introduced. Obstacles remain to the sales and service of offshore funds, inhibiting firms from taking a proactive approach to marketing the offshore products of their affiliates.

While restrictions on side business licences have in general been relaxed since the introduction of the FIEL in 2007, different firms have received different authorisations, depending on the scope of the application submitted, even though the underlying business objectives do not differ substantially between firms. Although it was supposed to become a comprehensive law for all financial services, the FIEL does not incorporate the Investment Advisory Service Law and the Investment Trust Law.

Currently, financial services companies cannot provide clients with the same trust management and investment advisory services in Japan as they do in Europe, due to strict firewall and severe licence restrictions. The result of such regulatory barriers is inefficiencies in resource allocation in the economy as a whole and less than optimal return on capital. Without a joint framework extending to all financial services, European and Japanese financial services companies will never be able to fully integrate their European and Japan operations and will continuously be restrained from providing the same products on both markets. The EU and Japan should overcome this problem through an Economic Integration Agreement.

Key Issues and Recommendations

■ Creation of a single regulator for asset management

Yearly status report: limited progress. Although the businesses of investment trust management and investment advisory services do not differ in content, these businesses are subject to separate licensing, filing and customer disclosure requirements. The EBC is disappointed that the new Financial Instruments and Exchange Law (FIEL) fails to truly integrate the competing legal frameworks governing the asset management industry. The EBC welcomes the launch of a study on the part of the Japan Investment Trust Association (JITA), and the Japan Securities Investment Advisers Association (JSIAA) on how a merger between the two associations could materialise.

Recommendation:

- The Government of Japan should harmonise its rules and regulations governing the asset management industry. The licensing system should be revised to ensure more consistency and transparency in the application process. Regulations related to licensing, filing and customer disclosure should be put into one regulatory framework under the supervision of the FSA only.

■ Reporting requirements for publicly traded funds

Yearly status report: limited progress. A revision to the Securities Exchange Law in 2006 altered the reporting system for professional investors, requiring them to report within five working days if their own stake in a listed company exceeds 5% of total stock, and every second week with regard to the consolidated holdings of the whole financial group. When applied to asset management companies, this imposes not only a significant new administrative burden, but also necessitates the sharing of customer information with other companies in the same financial group, which is strictly forbidden under the very same law. The EBC believes that discretionary investment advisors and investment trust managers should be treated differently from activist professional investors, and allowed to continue to report their share holdings once every three months and within 15 days when acquiring a more than 5% stake in a listed company.

Recommendation:

- The mandatory reporting by publicly traded funds to disclose holdings of shares in listed companies in excess of 5% every second week on a consolidated basis should be reconsidered. Such a measure would potentially entail violation both of firewall restrictions and of fiduciary duties towards customers, as well as imposing undue administrative burdens on asset management companies.

■ Improve inspection regime

Yearly status report: new issue. Firms under inspection by the FSA are usually allowed very little leeway for discussion and explanation. The regulated entities are generally advised to agree with the conclusions of the inspectors, since failure to agree is deemed by the FSA to demonstrate a "lack of compliance consciousness", warranting harsher sanctions against the regulated entity itself, in addition to the usual guidance to the entity on appropriately punishing any employee responsible for infractions. Implementation of the FIEL will add another inspection layer on top of mandatory internal audits, FSA and conglomerate inspections. Article 78 of the new law is about to be implemented and prescribes that Industry Associations act as "independent regulators", controlling the financial and compliance vigour of members. This provision seems merely to duplicate the burden on the regulated body with no obvious improvement to compliance, as the FSA and Industry Associations are given the same areas of responsibility.

Recommendation:

- Transparency and inspections should be improved by allowing third party lawyers to take part in inspections and give advice on the interpretation of laws, and also by making the findings handed down to one regulated entity generally available to the industry as a whole, by issuing ex parte "interpretive statements".
- Inspections by the FSA and industry associations should be complementary and not repetitive.

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BANKING

Introduction

Japan's relative prosperity has decreased considerably in the past decade, apparent in the steady decline of Japan's GDP per capita ranking, from second highest in the world in 1995 to a ranking of twentieth in 2006. Japanese consumers have continued to save throughout this period, but while the rest of the industrialised world has enjoyed record capital growth, their own return on their capital has been extremely poor. Innovative financial products and instruments commonly used in Europe have not been available in Japan, as the regulatory framework is not conducive to services and structures that do not fit into predetermined categories and prescriptions. This has not gone unnoticed. Reform of the Japanese financial sector has been high on the Government's agenda ever since the burst of the bubble in the early 1990s. The Hashimoto "Big Bang" reforms initiated in 1998, which allowed for the formation of financial holding companies, were followed by consolidation of the banking sector and efforts to clean up bad debts and non-performing loans under the Koizumi cabinet. Multiple financial services regulators were streamlined and a no-action letter process was introduced to enhance transparency, while limited structural reform was achieved by enabling Japanese city banks to engage concurrently in trust and banking businesses.

Challenges for EU- Japan Economic Integration

Although an integrated legal framework supposedly covering all financial products was introduced with the Financial Instrument and Exchange Law in 2007, Japan has persisted in trying to manage risk through firewall regulations. This means the costly separation of banking, securities and asset management operations, long after recourse to such regulations was abandoned in other major financial jurisdictions. The EBC is therefore extremely pleased to see the inclusion of firewall reforms at the core of the FSA plan, issued this year, to revitalise Tokyo as a financial centre. The focus of financial regulators across the world has shifted from simply forbidding companies to engage concurrently in certain types of businesses, to enforcing internal control and corporate governance mechanisms, which ensure that potentially conflicting interests (such as underwriting and brokerage) are kept separate. Provided that the guidelines to be issued later this year do not seek to manage potential conflicts of interest by imposing overly strict constraints on internal structures, this move may considerably narrow the difference between European and Japanese regulatory regimes and make it substantially easier to integrate operations in Japan into the global financial group.

The EBC also welcomes the "better regulation" initiatives taken by the FSA over the past year and hopes that, in the not too distant future, it will be possible for industry participants to work together with regulators in Japan to develop clear codes of conduct and rules of enforcement. With a good regulatory regime and principles in place, the EBC believes that it should be possible for the EU and Japan to mutually accept the home country regulator of a European or Japanese institution as the core regulator for such generic aspects, as capital adequacy and proper governance structure. This would mean that the local regulator would focus on licences and the business carried out in his own jurisdiction. Moving forward, we also believe that when applying for new licences, it should be possible to assess capital adequacy on the basis of the global group. Currently, this is not the case in Japan, where capital adequacy is calculated on the basis of the Japanese entity in isolation, which can prove to be a substantial barrier for newcomers. Finally, working within an Economic Integration Agreement and with a view to making universal banking the norm in both regions, the EBC believes the EU and Japan should embrace the principle that a single branch in the other territory can be granted licences covering Banking, Securities, Trust Banking, Asset Management, and Insurance, without having to establish separate structures.

ABN AMRO Bank	Fortis Bank
Barclays Bank	HSBC
BNP Paribas	ING Bank
BNP Paribas Securities	Intesa Sanpaolo
Calyon Capital Markets Asia	Rabobank Nederland
Commerzbank	RBS
Deutsche Securities	Societe Generale Securities (North Pacific)
Dresdner Bank	Standard Chartered Bank
Dresdner Kleinwort (Japan)	Swedbank

Key Issues and Recommendations

■ Integrated financial services market

Yearly status report: progress. Foreign financial groups are not permitted to be represented by a single country manager in Japan. Each business entity needs to maintain certain separate functions and organisational structures, which could otherwise be shared on a group basis. Such duplication creates inefficiencies and extra costs and makes it very difficult to integrate Japan operations into the global business. The plan to strengthen the competitiveness of the Japanese financial market contains recommendations on relaxing firewall restrictions, but details are not available at the time this report goes to print. The issue of foreign bank branches not being allowed to concurrently engage in trust and banking business remains unresolved.

Recommendation:

- The Government of Japan should abolish Article 33 of the Financial Instruments Exchange Law (FIEL), which prohibits financial firms from operating banking and securities concurrently.
- The Government of Japan should revise Article 1 of the Law concerning Concurrent Management of Trust Business by Financial Institutions to allow branches of foreign banks in Japan to engage in trust and banking businesses concurrently, as is the case for Japanese city banks.

■ Transparency and regulatory efficiency

Yearly status report: progress. Duplicated inspections by the Financial Services Agency (FSA), Securities & Exchange Surveillance Commission (SESC), Tokyo Stock Exchange (TSE), Japan Securities Dealers Association (JSDA), Ministry of Finance (MOF) and Bank of Japan (BOJ) have long imposed an excessive administrative burden on regulated firms. The EBC encourages the Government to further increase efficiency and transparency and applauds the FSA for releasing an annual inspection programme, which clarifies the focus issues for the year, in advance. Despite this improvement, the overly rule-bound regulatory environment in Japan leaves little room for innovation by the regulated entity, without extensive prior consultation with the regulator on precisely how the rules are to be interpreted and applied. Such a prescriptive, yet unclear, regulatory framework cannot keep up with the pace at which financial products and markets are changing. A principle-based system would allow for greater flexibility for firms to decide by themselves what business controls and processes should be put in place to achieve regulatory outcomes decided by the regulator.

Recommendation:

- FSA rules and regulations should be applied consistently and clarified in accordance with fair and current universal guidelines.
- The FSA and other regulators should encourage innovation and competitiveness in the financial services markets by relying on published general principles of good governance and an open-ended dialogue with regulated entities on how to comply with these principles.

■ Provision of core services from global network through Foreign Bank branches

Yearly status report: new issue. A revision of the bank law will make it possible for branches of foreign banks to apply for licences to market and provide key services available within their global networks in Japan. The EBC believes that enabling firms to get official sanction for providing such services in Japan is an important measure to revitalise the financial market, but fears that applying too stringent conditions on applicants or applications may also suppress businesses that are already being undertaken within the current legal framework.

Recommendation:

- The FSA should streamline applications for licences to provide services available within an institution's global network in Japan under the revised banking law and closely coordinate with foreign banks to ensure smooth implementation of the revision.

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INSURANCE

Introduction

The Japanese insurance market is the second largest in the world, and is key to global insurance groups. European insurers bring their expertise to the market and provide proven insurance products to the Japanese consumer to meet their insurance needs. The market share of foreign affiliates in Japan is increasing, but they continue to encounter regulatory obstacles that can limit efficient development of their businesses. An example of this is the rigid reserving and solvency regulations on variable annuity and variable life insurance products. Future growth in Japan will come from the aging of the population, driving a need for products dealing with extended retirement, difference in family structures and rising demand for medical products. With a principles-based regulatory regime, under which the regulator focuses on risk management and allows innovation and flexibility, the insurance market can adapt appropriately to deal with changes in policyholder needs and changing financial conditions.

Challenges to EU-Japan Economic Integration

The EBC welcomes the Financial Services Agency's (FSA) Better Regulations Initiative and the high priority given to improving the regulatory environment. The desire to move towards a principles-based regime to improve responsiveness to a rapidly evolving market is highly commendable. The EBC wishes to see the statements of good intentions translated into a concrete plan with clear timeframes to enable appropriate and timely development of the market to meet changing needs. The move to principles-based regulation must also be accompanied by an enhanced, open-ended dialogue between the insurance industry and the regulator on the practical implication of the principles; if not, the principles risk becoming just another layer of rules.

As regards Japan Post privatisation, we welcome the clear statements from the regulator confirming the consistent implementation of regulations across the private sector and the new companies. The EBC welcomes the use of third company products by Japan Post as a way to expand the product range as this will provide both good distribution opportunities to current players and know-how in terms of risk management and product structure to Japan Post. There is still work to be done, however, on bringing risk management and compliance practices to the standards set in the private sector. The EBC welcomes also the last stage of bancassurance deregulation, but regrets the continuation of unduly restrictive sales controls.

Japanese regulations need to converge with global methodologies in terms of market based solvency (Solvency II) and International Financial Accounting Standards (IFRS) in order to improve risk management, understanding among insurers, provide confidence to the market, and reduce the costs of operating across different territories. Such harmonisation would have a direct positive impact on the ability of European companies to do business in Japan. For the Policyholder Protection Corporation (PPC), a permanent and post-funded scheme needs to be put in place.

Enhancing the regulatory environment for the insurance industry is critical to future development, particularly ensuring a level playing field for all sellers of insurance. Appropriate handling of issues such as the way Japan Post is privatised, bringing Kyosai into the insurance framework, streamlining the product approval process, and clear and consistent application of rules and regulations will prove beneficial for the domestic financial services industry, consumers and Japan's ability to retain foreign investment. An EU-Japan Economic Integration Agreement (EIA) should contain common rules on competition and regulation to ensure transparent, fair and equal rules for all issuers of insurance. Furthermore, it should have common rules for solvency calculations using market-based techniques based on Solvency II, and common rules for improving the transparency and predictability of regulations using a risk-focused approach.

EBC Insurance Committee Member Companies

Allianz	ING Life
AXA Life	Jardine Lloyd Thompson
AXA Non-Life	Manulife
Coface	Marsh
Credit Agricole Life	PCA Life
Deloitte Touche Tohmatsu	Swiss Re
Hartford Life Insurance	Watson Wyatt
HDI-Gerling Industrie	

Key Issues and Recommendations

■ Harmonisation with global standards for Accounting and Solvency Margins

Yearly status report: some progress. The EBC welcomes the update of the Solvency Margin factor and positive statements made by the FSA on establishment over the medium-term of a market-based methodology, consistent with the principles of Solvency II. Alignment with the approach of Solvency II is crucial for European insurers in Japan as it would enable them to use the same methodologies in all territories and better develop group-wide risk management strategies. Such a move will both encourage and reward improved risk management within insurance companies – a goal shared between the regulator and insurers.

Recommendation:

- The Government of Japan should accelerate reforms aiming at attaining convergence between Japanese and global standards by establishing a roadmap for convergence with IFRS and Solvency II.
- The Solvency Margin calculation methodology should be market based, to better reflect underlying risks and changes in product designs, in line with Solvency II.

■ Policyholder Protection Corporation (PPC)

Yearly status report: little progress. The current framework for the PPC expires March 2009, but open discussions with the industry on how to move forward have not yet started. There is a need for a permanent scheme with Government backing, to provide the required level of reinsurance to the public and maintain confidence. A move to a post-funded scheme would be optimal as it would remove the unnecessary burden of providing early funding to the PPC. An already available PPC fund is a potential moral hazard as it reduces the onus to find a market based solution, and raises costs for well-managed healthy insurers. It is also not acceptable that Guaranteed Minimum Benefits are excluded for Variable Annuity (VA) products as this situation results in incomplete coverage for policyholders of these products and an inappropriate burden, since contribution rates are the same, but not all benefits are covered.

Recommendation:

- The Government of Japan should introduce a permanent PPC with the backing of a Government guarantee backing and post-funded contributions. Wider industry discussion is needed before decisions are made on the new setup, building on the expertise and requirements of all PPC members.
- All VA benefits should be covered by the PPC scheme, consistent with other product lines. The contribution methodology for both premiums and reserves should be appropriately differentiated.

■ Product Approval

Yearly status report: no progress. The FSA product approval process is overly lengthy, and FSA availability is limited. This results in product development delays and makes effective planning difficult. Further, approvals, when granted are not flexible enough for the development of new products and features that are sensitive to volatile capital markets.

Recommendation:

- The FSA should increase the efficiency and flexibility of the approval process, enabling faster, more frequent and innovative development sensitive to changing markets. The FSA should allow certain flexibility that can react to changing markets. In the long-term, a “file and use” system should be introduced.

■ Encourage long term savings

Yearly status report: no progress. In Japan there are insufficient incentives to encourage long-term savings.

Recommendation:

- Tax advantageous schemes to encourage savings for retirement or medical needs such as long-term care should be introduced, drawing on successes in other countries.

Transportation & Communications

Airlines
Business aviation
Logistics & freight
Media & communications
Shipping
Telecommunications
Telecommunications equipment

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AIRLINES

Introduction

The global economy depends on networks, be they for telecommunications or transport on the ground or in the air. The services provided by airlines are indispensable for the efficient functioning of the global economy. By the same token, the success of the Japanese economy is to a large extent dependent on well-functioning links between Japan and other countries. European airlines are willing and ready to increase capacity to and from Japan, but currently the infrastructure constraints and regulatory environment do not permit the expansion of services.

Increased security concerns and sky-rocketing fuel costs have severely affected the global airline industry in the past few years, leading to higher costs and a substantial negative impact on route profitability. For European airlines operating in Japan, this situation has been exacerbated by the country's underdeveloped air transport infrastructure and high operating costs.

Challenges for EU-Japan Economic Integration

Japan's restrictions on pricing and distribution have been relaxed for most ticket types in the past two years, but a few IATA categories remain restricted. With pricing largely liberalised, it is high time to also modernise the fare filing system, by enabling carriers to file all fares to the Ministry directly without going through the Official Filing Company, OFC. Japan must, furthermore, face the cost issue squarely. While welcoming the drive to lower costs initiated by the management of the privatised Narita Airport, the EBC urges the Government of Japan to continually work towards reducing charges overall. To date, the scope and pace of change have been disappointing. Airlines have long been required to pay prohibitive landing fees, navigation charges, airport terminal rent, airport terminal common user charges, and cargo handling fees. Heavy political involvement in the air transport sector has resulted in an over-establishment of local airports outside the Kanto area, exacerbating the situation further, since losses at local airports are covered by collective funds drawn from the user fees collected at all airports.

While over-capacity is a problem in local areas, the lack of landing and take-off slots in Tokyo for routes to and from Europe is still an acute issue. It is crucial that the Government of Japan does not introduce new discrimination between carriers, types of operations and destinations when new slots become available at Haneda.

Improved access to the Kanto-market, complete freedom in setting prices, and lower charges would enable European airlines to contribute to the economic development of Japan and support the Government in its ambitious plans to double foreign direct investment by 2011 and to increase the number of visiting foreign tourists to ten million per year by 2010. The EU and Japan should address these issues as an essential part of an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ High costs

Yearly status report: no progress. For Narita Airport, an average net cost reduction effect of approximately 10% was negotiated in 2007, but nothing has happened this year and the cost of air transport in Japan remains the highest in the world. The EBC urges a further decrease and that costs related to security measures at the airports be handled within the balance sheet of the airports and not, as now, levied directly on the airlines. Imposing costs related to security directly on airlines goes against common practice in any other major international market and counteracts the much desired lowering of fees. In the long term, the Government of Japan needs to reduce the costs associated with the provision of air transport in Japan by as much as 50% in order to remain competitive with other hubs in Asia. This has become even more imperative as higher fuel prices have the most severe effects on the profitability of Japan operations, which involve the longest flights for most networks.

