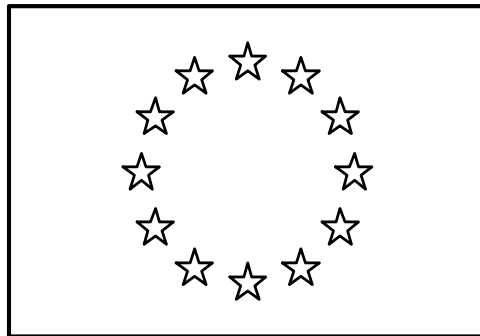


Thursday, 27 October 2005

EU Proposals
for Regulatory Reform in Japan
Final Version



October 2005

Table of Contents

Page 2-3	Table of content
Page 4-6	Introduction

1. Investment

Page 7-9	1.1 Corporate restructuring and related tax measures
Page 10-11	1.2 Legality of branches
Page 12-13	1.3 Transparency and predictability
Page 14-15	1.4 Human resources
Page 16	1.5 Accessibility of legal texts

2. Government Procurement

Page 17-23

3. Information and Communications Technology

Page 24-28

4. Financial services

Page 29-31	4.1 Banking and investment services
Page 32-34	4.2 Insurance

5. Privatisation of Japan Post

Page 35-36

6. Transport

Page 37-40	6.1 Air transport
Page 41-42	6.2 Sea transport

7. Healthcare and cosmetics

Page 43	7.1 Pharmaceuticals
Page 44-45	7.2 Medical devices
Page 46	7.3 Blood Plasma
Page 47-48	7.4 Cosmetics

8. Food safety and agricultural products

Page 49-50	8.1 Food additives and flavourings
Page 51-52	8.2 Imports of bovine and ovine products
Page 53	8.3 Organic food certification system
Page 54-56	8.4 Phytosanitary regulations
Page 57	8.5 Minimum residue levels
Page 58-59	8.6 Breeders' rights (farmers' privilege)
Page 60-61	8.7 Regionalisation

9. International standards

Page 62-63	9.1 Building standards
Page 64-66	9.2 Motor vehicles
Page 67	9.3 Packages for foodstuffs

10. Distribution

Page 68	10.1 Retail licences for large stores
Page 69-70	10.2 Alcohol licensing
Page 71	10.3. Customs control and boarder inspections

11. Other issues

Page 72-74	11.1 Animal health products
Page 75-76	11.2 Leather and shoes
Page 77	11.3 Ski-boots

Introduction

1. The European Union is grateful to the Government of Japan for providing the opportunity to offer a contribution, through the EU-Japan Regulatory Reform Dialogue, to ongoing economic reform and restructuring activities in Japan. The EU expresses its hope that this contribution will be taken into consideration when the Council for the Promotion of Regulatory Reform (CRR) elaborates its recommendations for 2005 and that the Government of Japan will be in a position to implement as many as possible of the EU proposals submitted. The EU considers that current circumstances should encourage an even more ambitious approach than heretofore particularly after the recent elections for the Lower House of the Diet.

2. There are growing indications that Japan's economy has returned to a sustained growth path. In recent quarters, domestic demand has joined net exports in driving economic growth; regular employment has begun to recover and signs of an end to deflation are increasing. There are, of course, some risks - the development of world trade, and of demand in the US and China in particular, the impact of high energy prices, the need to reduce the high level of public borrowing in Japan and the migration of monetary policy from quantitative easing to a "normal" policy stance – but overall, the economic outlook is now quite good.

3. Nevertheless in view of the fast-ageing population, an urgent medium to long-term policy priority must be to raise Japan's economic growth potential and productivity. This policy objective will be greatly helped by stepped up efforts to promote regulatory reform and economic structural change. The EU understands the challenges facing Japan as it is itself facing major economic adjustment tasks in the coming years and is tackling these through the Lisbon Process,.

4. In making its proposals for regulatory reform in 2005, the EU is encouraged by the fact that, over the past year, a lot of progress has indeed been made. Most recently, the Post Office Reform Bills have passed through the Upper House of the Diet successfully; this will, in the long run, lead to a more optimal allocation of the huge amount of funds (currently estimated at some ¥ 335 trillion) held by that organisation to the benefit of Japanese consumers and economy alike. A second big reform initiative is the revision of the Corporate Law which has been a major step forward in modernising the legal structure for Japan's business. Moreover, the announcement by the Financial Services Agency of a Programme for Further Financial Reform aimed at promoting the vitality and further liberalisation of Japan's financial markets is also highly welcome. This will build on the good progress that has been made over the past few years in strengthening the balance sheets of the financial institutions by enhancing their domestic and international competitiveness.