Recommendation:

- Prohibitive landing, navigation, and common user and security fees charged by airport authorities in Japan should be substantially reduced and the cost of security measures at airports not levied on airlines.

■ Airport infrastructure

Yearly status report: limited progress. The construction of a fourth runway at Haneda will be finalised by 2010. An expert group under the Council on Economic and Fiscal Policy of the Cabinet Office has recommended the unconditional opening of Haneda for international traffic and the Ministry of Land and Infrastructure (MLIT) has announced its intent to allow regular international night flights after 2010. The MLIT has expressed an intention to allocate some 60,000 new slots to international routes and permit flights from and to non-Asian destinations during the night-time (23.00-06.00). It is practicable to use the allocated time frame for take-off for flights to Europe, but the time difference does not allow landings at commercially reasonable times for inbound flights.

Recommendation:

- Haneda Airport should be opened up to regular international traffic, including flights to/from Europe, on a non-discriminatory basis. Time restrictions, if introduced, should be limited to take-off times and not applied to landing times.

■ Fare filing

Yearly status report: substantial progress. The EBC welcomes the price liberalisation implemented in 2008. Though restrictions on price remain for some IATA price categories (mainly business class), the airlines are now basically free to set and market their own fares. Fares have, however, still to be filed with the MLIT and must go through the official filing company, OFC, which is the only entity that has a licence to conduct such business. This practice makes the filing process unwarrantedly bothersome and expensive.

Recommendation:

- The Government of Japan should introduce free pricing for all ticket categories and abolish the system of using licensed fare filing companies by allowing airlines to file directly to the Ministry.

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BUSINESS AVIATION

Introduction

The business aviation industry is experiencing growth worldwide and forecasts indicate that the demand for business aircraft will continue to rise. With new airline safety and security requirements in place at all international airports, many business people and governments are chartering aircraft or considering buying a corporate jet to increase the efficiency of their respective operations. Nevertheless, there are relatively few business aircraft in Japan considering Japan's position in the global economy. In 2005, close to 1000 flights were registered in Japan, 30% of which came from the USA, 30% from China, 10% from Europe, and the rest from other countries in Asia, while only 38 flights were operated by Japan-registered aircraft.

Challenges for EU-Japan Economic Integration

A range of issues and factors accounts for the slow development of business aviation in Japan. These include restrictive Extended-range Twin-engine Operational Performance Standards (ETOPS) requirements, a lack of suitable airports and infrastructure, difficulties in obtaining slots for landing at Haneda and Narita (Narita has just five slots a day allocated for business aviation), high landing fees and navigation costs, the lack of FBOs (Fixed Base Operators), and a lack of understanding within businesses and the Government about the efficiency gains that can be achieved by using private aviation.

Nevertheless, general interest in business aviation is gradually increasing in Japan. Discussions on deregulation with the Japan Civil Aviation Bureau (JCAB) of the Ministry of Land, Infrastructure and Transportation (MLIT) are ongoing in the areas of operating certificates, continued airworthiness certificates, airport slot allocations, and landing and navigation fees. Although the problems faced by the industry are generally understood, progress is very slow and in some cases the business environment is deteriorating.

The lack of a prosperous business aviation industry puts Japan at a relative disadvantage in relation to other global financial centres. A more prominent business aviation industry would not only generate considerable revenue opportunities within Japan, but also make Japan much more accessible to foreign businesses and governments. Given the nature of the firms using corporate jets, Japan could be losing a major business opportunity every time a decision is made not to fly to Japan because of Japanese flight restrictions. More importantly, the relatively small business aviation industry also translates into a disadvantage for any global business based in Japan. Furthermore, Japanese corporations cannot use private jets for their operations to the same degree as their overseas competitors.

Key Issues and Recommendations

■ Creation of a regulatory framework for business aviation

Yearly status report: limited progress. Japan does not have a regulatory framework specific to business aviation and on-demand charter flights. Instead, rules and standards for scheduled airlines are applied, without consideration of the special nature of the business. The application of complicated and strict rules created for operations involving several hundred passengers to operations requiring high flexibility is excessive and effectively hinders the development of business aviation in Japan. Japanese operational requirements for charter operators follow Federal Aviation Regulations (FAR) Part 121, rather than FAR Part 135, even though the latter standard was developed and is used for chartered and private flights globally. The Japanese situation is unique in that Extended-range Twin-engine Operational Performance Standards (ETOPS) requirements are applied to privately owned jets. This results in Japan-registered airplanes having to make detours while others can fly direct. Such excessive regulations force Japan-based operators to fly their aircraft under foreign registrations.

Recommendation:

- The Government of Japan must acknowledge the lack of services and infrastructure for business aviation in Japan.
- The EBC urges the Government to establish a regulatory regime enabling greater use of business aviation and on-demand charter flights in Japan.

■ Infrastructure for business aviation

Yearly status report: no progress. The requirements of business aviation are different from those of other airlines. VIP clearance, direct access to the aircraft, separate customs and immigration counters, fixed-base operators, and the availability of hangars are just a few of the factors that contribute to the efficiency of business aviation. These requirements are commonly met around the globe, but are not available in Japan.

Recommendation:

- The Government of Japan should establish a committee to assess the need for business aviation infrastructure in Japan and issue recommendations for the next steps.
- The Government of Japan should establish the proper infrastructure to deal with the increased demand for business aviation. VIP treatment for users requiring smooth entry in and out of the country and direct access to aircraft must be improved.
- Foreign investors and companies should be encouraged to participate in the build-up of infrastructure for business aviation in Japan.

■ Maintenance and airworthiness

Yearly status report: limited progress. Certificates of airworthiness need to be renewed every year in Japan, irrespective of the number of hours flown, requiring a plane to be on the ground for about a month every year at high cost. Other countries have established programmes with aircraft manufacturers and are using progressive inspection schedules, which guarantee that the aircraft is always airworthy and not grounded for a “one-month” inspection. Such progressive inspections are tied to hours flown and ensure that aircraft are repaired when necessary. Furthermore, Japanese maintenance requirements are out of line with international practice, exemplified in the type-certified mechanics system. Moreover, replacement parts have to be pre-certified making maintenance very slow, especially overseas, where Japanese certified parts are not accessible. Unnecessarily rigorous and Japan-specific regulations increase costs to such an extent that it makes little economic sense to own a business aircraft in Japan.

Recommendation:

- Regulations covering airworthiness and maintenance requirements should be brought in line with global best practice.
- Foreign maintenance companies should be encouraged to build facilities at Japanese airports.

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LOGISTICS & FREIGHT

Introduction

A well-functioning freight forwarding and logistics services market is crucial for the global integration and competitiveness of Japanese industry. All companies active in Japan, whether foreign or Japanese owned, with customers and/or operations outside of the country, depend on efficient freight services both domestically and across borders. European companies offering Japanese consumers access to their worldwide logistic operations have largely been successful, but still face serious regulatory challenges. Distorted competition caused by a discrepancy in the rules and regulations applied to carriers providing the same services, prohibitive costs, insufficient infrastructure at airports, and restrictions on foreign-owned carriers ultimately result in inefficiencies and higher prices for users.

Challenges for EU-Japan Economic Integration

European carriers and forwarding companies in Japan struggle with high costs and insufficient infrastructure at international airports, rigid custom clearance procedures and outdated restrictions on foreign-owned companies engaging in domestic freight forwarding business in Japan. The newly privatised Japan Post aims to aggressively expand while still enjoying preferential regulatory treatment, thereby posing a serious threat to the functioning of the market and the ability of competitors to provide services to the Japanese public.

Japan Post is already competing with private-sector express carriers with its Express Mail Service (EMS), a special value-added international express package that today accounts for around 18% of the outbound express market. EMS is increasingly popular among businesses, as well as with individual consumers. Japan Post is working hard to improve the quality of service in terms of speed, traceability, reliability and increased weight range. It has further made EMS a key part of its business expansion plans, and focused on its expansion by collaborating with China Post and launching an advertising campaign in leading business newspapers. As EMS is not subject to the same strict regulations that apply to other express services, the expansion is highly questionable from a competition point-of-view.

The Ministry of Internal Affairs and Communications (MIC) defends this regulatory discrepancy by arguing that EMS is part of the basic universal postal service and, hence, should be regulated like regular letter mail. However, this argument disregards the fact that with EMS, Japan Post is directly competing with private-sector operators. Therefore EMS should be removed from the universal postal service, just as Japan Post's domestic parcel service ("Yu-Pack") was removed in 2005.

The privatisation implementation plan submitted by Japan Post has been accepted by the Postal Privatisation Committee to "be in line with the general guidelines" and hence consistent with equal footing requirements. However details of the plan are not publicly disclosed, preventing any opportunity for questions or debate. The Government of Japan should make the complete privatisation plan public and address the issues and concerns raised by the express delivery industry. Common competition rules ensuring the elimination of any regulations that cause discrepancies in treatment between companies and distort free and open competition, and abolishment of any restriction on foreign ownership in freight businesses should be included in an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Customs clearance and declaration

Yearly status report: new issue. Currently the minimum threshold value for import shipments is 10,000 yen. Compared with other major developed countries, there should be room to increase this value; e.g.: in EU Member States the minimum is Euro 150 (from December 2008), in the USA: USD 200, in Australia: USD 750. By increasing the minimum value, the burden on customs offices and brokers will decrease and importers will have the benefit of reduced duty payments. For consumption tax purposes, the threshold can remain at 10,000 yen. Customs declaration procedures should also be improved. Currently, declarations are submitted from a customs clearance operation, which is physically located within the territory of the responsible customs office. However, if for example, the customs declarations for shipments warehoused in Kansai Airport are allowed to be declared from Tokyo, this would increase flexibility and improve capacity planning for operators.

Recommendation:

- The Government of Japan should increase the minimum threshold value for import shipments to at least 20,000 yen.
- The Government of Japan should introduce freedom in terms of the declaration location, independent of the territory of the responsible Customs Office.

■ Level playing field with EMS of Japan Post

Yearly status report: no progress. Currently, EMS packages are subject to customs declaration only on goods exceeding 200,000 yen in value, substantially above the level applied to private sector operators. The Parking Law is in practice not applied to EMS-carrying vehicles, although the National Police Agency has declared that EMS is subject to its provisions. EMS shipments containing-quarantine related goods are not checked by quarantine offices at the airports, in stark contrast to the thorough check performed on packages arriving with private operators.

Recommendation:

- The Government of Japan should announce a time schedule by which the customs threshold for EMS will be lowered and instruct local police offices to apply the Parking Law correctly to EMS vehicles.
- The Government of Japan should change the import process for EMS so that no EMS quarantine shipments can be transported out of international airport facilities without inspections and approvals by MAFF and MHLW.

■ Competition safeguards

Yearly status report: new issue. Accounting procedures related to the co-use of universal service operations processes and assets by any new competitive services of Japan Post are not transparent. Moreover, the approval process for starting any new competitive service by Japan Post is not transparent.

Recommendation:

- The Government of Japan should establish a third party organisation to supervise and assure the arm's length nature of transactions between the universal services and competitive services of Japan Post. The private sector must also be granted an opportunity to voice comments on any new competitive services planned by Japan Post.

■ Ban on foreign operations

Yearly status report: limited progress. The Freight Forwarding Business Law defines “foreigners” and forbids them to engage in domestic air freight forwarding business. From July 2008, foreign freight forwarders have been allowed to contract air freight services through Japanese freight forwarders. This is a welcome step, but the discriminatory practice of not allowing foreign freight forwarding companies to contract air freight services directly still exists in the Law.

Recommendation:

- The Government should revise the Freight Forwarding Business Law so that the definition of “foreigners” is completely removed, thereby creating equal conditions for domestic and foreign freight forwarding companies.

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MEDIA&COMMUNICATIONS

Introduction

The Japanese media market is massive. No country in the world prints more newspapers per day, and few countries have such a high rate of television penetration and viewing. Some 3,600 separate magazine titles publish over 4 billion copies per year, while the advertising market remains the second largest in the world. Although these figures suggest a thoroughly modern industry, it is difficult to maintain that the Japanese media functions similarly to other leading markets in the world. The Japanese media industry continuously places emphasis on traditional face-to-face meetings and harmonious relations, resulting in a rather closed market that is difficult for outsiders to penetrate. After the economic hardship of the past decade, demand for advertising has started to grow again and overall expenditures have increased during the past three years.

Challenges for EU-Japan Economic Integration

The media and advertising industry in Japan remains relatively closed and highly influenced by the Government, public organisations and mega-corporations. Closed and exclusive business practices pervade most sectors of the media industry. In journalism for example, the prevalent *kisha* clubs continue to control a major part of the flow of information from official sources to consumers. Although membership at *kisha* clubs was extended to include properly accredited European journalists in 2002, following criticism from the Delegation of the European Commission to Japan, the nature of these clubs makes them structurally inclined to favour the source rather than the public's right to information. Moreover, the fact that freelance and magazine journalists – including Japanese nationals – are still barred from joining the *kisha* clubs constitutes a de facto restriction on press freedom.

Currently dominated by a handful of firms, the advertising industry employs methods that are not in line with international standards. The cost of media buying, for example, is often not disclosed by agencies to advertisers, a practice that clearly benefits the agency. The largest agencies have a near total monopoly of the market and maintain a status quo by agreeing not to interfere in each other's business. The dominant agency is directly involved in monitoring both print and television, casting further doubt on the impartiality and fairness of the industry. In comparison, the media market in countries such as the UK or France are much more competition-driven. In the case of the UK, auditing of circulation numbers is thorough and provides transparency for advertisers, while in France, legislation makes the disclosure of fees and rewards mandatory. As a result, advertisers are properly protected in both markets.

The Government of Japan has been slow in taking on the issue of media convergence. Piecemeal legislation has delayed the transformation to a consumer-driven media market and prolonged the dominance of the quasi-monopolistic traditional broadcasting firms. Rather than enabling the access of smaller players to the growing content-provision area of the Internet, the status quo has been protected, limiting user access to new content via new technologies. An effective flow of information and a transparent communications structure are of crucial importance to allow for deeper economic integration across borders. European companies and foreign journalists have specifically highlighted the limited flow of information to foreign press, the restrictive *kisha* club system and the lack of transparency and competition in the advertising industry. Recent attempts by new IT companies to buy into or merge with 'old' media organisations have so far failed. As a competitive global economy that aims to attract foreign investment and become an international financial centre, Japan should take measures to promote the free flow of information and foster market competition in the communications sector. Common EU-Japan competition rules should include mandatory pricing disclosure for advertisement positions in the media.

Key Issues and Recommendations

■ Competition and transparency in advertising

Yearly status report: no progress. The advertising market in Japan lacks fair competition. Publishing companies are not required to transfer advertising positions to the paying advertiser and instead sell these positions to middlemen – the advertising agencies – without the knowledge of advertisers. In addition, advertisers are normally not informed about the net prices as this information is often kept between publishers and advertising agencies. This practice leads to monopolisation and a structural bias towards established interests. The industry also lacks reliable and meaningful circulation figures, which puts buyers and newcomers to the industry at a further disadvantage. The Fair Trade Commission has been looking into these problems, but corrective measures have not yet been undertaken in the sector.

Recommendation:

- The Government of Japan should enforce accurate circulation reporting by establishing meaningful benchmarks for auditing. It should also ensure that third party auditing firms are impartial and free from undue influence.
- The Government of Japan should foster an open market among publishers by mandating the disclosure of advertisement positions in the media.

■ Reporting of financial information

Yearly status report: some progress. Financial news regarding listed companies is often leaked in advance to the largest business-daily newspaper ahead of the scheduled release date, placing foreign media (and their readers) at a major disadvantage. This practice seems to be much more widespread among Japanese companies than foreign companies operating in Japan. The Government of Japan has openly claimed an interest in boosting foreign investment, therefore the needs of these investors – and the media who serve them – should be met in a fair and equal manner.

Recommendation:

- The Government should monitor and punish companies that do not control leaks of sensitive financial information ahead of the established reporting time.

■ Kisha Clubs

Yearly status report: no progress. The *kisha* club system still nurtures an environment where public organisations and semi-private companies control the flow of information, to the detriment of fair and unbiased reporting. Loyalty is rewarded by “leaks” of sensitive information, further perpetuating inherent bias in the media.

Recommendation:

- The Government of Japan should continue to monitor the practices of *kisha* clubs and ensure that the needs of the public are met by the *kisha* club system and the way it functions.

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SHIPPING

Introduction

The international supply chain provides the vehicle for globalisation and thus facilitates the development of vast new opportunities for countries, companies and consumers. To maintain its position as one of the largest economies in the world, Japan needs to remain part of this supply chain by offering competitive and efficient port and harbour facilities. Costs associated with the provision of shipping services and port operations in Japan are amongst the highest in the world. Foreign shipping companies account for 70-75% of all containerised traffic in and out of Japan. Amongst them, European companies offer considerable experience in operating in Japan and internationally, including in the global containerisation business. They would be pleased to share their experience and insights in a regular dialogue with the Ministry of Land, Infrastructure and Transport (MLIT), aiming to identify opportunities where mutual efforts could lead to increased productivity and efficiency gains at Japanese ports.

Challenges for EU-Japan Economic Integration

Reforms aimed at improving Japan's overall business infrastructure have not done much to remedy the challenges to shipping services. The Super Core Port initiative, announced by the MLIT in November 2002, has yet to yield tangible improvements to the high cost structure of Japan's ports. The development of Japanese container ports and terminals is being initiated by local authorities rather than by the central Government such that the anticipated economies of scale and efficiencies will remain difficult to achieve.

The Government of Japan has begun promoting local Japanese ports as part of the 'Asia Gateway' programme, striving to enhance shipments between Japan and other Asian countries. Usually smaller sized vessels are employed on these routes and such smaller vessels have more port and terminal alternatives in Japan. These alternatives also create competition and thus terminal costs for the 'Asia Gateway' are much more competitive than costs for major trunk line shipping operators.

Initiatives such as the 'Asia Gateway' could be the first genuine step towards creating competition if it were extended to larger terminals. Offering a wide array of ports for shipping lines to foster competition is critical at this point, because cargo will continue to shift away from direct Japan services to transshipment services through other Asian countries if low cost and efficient alternatives are not provided. Japan risks becoming more dependent on the services and reliability of other countries for the handling of its own exports and imports rather than on direct connections provided by its own ports. Such a situation, if allowed to develop, would significantly undermine Japan's international trading interests and its economy as a whole.

Competition on the Japanese waterfront is stifled by the current system of "prior consultation". Under this system, all changes to shipping line operations that might possibly reduce employment or adversely affect working conditions require prior approval from the Japan Harbour Transportation Association (JHTA), an organisation comprised of all major waterfront businesses except shipping lines. The JHTA reviews applications for changes (from the extremely minor to the potentially significant) and, after consulting with labour unions and other relevant parties, hands down a decision that shipping lines are effectively bound to accept. The system lacks transparency and effectively gives the JHTA and its members the means to inhibit shipping lines from seeking competitive bids for waterfront services.

Key Issues and Recommendations

■ Port costs and development

Yearly status report: limited progress. Port costs in Japan are exceptionally high in comparison to other advanced economies. High costs not only hinder European companies from operating to their maximum potential in Japan, but also drive many Japanese companies to switch production overseas and ship lower volumes through Japanese ports. High port costs also undermine the competitive position of Japanese ports in Asia, for example in the provision of trans-shipping services, since South Korea and China offer far more competitive services. Furthermore foreign shipping lines are still not allowed to trans-ship their own overseas cargo on their own vessels in Japan, thus encouraging them to trans-ship such cargo in other countries, further reducing business at Japanese ports. Whilst this applies to shipments within a European country as well, it is possible for a Japanese carrier to transport cargo within the EU e.g. from Germany to France, which meets geographical and business requirements.

Recommendation:

- The Government of Japan should address the high cost of the port operations structure within the Asia Gateway Strategy Council.

■ Promote competition in port operations

Yearly status report: limited progress. The Japan Harbour Transportation Association (JHTA) still wields enormous discretionary power on the waterfront. Shipping lines wishing to make changes to their operations require prior approval from the JHTA. The process lacks transparency and effectively prevents shipping lines from seeking alternative, competitive services on the waterfront. If shipping lines want to operate a terminal independently, they may apply for a licence. Whilst MLIT has committed to process applications within two months of receipt, requirements such as minimum employment levels will prevent firms from developing true competition for port services in Japan. It is not yet possible for a foreign company to set up its own terminal handling operations in Japan.

Recommendation:

- The Government of Japan should promote competition by establishing a system through which shipping companies could change their operations without seeking prior approval from the JHTA for routine business matters.
- The Government of Japan should allow foreign shipping companies to own their own handling facilities or, at the very least, be allowed to run port operations in a competitive manner.

■ Competitive bidding for stevedore services

Yearly status report: no progress. While changes to the Harbour Transport Law implemented in November 2000 have enabled shipping lines to subcontract with multiple stevedore firms at confidential rates, in reality the concept of independent and systematic competitive bidding has yet to be implemented.

Recommendation:

- Competitive bidding for stevedore services through open tenders should be promoted and regulated.

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TELECOMMUNICATIONS

Introduction

The global economy is increasingly dependent on access to well functioning networks. The fee structure for connectivity is a crucial element for the success of many businesses. Whilst Japan has developed one of the most sophisticated information infrastructures in the world, it remains one of the most regulated telecommunications markets. Operators in Japan can do very little without first consulting and obtaining the formal or informal approval of the regulator.

Challenges for EU-Japan Economic Integration

In 2001, the Diet passed legislation reforming the Telecommunications Business Law (TBL). This introduced the dominant carrier concept and addressed anti-competitive conduct, structural and accounting separation, and the establishment of a dispute resolution commission. In 2002, further revisions were announced, including the elimination of licensing categories based on the ownership of facilities and the elimination of the requirement for carriers to file tariffs. However, while welcoming the reduction in the regulatory burden, the EBC raised concerns that the new laws and their implementing ordinances would not sufficiently regulate the market power enjoyed by the NTT Group of companies and could actually facilitate NTT's leveraging of its dominant position into new business areas. The EBC, therefore, found it necessary to press for the strengthening of competitive safeguards against the abuse of dominance.

Despite the changes in the Japanese market over the past five years, interconnection fees have remained stubbornly high compared to other OECD countries and were the subject of an unprecedented court case brought against the regulator by a group of Japanese and foreign carriers when further fee increases were announced. Benefits of the decision to exclude Non Traffic Sensitive (NTS) costs from the fixed interconnection charge were undermined by the very long phase-out period (five years) granted to NTT and the creation of a Universal Service Fund, which will simply allow NTT to recover NTS costs by another route.

Regulatory supervision and control extends to almost every aspect of business. This restrictive business environment has been a major factor in the decisions of successive European carriers to withdraw from Japan. In order to recreate confidence in the market, the EBC urges the Government of Japan to implement measures that guarantee transparent costs, ensure that charges to competitors are cost-based, and monitor anti-competitive behaviour in relation to the price and non-price terms of supply. EU-Japan common competition rules should include guidelines on funding Universal Services and calculating the connection fee.

Key Issues and Recommendations

■ Strengthening the competitive safeguard

Yearly status report: limited progress. The existing regulatory framework is not sufficiently effective in preventing anti-competitive behaviour by the dominant carrier. In many ways, revisions to the Telecommunications Business Law in 2003 have made the situation even worse. In light of the rapid development in the telecommunications market, i.e. broadband market deployment, transition from PSTN (Public Switched Telephone Networks) to IP (Internet Protocol) networks and diversification of business models, the Ministry of Internal Affairs and Communications (MIC) initiated the New Competition Promotion Program 2010 on 19 September 2006. The main objective of the Program is to set out fair competition rules by the early 2010s in order to further promote competition in telecommunications markets and to secure user benefits. MIC has identified 10 specific measures in the Program and will commence discussions on the restructuring of NTT in 2010 to enhance fair competition in the telecommunications industry in Japan.

Recommendation:

- The MIC should emphasise effective process and procedure to ensure the equality of access to the bottleneck facility, including in many cases the last mile offered by the dominant local access provider, NTT. The Government should ensure that all operators receive services from the dominant provider on the same terms and conditions as those offered by NTT to its retail arm companies. The dominant carrier should be obliged to work with other carriers to also ensure interconnectability on IP networks.

■ Interconnection charge and Universal Service

Yearly status report: limited progress. Interconnection charges remain unreasonably high. A new formula in which all subscribers to telecom services contribute a set monthly amount to establish a Universal Service Fund has been implemented without the dominant carrier being forced to divulge the costs they must bear to maintain the network. In the longer term, the EBC welcomes plans to suspend the universal fund, thereby ultimately freeing NTT from its universal service obligation by establishing a tax-financed scheme providing IP telephony and other voice services also to rural areas.

Recommendation:

- The Government should ensure that interconnection charges and universal service obligations reflect costs, which should be detailed in terms of the cost structure for incumbent carriers. Without details of cost structure, any discussion will be useless. Moreover, to help avoid an unfair cross-subsidy, operators with significant market power should keep transparent, publicly available, separate accounts to identify interconnection activities from other activities.

■ Institutional reform

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

Recommendation:

- An independent, well-resourced and empowered telecommunications regulatory authority should be established with a pro-competitive mandate that measures its success in terms of a market that provides choice and rapid new service innovation as well as reliable and cost effective basic telecom/other services. To be independent, the regulatory organ should report directly to the Diet.

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TELECOM EQUIPMENT

Introduction

Japan is the second largest telecommunications equipment market in the world. Telecommunications equipment accounts for 12.5% of Japan's total industrial output, worth an estimated Euro 108 billion. Structural reforms under the Government of Japan's ICT Strategy have supported the introduction of high-speed, large-capacity ICT infrastructure, lowering of communications rates, and the development of e-commerce and e-government. The Government was largely successful in implementing the national "ICT Strategy" goal of making Japan a leader in ICT by the year 2005. Internet access costs have decreased dramatically and access to broadband infrastructure is now amongst the most developed in the world. Following this success, in 2006, the e-Japan Strategy devised by the ICT Strategic Headquarters set out to improve the hyper-speed network infrastructure, competition policy, e-commerce, and e-government. The agenda also includes a new competition framework under discussion in a special committee on the "Optimum Competition Policies for the Telecommunications Industry to Promote the ICT Revolution". The Government of Japan is also considering strategic measures to further strengthen Japan's competitive edge in the global telecommunications market, in terms of research, development, standardisation and structure of the domestic market.

Challenges for EU-Japan Economic Integration

The EBC appreciates the opportunity to contribute to Ministry of Internal Affairs and Communications' (MIC) policy committees as an official participant and respects the Government's overall commitment to an industry-led, global approach to standards and platform development. Important steps have been taken to facilitate the product approval process firstly, by signing an EU-Japan Mutual Recognition Agreement (MRA) for telecommunications terminal equipment in 2001 and, secondly, by introducing a Supplier's Self Verification of Conformity in 2004. Despite these significant achievements, however, implementation to date has been disappointing. The number of accredited testing bodies designated under the Mutual Recognition Agreement (MRA) remains low and the Self Verification of Conformity still applies only to wired telecommunications terminals, with limited application to wireless/radio equipment.

The EBC urges the Government of Japan to further strengthen international competitiveness, innovation and productivity in the sector. The blanket-licensing system of mobile phone handsets has resulted in an operator-centred market for mobile handsets and restricted competition. This is becoming more obvious as the Government is also considering extending the blanket licensing to units entering the market outside of traditional operator sales channels (e.g. laptops with WiMAX access). The EBC is concerned that a blanket licence would also extend the barrier to market access to handsets operated by an MVNO (Mobile Virtual Network Operator) on an MNO's (Mobile Network Operator) network.

With a view to deepening economic integration between the EU and Japan, duplication of telecommunications equipment product certification for the European and Japanese markets should be eliminated. An Economic Integration Agreement between the EU and Japan should establish true mutual acceptance in which telecommunications equipment products certified for either the European or Japanese markets would automatically be approved in the other. The current framework provides only for recognised certification organisations to test for both markets. Mutual acceptance of technical standards and certifications for all telecommunications equipment would be a natural part of an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Establishing Common Technical Standards and Certification Procedures

Yearly status report: some progress. The EU and Japan maintain different technical standards for the same products, which, although not substantially different in details, imply double testing and certification for manufacturers. The current EU-Japan Mutual Recognition Agreement provides only for recognised certification organisations to test for both markets. The Japanese certification process is also different from Europe's. The EBC welcomed the introduction of Self Verification of Conformity by the Government of Japan at the beginning of 2004, which is similar to the Suppliers' Declaration of Conformity (SDoC) introduced in Europe. However, the EBC is disappointed that this system is limited to wired telecommunications terminals with limited application to wireless/radio equipment, and that the application has not been expanded to other telecommunications equipment.

Recommendation:

- The EU and Japan should mutually accept each other's technical standards and certifications for telecommunications equipment.
- SDoCs issued by European producers should be accepted in Japan without any additional testing or administrative requirements, not only for wired terminals, but also for specified radio equipment.

■ Harmonisation in Spectrum for IMT (IMT-2000 and IMT-Advanced)

Yearly status report: some progress. The International Telecom Union identified spectrum for IMT (IMT-2000 and IMT-Advanced) according to Agenda Item 1.4 of the World Radio Communication Conference in 2007. The EBC acknowledges that the Government of Japan has been active in trying to identify globally harmonised spectrum for IMT systems, which would bring enormous benefits to the industry and consumers by eliminating the need to develop local variations of new telecommunications equipment, while creating economies of scale that would bring down prices on products and facilitate international roaming.

Recommendation:

- The Government of Japan should work jointly with other Governments to achieve a globally harmonised spectrum allocation for IMT systems according to the findings of the World Radio Communication Conference in 2007.

■ Blanket Licensing

Yearly status report: new issue. Mobile handsets theoretically need a radio licence to be used lawfully in Japan. Mobile operators are, however, as an exception, granted a so-called blanket licence, which automatically covers the radio licence for each user within its network. Unlike in Europe, mobile operators also maintain operator-specific technical protocols for services (such as connection to the web), which further strengthen their ties to individual clients. As a result, manufacturers of mobile phone devices cannot sell to consumers directly in Japan, but have to go through mobile operators, which limits competition and prevents manufacturers from introducing their own technical solutions to the market. The EBC is concerned about reports that a similar system is also under consideration for Broadband Wireless Access (BWA), risking the introduction of this competition-distorting system to these products as well. The EBC believes that the best way to foster competition is to abolish the current system and, instead, introduce a self declaration of conformity to regulatory requirements for manufacturers. This would bring benefits through lower research and development expenditures by the operators, and cost savings for manufacturers.

Recommendation:

- The Government of Japan should introduce a Supplier Self Declaration of Conformity regime in line with the EU's R&TTE Directive to enable manufacturers to sell directly to the market, without having to go through operators.

Health Science

Animal health
Medical diagnostics
Medical equipment
Pharmaceuticals
Vaccines

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ANIMAL HEALTH

Introduction

Japan is the second largest market in the world for animal health products, with annual sales of approximately 83 billion yen. While the total market has been stable in recent years, some segments, such as companion animal products, are growing. Due to the high cost of development of animal drugs, most new products are now developed on a worldwide basis by a few global companies. Many new innovative products come from Europe. Even though each product can only be registered after going through a rigorous review process in Europe and the USA, additional testing is required in Japan before approval is granted to bring it to market. In some cases, a product that is readily available to veterinarians and animal owners in Europe cannot be registered in Japan due to the unique local regulatory requirements. Increased harmonisation of regulatory requirements would certainly improve access in Japan to innovative animal health products.

Challenges for EU-Japan Economic Integration

Marketing authorisation of an animal health product is granted by the Ministry of Agriculture, Forestry and Fisheries (MAFF). For an animal health product intended for use in food-producing animals, the Food Safety Commission (FSC) and the Ministry of Health, Labor and Welfare (MHLW) are also involved in establishing the acceptable daily intake and maximum residue limit, respectively. The review process, involving three different authorities, is complex, inefficient and sometimes takes an extremely long time due to lack of proper coordination.

International Cooperation on the Harmonisation of Technical Requirements for Registration of Veterinary Medicinal Products (VICH) in which Japan, Europe and the USA participate, has significantly accelerated the harmonisation process by generating harmonised study guidelines to avoid the repetition of similar studies. However, the VICH guidelines are sometimes interpreted in different ways in different countries. While the VICH is tackling several new topics, it is still far from covering all elements of the registration dossier, and a substantial number of additional new studies have to be conducted in order to meet the unique regulatory requirements of Japan. Since the pharmacopoeia have not yet been fully harmonised, product specifications have to be newly established on the basis of the Japanese Pharmacopoeia. Most specification items for biological products are unique to Japan, including the requirement for a serological potency test of live vaccines, which means that product specifications have to be newly established specifically for this market. For these reasons, stability studies sometimes have to be repeated using the newly established specifications. Some studies, including bioequivalence studies or tissue residue studies, have to be repeated in Japan despite the lack of an obvious scientific rationale.

Although studies conducted under European Good Laboratory Practice or Good Clinical Practice are usually accepted by the Government of Japan for inclusion in the dossier, there is still no mutual recognition of Good Manufacturing Practice (GMP) for veterinary medicinal products. Hence any overseas production facilities that are involved in the manufacture of veterinary medicinal products imported into Japan have to be accredited by MAFF, even though their GMP status is authorised by the European authorities.

Several new steps have been taken by MAFF to improve the administrative process of reviewing the registration dossier. However, there are still many questions raised during the review process that apparently have low relevance to the safety or efficacy of the veterinary medicinal products in question. Much time is spent by the applicant in addressing these questions, thereby delaying the overall process. These factors all contribute to decreased speed, predictability and quality of the registration process in Japan, as reflected in a benchmark survey conducted by the International Federation of Animal Health in 2007. An EU-Japan Economic Integration Agreement should aim for mutual recognition of European and Japanese marketing authorisations for veterinary products, starting with mutual recognition of GMP certification of veterinary medicines. Harmonising regulations on animal vaccines without the use of national assays and ensuring product conformance under a unified GMP regime should also be addressed under such an agreement.

Key Issues and Recommendations

■ Product approvals

Yearly status report: some progress. Products already approved in the EU have to undergo further rigorous controls and tests before being accepted in Japan. Requirements for additional animal testing without an obvious scientific rationale provoke serious animal welfare concerns. The procedure of the so-called “hearing” at MAFF, which had been a major cause of delays, has been significantly improved. However, there are still many questions of low relevance to safety and efficacy of the product that the applicant is required to answer. Sometimes, the review of the dossier at the Committee is delayed due to a lack of proper understanding of the internationally harmonised (VICH) guidelines by the reviewers. Registration of food-animal products can take an extremely long time, despite the standard administrative review process of 12 months set by MAFF, due to the fact that three different regulatory authorities (MAFF, FSC and MHLW) are involved without proper coordination between them. Apparently MAFF is positively considering a reduction in the requirement for translation of English reports, but a concrete proposal or implementation has not yet emerged.

Recommendation:

- The Government of Japan should take all measures available to speed up product approvals and completely harmonise domestic regulations with international standards, including recognition of European certification schemes.
- Requirements for additional animal studies should be minimised where similar studies are already available in other countries.
- MAFF should take the initiative to coordinate with MHLW and FSC to reduce the registration timeline of veterinary medicinal products for food-producing animals.
- MAFF should accept technical reports written in English with only a summary provided in Japanese.

■ Seed-lot system and national assay of vaccines

Yearly status report: progress. The seed-lot system is a system in which successive batches of a product are derived from the same master seed virus. For routine production, a working seed virus may be prepared from the master seed virus. The seed-lot system ensures consistency of vaccine production, thus reducing the need for extensive batch release controls. The EBC commends the MAFF initiative to introduce the seed-lot system and reduce or eliminate the current batch release requirement based on national assays for animal vaccines. However, the EBC is concerned about some additional eligibility requirements for the seed-lot system, such as the unique design of the immunogenicity study, which is not consistent with the requirements for the seed-lot system elsewhere in the world. Requirements for the master seed safety study also go beyond the framework of the VICH guidelines for the reversion-to-virulence study. According to recent requirements of MAFF, an inactivation test with the finished product is required only for imported inactivated vaccines and it is not required for similar domestically produced inactivated vaccines. The inactivation test with the finished product can be technically very difficult to conduct for oil adjuvant vaccines, and limits or delays the availability of useful inactivated vaccine to animal producers. The EBC considers that the inactivation test conducted in-process with the antigen bulk and GMP process validation should be sufficient, as is the case in other countries.