5. Other positive developments include the continued increase in enforcement activity by the Japan Fair Trade Commission (JFTC) and particularly the intensified crack-down on bid-rigging, as well as the amendment to the Anti-Monopoly Law which significantly strengthens the enforcement powers of the JFTC. Also to be mentioned in this context is the initiative by the GOJ to translate 180 basic legal texts into foreign languages, the overall positive development of the No Action Letter System and liberalisation of the market for foreign lawyers.

6. Looking towards the future, the results of the recent general elections for the Lower House of the Japanese Diet, which have been widely seen as a choice by Japanese citizens for political and economic renewal, create an opportunity for more ambitious efforts in regulatory reform, in line with the recommendations by the Council for the Promotion of Regulatory Reform and the Japan Investment Council.

7. Privatisation of State-owned financial institutions, which is now pinpointed in the domestic policy debate, would certainly help to consolidate a much healthier and competitive financial sector overall. Likewise, a reduction in public service numbers, particularly in areas where there is currently, or has been, a history of heavy regulation, would greatly help not only to achieve effective and small government, but, also an environment where businesses can start up easily and grow through innovation and competitive energy. Likewise, reform of the pension and health insurance systems would give these a more secure long-term foundation and thus promote consumer and investor confidence. Of more immediate importance, however, in the context of the EU's proposals for 2005, are a number of issues affecting the investment and business environment.

8. For instance, the legal framework for M&A transactions, although significantly improved by the revised Corporate Law, is still not up to a standard that will attract the inflow of foreign firms and capital into the Japanese market that is needed to reach the official target of doubling the stock of FDI in Japan over the five years from 2001. Rules for the so-called triangular merger option, which in itself was in the view of the EU a second-best option for foreign companies compared with direct cross-border mergers, will only enter into force after yet another year. A continuing lack of clarity about what the implementation of these rules will actually require causes further uncertainty. Moreover, a positive decision on tax deferral on capital gains has still not been made. When account is taken of the development of M&A defence measures in Japan, significant legal aspects of which still remain obscure, the overall message to potential foreign investors is not reassuring.

9. Another setback for Japan's overall goal of sending out an emphatic message that more foreign investment is welcomed in Japan has been the last-minute inclusion in the revised Commercial Code of Article 821 which could undermine the operation of many foreign companies in Japan through bringing into doubt their legal status.

10. In the public procurement market, procedures, and tender and evaluation mechanisms still do not encourage the entry of outside firms and deprive the public authorities and ultimately the Japanese taxpayer of better value for money and innovative solutions. In addition, the approach to liberalisation in the transport sector, seen from tourism as well as a transport business viewpoint, remains slow. Finally, in the area of regulation of food safety and agriculture, there has been very little movement in liberalisation.

11. The Regulatory Reform Dialogue (RRD) was acknowledged by Summit Leaders at the 2004 EU – Japan Summit on the occasion of the 10th year of its existence as a “uniquely successful and adaptable instrument for dealing with regulatory issues affecting business environment”. The important role of the Dialogue in helping to ensure a smooth and fruitful development of the dynamic EU/Japan economic relationship was again emphasised at the 2005 Summit. Based on this successful

experience working together for more than a decade, the EU and Japan combined should be a positive force for progress in economic reform, both on the national as well as on the international level. It is in this spirit that the EU submits its proposals for Regulatory Reform in Japan for 2005 and hopes that building on the achievement so far it will be possible to aim even higher in the coming year.

12. Finally, it may also be that we need to consider how to tackle regulatory issues before the relevant laws or regulations are finally adopted and put into operation through so-called dialogues of regulators, as we have agreed in the investment framework. This would avoid the EU and Japan adopting different approaches to the same problem. Promoting convergent regulations would require a dialogue of regulators in areas like auditing, financial services, telecommunication, transport, etc. to explore "best practice" regulatory approaches and find common solutions to common problems. It may be appropriate therefore to deepen our discussions on this issue in the future, building on the sound record of cooperation and concrete results achieved to date in the Dialogue.

1. Investment

1.1 Corporate restructuring and related tax measures

Figures for recent years show an important divergence between the trends in domestic mergers and acquisitions (M&A) activities and cross-border transactions. The number of domestic M&A, having averaged around 500 transactions per year throughout much of the mid-nineties, has increased fourfold to almost 2.000 deals in the year 2000 and thereafter. By contrast, the number of cross-border mergers has remained small, and their aggregate value fell drastically after a short peak in 1999. This does not bode well for the achievement of the GOJ's policy objective, announced in early 2003, to double the cumulative stock of FDI within 5 years.