Recommendation:

- The eligibility requirement for the seed-lot system should be aligned with the internationally recognised requirements, and no new unique requirements should be added.
- The requirements for the inactivation test using the finished product for inactivated vaccine should be eliminated.

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MEDICAL DIAGNOSTICS

Introduction

Medical diagnostic reagents and equipment are used to perform diagnostic tests in hospitals, commercial laboratories, physicians' offices and blood banks. Reagents are an essential component of any healthcare regime, indispensable in preventing sickness, detecting and diagnosing diseases, ascertaining the side effects of drug therapy, monitoring treatment, improving patient quality of life and decreasing total healthcare costs. Repeated cuts to reimbursement prices have reduced pricing levels in Japan below those of comparable overseas markets.

The EBC welcomes the national health insurance review in 2008 through which reimbursement of In Vitro Diagnostics (IVD) was improved significantly, and encourages the Government to also address structural issues. The current approach of treating medical diagnostics only as another expense, with a reimbursement price that does not respect the added-value of each product, can, ultimately lead to incorrect diagnoses and unnecessary or inappropriate treatment, and in the end, excessive healthcare. The EBC is encouraged to see that the topic of IVD has now been introduced into the Medical Industrial Vision study in which not only the Ministry of Health, Labour and Welfare (MHLW), but also the Ministry of Economy, Trade and Industry (METI) and the Ministry of Finance (MOF) are participating. The EBC is actively joining in the dialogue and sincerely hopes that the new tone of the debate will bring a shift in focus to areas, such as product approval and reimbursement.

Challenges for EU–Japan Economic Integration

Reimbursement prices for medical diagnostic procedures and facilities were cut by 10% in the previous round of price revisions in April 2006. Reimbursement prices have now been cut by about 50% on a cumulative basis since 1998, with double-digit reductions in 2002, 2004 and 2006, although the revision in 2008 was not quite so drastic, especially for IVD products.

Recent years have witnessed a number of improvements in the regulatory environment for medical diagnostics. Efforts to reduce bureaucratic delays in approving new products were boosted by the revision of the Pharmaceutical Affairs Law in 2005, introducing a third party/self-certification process based on risk classifications. More substantial progress was, however, impeded by the absence of practical guidelines for companies wishing to initiate applications under the new regime, and by the retention of risk classification methodologies and data requirements that are unique to Japan. Meanwhile, biennial revisions of reimbursement prices have led to continuous erosion of prices for medical diagnostics, with little information made public about the formula for price-setting and little heed taken of the relative economic or clinical benefits or the innovative nature of individual products. All together, these factors raise significant concerns not only for European manufacturers, who find Japan an increasingly unattractive market for their products, but also for the country's healthcare system, which in a mistaken short-term attempt to save money, may miss out on the longer-term economic benefits of deploying modern medical diagnostics. The EBC can see no reason why products that have undergone thorough tests in Europe and are certified with CE marking for the European market have to go through additional tests for Japan. Mutual acceptance of standards and certification between the EU and Japan would not only deliver a wider range of products in a more timely way to Japanese consumers, but also provide a significant business opportunity in Europe for Japanese manufacturers. Mutual acceptance of standards and certification for medical diagnostics products should be part of an EU–Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Product approval and smooth introduction

Yearly status report: no progress. New product approval systems have been implemented in accordance with Japan's revised Japan Pharmaceutical Affairs Law. The introduction of a Ministry-approved system, third-party certification and a self-certification system based on risk classifications and strengthened safety measures, is an important step in the right direction, but still falls short of what is needed. In addition to these regulatory aspects, risk classification methodologies and data requirements that are unique to Japan, make the application and review process technically slow and/or redundant. This makes it impossible to initiate application procedures for many products - a situation that should be remedied immediately. A new In-Vitro Diagnostic Directive (IVDD) came into effect in the European Union in June 2000, from which time products bearing the CE marking have been granted free movement within the European Economic Area. IVDD should be considered as a good example of an integrated cross-border standard.

Recommendation:

- The EU and Japan should accept products certified for either market as equivalent to the products certified for their home market and make the product approval process more efficient. Application data requirements unique to Japan should be eliminated.
- With the purpose of speeding up assignment of the reimbursement price, the Government of Japan should establish a new scheme by which manufacturers and relevant third-party organisations jointly evaluate a product after the submission of an application for product approval, but before the formal acceptance notice is received.

■ Reimbursement

Yearly status report: progress. The EBC welcomed the national health insurance review in 2008 through which reimbursement of IVD was improved significantly following a better recognition by the Government of their value. The Government needs also to tackle structural issues within its reimbursement regime for medical diagnostics if it is to create a competitive market of interest to European and Japanese manufacturers alike. The fact that reimbursement prices remain the same for the same type of assay, even when the speed, quality, and contribution to patient care provided by different products are totally different, acts continuously as a disincentive for conducting better IVD tests.

Recommendation:

- The reimbursement price of IVD should better reflect their clinical value, based on differences in quality (accuracy, specificity, laboratory certification), speed (emergency response, urgent test for out-patients), and contribution to comprehensive patient care (infection control, risk management, qualitative indications).
- The Government of Japan should establish a periodic performance assessment system to evaluate the performance of products already on the market.

■ Diagnosis Procedure Combination (DPC)

Yearly status report: no progress. DPC was introduced in selected Special Function Hospitals in 2003. The introduction of this system has led to a reduction in the number of diagnostic tests performed, as hospitals focus on reducing costs and outsourcing procedures. The underlying infrastructure for diagnostic testing is likely to erode if this situation persists.

Recommendation:

- The Government of Japan should establish guidelines in consultation with the medical community to promote the effective use of medical diagnostics, with the aim of improving the quality of care, reducing the risk of misdiagnosis, and reducing total healthcare cost.

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MEDICAL EQUIPMENT

Introduction

Healthcare in Japan is generally of a high standard, as suggested by the country enjoying the highest average life expectancy and lowest infant mortality rates in the world. However, inefficiencies in the system, such as structural over-consumption of certain services and unparalleled long stays in hospital, need to be addressed urgently. The method of financing the healthcare system and demographic changes are leading to lower contributions and higher consumption. Consumers expect higher quality medical services, which will come under increasing strain in the years ahead. Efficient medical equipment should be seen as an investment not only offering the individual patient a substantially higher quality of life, but also offering reductions in total expenditure on medical care over time. However, the current regulatory structure and reimbursement regime constitute an obstacle to introducing such equipment to the Japanese market and deprive Japanese consumers of access to products available in other industrialised countries, including China and South Korea.

Challenges for EU-Japan Economic Integration

The EBC has long called for a reduction in the time and costs associated with introducing innovative new treatments to the Japanese healthcare system. Despite the Government's original intent of using the revision of the Pharmaceutical Affairs Law (PAL) to facilitate procedures and bring Japanese rules in line with global standards, the revised Law resulted in the introduction of longer approval times. A major factor explaining this is the discrepancy between international standards and Japanese guidance related to Good Clinical Practices (GCP) and international Quality Management Systems (QMS).

As a condition of marketing authorisation both in Europe and Japan, satisfactory evidence of the clinical safety and performance of a medical device is required. Information from the Japanese Ministry of Health, Labour and Welfare (MHLW) indicates that, in the case of a large majority (about 70%) of medical devices subject to pre-market authorisation and for which clinical investigation data are required, data gathered outside Japan are accepted as the sole or primary clinical data. However, in those cases where such data are not accepted, significant additional delay and expense are incurred by having to conduct a new clinical investigation in Japan.

One of the more significant reasons for the failure to accept foreign clinical investigation data in Japan is non-compliance with MHLW's GCP requirements. Whereas the international standard ISO14155 is generally accepted in Europe and elsewhere as GCP for medical device clinical investigations, MHLW requires conformity with Japan-specific guidance. There are no scientifically important differences between the two regimes, but several non-substantive differences lead to significant administrative costs and requests for new data. In Europe, manufacturers are obliged to ensure conformity with Quality Management System requirements and International standard ISO13485 is generally applied as the basis for demonstrating conformity with the QMS requirements of European medical device directives. Similarly, in Japan, MHLW has issued medical device QMS guidance substantially based on, and compatible with, ISO13485. The systems are, however, completely separate and manufacturers are therefore plagued with duplicate fees and inspections. In Japan, because marketing authorisation of a medical device is tied to, and dependent on (amongst other conditions) timing of QMS audits by PMDA, this often leads to delays in authorisation and considerable loss for both the manufacturer and patients who may be denied access to current technologies.

An Economic Integration Agreement between the EU and Japan should ensure that products certified in one market be automatically accepted in the other market. Such a measure would lower costs and, in the long-term, eliminate the device-gap between Japan and other industrialised countries as virtually all devices on the world market today are certified according to EN standards. Special focus should be placed on mutual acceptance of certifications for medical equipment by establishing common Good Clinical Practice (GCP) and Quality Management System (QMS) regulations.

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Philips Electronics Japan
Radiometer
Sata
Senko Medical Trading
Siemens-Asahi Medical Technologies
Smith & Nephew Wound Management
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Key Issues and Recommendations

■ Mutual recognition and alignment of GCP and QMS

Yearly status report: no progress One major reason for revising PAL in 2005 was to facilitate the entry of medical equipment onto the Japanese market by aligning domestic rules to international standards, as recommended by the “Global Harmonisation Task Force.” However, GCP and QMS were not implemented in a way consistent with international standards. Japanese GCP guidance applies to clinical investigations of medicinal products, medical devices, and biological products, whereas the ISO standard is specific to medical device trials. This creates slightly different requirements and results in the requirement for foreign manufacturers to adapt the internationally recognised GCP and skip general guidelines that apply to a larger range of medical products. The QMS of the medical device manufacturer is analogous to Good Manufacturing Practices (GMP) for medicinal product manufacturers. In Europe, Japan, and elsewhere, QMS forms the basis for ensuring the quality, safety, and performance of medical devices, from early design stages through marketing and obsolescence. Conformity with QMS requirements is an obligation of the manufacturer under both regulatory systems, but the systems are separate, leading to duplicate inspections and significant delays in market introduction..

Recommendation:

- The Government of Japan should shorten the medical equipment certification process by accepting clinical trial data generated overseas, and by harmonising its GCP guidance with international standards. Moreover, in the meantime, the Government should work towards regarding clinical data generated according to European standards as also sufficient for Japan.
- The Government of Japan should acknowledge that, for the purposes of issuing market authorisations, QMS audits conducted by responsible Notified Bodies in the EU are generally sufficient as evidence of compliance with quality management system requirements.

■ Reimbursement prices

Yearly status report: no progress. The 2006 revision of prices paid out under the reimbursement scheme resulted in price reductions for medical material equivalent to 60 billion yen in total. Reimbursement prices were reduced by more than 25% in the case of more than 34 product categories. The purported reason for this largest ever cut was to correct price differences between Japan and foreign markets, although the merits of directly comparing final price levels are clearly limited. The Government is considering introducing regular price revisions every year and using prices in other Asian markets as points of reference in its blind pursuit of further reductions. In the long run, this will only undermine the interest of foreign manufacturers in the Japanese market. Reimbursement setting is now decided following the safety and review process prescribed within PAL, which exacerbates the “device-lag” between Japan and other industrialised countries.

Recommendation:

- The reimbursement price set by the Government for medical equipment should more accurately reflect the technical sophistication of the product and its associated research and development costs. It should also reflect costs unique to introducing the product to the Japanese market, such as cumbersome certification processes, and maintaining old production lines for equipment used only in Japan because of the time lag. The Government of Japan should allow applications for reimbursement pricing earlier in, rather than at the conclusion of, the safety review process for category C1 and C2 devices.

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PHARMACEUTICALS

Introduction

The pharmaceutical industry in Japan is undergoing structural change following a critical evaluation of the development, review and registration of products as well as the healthcare funding system. The general drive for lowered costs in public health insurance seems to have reached an end with the realisation that cuts over the line cannot ensure sustainable healthcare. Drugs are not simply an expense, but a way of reducing social costs and boosting economic performance as the population is allowed to benefit from improved therapeutic and preventative healthcare. Cost-cutting and innovations to protect people's health should be treated as investments and rewarded accordingly. Revision of the social security system, including that of the healthcare system and the drug pricing system, would be an important step in that direction. Nothing less than a comprehensive overhaul of the current system will suffice to cope with the burden posed by the demographic changes in Japanese society. Appropriate protection of intellectual property rights is also crucial if pharmaceutical companies are to be confident about continuously developing new products for the market. With Japan approaching European protection rules for data, progress is gradually being achieved. Japan is also addressing the development of new drugs and the long lead times for introducing new drugs to the Japanese public. Faced with the need for improvement in the clinical trial environment, the Government seems to have realised that Japan can no longer afford to refrain from participating in international cooperation on drug development and has announced its intention to improve the environment for clinical trials and begun to take action. EFPIA takes an active part in the dialogue on improving the clinical trial environment and hopes that good intentions will be translated into real policy change. The Government of Japan has also decided to boost the review and regulatory capacity of the Pharmaceuticals and Medical Devices Agency (PMDA) with the goal of eliminating the drug-lag between Japan and other advanced countries by increasing the user fee.

Challenges for EU-Japan Economic Integration

The global pharmaceutical industry has consolidated and put most of its efforts into developing drugs on a global scale and many pharmaceutical companies in Japan have also recognised the benefits of global simultaneous drug development. Japan's Good Clinical Practice (GCP) rules, which were different in many respects from the global standard, have begun finally to move toward concrete revision. No movement has, however, been seen on the expansion of the EU-Japan Good Manufacturing Practice (GMP) mutual recognition agreement (MRA) which is still limited to oral solid preparations, which leads to duplicate inspections of manufacturing facilities for all other products and, hence, potentially longer introduction times and a resource burden on the industry. By developing common rules, the EU and Japan could boost cooperation in the development of drugs, cut introduction costs, and thereby substantially improve the competitive strength of their domestic industries.

The PMDA has been struggling with capacity problems since its inception in 2004. EFPIA welcomes new plans to expand capacity, but invites the Government of Japan to consider taking advantage of the data and evaluations already undertaken by the European Medicines Agency (EMA) for drugs circulated on the European markets. Many of the EU guidelines for pharmaceutical development would be useful for pharmaceutical development in Japan. Expanded reference to EU guidelines and increased use of overseas data will substantially cut costs, reduce introduction times and eliminate the drug-lag between the economies, to the benefit of everybody - patients, society and the industry. Finally, the EU and Japan should also work together to ensure that registration data and brand names are protected with a view to stimulating further innovation. Japan must create an environment in which innovation can thrive. Innovation leads to a better quality of life for patients, decreased social costs, and a strong industry. Working with Europe would be a very cost-efficient way to achieve all of these objectives. An Economic Integration Agreement between the EU and Japan should contain expansion of the scope of the mutual recognition agreement to the quality and non-clinical areas of pharmaceuticals, guidelines for pharmaceutical development and data protection, and rules for brand names for new drugs

Key Issues and Recommendations

■ Pharmaceutical pricing reform

Yearly status report: some progress. The 2008 revision of pricing rules followed the revisions of 2006 and further improved the premium rate for innovative or high value new drugs and relaxed the requirements for usefulness price premiums. However, discussions on relaxing varieties of scientific data or other evidence to be used for price premium claims for new products as a whole have been inconclusive. Under the current NHI drug price system, the re-imburement price of innovative drugs continues to decrease, including the products still protected by intellectual property rights. Therefore, EFPIA maintains that rather than partial revision, the system needs comprehensive reform so as to ensure genuine reward of innovation. Japan needs a new NHI drug pricing system that takes into account the need to properly value each drug, reward innovation and respect intellectual property.

Recommendation:

- The Government of Japan should fundamentally revise the NHI drug price system so that it rewards innovation and more properly reflects the value of drugs.

■ Improved environment for clinical studies

Yearly status report: limited progress. Following calls for alignment of Japanese GCP with international GCP as defined by ICH, the Government of Japan has revised GCP rules related to IRBs and reduced the number of essential GCP documents required. EFPIA welcomes this move, but it remains to be seen if these revisions will improve the efficiency of clinical trials, as dissimilarities between Japanese and international standards remain.

Recommendation:

- The Government of Japan should promote the environment for clinical studies by continuing the endeavour to align Japanese GCP with ICH-GCP.

■ Introduction of new products to the market

Yearly status report: limited progress. PMDA has increased the number of reviewers in an effort to solve the drug-lag issue in accordance with the mid-term plan issued by the MHLW, supported by increased user fees. This has, however, not yet resulted in any substantial reduction of the review times. EFPIA welcomes the introduction of an improved system for clinical trial consultation and believes that the PMDA should improve its capability further to allow also for meaningful consultations on strategy in the development phase of complicated products. The EU-Japan mutual recognition agreement on Good Manufacturing Practices (GMP) is still limited, leading to potential delays caused by duplicated inspection of all non-solid products.

Recommendation:

- With the objective of streamlining future applications, the Government of Japan should introduce a new system in which, following the approval of a new drug, the reviewer and the applicant, together with a third party, assess the appropriateness of the review process.
- The EU-Japan mutual recognition agreement on GMP should be expanded to cover non-solid products.

■ Intellectual property protection

Yearly status report: limited progress. MHLW issued a notification in April 2007 to extend the re-examination period for new drugs from six to eight years. The welcome change is in line with EFPIA's request that the data protection period for new drugs be eight years, but regrettably, the notification only applies to drugs containing a new chemical entity. EFPIA is also concerned with the restriction imposed on the selection of brand names. Global companies have invested heavily in brand names and their management strategy will be severely affected if their brand names are not acknowledged in Japan as well.

Recommendation:

- EFPIA requests that new combination drugs, drugs with a new indication, and drugs with a new administration route also be eligible for an eight-year extension.
- To secure intellectual property protection and prevent medication errors, the Government of Japan should take measures to ensure that globally used brand names of drugs are recognised.