Against this background, the EU welcomes the new Corporate Law, enacted on 29 June 2005, that will allow cross-border stock-for-stock mergers, under the 'triangular merger' formula (foreign parent companies are entitled to use their shares through a 100% Japanese subsidiary when merging with/acquiring another Japanese company). While the one-year delay for the entry into force (now envisaged for May 2007) is regrettable, this change is nevertheless a strong signal to foreign investors that their engagement in Japan is indeed welcome.

The Corporate Law does not however address taxation aspects. Thus, the rules for qualified tax-neutral mergers are not applicable. Therefore, shareholders of the Japanese company involved in such a triangular merger transaction will be taxed on the unrealised capital gains when they exchange their shares for those of the European parent company. The EU strongly urges the Government of Japan to follow the recommendation made by the Japan Investment Council, in March 2003 already, to ensure that the same tax-deferral rules on capital gains currently available for domestic corporate reorganisations between Japanese companies are extended to cross-border stock-for-stock mergers, thereby ensuring a viable and attractive M&A market for foreign operations in Japan.

The case for an early adaptation of the taxation rules is compelling now that the change in the M&A rules – while not yet in force – has been decided. Foreign investors need a predictable business and tax environment. While such tax deferral is not possible, it will be much more difficult for foreign investors to plan their entry strategies into the Japanese market.

The EU appreciates the assurances already given by the Ministry of Finance (MoF) that domestic and cross-border merger transactions will be dealt with in a strictly equitable manner. Tax deferral treatment should therefore be granted on the same criteria as apply to wholly owned subsidiaries created through stock swaps between Japanese domestic companies on the basis of Section 352 of the Corporate Law.

Furthermore, while the implementing rules for the triangular merger provisions in the Corporate Law remain to be drafted by the Ministry of Justice (MoJ), the EU would appreciate assurances that the triangular merger model will be possible without further qualifying conditions such as a requirement to be listed on Japanese stock markets. This is very important, bearing in mind that Japan did not accept the earlier suggestion made by the EU to allow direct cross-border share-for-share swaps. Since

the triangular merger model already requires the additional step of establishing an 'intermediate' legal entity in Japan, there should be no additional obstacles or limitations introduced for the European parent company or its Japanese subsidiary.

Moreover, the EU has followed closely the work undertaken by the Ministry of Economy, Trade and Industry (METI) and the Ministry of Justice (MoJ) to better identify measures by which Japanese companies could defend against takeover bids, e.g. by dilution of share capital and other anti-takeover measures. The EU appreciates the official policy intention to establish, through Guidelines announced on 27 May 2005, a level-playing field between attack and defence measures in that context, while pointing out the risk that an over-emphasis on defensive measures could be used by management to defend vested interests and would thus be detrimental to boosting corporate competitiveness. Such measures may anyway not be necessary, given that the Corporate Law already contains quite stringent requirements for M&A, such as the need to obtain approval of two thirds of the shareholders of the target company. Utmost care should be taken to ensure that the additional enforcement rules and regulations, currently under preparation, will not offset the relaxation of rules in the Corporate Law and create new barriers for cross-border activities.

Finally, the EU repeats the points made in previous years concerning tax aspects of business consolidation. The EU pleads in favour of changes in the system that would allow European companies to take full advantage of the possibilities of corporate restructuring. In particular, European firms request that the 100% ownership rule for application to subsidiaries be reduced to a 50% threshold. Furthermore, the expiry of companies' pre-consolidation losses should be abolished, as well as the obligatory taxable revaluation of assets upon entry into the consolidated group, and the obligatory integration of 100% subsidiaries to be eligible for consolidation. Finally, European companies request that local taxes should be included in the consolidation.

Reform proposals

- **a) The EU requests the GOJ to further "mainstream" investment measures across the range of government policy-making, on the basis of the broad cross-sectoral approach taken by the Japan Investment Council. This applies, also for measures promoting investment in the Three-Year Regulatory Reform Programme and in the work of the Council for the Promotion of Regulatory Reform.**
- **b) The EU strongly urges the GOJ to facilitate corporate restructuring and to allow tax-neutral share-for-share M&A by foreign companies in all cases. A decision on this should be taken swiftly so as to allow companies sufficient lead time before the entry into force of the Corporate Law.**
- **c) The EU would appreciate assurances by the GOJ that the triangular mergers will be possible for European companies as of spring 2007 without further qualifying conditions such as a requirement that the subsidiaries need to be listed on Japanese stock markets, or other restrictions of a similar nature.**

- **d) The EU urges the GOJ to address industry's concerns for companies to be able to make effective use of the consolidated tax system, and to:**
 - **replace the requirement that only 100% subsidiaries may be consolidated by a 50% threshold;**
 - **eliminate the expiry of pre-consolidation period losses of companies when they enter into the consolidated group;**
 - **eliminate the obligatory taxable revaluation of assets of companies entering into the consolidated group;**
 - **eliminate the obligatory integration of all 100% subsidiaries if a group wishes a consolidation; and**
 - **include local taxes in the consolidation. The taxation system related to Corporate Inhabitant Tax (hojin-jyumin-zei) and the Corporate Enterprise Tax (hojin-jigyo-zei) should be simplified as much as possible in order to reduce the administrative burden on companies in the preparation of related local tax returns.**

1.2 Legality of branches: quasi-foreign companies

On 29 June 2005, the Diet enacted the new Corporate Law, scheduled to enter into force in spring 2006. Article 821 of that law has profound repercussions for many European companies, as it puts into doubt the legality of their business operations in Japan.