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VACCINE

Introduction

The Japanese vaccine market, amounting to Euro 570 million, represents only 5% of the global vaccine market while, in contrast, Japan accounts for 10% of the worldwide market in pharmaceuticals. To date, the Japanese vaccine market has been dominated by domestic products, representing more than 98% of the market, while cutting-edge vaccines readily available in other developed countries are not available here. The fact is that, over a period of many years, Japan has been falling behind other markets both continuously and with increasing speed. Vaccines widely available in the EU and US, such as MMR (Measles-Mumps-Rubella), Rotavirus, Human Papilloma Virus, IPV (Inactivated Polio Vaccines), DTPa (Diphtheria-Tetanus-Pertussis), combination vaccines that reduce the number of injections and increase compliance, pneumococcal 7v, overseas travellers' vaccines and others, are still not available to Japanese risk group populations. This is happening at a time when fiscal restraints caused by an ageing population and a declining birth rate are putting the whole Japanese healthcare system under pressure. Under such circumstances, the role of preventive medical care is increasingly important, as it can substantially reduce medical costs and offers the Japanese population the benefits of a life free from preventable diseases thanks to vaccines. Clearly, vaccines can play a greater role in Japan's future preventive medical care.

Challenges for EU-Japan Economic Integration

No new vaccine has been introduced in Japan over the last ten years and only a very few new candidate vaccines, mainly originating from foreign companies, are under development and close to reaching the market. The level of Japan's new vaccine development, compared to the rest of the world, is quite limited. This exceptional situation may result from historical factors such as Japan's domestic-led vaccine supply policies, but the lack of clinical guidelines and recognition of overseas product specifications for biologicals also make vaccine development in Japan difficult and lengthy.

From a public health perspective, the vaccine gap between Japan and other developed economies, such as the EU, poses a high risk of outbreaks of disease that could be prevented by new vaccines commonly used and readily available overseas.

Recent outbreaks of measles in Japan have made the public aware of the need for modern vaccines and supportive vaccine policies and the Government has started to reformulate its policies. The EBC has seen a few signs of changes in vaccine policy, though this shift is not yet discernible in terms of tangible measures. The "Vaccine Industry Vision" paper published by the Ministry of Health, Labour and Welfare (MHLW) in 2007 provided some direction and an opportunity for dialogue between the Ministry, the medical community and the vaccine industry.

The EBC encourages the Government of Japan to pursue this effort to engage in dialogue and undertake the reforms needed to encourage local and international vaccine industries to invest in developing and manufacturing innovative vaccines that will contribute to improved preventive healthcare for the Japanese population. Japan lacks clinical development guidelines and could make good use of examples established by the European Medicines Agency (EMA). Products accepted in the European Union should also be available in Japan. Harmonisation of clinical development guidelines and biological product specifications should be included within an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Vaccine Gap

Yearly status report: some progress. Japanese citizens are exposed to preventable infectious diseases to an unacceptable degree, considering the large number of vaccines commonly used and readily available overseas, but still not available in Japan. Although Japan is the second largest economy in the world, the number of vaccine products available to Japanese patients is considerably lower than in Europe and the US. This phenomenon, called the Vaccine Gap, has a detrimental effect on public health both in Japan and overseas, resulting in less efficient preventive healthcare and increased indirect costs of treating preventable infections.

Recommendation:

- The Government of Japan should close the Vaccine Gap between Japan and the rest of the developed world by making global standard vaccines available in Japan.

■ Harmonisation of clinical development guidelines and biological product specifications with the EU

Yearly status report: progress. The lack of clear clinical and regulatory guidelines for vaccines, in combination with unique Japanese specifications included in the MRBP (Minimum Requirements for Biological Products), is obstructing the development of a sound and competitive vaccine industry in Japan. The discrepancy in the regulatory approach adopted by Japan versus that of the EU results in considerably lower protection of the Japanese population from the threat of infectious diseases for which existing vaccines overseas offer solutions. The EBC welcomes recent initiatives from the Ministry of Health, Labour and Welfare (MHLW) in creating Working Groups for the establishment of pre-clinical, clinical and adjuvant guidelines for vaccines.

Recommendation:

- The EU and Japan should urgently work together on aligning vaccine standards and technical specifications through an expert group with a clear mandate and fixed timelines and milestones.
- For guidelines on the clinical development of vaccines, best practice examples should be found using reference agencies such as the European Medicines Agency (EMA), in order to give clear direction on licensure requirements to vaccine manufacturers as early as possible before the initiation of vaccine development and associated investment. To speed up clinical development, the Government of Japan should encourage the recognition of foreign clinical data and thus avoid unnecessarily repeating clinical studies.

■ Public funding for new vaccines

Yearly status report: no progress. As vaccines are not covered by the National Health Insurance System in Japan, there is a risk that new vaccines currently under development will not reach the people with the highest need. Only 40% of vaccines available in Japan are publicly funded. The funds are, moreover, not provided by central Government but by local authorities, inevitably resulting in regional disparities and insufficient immunisation coverage in regions under financial stress. The National Health Insurance System is well established as the standard healthcare funding system for pharmaceuticals and is accepted by the Japanese population, the pharmaceutical industry and the medical profession. It delivers healthcare on an equal basis, regardless of social disparities, and is not subject to the variability of local authority finances as is currently the case for vaccines.

Recommendation:

- Vaccines should be incorporated into the National Healthcare Insurance System, which offers a better and more consistent approach than the current local funding model for vaccines.

Consumer Goods

Cosmetics
Cut flowers
Liquor
Organic products
Food

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COSMETICS

Introduction

Japan is the second largest market for cosmetics in the world, worth about 1.5 trillion yen in 2007, which was the second highest level in its history. The total amount of imported cosmetics reached 178.5 billion yen, which was an increase of 7.9% from the previous year. European firms have a large market share of the imports, but continue to face substantial market access barriers, such as an overly restrictive regulatory environment, an overly complex product approval system and complicated manufacturing requirements?. Aligning Japanese regulations with the rules of the EU would substantially improve market access and unlock significant potential in the market.

Challenges for EU-Japan Economic Integration

The Japanese cosmetic industry differentiates between cosmetics and quasi-drugs, in contrast to the European system. This results in products that are classified as cosmetics in Europe being classified as quasi-drugs in Japan. The inherent lack of clarity of the Japanese quasi-drug system makes it difficult for newcomers from the EU to launch new products in Japan. The EU and Japan also maintain different rules governing what ingredients are allowed in cosmetics, through negative and positive lists, a problem that has yet to be addressed. The EBC believes that the Government of Japan should carefully consider the current situation and proactively pursue the harmonisation of standards.

Building upon best global practices and with an emphasis on the safety of post-marketing control, the revision of the Pharmaceutical Affairs Law (PAL) resulted in the adoption of Good Vigilance Practice (GVP) and Good Quality Practice (GQP) as requirements for post-marketing control. Despite the introduction of these mandatory post-marketing control schemes for quasi-drugs, the resource-draining, pre-marketing product approval system remains unaltered.

Guidelines for the evaluation of cosmetics functions have been established. Based on these guidelines, requests for new efficacy claims “to make wrinkles due to dryness less noticeable”, and “to prevent photo-aging caused by exposure to UV” have been made to the Ministry of Health, Labour and Welfare (MHLW), which is a positive step as the old system of 55 pre-defined efficacy claims desperately needed renewal after remaining unchanged for 47 years. It is discouraging, however, that an expansion of efficacy claims was not included in the advertising guidelines recently supervised by MHLW and local governments.

The International Cooperation on Cosmetics Regulations (ICCR), consisting of the Japan Cosmetics Industry Association (JCIA), the US Personal Care Products Council (PCPC), The European Cosmetics Association (COLIPA), and Canada Cosmetics Industry Association, has decided to work for global harmonisation of good manufacturing practices (GMP), ingredient labelling/INCI, nano-technology definitions, market monitoring, approved materials and alternatives to animal testing. The EBC hopes that the ICCR can make progress on all these issues. The EBC also expects in the meantime, the EU and Japan to show leadership by bilaterally negotiating regulations for quasi-drugs (disclosure of usable ingredients with precedent of use, creation of approval standards, shortening of standard application times) and expansion of efficacy claims. Harmonisation of the positive and negative lists between Japan and the EU should, furthermore, be a part of an EU-Japan Economic Integration Agreement.

Key issues and recommendations

■ Reform of quasi-drugs approval system

Yearly status report: no progress. While there is only one product category for cosmetics in the EU, the very same products are classified as either cosmetics or quasi-drugs in Japan. Standard application times for quasi-drug product approvals have not been shortened over the last 20 years, while disclosure of what are approved ingredients for quasi-drugs remains unsatisfactory.

Recommendation

- The approval system for quasi-drugs should be revised urgently in order to clarify the process and shorten standard application times for quasi-drugs.

■ Efficacy claims

Yearly status report: Some progress. Allowable efficacy claims for cosmetics have not been expanded since 1961, although they have been administered under a unified system since 2000 and not as previously under different product categories. The narrow scope of pre-defined efficacy claims makes it impossible to differentiate between products. This stands in stark contrast to the progress of research and technology, which has enabled the industry to put advanced products on the market and heightened consumer expectations. The Japan Cosmetics Science Society (JCSS), in an effort to respond to these expectations, has recently released reports on “Guidelines for Evaluation of Anti-Wrinkle Products for New Efficacy Claims”, “Guidelines for Evaluation of Quasi-Drug Whitening Products for New Efficacy Claims”, “Guidelines for New Efficacy Claims of Sunscreen Products” and “Guidelines for Evaluation of Safety of Functional Cosmetics”. Following these reports the Japan Cosmetics Industry Association (JCIA) is currently requesting the MHLW to approve two new efficacy claims; “to make wrinkles due to dryness less noticeable” and “to prevent photo-aging caused by exposure to UV”.

Recommendation:

- The current 55 efficacy claims should be expanded. In particular, the two claims proposed by JCIA following reports by the JCSS, should be given priority.

■ Ingredients

Yearly status report: no progress. The difference between Japan and the EU in their respective maintenance of positive and negative lists of ingredients remains unaddressed. Furthermore, the lack of transparency in the Japanese approach makes it extremely troublesome to know beforehand which ingredients can be used in cosmetics - while the rule is that medical ingredients can not be used in cosmetics, there is no effective mechanism for determining which ingredients fall into that category.

Recommendation:

- The EU and Japan should work towards the harmonisation of regulations on ingredients.

■ Establishing alternatives to animal testing

Yearly status report: no progress. Following the EU Cosmetics Directive that will severely restrict animal testing from 2009, the global cosmetics industry is presently working towards developing and validating alternative methods. The EBC appreciates the general positive stance to alternative testing expressed by the MHLW in July 2006, but maintains that an application using animal testing alternatives is practically impossible unless the Ministry also validates specific alternative methods.

Recommendation:

- An evaluation system for alternatives to animal testing in line with the JaCVAM should be urgently established and animal protection environments should be established based on the 3R concept.
- Following implementation of the 7th revision of the EU Cosmetics Directive, the Government of Japan must establish a system for accepting ingredients and products developed under an animal test ban regime.

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CUT FLOWERS

Introduction

Alongside Europe and the United States, Japan is one of the leading consumers of flowers, yet domestic growers control an exceptionally high market share of nearly 90%; in most other industrialised countries, over 85% of flowers consumed are imported. The current situation in Japan is unsustainable: imports are bound to increase as a result of natural market forces and domestic demographics. The ageing profile of Japanese growers, the small scale of the average nursery, in combination with the high cost of operating in Japan amidst rising fuel prices, make it extremely difficult for Japanese growers to compete on a global scale. While maintaining product safety remains important, it is also in Japan's interests to make sure that Japanese consumers can enjoy quality imported flowers. Unfortunately, excessively strict plant quarantine regulations, a lack of cargo handling capacity at Narita Airport and a lack of competition between fumigation companies make the importing of perishable goods costly, risky and difficult. Swift and decisive Government action is needed to ensure a fair and efficient market with lower prices and a wider selection of high-quality flowers available to Japanese consumers. The need for vastly improved airport cooling facilities for perishable products could not be more imperative, given the increased attention to both food safety and global warming.

Challenges for EU-Japan Economic Integration

Foreign companies interested in importing cut flowers into Japan have seen very slow improvement in the business. The Government of Japan has gradually addressed some of the barriers to trade in cut flowers: airport procedures have been slightly improved through extended inspection schedules, inspection fees have been reduced, the number of plant quarantine inspectors has increased, and the number of insects regarded as non-quarantine pests has also risen. Nevertheless, the lack of adequate temperature-controlled warehouse facilities and insufficient fumigation capacity remain recurring problems. Moreover, restrictive Japanese plant quarantine regulations still constitute the largest barrier to trade in cut flowers. The list of non-quarantine organisms was expanded in 2005, but many non-harmful organisms that are widespread in Japan still require fumigation if found in shipments from overseas, even though, under the Sanitary and Phytosanitary chapter of the GATT Uruguay Round Agreement, zero-tolerance should be applied only to organisms that are considered harmful. In 1996, a risk assessment chapter was added to Japan's plant quarantine law, but this revision has not had any beneficial effect on cut flower imports, as Japan's zero tolerance policy does not make a practical distinction between harmful and non-harmful organisms.

It still takes too long for shipments to be made available for inspection and customs procedures after arrival, and for the shipment to be distributed after clearance. Due to several changes in the plant quarantine process, the time to clear customs has become even longer, as inspectors must go on foot or by bicycle to the cargo, and the clearing agents or the importers themselves have to fill out papers that were handled previously by the fumigation companies.

The EBC advocates that a system of ad random inspection replaces the current re-inspection of pre-inspected flowers at ports of entry. This has been a long-standing request, but no action has yet been taken. It is in the best interests of Japanese consumers that the Government of Japan proactively sets up the proper infrastructure to facilitate the import of quality flowers by increasing the capacity of Plant Quarantine Inspection Offices; increasing the cooling facilities to ensure faster and better handling of products at ports of entry; and further updating the list of non-quarantine pests. A flower that has been stored in cool conditions and not been fumigated is a better product. Joint plant quarantine standards and competition rules should be included in an EU-Japan Economic Integration Agreement. Competition rules should include a provision on unfair pricing by firms.

Key Issues and Recommendations

■ Plant quarantine regulations

Yearly status report: some progress. In March 2006, the non-quarantine list was expanded to include thrips and from September 4, 2008, five more insects were added to the list. The EBC welcomes the expansion of the list and urges the plant quarantine office to also boost its capacity to identify these insects. Currently, the office is only able to identify adult insects and in the case of mites, only males. Adding new techniques to identify insects, for instance through DNA testing, would reduce the number of unwarranted fumigations.

Recommendation:

- The Government of Japan should further expand the list of non-quarantine organisms to include all non-harmful organisms found in cut flowers until plant quarantine regulations are in line with the GATT's Sanitary and Phytosanitary chapter.
- The Government of Japan should focus on the main insect pests (mites, aphids and thrips) and accelerate the process for abolishing the zero tolerance regime for insects common in Japan. The Government of Japan should also introduce alternative methods for identifying insects.

■ Capacity problems at Narita

Yearly status report: no progress The surge in imports of perishables has not been met by an equal increase in the capacity of the cooling facilities at Narita Airport. Cooling facilities are essential for the importation of not only cut flowers, but also all edible perishables. The specialized cooling space in the JAL warehouse and International Air Cargo Terminal A (IACT-A) are both limited and importers are often denied access to these facilities as they are full, while International Air Cargo Terminal B has such facilities at all. This is unacceptable as the average temperature during the daytime exceeds 20 degrees for around seven months of the year.

Recommendation:

- Bonded warehouses and dispatch areas at Narita urgently require improvement by expanding the cooling facilities capacity. The semi-transparent area of IACT-A, which admits heat and light, should be insulated and the capacity in the "Carrying Out" area boosted at peak-times by maximising the number of boxes per pallet when cargo is transported in the area.

■ Fumigation costs

Yearly status report: no progress Prices have not been reduced and remain approximately five times higher than at airports in countries with similar quarantine restrictions, such as New Zealand. Furthermore, previously it was the fumigation companies who filled in the technical application details, whereas now it is the importers themselves who must complete this task. This increased administrative burden also represents an additional administrative burden with higher cost implications.

Recommendation:

- The EBC encourages further competition in the provision of fumigation services to help reduce fumigation costs at Japanese airports, and a return to the swifter process in which the fumigation companies fill in the technical data on the application for fumigation.

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LIQUOR

Introduction

Europe is the leading exporter of liquor and wine worldwide. The Japanese liquor market is one of the largest in the world with estimated annual liquor sales of 6 trillion yen and growing wine consumption. Despite such figures, in terms of volume, foreign imports account for only 3.7% of the total Japanese liquor market (including beer and beer-like products) while Japanese producers account for almost 96.3%. The Government of Japan has implemented a notable reduction in taxes. However, Japan lags behind the rest of the world in the application of international standards for product definition and in elimination of non-tariff barriers to market access.

Challenges for EU-Japan Economic Integration

In recent years, market conditions for the sale of European liquor in Japan have been substantially improved through a series of reforms and deregulation. In compliance with World Trade Organisation (WTO) rulings, the Government of Japan reduced the gap in liquor tax rates between domestically produced distilled liquor or *shochu* and imported liquors. By 2002, Japan had eliminated tariffs on whisky, brandy, vodka, rum, liqueurs and gin. This progress was followed in 2003 with an attempt to deregulate retail channels by eliminating requirements for minimum distances between retail licensees. The deregulation was temporarily undermined by the designation of large numbers of “Urgent Adjustment Areas” to which it did not apply. Fortunately, by September 2006, such exceptional measures had been discontinued and the deregulation of retail channels was uniformly applied. In 2006, the Ministry of Finance launched a programme aimed at long-term reform of the liquor tax regime that entails streamlining tax categories and adjusting tax rates.

The goals of the reform programme are positive, but certain provisions, including the current system of product categorisation do not comply with WTO rulings and international standards. The Ministry of Finance has made clear its long-term goal of putting wine and Japanese *sake* in the same category, ignoring fundamental differences between the two products. The EBC is concerned that this would be in contradiction of the 1998 WTO ruling, which prescribes that the level of substitutability in terms of production and consumption should be the overriding determinant when setting tax categories for alcoholic beverages. In contrast, the EU, US and Australia have implemented the WTO ruling so that spirits, beer, wines and intermediate products are placed in separate general categories complemented by specific categories for country-typical products. The lack of accurate product definitions and categorisation for taxing purposes in Japan indirectly protects domestic producers and in the long term, will limit competition from European businesses. The EU and Japan should eliminate tariffs on alcoholic beverages and adopt definitions and categories for liquor within an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Product definition

Yearly status report: no progress. Product definitions for alcoholic beverages in Japan are broad and do not comply with internationally accepted product specifications that are based on production methods and geographical indications. Many brands of Japanese liquor marketed under the name of "whisky" and "liqueur" would not qualify as such in Europe. Domestic products like *shochu* and *sake* are not subject to the same rate of liquor tax as authentic whisky, liqueur and cognac imported from Europe. This provides domestic producers with a competitive advantage in terms of lower costs. Such inaccurate use of definitions also misleads Japanese consumers and undermines the perceived quality and brand integrity of the genuine European liquor.

Recommendation:

- Product definitions for alcoholic beverages 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.

■ Licensing

Yearly status report: progress. In 2006, licensing requirements for retail channels such as minimum distance and population quotas were abolished. However licence applications for wholesale and retail continue to be complex and are not processed in a clear, transparent and consistent manner.

Recommendation:

- The EBC endorses deregulation of liquor retailing in Japan and requests the Government to further simplify the liquor licensing process for both retail and wholesale channels.

■ Liquor tax

Yearly status report: no progress. The current liquor tax regime is complex, with ten different tax rates applied to beers, wines and spirits. The Ministry of Finance has announced its intention to apply the tax rate on *sake* to wine, a change that may increase the current tax from 80 yen to 120 yen per litre.

Recommendation:

- Categorisation of alcoholic beverages for tax purposes should use the same categories as in the EU and the US, which distinguish between spirits, beer, wines and intermediate products.

■ Tariffs

Yearly status report: no progress. The Government of Japan has drastically reduced the tax rate on non-*shochu* liquor over the past five years in compliance with a WTO ruling issued in 1996. However, certain tariffs are still applied to sparkling wine, still wine, sherry, port and fortified wine.

Recommendation:

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

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ORGANIC PRODUCTS

Introduction

The market for organic products is growing rapidly around the world. There is a proliferation of product concepts that relate to ecology, social responsibility and wellness. The Organic Products Committee covers all products/concepts within this sphere, including fair trade and rainforest alliance. There is a growing understanding that, in carrying out economic activities, we need to consider the welfare of the planet as well as its inhabitants.

Organic agriculture is based on the absence of use of artificial and chemical pesticides and fertilisers. It relies on natural systems, including crop rotation and other natural techniques, as a way to minimise infestations and maximise nutrition and yields. Numerous studies have shown the benefits of organic agriculture, in terms of human health as well as in environmental protection. Initially, the organic concept was focused on food. However, it now applies to other sectors such as personal care products, household products, clothes, pet food, and more. The global market for organic food and drink products is worth about Euro 30 billion. If we add the various other organic sectors, we speak of a total cross-cutting sector worth approximately Euro 40-50 billion and displaying continuous healthy growth.

Challenges for EU-Japan Economic Integration

Europe plays a leading role in the organic sector. Japan is restricted in its ability to meet demand for organic products. Only 0.6% of agricultural land in Japan is certified organic, one of the lowest penetration levels amongst developed countries. Austria, by contrast, now has 17% of its agricultural land certified as organic. It seems that Japan's hot and humid climate, combined with small-scale farming (and associated risks of contamination from surrounding farms) are key contributing factors. This means that Japan must rely on imported organic agricultural products and/or organic packaged goods to meet growing domestic demand.

The lack of availability of locally grown organic agricultural produce, combined with a restrictive importing environment, has limited development in Japan to a remarkably small market for organic products. Over 51% of the global market for organic food is found in Europe, 45% in the Americas, and only about 3% in Asia-Pacific. Japan has only the 9th largest organic packaged food market, smaller than even The Netherlands and Switzerland. The Japanese spend only 320 yen/person/year on organic packaged foods, the equivalent of a single cup of coffee. This is below the level even of South Korea. The Swiss and Danes spend over 20 times this amount. The penetration of packaged organic foods versus total packaged foods is only 0.2% for Japan. The average world penetration is 5 times more, whilst in Switzerland and Denmark it is over 15 times greater.

Successive food scandals, in some cases related to pesticides, together with increased vigilance regarding maximum residue levels of pesticides in food, along with a general increased desire for more natural products, all point to a growing consumer interest in organic products. Retailers are also increasingly aware of the need to differentiate their offerings. All these factors bode well for the development of the Japanese organic market.

The EBC urges the Governments of Japan and the EU to ensure that Europe's leading role in organic products is used to stimulate market development in Japan. A level playing field for European organic products, including the removal of all redundant regulations and meaningless bureaucracy as well as burdensome tariffs through an EU-Japan Economic Integration Agreement, would be the most efficient way to ensure access of quality European organic products to the Japanese market. Japan would benefit enormously from recognising Europe's stringent organic certification standards, and accepting organic and related products from Europe without requiring additional certification or bureaucracy.

Key Issues and Recommendations

■ Supplementary Organic Certificates

New Recommendation: Organic JAS regulations specify that organic products can only be marketed as such in Japan if: 1) they are organically certified in their own country, 2) the importer is organic JAS-certified, and 3) the products meet organic JAS regulations (minimum 95% of ingredients must be of organic agricultural origin, excluding water and salt). Products which have a Japanese legally compliant label affixed at the production site in Europe can then be organic JAS-certified only if the European supplier itself is organic JAS-certified. Products that have the Japanese label affixed in Japan (which is often the case as smaller quantities are involved) are subject to a time-consuming, costly, wasteful bureaucracy, which seemingly fulfils no function whatsoever. Every single shipment has to be accompanied by a specific organic certificate from the supplier's certifying body, containing details of the order (e.g. products, quantities and best before date). The supplier must pay for this certificate to be issued each time, and the importer must send this organic certificate to the relevant embassy of the country from which the products were imported, together with the invoice, packing list and waybill. The embassy can then issue the "supplementary organic certificate" to the importer, a certificate which is necessary for the products to be labelled as "organic" in Japan.

Recommendation:

- The Government of Japan should abolish the need for issuing supplementary organic certificates. It should be sufficient that the importer be required to be organic JAS-certified, as well as keeping a file copy of the organic certificate for each product that it is importing and selling.

■ Tariffs

Yearly status report: no progress. The import duty rates for many foods and food ingredients remain far too high. Severe inflation in food and transport prices, coupled with high import duties, make some imported foods prohibitively expensive, for example, butter (with an import duty of 35% +1,159 yen/kg), cheese (26-40%), chocolate for professional use (29.8%), confectionery (25%), fruit juice and fruit puree for babies (21.3%), and herbal tea (15%). Although import duties unnecessarily inflate prices for conventional foods as indicated above, the impact on organic products is particularly acute as the original price tends to be higher. Since most organic products have to be imported due to lack of local supply, organic products can be up to 2-3 times more expensive than their non-organic counterparts in Japan, rather than the 20-50% premium commonly seen in Europe.

Recommendation:

- The Governments of Japan and the EU should abolish tariffs on food products as part of an EU-Japan Economic Integration Agreement.

■ Allowed Additives for Organic

New Recommendation: The organic JAS list of additives allowed for organic products excludes certain additives used in EU organic products.

Recommendation:

- The Government of Japan should recognise the EU list of allowed additives for organic products.

■ Mutual Recognition

New Recommendation: Any products certified and sold as organic in the EU should be allowed to be described and sold as organic in Japan, and vice versa.

Recommendation:

- The EBC urges the Governments of the EU and Japan to mutually recognise organic certification.

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FOOD

Introduction

Japan's economy and food market both rank second in the world. Japan's food retail market is worth about 38 trillion yen (about Euro 240 billion). Japan's packaged food market is worth about Euro 140 billion, which is about 11% of the world total of Euro 1.2 trillion. The food processing industry is estimated to have a value of about Euro 150 billion, making it the third largest sector in Japan after electronics and car manufacturing.

Agriculture's share of the Japanese economy has progressively declined since 1950. It accounts for only 1.7% of national GDP, employing 4.6% of the total labour force. Japan has a shortage of farmland, with some 12% of the total land area being cultivated in 2005. Consequently, Japan is a major importer of food. According to FAOSTAT (2005-06), Japan is the largest importer in the world of pork, maize and canned chicken, the second largest importer of beef, soybeans and wheat, and a major importer of fruit and vegetables. Rice is the principal domestically produced crop. Japan depends on imports for about 60% of its food supply on a calorie basis. Its self-sufficiency ratio has steadily declined, dropping recently to just below 40%. This is very low compared with France at 130%, the US at 119%, Germany at 91% and the UK at 74%. Japan is seeking to improve this ratio and has set a target of 45% by 2015.

The value of food imports is about Euro 35 billion. This represents about 8.4% of Japan's total imports (about Euro 416 billion). The biggest category of food imports is fish (28%), followed by meat (17.6%), grain (12.6%), vegetables (7.3%) and fruits (5.8%). This is followed by oilcake seeds (4.5%), beverages (5%), and coffee, cocoa, tea & spices (4.2%). Japan's food imports are accounted for by the USA (22% of total), China (17%), Australia (8.5%), Canada (5.6%), Thailand (5.3%), France (3.3%), Chile (2.9%), Brazil (2.7%), Korea (2.5%) and New Zealand (2.1%). These top 10 countries account for 72% of total food imports. It is worth noting that only one European country can be found in this list.

Challenges for EU-Japan Economic Integration

The aforementioned facts may make it seem difficult to argue about the challenges of importing and selling food in Japan. The EBC's view, however, is that Japan's heavy dependence on imported food makes it all the more important to ensure that the systems in place are both effective as well as efficient in providing consumers with the maximum choice and safety at a reasonable price. We feel that this is not presently the case.

In broad terms, we ask the Government of Japan to reassess its objectives and policies regarding food supply. Japan's goal of improving its self-sufficiency for food should focus on improving local supply rather than restricting imports. Regarding imports, the EBC would encourage a systematic review of demand and supply, as well as considering existing strengths and weaknesses, and opportunities and threats, in a prioritised manner.

The EBC is very keen to work closely with all related parties in the Governments of Japan and the EU to help bring about effective, positive change in the trading environment for food between our two regions. Ultimately, we believe that our closely shared principles strongly support the establishment of an EU-Japan Economic Integration Agreement. Under such an agreement, all tariffs, quotas, minimum prices and state trade in food products would be abolished.

With this goal in mind, and working systematically on a "greenfield" approach to improve Japan's food supply, existing ineffective practices could be identified and abolished, and new opportunities to improve choice, safety, and the affordability of food - three fundamental requirements of any supply system - identified and implemented. Within such a framework, this Annual Report highlights some areas that it considers could be addressed. These include tariffs, food safety, and logistics. Organic food, an area growing rapidly throughout the developed world, has largely bypassed Japan until now. Due to the scope and importance of this area, it is covered in a separate section.

Key Issues and Recommendations

■ Tariffs

Yearly status report: no progress. Import duty rates for many foods and food ingredients remain far too high. Severe inflation in food and transport prices, coupled with high import duties, make some imported foods prohibitively expensive - for example, butter (with an import duty rate of 35% +1,159 yen/kg), cheese (26–40%), chocolate for professional use (29.8%), confectionery (25%), fruit juice and fruit puree for babies (21.3%), herbal tea (15%).

Recommendation:

- The Governments of Japan and the EU Member States should abolish tariffs on food products as part of an EU-Japan Economic Integration Agreement.

■ Food additives

Yearly status report: some progress. In December 2002, the Ministry of Health, Labour and Welfare prepared a list of 46 food additives which, in their own words, “have been proven safe and are widely used in the world”. At the time of writing, only 14 (7 more than last year) of the 46 additives have been approved for use in Japan. Approval of 12 more additives is expected shortly. Thus a total of 26 additives will have been approved, leaving 20 more additives still requiring approval.

Some widely used additives (especially preservatives), such as sulphur dioxide and sorbic acid/potassium sorbate, have significantly different allowed usage levels in Japan, based on the food category. For sulphur dioxide, the allowed usage level can be as high as 5 g/kg for certain foods, to as low as 0.3 g/kg for “other foods”. This prevents many European foods with reasonable levels of sulphur dioxide from entering Japan simply because they do not fit any existing category. The situation is worse for potassium sorbate/sorbic acid as no “other foods” category exists, meaning that even a trace (possibly carryover) of sorbic acid found in such a food would result in a total recall of such a food, despite there being absolutely no health risk whatsoever.

Recommendations:

- The Government of Japan should approve all remaining additives on the priority list without delay. Standards of use should, furthermore, be reviewed so as not to penalise imported food.
- Beyond this list, the EBC recommends a review of all additives; other widely used additives, recognised as safe in the EU and US, should be considered for approval in Japan.
- The regulations for use of commonly used preservatives such as sulphur dioxide and sorbic acid should be modified to have more practical (higher) allowed usage levels for “other foods”.

■ Meat / Beef

Yearly status report: some progress. In May 2005, the Food Safety Commission recommended that meat from animals younger than 20 months should be considered safe for import, a recommendation that was also endorsed by the Ministry of Agriculture, Forestry and Fisheries (MAFF). The European beef industry is perfectly capable of tracing and guaranteeing the age of individual animals. Several interested Member States are currently working on technical questionnaires submitted by MAFF and MHLW and have already submitted data. The process is extremely slow and still only at discussion level.

Recommendation

- The first step for the Government of Japan should be to speed up the process of examination of the data submitted by the Member States, and to limit the questions to what is necessary for risk assessment. Ultimately, imports should be authorised again in the short term, considering the high level of safety of beef in the EU, and also considering the fact that the ban on US beef was lifted more than 2 years ago.

■ Listeria Monocytogenes in Ready To Eat (RTE) Food Products

Yearly status report: no progress. Listeria monocytogenes is a pathogenic bacterium widespread in the environment. It can contaminate foods causing a mild illness, called Listerial Gastroenteritis, or in certain cases, a potentially lethal disease called Invasive Listeriosis. The EU standard, fully taking into account consumer safety, stipulates zero tolerance for RTE foods that support the growth of the bacteria, whilst accepting minute levels of L.

monocytogenes (less than or equal to 100 cfu/g) in RTE foods that are scientifically proven to not support the growth of the bacteria due to particular characteristics (such as pH, water activity, certain processes or treatment).

Recommendation:

- Japan should review its position regarding *L. monocytogenes*, and consider aligning its regulations with the “double approach” adopted by the EU, Canada and other countries, also supported by the principles of Codex Alimentarius and USDA’s Food & Drug Administration (FDA). This would improve food safety by focusing attention and action only on those products which pose a health risk.

■ **Best Before Date**

New Recommendation. In Japan, the Best Before Date (BBD) must be shown as Year.Month.Day (YYYY.MM.DD). In Europe it is shown as Day.Month.Year. Japanese regulations require all imported food to be re-date-coded as Year.Month.Day. This involves additional work and costs, which are unnecessary.

Recommendation:

- The Government of Japan should allow imported food to retain its own Best Before Date as long as the label indicates how the Best Before Date should be read; for example “For Best Before Date, please read as Day.Month.Year”. This would allow consumers to know what the Best Before Date is without unnecessary costly re-stamping of BBD on each pack.

■ **Proposed Revisions in Labelling & Food Sanitation Laws**

New Recommendation. A number of incidents in the Japanese food industry involving negligence and fraud have led to policy proposals to supposedly remove future risks: 1) Mandatory indication of country of origin for all ingredients; 2) In addition to Best Before Dates, also making printing of Production Dates mandatory; and 3) Mandatory analysis of all products for every single import. Whilst the EBC shares the concerns of consumers and the Government regarding food sanitation and proper labelling, it urges a realistic response by the Government.

Recommendations:

- The Government should carefully consider the most effective actions to ensure consumer safety and reduce the incidence of accidents and fraud; this can best be done by following the guidelines from CODEX and ISO and HACCP. The Government should not allow variations in labelling requirements set by local governments.

■ **Testing of food in the market place**

Yearly status report: no progress. Local authorities inspect food in market circulation. When products not fulfilling prescribed standards are found, the retailer, rather than the manufacturers and importers, are notified. This notification practice often causes the retailer to overreact and withdraw the tested product and related products even if the deviation from the standard is minor and does not pose a health risk.

Recommendation:

- The Government of Japan should oblige local food inspectors at public health centres to communicate a violation to the manufacturer or importer before notifying the retailer. A demand for an immediate recall should only be made where a health risk is involved.

■ **Handling of Perishables at Narita**

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

Recommendation:

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

Industry

Automobiles
Automotive components
Aeronautics
Space
Defence
Construction
Materials
Environmental technology

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AUTOMOBILES

Introduction

The Japanese domestic car market is in crisis. Sales, which have declined for the last three consecutive years, are some 60% lower than in the peak year of 1990. Car imports peaked in 1996 when some 311,000 units were sold. EBC Automobile Committee member companies imported 218,000 units into Japan in 2007. In 2008 total imports are unlikely to exceed 200,000 units. Nonetheless, Japan is still the world's fourth largest passenger car market after the US, the EU and China. In 2007, European cars exports to Japan at Euro 4.2 billion accounted for 6% of all EU car exports by value. Cars represented 9.6% of total EU exports to Japan. European importers are particularly strong in the luxury segments of the market. The European share of the Japanese car market is similar to its share of the US market

Japan is a mature market. Car ownership by household is broadly comparable to that in the EU. As a result of the declining birth-rate and the ageing population, the overall market is unlikely to expand in the mid-term. Changes in the pattern of consumer spending, higher petrol prices and environmental concerns will affect the model mix of cars sold in Japan. The desire of the Japanese consumer for greater product variety and the bipolarization of the market by price create opportunities for European importers. Regulatory changes can reduce the cost of doing business and ensure that European safety and environmental technology is available to the Japanese consumer in a timely manner. There are however no changes in the regulatory environment that would lead to a significant growth in sales.

Challenges for EU-Japan Economic Integration

European cars must undergo a rigorous homologation process to demonstrate compliance with Japan's safety and environment standards before they can be sold in the Japanese market.

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.

Since Japan became a signatory of the UN/ECE 1958 Agreement, Japan has adopted 37 out of some 120 UN/ECE Regulations, including most of those of greatest interest to European importers. But there are still areas where Japan has unique national technical requirements e.g. noise testing.