Article 821 replaces an older provision (Article 482 of the Commercial Code) which essentially stated that foreign companies having a main office in Japan or whose primary business purpose was to conduct business in Japan (so-called "*quasi-foreign companies*") must, even though established abroad, obey the same laws and rules as firms established in Japan.

By contrast, the new Corporate Law will provide that such companies are not allowed to engage in transactions on a continuing basis in Japan (Art. 821 para 1). Persons acting in violation to this rule are jointly "and in severe terms" liable to contractual counterparts (Art. 821 para 2), with the possibility of sanctions (Art. 979 para 2) exists.

During recent decades, many European companies found it convenient, for regulatory and tax reasons, to establish themselves in third countries (as so-called Special Purpose Companies, or SPC) and operate through branch offices in Japan. In the financial sector in particular, the legal separation of banking and securities operations in Japan (Article 65 of the Securities and Exchange Law) was the reason why basically all European companies used such business structures.

The current situation is that a literal reading of Article 821 means that those business entities risk to be prosecuted for engaging in transactions on a continuous basis. Companies which are not prepared to accept this new legal risk have to convert to domestic status. While there is evidence that a number of companies are considering, or are already in the process of incorporating their business operations in Japan, many others are reluctant to take such a step since conversion is extremely costly and time-consuming for the following reasons. Capital gains tax and consumption tax would be levied at the time of transfer of assets, and all contracts with suppliers and customers would need to be re-negotiated. The potential tax burdens in case of a transfer of franchise business is the most significant risk factor for some firms, in addition to costs for accountants, legal counsel, renewal of contracts, systems, publications and stationary, registration fees for paid-in capital, plus immeasurable labour costs.

During the drafting process of the Bill, the provision of Article 821 had not been subject to public consultation (even though there had been some consultation on how to deal with the issue of quasi-foreign companies in general), and the foreign business community was taken by surprise when the actual text of the Article appeared, just before the Bill was about to be adopted by the Diet.

While the Ministry of Justice (MoJ) has made interpretative statements on the record during the Diet hearings on the scope of application of Article 821, and while the Diet has taken the rare step of issuing a Parliamentary Statement (*futai ketsugi*) together with the adoption of the bill, many corporate headquarters are concerned about the legal risks which the new rules will entail. As courts are bound only by the letter of

the law, and not by statements made during the legislative process, chief representatives of branches are concerned about how to protect against the risk of liability in case of litigation.

The EU has been informed that European companies affected by the new legislation include not only companies in the financial sector (especially securities) but also trading companies, pharmaceutical companies, law firms, as well as consultancies and project management firms.

Thus, while the GOJ has made considerable efforts to clarify that Article 821 does not intend to target 'legitimate' foreign business operations, the prevailing sense in the foreign business community is that the current situation continues to be unsatisfactory from the point of view of legal certainty. While the assurances given have been helpful for the European business community in the *interim*, there is a strong sense that only a formal amendment of the law itself would give the legal clarity sought by foreign investors.

The EU has already brought to the attention of the GOJ that Article 821 may constitute a restriction regarding the type of legal entity and therefore a measure specified in GATS Article XVI:2(e). The restriction proposed under Article 821 applies to all areas of economic activities, including services. This would be inconsistent with Japan's GATS obligations which do not foresee any kind of limitation on legal form, neither in general or for the financial services sector specifically. Moreover, legal uncertainty of this kind is counter-productive for Japan's efforts to create a more business-friendly and thereby investment-friendly environment. There is a risk that planned investments by the affected companies could be postponed or been shelved as a result.

The EU also believes that an early amendment of Article 821 should be initiated by the Government of Japan itself, and not be left to proposals by individual members of the Diet.