Japan is now considering proposing to other UN/ECE signatories the introduction by 2015 of a system of Mutual Recognition of Whole Vehicle Certification. The EBC Automobile Committee welcomes this initiative. If implemented, it would mean that once a vehicle had been certificated in either the EU or Japan, that vehicle would require no further testing to be sold in either region. This would go a long way towards the integration of the European and Japanese automobile markets. Even in advance of the realisation of this long-term goal, there are other steps set out below which the Government of Japan could take to facilitate the sales of imported vehicles in Japan.

Member Companies

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

Key Issues and Recommendations

■ Harmonisation of Technical Standards and Certification Procedures

Yearly status report: Some progress. Discrepancies between Japan and the EU remain in the interpretation of ECE Regulations *and* in the documentation that is required to demonstrate compliance. MLIT plans to propose in WP29 in Geneva the adoption by 2015 of a global Whole Vehicle Certification system. This would make possible the mutual recognition of vehicle certification between Japan and the EU.

Recommendation:

- The Government of Japan should streamline the procedure for demonstrating compliance with ECE Regulations.
- The Government of Japan should work closely with EU Member States and the European Commission to implement the proposal for a global Whole Vehicle Certification system.

■ Tax Reform

Yearly status report: No progress. Compared with other countries, Japan still imposes an excessively heavy tax on the purchase and ownership of motor vehicles. The Government of Japan has undertaken to review the taxation of automobiles as part of an overall review of the tax system.

Recommendation:

- The Government of Japan should:
 1. Simplify the structure of the tax on automobiles and reduce the overall tax burden on motorists.
 2. Introduce tax incentives for those car owners who trade in a car more than 10 years old.

■ Diesel Promotion

Yearly status report: encouraging progress. At the request of EBC Automobile Committee members, MLIT has adopted technical guidelines for the use of urea SCR catalysts in diesel powered passenger cars. This will facilitate the introduction of additional diesel models, which comply with the latest Japanese emission standards.

Recommendation:

- The Government of Japan should cooperate closely with overseas automakers further to amend, where necessary, the technical guidelines for urea SCR catalysts to ensure that no technical obstacles delay the launch in Japan of diesel passenger cars incorporating the most advanced emission control technology.

■ Kei Cars

Yearly status report: no progress. The continued existence of regulatory and fiscal privileges for kei cars distorts competition.

Recommendation:

- The Government of Japan should put kei cars and other motor vehicles on the same footing.

■ Technical Guidelines for New Safety Technologies

Yearly status report: Little progress European importers continue to experience difficulties in obtaining approval for the use in Japan of advanced safety devices which do not comply with the technical guidelines set by MLIT. Amending existing guidelines to accommodate proven European technologies has proven difficult and time-consuming. MLIT has, however, shown increased awareness of the problem and is discussing a solution with the Japan Automobile Importers Association (JAIA).

Recommendation:

- MLIT should reach early agreement with JAIA on a transparent and flexible procedure for amending existing technical guidelines and for setting new ones. In the meantime, MLIT should allow the type approval of an imported vehicle, which does not conform to existing Technical Guidelines if that vehicle has already been exempted from the relevant EU safety requirements.

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AUTOMOTIVE COMPONENTS

Introduction

More and more European automotive components firms are dedicating resources to attracting business in Japan by investing in the 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 the 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 their procurement strategies, placing more emphasis on global procurement and cost-effective product development.

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 the industry to outsource 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 requirements, which defies the global trend towards single platform development and volume production.

The process of globalisation and intense competitive pressures have meant that outsourcing of automobile component development and supply has emerged as a clear trend in the European automobile industry. The European system offers low risks, reasonable prices and flexibility. However, European component manufacturers that have enjoyed success with Japanese transplants in Europe have seldom been able to build on this to become suppliers of the parent company in Japan. Against this background, the EBC greatly values the ongoing, regular dialogue between European component manufacturers and Japanese carmakers as a vital mechanism for sharing information and promoting understanding. It is hoped that this will, over time, foster increased opportunities for mutually beneficial business development.

Challenges for EU-Japan Economic Integration

Japan is the second largest market in the world, yet European automotive manufacturing companies hold only a small share of the market. As the businesses of Japanese automakers are steadily growing overseas, this should provide an opportunity for growth for European automotive component manufacturers. The process of globalisation and intense competitive pressures has meant that outsourcing of automobile component development and supply has emerged as a clear trend in the European automobile industry. The European system offers competitive price, reliability and flexibility. However, for European component manufacturers these advantages have yet to translate into significant new opportunities to supply the Japanese automobile industry.

Key Issues and Recommendations

■ Globalisation of the automobile industry

Yearly status report: limited progress. The EBC welcomes the opportunity that internationalisation presents for innovative European firms to strengthen their relationship with Japanese automobile manufacturers in developing new products and sharing technical expertise. European firms are not tied to specific European automobile manufacturers, and have products proven to the rest of the auto industry. Japanese automobile manufacturers are increasingly making use of foreign tie-ups to develop their business and respond to competitive pressures both at home and abroad. Many firms are also reassessing their procurement strategies. Nevertheless, European automotive component and system manufacturers continue to face numerous challenges in promoting European technical expertise to automobile manufacturers in Japan. In general, Japanese manufacturers are still reluctant to outsource product development on a global basis and procure from non-traditional sources. Japan-specific requirements are common, and it is not unusual for specifications to differ between domestic and overseas production, even within the same company. Hence, even European component manufacturers successfully supplying to Japanese transplants in Europe are seldom able to build on this to become a supplier of the parent company in Japan.

Recommendation:

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

■ Promoting information exchange

Yearly status report: limited progress. 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 for discussing issues of mutual concern relating to products, platforms, global strategies and other important matters affecting the industry. The next meeting will be held in Ljubljana, Slovenia, June 2-5, 2009 and the EBC encourages top-level Japanese industry participation. The EBC also sees much potential in the Japan Society of Automotive Engineers' (JSAE) Automotive Engineering Exhibition and the annual congress/paper presentation scheduled for 20-22 May 2009 in Yokohama.

Recommendation:

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

■ Green procurement

Yearly status report: new issue. A significant number of Japanese companies' purchasing departments are introducing "green procurement" (*green chotatsu*) requirements. Suppliers are required to document, specifically for Japan, a list of substances used in their manufacturing process, instead of accepting conformity to an RoHS-type "negative" list.

Recommendation:

- The EBC urges the Japanese automobile industry to adhere to accepted international practices when setting procurement requirements.

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AERONAUTICS

Introduction

The Japanese market for commercial aircraft and helicopters is one of the largest in the world, and historically has been dominated by the United States. The EBC would like Japanese airlines and operators to recognise the benefits of competition, the risk of depending on a single source, and the benefits of diversifying their suppliers. European companies provide state-of-the-art technology, high-quality final products and goods, as well as second-to-none customer support services. For instance, the availability on the market of the unique A380 commercial aircraft offers unprecedented possibilities to airlines in terms of innovative customer services, whilst reducing congestion at major international airports.

Challenges for EU-Japan Economic Integration

The cooperation between Kawasaki Heavy Industries (KHI) and Eurocopter on the BK117 helicopter, and also between KHI/Mitsubishi Heavy Industries (MHI) and Rolls-Royce on Trent 1000, are encouraging examples of successful collaboration between the European and Japanese aeronautics industries. In the field of commercial aircraft, Airbus has been trying to forge ties with the Japanese aerospace industry since the 1980s. Though there are currently 21 suppliers in Japan to the A380 programme, the Japanese aerospace industry has recently been offloading manufacturing work from Airbus A320/A321, Bombardier and Embraer programmes to free up capacity to support other ongoing developments with US firms.

Due to the long-standing defence-influenced relationship with North American companies, and limited awareness of the European aerospace sector, the Japanese industry is at times reluctant to work with European companies, thus depriving itself of participation in many successful European programmes. Proactive collaboration with successful European companies would enable Japanese companies to strengthen their position in commercial aeronautics. By participating in a wider range of projects, they would be able to expand their international business opportunities and further develop their technological base to improve the penetration into Europe of Japan's own aerospace projects like the Mitsubishi Regional Jet (MRJ). The EBC feels that there is huge potential for large-scale joint development programmes between the Japanese and European industries in the field of commercial aviation, and urges the Government of Japan and the Japanese aerospace industry to give serious consideration to such an initiative.

An Economic Integration Agreement (EIA) could efficiently solve the issues confronted in the field of aeronautics and facilitate constructive commercial and industrial cooperation. Mutual recognition of aeronautics standards implies that trading partners accept each other's rules and administrative procedures. The differences between European and Japanese rules and regulations are not substantial, therefore comprehensive case-by-case discussions and mutual recognition are feasible.

Key Issues and Recommendations

■ Promoting competition

Yearly status report: limited progress. Although European manufacturers of commercial aircraft, engines, components and navigational equipment offer state-of-the-art technology at internationally competitive prices, the European share of the Japanese market for commercial aircraft and related equipment is still considerably less than the worldwide average. The Japanese aeronautical sector sometimes lacks transparency in equipment procurement, as exemplified in its procurement practices associated with the modernisation of air traffic management. Although European companies are recognised worldwide as setting state-of-the-art standards, they face the greatest difficulties in terms of new equipment procurement in Japan.

Recommendation:

- Procurement decisions should be made on a competitive basis, free from political influence. The EBC encourages Japanese firms to diversify their sources of supply and consider the advantages of European products in the aeronautics field, to the benefit of their customers and the general public. Besides economic advantages, the Japanese authorities should also consider the fact that use of foreign companies' equipment can help address the need for improvements in air transport safety.

■ Promoting industrial co-operation

Yearly status report: limited progress. Japan's cooperation in commercial aircraft development is still heavily biased in favour of North America, as shown for instance by the fact that, contrary to their American counterparts, European companies were not invited to recent aircraft manufacturing business seminars organised by the Japanese authorities. So far, putting aside some fundamental research on supersonic technology, the Ministry of Economy, Trade and Industry (METI) has not supported any single aircraft development with Europe. METI's support for the Boeing 787 programme should not limit the potential for future collaboration with European makers. The EBC is still convinced that there are mutually beneficial opportunities for cooperation between European and Japanese firms. METI's support for the Trent 1000 engine, the agreement on supersonic technologies, and the development of SHM (Structural Health Monitoring) technologies should pave the way for more aeronautic cooperation. Although this may have symbolic significance, the scale of Japanese financial support for such activities with European companies remains significantly below that of activities with US companies.

Recommendation:

- The EBC is looking for increased industrial cooperation between Japan and Europe, particularly in the field of commercial aircraft, engines, components and navigation systems. New challenges lie ahead in the development of innovative solutions designed to meet future needs in civil aviation. The EBC considers these challenges as a great opportunity to enlarge the scope of cooperation between Japan and Europe and encourages METI and other government-affiliated institutions to openly promote and fund collaboration with European companies in a similar manner to that with North American firms.
- Europe is supporting ambitious research programmes to tackle environmental issues, from noise to emissions. The EBC believes the environment to be one of the fields where further links to Japanese academia, technology clusters and industry at large could yield significant cooperation and business opportunities.

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SPACE

Introduction

Japan is a leading space-faring nation with independent access to space. State-of-the-art programmes include launchers, satellites, satellite components, and ground equipment. Despite such advances, the commercial success of Japan's space industry is limited because of low domestic volumes and past US political pressure. Only recently has Mitsubishi Electric Corporation been able to sell a communications satellite to a Japanese commercial satellite operator. Government budget decreases have only recently been balanced by moves into earthquake and disaster prevention areas as well as the security area. Ariane launchers have been successful in Japan. Cooperation between the Ariane 5 and H-IIA launchers is progressing on the commercial side: Arianespace and Mitsubishi Heavy Industries (MHI) are making it easier for customers to shift satellites from Ariane 5 to H-IIA and vice-versa in case of technical problems with the originally contracted launcher. However, talks between European and Japanese space authorities towards a mutual back-up of Japanese and European government launch missions have been slowed by a lack of consistent space utilisation policies across ministries, resulting in a loss of European interest.

Challenges for EU-Japan Economic Integration

Japan's commercial satellite market is open. Exchange rates permitting, European satellite makers could soon sell their first complete satellite to Japan. Their high reliability is a key factor, together with their transparency policy towards Japan, which compares favourably with opaque and unreliable US control policies. Japan's cooperation in satellite development, however, is biased towards the US, whose political influence has had an adverse effect on the development of both the Japanese and European space industries in Japan. The Japan Aerospace Exploration Agency (JAXA) is a member of Europe's Space Components Steering Board.

Ground equipment is a new field spurred by the recent thrust of Japan's space activities into security and defence applications. Japan's space activities increasingly involve space imaging and the use of associated ground equipment for image processing and interpretation, for applications in agriculture, fisheries and geophysics (such as tsunami warnings). In addition, several homeland security-type applications naturally enhance a nation's defence capability. Non-transparent procurement methods are still being used in this sector to the disadvantage of foreign suppliers.

A Basic Space Law was passed in May 2008. Its main objective is removing the previous ban on space activities for defence purposes and utilisation (such as allowing the Defence Ministry to own dedicated satellite capacity) and reorganising the structure of space-related jurisdiction. In late August 2008, a Strategic Headquarters for Space Policy was established within the Cabinet Secretariat, with the Prime Minister as its President and the Chief Cabinet Secretary as its Vice-President. A Space Minister was nominated. The Strategic Headquarters for Space Policy has a permanent Secretariat headed by a high-level civil servant as its Secretary-General. The current tentative agenda of the Headquarters is the formulation of a Space Basic Plan, a review of Japanese space-related organisations, and preparation of new legislation on space-related activities. The EBC welcomes the new Basic Space Law. The potential to formulate nationwide space policy is much higher than under the previous structure, where very general policies were issued by the Cabinet Office's Council on Science & Technology Policy, which is naturally interested mainly in Science & Technology and had no Space Minister or permanent Space personnel. The challenge, however, lies in the priorities that the new Strategic Headquarters for Space Policy will set for itself. If care is not taken to rethink Japanese space policies on a wider scale, the new national space policies may only perpetuate the old ministry free-for-all and continue making many mutually valuable European-proposed cooperation opportunities all but impracticable or meaningless. The proposed mutual back-up of government launch missions mentioned above is one case in point. The tropism of Japanese satellite development policies towards the US is another.

The EBC is encouraged by the recent trip to Europe of the Strategic Headquarters for Space Policy's Secretary General and his wide consultation with major European Space authorities and companies. The EBC is ready, willing and eager to conduct wide-ranging consultations with the Headquarters in the weeks and months ahead.

Key Issues and Recommendations

■ General environment

Yearly status report: awaiting practical implementation. Up to now, Japan's official space policies have largely ignored Europe, to the increasing frustration of the European space industry. Other countries being more responsive, Europe now concentrates its cooperation efforts where they are more likely to be rewarded. The new Basic Space Law offers a unique opportunity to reverse this trend, allowing both sides to make better use of their limited space budgets. The export licensing delay problem that affected several European space manufacturers seems to have subsided.

Recommendations:

- The EBC urges more Japanese cooperation with European space agencies and industry.
- Space agencies should compare plans in new application areas at an earlier stage in order to take better advantage of cooperation opportunities.
- The EBC also urges mutual recognition of Japanese and European export control procedures.
- The Strategic Headquarters for Space Policy should increase cooperation with Europe as a way to reverse Europe's trend away from Japan. The EBC is ready to contribute ideas towards this goal through meetings with Headquarters' personnel.

■ Satellites

Yearly status report: limited progress. European and Japanese Agencies met in 2008, but did not achieve meaningful cooperation progress, except for an agreement between the Japan Aerospace Exploration Agency (JAXA) and the French Space Agency (CNES) to co-develop satellite field programmable gate array (FPGA) devices.

Recommendation:

- The EBC recommends closer cooperation between the space agencies in satellite technology development and applications, and strongly requests pro-active promotion and actual execution of cooperation projects. The Government of Japan should encourage international cooperation with Europe through satellite or satellite equipment procurement in fields related to national security.

■ Launchers

Yearly status report: limited progress. The Japanese and European space authorities are still studying the possibility of backing up each other's government launch missions. This should solve the problem of government mission delays in cases of technical trouble with a launcher, and prevent a damaging one-sided flow of government missions away from the delayed launcher. But this idea is now more than six years old, and no official agreement is in sight. Although companies on both sides have initiated some promising commercial cooperation, more government leadership is needed.

Recommendation:

- The EBC hopes that the Strategic Headquarters for Space Policy will bring about vigorous official cooperation between our respective heavy-lift launchers. For technical and cost reasons this cooperation must be comprehensive and systematic in order to succeed. The EBC also hopes that Japan's new launcher projects will take into account, and help to consolidate, current cooperation projects.

■ Ground equipment

Yearly status report: no progress. Japan's international procurement activities in this area typically exclude entire systems and remain limited to small subsystems and components. Non-transparent procurement methods are still being used in this sector to the disadvantage of foreign suppliers.

Recommendation:

- The EBC hopes that Japan's international procurement activities in ground equipment will soon include whole systems. We also hope that full transparency can be granted in respect of procurement for standard ground processing products.

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DEFENCE

Introduction

Japan's current five-year defence plan includes a defence equipment procurement budget of around 4 trillion yen, of which an estimated 85% will be spent on weapon systems developed and built locally. Products built under licence from US manufacturers or directly imported from the US make up most of the remaining 15% of Japan's defence hardware market. With a few exceptions, European defence sales to Japan have consisted of minor equipment or components for Japanese-made weapon systems. The Japanese Ministry of Defence (JMoD) has recently announced a plan in the Defence Equipment Acquisition Reform Report, which presents an opportunity to change this globally unique and unusual market situation.

Challenges for EU-Japan Economic Integration

European defence contractors face a number of non-tariff barriers in accessing the Japanese defence market. The Japanese defence procurement process lacks transparency, creating difficulties for foreign companies in knowing the timing, decision makers, and requirements of new programmes. The defence establishment remains relatively uninformed due to lack of exposure to European products, and this lack of understanding leads to narrow views. As a result, European defence firms face an uphill battle in their efforts to increase cooperation in product development with Japanese companies. US political pressure stemming from the bilateral Defence Security Agreement, incentives to buy US products through the Foreign Military Sales programme, and unfounded Japanese fears of non-interoperability of EU products with US products have further restricted European access to the Japanese defence market.