Reform proposals

- **a) The EU strongly urges the GOJ to amend Article 821 of the new Corporate Law at the earliest possible opportunity in order to create legal clarity. The EU would appreciate an early indication of a commitment by the GOJ towards that end.**
- **b) The EU would appreciate an assurance that the European business community in Japan will be given an appropriate opportunity to participate in the revision process.**
- **c) In line with the two-way investment framework agreed at the EU-Japan summit in 2003, the EU would suggest considering jointly how to improve the mechanism for mutual 'early warning' on pending legislation, so as to avoid recurrence of similar incidents.**

1.3 Transparency and predictability

An area of continuous concern remains the transparency and fairness of the regulatory process. Transparency means dissemination of, and access to, information for all interested operators in order to ensure fairness as well as economic efficiency.

The **Public Comment Procedure**, which is one of the major instruments to promote transparency, is designed to allow all interested parties to comment on administrative measures and draft regulations. It has recorded significant progress since its creation in 1999, most importantly through its integration into the Administrative Procedure Law. The legislative amendments necessary to do this will enter into force on 1 April 2006 and provide a legal basis for the Public Comment Procedure, while ensuring a general and uniform application within the government. The EU welcomes this initiative but would still appreciate having clarification on certain aspects of the Public Comment Procedure under the revised Administrative Procedure Law. The new law obliges the cabinet, ministries and agencies to refer their draft orders and ordinances to the Public Comments Procedure. Yet, it is not clearly stipulated whether the quasi-regulations defined by advisory councils will also be subject to the same obligations.

According to the latest annual survey of the Ministry of Internal Affairs and Communications (MIC) released in September 2005, 486 Public Comment Procedures took place in fiscal year 2004. The annual survey pointed out that there were a number of cases where the Public Comment Procedures were not appropriately applied as foreseen by the rules defined by the cabinet. One of the main concerns relates to the period of time during which stakeholders can submit comments on a draft. The process of submission of a public comment requires sufficient time to analyse the issue and reflect on it. It also implies translation work for foreign interested parties wishing to submit a public comment. The 30 days rule, a non-binding guideline so far, will become binding as of 1 April 2006. The EU regards the 30 days period as reasonable but regrets that this rule is often not respected. In fiscal year 2004, more than 50% of public comments fell short of the 30 days period. Moreover, according to the same cabinet decision, if ministries or agencies decide to shorten this period, reasons have to be given implying that such cases should be the exception to the rule. Nevertheless, the annual MIC survey demonstrates that this rule was only complied with in 10% of the cases in fiscal year 2004.

It is also essential that public comments have due impact on the outcome of the regulatory process. But in 2004, for instance, in 70% of all cases, the draft cabinet orders or ministerial ordinances were not modified at all following the receipt of public comments. This gives reason to doubt whether the Public Comments Procedure, as currently applied, serves its intended purpose.

The **Regulatory Impact Analysis (RIA)** consists in carrying out objective assessments of the impact of regulatory measures whenever the government plans to introduce, revise or abolish them. RIA is promoted by the OECD as an effective instrument for more objective decision-making and enhanced fairness in assessing

both positive and negative implications of regulations. It also helps economic efficiency as it allows unnecessary burdens to be identified both for the administration and economic operators. The EU welcomes the increased attention of the GOJ on RIA, as demonstrated for instance by the Government Policy Evaluations Act. In order to make the RIA an objective and efficient tool, the EU suggests that the GOJ reflects on taking into account public input, for example by using the opinions collected through the Public Comment Procedure. Furthermore, the publication of the results of the RIA through the Electronic-Government (e-Gov) Programme, would contribute to improve transparency of government regulatory action.

Reform proposals

- 1. With regard to the Public Comment Procedure, the EU urges the Government of Japan to improve its implementation and furthermore to:**
 - **a) Clearly state whether the quasi-regulations defined by advisory councils are subject to the revised Administrative Procedures Law;**
 - **b) Enforce and monitor the use of the Public Comment Procedure by ministries and agencies, and in particular ensure that the 30 days period is applied effectively across all ministries and government agencies, until the entry into force of the revised Administrative Procedures Law;**
 - **c) Ensure that those ministries, agencies, and, where applicable, advisory councils allow sufficient time to take into account properly public comments in draft regulations and reports.**
- 2. With regard to the use of Regulatory Impact Analysis, the EU requests the GOJ to:**
 - **d) Extend the use of RIA to all fields of activity, enhancing its use in public works, research and development, and official development assistance;**
 - **e) Take into account public input while processing the RIA;**
 - **f) Provide public information access by publishing the conclusions of RIA.**

1.4 Human resources

The importance of human resources for a dynamic investment environment is recognised by the Japanese government and the EU. In this respect, both will continue to address the issue of employability in the context of globalisation on the occasion of the 11th EU-Japan Symposium in Brussels in March 2006.

Continuing regulatory reform steps remains a priority in order to secure a high standard of foreign employees and efficient management of foreign companies having an office in Japan. In this context, the EU would like to point out that existing pension schemes and some rules and procedures related to immigration and residence status can significantly limit the incentive for expatriates to engage in professional activity in Japan.

For instance, the current obligation for foreign employees to pay into the Japanese pension system has an adverse impact on business development and investment, since in many cases they will not stay in Japan long enough to receive benefits or a full refund at the time of their departure from Japan.

The conclusion of bilateral agreements with Member States will be conducive to a solution in the longer term. The EU welcomes the fact that a number of bilateral social security agreements with EU Member States have been concluded, or are being negotiated at present. However, it will still take a considerable time at the current pace to solve the problem of dual pension membership and wasted premium payments for all EU citizens.

In the absence of bilateral social security agreements, departing foreign workers can benefit from a partial refund system of exceptional and temporary nature (*tanki zairyu gaikokujin ni taisuru dattai ichijikin*), adopted by the Japanese government in the Pension Law in 1994 in order to alleviate this specific problem. Foreign workers living in Japan must contribute to the Japanese pension system as do their employers. When leaving Japan, they can receive a partial refund of pension contributions, capped at 3 years, if they have worked in Japan for longer than 6 months and less than 25 years.

The Japanese government response to the 2004 EU proposal on this issue states that as the designated term of the residence permit is three years at maximum, the three-year limitation of the refund system should be maintained. Nevertheless, the EU continues to request that (i) departing expatriates should receive a full refund of the equivalent of all mandatory pension contributions paid in to the date of departure from Japan, or (ii) the period and the amount for the refund should at least be extended to 5 years in line with recent developments to extend the length of stay of certain foreign groups of workers (e.g. those working in Special Zones for Structural Reforms).

The EU would like to point out that in order to improve the investment environment, some additional unilateral measures on pension schemes would help to offer more flexibility for personnel management. There is reason to believe that many European residents in Japan not yet covered by a bilateral agreement would envisage a longer stay if the 3-year cap was to be extended or lifted.

The argument cited above for improving the investment environment applies similarly to the EU's requests for increasing tax-exempt contribution levels for

defined-contribution pension schemes, allowing matching contributions, and allowing borrowing against pension reserves, as well as for making contributions to foreign-based pension plans subject to the same tax-exemption rules in force for pension plans in Japan.

The EU also requests an urgent relaxation of residence and immigration rules and accelerated implementation of relevant procedures, such as visa rules, work permits and other stay-related requirements in order to encourage foreign investment.

In addition, European companies face difficulties in securing personnel with specific skills in areas such as legal services, engineering, biotechnology, financial accounting and IT when operating in Japan. The EU takes note of the efforts of the Ministry of Justice to stimulate the inflow of workers possessing relevant skills, but, relaxation of immigration laws alone is not enough. The Japanese education and certification system does not effectively address the widening gap between competency levels and the specific skilled labour needs of employers in all areas in today's increasingly global economy. The EU would like to emphasise the need for increased recognition of foreign certificates and licences so that employees with certified special skills, but, lacking a university degree or ten years working experience are also able obtain a working visa.

Concerning foreigners already present in Japan, with a resident visa status, the Japanese immigration law demands that each time they leave Japan, for whatever purpose, they must apply for a re-entry permit in person and in advance of departure for a fee (yen 3,000 or yen 6,000 for a multiple re-entry permit). The EU considers this system as unnecessarily burdensome and peculiar, as most other countries do not have such rules, and requests its swift abolition.

Reform proposals

1. Concerning pension schemes, the EU encourages the GOJ to:

- **a) Conclude bilateral social security agreements with all EU Member States as soon as possible.**
- **b) Increase the cap to 5 years as a first step towards allowing for a full remittance of the actuarial equivalent of mandatory contributions to the Japanese public pension system to departing expatriates.**
- **c) Make contributions to foreign-based pension plans subject to the same tax relief as contributions made to pension plans in Japan.**
- **d) Improve the defined-contribution pension scheme by increasing tax-exempt contribution levels, allowing matching contributions, and plan-holders to borrow against their pension reserves.**

2. Concerning the rules and procedures related to immigration and residence status, the EU proposes:

- **e) Consider further relaxation of visa requirements to meet the needs of European companies, especially regarding personnel with specific skills.**
- **f) Abolish the system of requiring re-entry permits**

1.5 Accessibility of legal texts

In the global business environment, the aspect of translation and harmonised use of terminology has become of utmost importance. Foreign companies depend hugely on access to a uniform and authoritative translation of legal texts.

The EU therefore welcomes and fully supports the initiative taken in early 2005 by the GOJ to create a consolidated approach to translation of Japanese laws and ordinances into foreign languages.