This combination of factors has led to a monopoly situation, which, over time, inevitably reduces value for money for the JMoD and the Japanese taxpayer, and reduces the quality of aftermarket support. In an era of shrinking defence budgets, making optimal use of a lower budget is imperative. Fortunately, the Ministry of Defence has recognised this and is committed to reforming its defence equipment acquisition policy. The details announced so far are very encouraging and offer many ways for EU defence companies to assist the JMoD in meeting its goals, although it must be recognised that the era of change could be protracted.

Key Issues and Recommendations

■ Competition

Yearly status report: some progress. The EBC welcomes a Japanese Ministry of Defence (JMoD) plan that includes an initiative to increase accessibility for foreign manufacturers to the tendering process. The greater transparency provided to foreigners, for example, by the JMoD publishing statements of requirements (SOR), would increase the competitive energy of any tendering process.

A greater emphasis in the plan on Life Cycle Costs (LCCs) is also welcome. EU companies have great experience in modelling and predicting LCCs, and are confident enough to guarantee their predictions or enter into fixed price contracts. This can benefit the JMoD's budgeting by preventing price shocks and escalation. LCC models used in the EU can be shared with Japan, and are likely to be more relevant than those used by the US, which have vastly higher manpower and equipment levels, requiring different maintenance and training policies.

Recommendation:

- The Government of Japan should follow the plan presented by the JMoD and improve transparency towards foreign suppliers by making the statement of requirements for each procurement process publicly available and by putting more emphasis on Life Cycle Costs.
- The JMoD would, furthermore, benefit from the adoption of NATO standards from the initial research and development phase, to widen and intensify competition, and reduce development risk by diversifying inputs and increasing the number of partners.

■ Industrial Partnership

Yearly status report: some progress. EU Defence Companies look forward to assisting the JMoD in meeting its cost reduction target with such initiatives as Performance Based Logistics (PBL), Private Finance Initiatives (PFI), Commercial Off The Shelf solutions, leasing schemes and procurement techniques to minimise costs. Examples of introducing LCC models, whether it be through an initial phase of performance-based logistic support or a fully integrated operational support programme, can be demonstrated by a number of European governments that have already taken the initiative to partner with industry and are beginning to see the through-life cost benefits. The experience of such partnerships has arguably put the European Industry ahead of its US competitors.

Recommendation:

- The Government of Japan should consider the opportunity to cut procurement costs by adopting innovative approaches and also source from more diverse partners.

■ New security policy arrangement

Yearly status report: new issue. The European aerospace industry has established a reputation for collaborative development ventures within Europe, the USA and across all other major markets. The current security restrictions within Japan prevent Japanese industry from benefiting from this experience.

Recommendation:

- Europe and Japan should work towards the establishment of a reciprocal Defence Security Arrangement in the long term as this would provide greater access to a number of development programmes required by the JMoD and open up the opportunity for Japan to enter development programmes in Europe.

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CONSTRUCTION

Introduction

Although the construction sector's share of Japan's total GDP decreased from 14.2% in 1998 to 10.2% in 2006, the absolute size of the sector (Euro 363 billion in 2006) makes it one of the largest such sectors in the world. The Government has made enormous efforts to increase the sector's efficiency by more than halving (54%) yearly public spending during the past eight years, yet inefficiencies in the structure and management of the sector continue to prevent the creation of a market environment based solely on cost-effective merit. It remains almost impossible for foreign companies to sell and install building materials and equipment in Japan directly to end-users, especially for new building projects. Moreover, opportunities for European firms to use innovative designs, imported materials and modern construction methods – the key to their competitive advantage – are effectively eliminated in Japan by over-prescriptive regulation, resistance to change by local officials and complicated procedures to obtain the necessary approvals.

Challenges for EU-Japan Economic Integration

In past years, the construction sector in Japan has undergone change, largely because of drastic cuts in public spending that brought construction costs closer to international levels. Yet relatively little has changed to increase competition in the industry. European firms still find that project bidding is often more trouble than it is worth, given the complexity of the bidding process, lack of transparency and lack of clear bidding criteria for performance requirements and quality control. Foreign involvement is relatively low with only a few European firms operating in niche areas of the market.

According to Japanese regulations, a company must hold a permit (*kensetsu gyo kyokasho*) to be a contractor or a direct subcontractor of a general contractor for projects that are worth over 5 million yen (roughly Euro 30,000) in value. To obtain this permit, the company must have a resident management staff member with more than five years of relevant experience in the same company or in another company in the same field. Small foreign firms that cannot find an appropriate person are forced to make "go-between" side-deals with a permit-holding subcontractor, which increases the cost of doing business in the Japanese market.

A lack of consistent performance criteria has caused Japan to lag behind in the development of safer and more energy-efficient buildings. For example, several accidents, including fatal accidents involving children, have occurred in Japan as a result of using annealed float glass, which is accepted almost everywhere in Japan both on and inside buildings. The lack of regulation on insulation and energy-efficiency enhancing methods is also alarming. Despite rhetoric underlining the importance of promoting technological solutions to global climate change, the Government of Japan lacks policies to promote energy efficiency in the sector with the largest consumption and hence the largest potential for savings. Residential and commercial buildings continue to be constructed with low insulation performance compared to standard practice in many other OECD nations with similar climates.

To promote competition, the Government needs to abolish the ceiling price system (*yotei kakaku*) for public tenders and relax requirements for bid participation. Rules peculiar to the construction of public works, such as the requirement for locally qualified and licensed engineers for all projects worth over 25 million yen, and burdensome inspection requirements not found in private sector projects, should also be eliminated. Finally, action should be taken to address the fact that current private financing initiative/public-private partnership (PFI/PPP) schemes provide little or no freedom in the means of delivery, do not reward innovation and are largely just a variant of contractor-financing (with deferred payments by the purchaser) rather than real PFI/PPP projects. An EU-Japan Economic Integration Agreement should include mutual acceptance of standards and certification for construction product convergence, improved transparency and strictly enforced common rules for government procurement, and joint recognition of the role of construction in promoting a sustainable society.

Key Issues and Recommendations

■ Promotion of environment friendly and safe construction

Yearly status report: limited progress. Space heating and cooling account for around 25% of energy use in commercial and residential buildings in Japan, but the Government has no apparent plan to improve the great inefficiencies either in new buildings or in the standing stock of buildings. Energy used in commercial buildings in Japan (offices, healthcare and educational facilities, retail establishments and warehouses) represents 8% of world energy consumption in such facilities. Schemes such as CASBEE, the Energy Efficiency Standard for houses, and the PAL/CEC assessment for larger office buildings are heading in the right direction, but key components of these schemes are diverging substantially from accepted international principles and are yet to be made mandatory. Japan continues to use building materials that Europe classifies as dangerous.

Recommendation:

- The Government of Japan should strengthen regulations to promote energy efficiency in residential and commercial buildings as a way to fulfil its international commitment to cut carbon emissions and increase the earthquake/typhoon safety of buildings.

■ Harmonisation of building materials standards

Yearly status report: limited progress. Building materials exported to Japan are tested according to both European and Japanese standards, although most of the tests are very similar. Few European testing institutes are accredited to test building materials for Japan. Inevitably, this raises the costs of imports to Japan and makes them less competitive than domestic supplies. In 2001, the Ministry of Construction (now the Ministry of Land, Infrastructure and Transport - MLIT) issued a Cabinet Order to the effect that foreign standards and certification may be used as a way to prove structural strength for structural lumber and glulam.

Recommendation:

- The Governments of Japan and the EU should work towards mutual recognition of JAS/JIS and EN standards for building materials. CE marking of construction products should suffice as a guarantor of high quality and safety when sold in Japan.

■ Public procurement

Yearly status report: limited progress. The public works procurement situation remains far from ideal. It continues to limit opportunities for European firms to participate and increases the cost of public works to the Japanese taxpayer. The single-fiscal-year budgeting policy leads to large projects being broken up into arbitrary bid packages that are unrelated to the content of the work. This reduces efficiency and increases the price as future year packages are often awarded to the successful first-phase contractor with little or no real competition. This practice can also lead to individual awards falling below the WTO minimum threshold – a manipulation that contravenes the WTO Government Procurement Agreement (GPA). The application of PFI/PPP in Japan continues to be mediocre, merely implying deferred payment via contractor-financing. Procurement policies that would greatly improve the transparency and efficiency of public works procurement already exist in Japan, but are not widely applied. For example, the EBC would like to see greatly expanded application of the Comprehensive Evaluation Bidding System, which enables bidders to submit technical proposals that may give them a competitive advantage – and makes it much harder for contractors or commissioning entities to rig the bidding process.

Recommendation:

- The Government of Japan should ensure that schemes such as the Comprehensive Evaluation Bidding System, which already exist in Japan, are more widely used. Similarly, the EBC believes much wider utilisation of third party CMr services would also improve the professionalism in and accountability of the procurement process.

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MATERIALS

Introduction

Japan has developed a depth of knowledge and expertise in processing materials, and is at the forefront of many sensitive technologies, such as rechargeable batteries for hybrid vehicles, nanotechnologies for manufacturing semiconductors, and various electronic components. These advanced technologies are largely based on the availability of key raw materials and Japan's ability to secure a stable high quality supply. It is therefore of utmost importance that Japan secures these raw materials by adopting a strategy based on security of supply, competitiveness, and unrestricted access to its domestic market by overseas suppliers.

Japan, one of the main consumers of industrial materials in the world, would benefit greatly from better access to the reliable sources of high-quality products at market-based prices that European companies can offer. However, Japan has been reluctant to reduce tariffs on industrial materials on a unilateral basis before formal negotiations on tariff reductions are concluded under the auspices of the World Trade Organisation (WTO). Following a number of bilateral trade agreements and continued difficulties in reaching a breakthrough in the WTO's Doha round, Japan has started to reconsider its policies. The unilateral lifting of tariffs on high carbon ferro-chromium (tariff code 720241000), a key ingredient in the manufacturing of all stainless steels, is a welcome step of major importance.

Challenges for EU-Japan Economic Integration

Tariffs damage competitiveness and threaten the future of domestic Japanese industry. Tariffs on processed nickel significantly increase local procurement costs at a time when companies in sectors such as stainless steel production are facing stiff challenges from overseas competitors, particularly those in South Korea and China. The same situation applies to fused aluminium oxide (artificial corundum, tariff codes: 281810010 sized grain and 281810090 non-sized grain), and to silicon carbide (tariff codes: 284920010 sized grain and 284920090 others), both widely used in the refractory and abrasive industry and in electric components. Silicon carbide, in particular, is used in wire-sawing for electronics and photovoltaic use, a rapidly expanding application in Japan. Imported fused aluminium oxide and silicon carbide are both subject to a 3.3% tariff, even though domestic production can only fulfil at best 10% of the yearly requirements. While consumers can currently import much of their fused aluminium oxide requirements from tariff-exempt countries under the Generalised System of Preferences (GSP), this is becoming more difficult, given the global shift in production to non-GSP countries with larger-scale facilities. Moreover, some categories of products are neither produced domestically nor available from tariff-exempt sources. The result is that Japanese consumers are dependent on imported products subject to high tariffs, and the global competitiveness of Japanese manufacturers suffers accordingly. In the case of silicon carbide, Japan is importing 97% of its requirements from only one source because it is a tariff-exempt country. A situation of dependency has been created, threatening the long-term stability of supplies to Japanese industry. Another similar case in point is manganous manganic oxide or Mn_3O_4 , used in the manufacture of soft ferrites and rechargeable batteries, and therefore many electronic devices. Only four countries produce Mn_3O_4 , most notably China and Belgium. Belgian material is the only product facing a 3.3% import duty (tariff code: 282090000). However Belgium is the sole producer in the world that does not use volatile Chinese manganese metal as an intermediate. Belgian Mn_3O_4 is made from in-house ore and in conformity to stringent environmental regulations. This is the required profile to guarantee a safe supply and stability on a long-term basis to Japanese industry. Import tariffs increase the dependency of Japan on Chinese suppliers and threaten the future of domestic Japanese industry. An EU-Japan Economic Integration Agreement should include the removal of all import duties on industrial raw materials such as refined nickel products, fused aluminium oxide, silicon carbide and manganous manganic oxide.

Key Issues and Recommendations

■ Nickel

Yearly status report: no progress. Approximately 60% of total stainless steel production contains nickel, corresponding to roughly 40% of total production costs. Therefore it is critical that Japanese manufacturers are able to procure their nickel requirements at competitive prices and are ensured easy and stable access to nickel products. However, Japan is the only developed country in the world to apply duties on processed nickel products, such as nickel metal (import code 750210000), ferro-nickel (import code 7202600100/7202600100) and nickel oxide sinters (import code 750120100/750120210). These products are subject to tariffs ranging between 3.0% and 3.3% or 44 yen/kg. The continuation of tariffs on imported processed nickel products and the impact this has on European producers can no longer be justified.

The impact of high tariff rates on refined nickel is a significant increase in costs for domestic users, particularly in the stainless steel industry. Japanese nickel producers have increased production to cover fixed costs, despite stagnant domestic demand, and so now export over 30% of their total output. They are competing with South Korean and Chinese companies, who have to pay very low or no import duties. The Japanese industry's global competitiveness is under threat from South Korean and Chinese rivals, operating two to three times larger factories than any Japanese facility. European stainless steel rivals have also improved their competitive strength by concentrating production in a few giant mills. The EBC believes that following the well-received removal of tariffs from ferro-chromium, eliminating tariffs on nickel would be another important step towards enhancing the competitive strength of Japan's stainless steel industry.

Recommendation:

- The Government of Japan should remove import tariffs on all industrial raw materials including nickel products.

■ Fused aluminium oxide, silicon carbide and manganous manganic oxide

Yearly status report: no progress. Fused aluminium oxide, silicon carbide and manganous manganic oxide are all subject to a 3.3% tariff, though most imports come from countries enjoying tariff exemption under the Generalised System of Preferences. For some categories, a duty is being applied to some products that are not even produced in Japan. This increases the price for imported fused aluminium oxide and effectively penalises the Japanese end-user, a situation exacerbated by a current shortage of supply. With regards to silicon carbide and manganous manganic oxide, almost all imports come from only one source. In this context, such dependency on only one source makes Japan vulnerable to supply shortages or market control attempts.

Recommendation:

- The Government of Japan should remove import tariffs on all industrial raw materials including aluminium oxide, silicon carbide and manganous manganic oxide.

■ Tariff classifications

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

Recommendation:

- The Government of Japan should rationalise its tariff classification regime and develop a comprehensive strategy to improve consistency between Customs Offices on classification rulings, and to strengthen dispute resolution mechanisms.

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ENVIRONMENTAL TECHNOLOGY

Introduction

Japan's environmental technology market accounts for 16% of the global market, making it the second largest market in the world. The mere size of the market implies tremendous opportunities for foreign companies with innovative environmental technologies, machinery or services. However, foreign firms trying to enter the market are hampered by a closed government procurement system. The environmental industry and technology are to a large extent created and developed through environmental regulations and large-scale investment plans of governments. Government policies are therefore crucial for opening up the market to efficient and innovative services.

Challenges for EU-Japan Economic Integration

Although the Government of Japan is placing increasing importance on environmental protection, energy-saving, recycling, global warming and other environmental issues, there has been relatively little progress towards a comprehensive strategy to deal with the numerous environmental issues in the area of pollution, soil remediation, waste removal and water treatment.

The regulatory regime governing environmental protection and the environmental business is relatively weak in terms of consistent application and enforcement of rules, especially in regards to soil remediation. Legislation, such as the new dioxin emissions standards introduced in 2002, is enacted on a piecemeal basis, leaving many questions unanswered about how the Government intends to address its long-term environmental challenges. In the private sector, certain Japanese companies are world leaders in developing innovative environmental technologies to improve fuel efficiency and reduce pollution, yet public and private entities remain hesitant to divulge their challenges in terms of the environmental problems they face today and expect in the future. This weakens the interest of European companies, greatly experienced in this field, in investing in Japan and bringing the benefit of their expertise to the market.

The EBC is encouraged by a number of recent developments that bode well for the future of the soil remediation sector. The new Soil Contamination Measures Law, for example, creates a strict new environment for the remediation of contaminated soil sites, which will likely result in increased interest in soil remediation technologies in the immediate future. However, the long-term impact of this reform will depend to a large extent on the ability of the regulatory authorities to effectively implement these new guidelines. The EBC also remains concerned about the regulatory environment governing the soil remediation practices themselves. The Government of Japan 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 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.

The EBC believes that Private Finance Initiatives (PFI) and Public-Private Partnerships (PPP) represent a way forward for Japan to enhance the development and delivery of such services and attract European companies specialising in this field. Revision of the Water Law in 2002 enabled delegation of the management of drinking water and wastewater services to private professional operators through PFI/PPP schemes, but take-up of this new provision has been limited. The EBC, therefore, urges the Government of Japan and the EU to unite on principles and practices for PFI/PPP within an EU-Japan Economic Integration Agreement.

Key Issues and Recommendations

■ Attitudes towards environmental remediation

Yearly status report: no progress. In Japan, environmental problems such as the illegal dumping of waste, high levels of soil contamination, low levels of plastic recycling, and an ageing waste management infrastructure pose significant health and financial risks. Environmental remediation should not be regarded as an expense. The development of new technologies to combat environmental problems generates important economic benefits, and these should be emphasised.

Recommendation:

- The Government of Japan must improve education on environmental remediation and promote the development of new technologies that prevent, reduce, and manage environmental risks.

■ Regulatory structure

Yearly status report: no progress. While the regulatory regime governing environmental protection and environment-related businesses is highly developed in Japan, it is not always conducive to the introduction of innovative solutions to environmental problems.

Recommendation:

- Japan should further strengthen the regulatory regime governing environmental protection and environment-related businesses with special emphasis on consistent application and enforcement of the rules.

■ Government procurement

Yearly status report: no progress. Private Finance Initiatives (PFI) and Public-Private Partnerships (PPP) are gaining popularity in Japan. These mechanisms 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 in Japan 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. Private companies are not yet able to provide comprehensive operational management to help boost performance. This has resulted in high initial capital investment, high running costs, over-capacity, and a growing debt burden on municipalities.

Recommendation:

- The use of PFI and PPP as efficient means of delivering public services should be further encouraged in Japan. The EBC urges more Japanese and European cooperation in the development of Japan's PFI/PPP strategy to draw on the wealth of European experience in this area.

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