The official target of translating 180 laws by the end of fiscal 2009 is ambitious, and it is to be hoped that sufficient financial resources will be dedicated to this endeavour in order to achieve it successfully.

In order to identify relevant areas better in detail, it may be advisable for the committee established in January 2005 under the Cabinet Secretariat - which is being supervised by the Office for Promotion of Justice System Reform – to be supplemented by an adequate number of European business and legal experts able to participate in the selection process of priority areas for translation. They could be helpful in exposing the range of legal concepts which exist among major foreign trading partners, and the detailed consequences therefore of choosing a particular uniform legal terminology in translations.

Reform proposal

- **The EU encourages the Government of Japan to ensure adequate representation of European business and legal expertise in the committee which oversees the project of translating Japanese legislation into foreign languages**

2. Government Procurement

The EU welcomes the continuation of the bilateral dialogue on government procurement. This helps to enhance mutual awareness of our respective government procurement systems and to share good practices in a field where tasks and challenges are similar. The EU and Japan, like any other signatory to the WTO Agreement on Government Procurement (GPA), are committed to achieving increased liberalisation and expansion of world trade.

In any competitive bidding process, the basic principle of non-discrimination is clearly of paramount importance. However, there is also a range of other practices which, although neither directly nor indirectly discriminatory in character, still have the effect of stifling competition. Procurement policy will therefore only deliver its benefits to society if it promotes open, transparent and competitive tendering. Only respect of these principles will help reduce budgetary pressures, stimulate innovation and counter collusive practices.

If potential suppliers have first to navigate through a complex web of administrative procedures before they are able to participate in competing in a call for tender, they are likely to be discouraged from participating. If, in addition, these procedures are felt to be applied in a manner lacking transparency, potential suppliers are likely to shy away from making the upfront investment involved in the sound preparation of a detailed bid. As a result, procuring entities which do not address these disincentives will forgo access to the most innovative solutions available.

The EU has noted with interest recent developments in Japan, such as the "Measures for preventing recurrence of bid-riggings" announced by the Ministry for Land, Infrastructure and Transport (MLIT) on 29 July. The EU proposes discussing these measures further at the 2005 Expert and High Level Meetings of the Regulatory Reform Dialogue. These measures also provide an opportunity to review together with the appropriate Japanese authorities the notion of "open and selective tendering procedures" under both the GPA and the Japanese legal system.

Placing procurement policy in the wider context of economic policy, the EU welcomes the determination of the Japanese Government to promote regulatory reform. One key initiative suggested in this respect is to use more market testing in order to determine which administrative tasks could be provided by market operators on an equivalent basis to governmental entities. The EU is confident that Japan, when inviting the private sector to find innovative approaches, will not fail high-quality and cost-effective solutions offered by suppliers with global expertise. The EU points out that the full range of such expertise will usually be accessible only through genuinely open tendering procedures in accordance with the GPA.

Moreover, the initiatives taken by Japanese authorities with regard to countering bid-rigging involving representatives of the private and the public sector (kansei dango) lend further credibility to Japan's commitment to continue on the path of economic modernisation and liberalisation.

Yet, despite these encouraging developments, the EU still considers that certain features of the Japanese procurement system for public works are not compatible with, transparent, open and competitive tendering systems, when viewed by reference to the following benchmarks:

- *A transparent procurement system provides potential bidders with an immediate overview and fast understanding of the full range of procurement opportunities, establishes clear and objective criteria for the evaluation of a bidder's qualifications as well as the final selection of the winning bid, and offers access to effective review procedures, including the possibility to obtain interim relief.*
- *An open procurement system recognises a firm's technical capacity irrespective of how this experience has been gained: such an approach bases specifications on performance and international standards, and generally encourages bidders to present alternative solutions for a procuring entity's requirements.*
- *A competitive procurement system does not offer undue advantages to certain bidders, as it is structurally and effectively set up to discourage collusive behaviour, and is designed to facilitate participation by potential competitors; in particular, this does not create a regulatory framework which deters suppliers not customarily competing on the market, for example through disproportionate qualifications requests and registration requirements.*

By reference to these benchmarks, the EU encourages the Japanese authorities to liberalise their procurement markets further and to reconsider their approach with regard to the following aspects:

MLIT's certification of foreign experience

A supplier demonstrating his capacity is only able to have his foreign experience recognised after obtaining a certification by MLIT prior to the bidding. The EU considers this two-step system to be potentially discriminatory and a deterrent for foreign bidders. In the EU, foreign experience is evaluated by the procuring entities on an equal footing with domestic experience. Foreign companies are entitled to present their technical capacity and other requirements according to the law of the site of establishment.

Business evaluation (*keishin*)

The EU considers that the business evaluation takes too long to allow companies to participate adequately in a *particular* tender after publication of a tender notice. Article XI of the WTO Agreement on Government Procurement provides for a minimum 40 days delay for the receipt of tenders from the date of publication of a tender notice.

The EU understands that it is often impossible to manage the business evaluation process within this time frame. As a result, the business evaluation tends to exclude new market entrants. Moreover, the entity directly responsible for a particular procurement is arguably the best suited to determine the level of capacity necessary for the task to be performed.

The business evaluation score is the result of a global assessment of financial and technical abilities. One particular area of concern is the lack of a minimum level required for each specific capability. The EU understands that it is not uncommon for companies with extremely low financial capacity to obtain a rather high business evaluation score because of being “compensated” with a strong score on technical capability, such as the number of engineers or total staff, past experience, etc. An overall business evaluation would better reflect the real financial and technical situation of a company by requiring a minimum level for each element assessed.

Compulsory registration before each procuring entity

In addition to the business evaluation, companies are obliged to register with each procuring entity. Registration is required every two years and there is no automatic renewal. In addition, it is to be underlined that the registration requirement is operated in parallel with the business evaluation process. The information required for the purposes of the registration procedure could be more efficiently collected either through the business evaluation, or through the actual submission of a tender. The EU is of the opinion that this requirement places a disproportionate burden on suppliers. It is in contradiction with an efficient tendering system, especially where parallel administrative procedures require bidders to submit overlapping sets of information. This being said, the EU recognises however that Japan has recently started to improve the system. Nevertheless, these changes do not go far enough to remedy the concerns raised by the registration process.

Price-ceilings (*yotei kakaku*) and bid-rigging

Procuring entities in Japan often calculate a ceiling price (*yotei kakaku*) aiming at preventing a price escalation, as provided for in Article 29 of the Accounting Law and Article 234 of the Local Autonomy Law. The ceiling price is the upper limit for a successful competitive bid for public works, and in case there is no bid with a lower price figure, the tender fails.

In addition, Japan also operates a minimum price system where, in case of an unusually low price, performance in fulfilling the contract at the offered price is assessed separately. Local entities often do not conduct an evaluation of performance in cases of abnormally low bids, but set a minimum low price below which any tender is automatically rejected. Furthermore, this often does not take into account new technologies which allow to lower prices. As a result, particularly efficient suppliers are eliminated from the bidding process.

Furthermore, the price ceiling system may also favour leaks and facilitate collusive practices such as bid-rigging, which undermine the competitive character of the tendering process. While the more determined administrative and judicial prosecution of collusive practices now under way in Japan is an important development, the scope for such practices could be much reduced by reforming the system itself.

EU procuring entities do not use price ceilings, although they sometimes publicly announce an estimate of the budget available for a given project. This EU practice prevents entering bids with a price well in excess of the available budget and adjusts the bids to available public funds, without putting a ceiling or giving a figure. Regarding abnormally low bids, the EU procurement system allows for this possibility

and calls for an examination of the reasons for such abnormally low prices rather than foreseeing a simple rejection of such bids.

Price references

The EU understands that procuring entities both at central and local level, when calculating their ceiling prices, usually refer to price reference books. These are being regularly updated and published by two non-judicial foundations, i.e. the Construction Research Institute and the Economic Research Association (originally established by MLIT and the Cabinet office, respectively). These reference books tend not to include many foreign products. The EU considers, however, that these reference books should include products which have successfully entered other overseas markets in a significant way. In order to avoid a structural perpetuation of the existing market situation, demonstrating a substantial market share in Japan should not be a qualifying criterion.

The EU understands that many local authorities seem to believe that they are bound to buy products contained in these reference books. This view seems particularly common when projects for public works include central government subsidies. To correct this misconception, it would be most helpful if the GOJ was able to address this issue, for example in a circular note. Procurement entities at prefectural and municipal level should be reminded that they are free to buy products directly from overseas suppliers.

Open and selective tendering.

According to Article VII of the WTO GPA, open tendering procedures are procedures under which all interested suppliers may submit a tender, whereas selective tendering procedures are procedures where the entity contacts suppliers individually under specific conditions. Notwithstanding these definitions, the EU understands that no interested supplier in Japan is eligible to submit a tender without having been examined first regarding his qualifications in one way or another. This situation also seems to be the case when procuring entities use the so-called "open and competitive" tendering procedure.

In these circumstances, the EU has difficulty to see the difference between an "open and competitive" procedure in Japan and a selective tendering procedure within the meaning of Article VII of the GPA. It appears that procuring entities systematically use what would be considered in the terminology of the GPA either selective or limited tendering procedures.

A systematic use of selective rather than open tendering procedures, as defined by the GPA, is a strong indicator that a procurement system is not 'open' as described above. Where potential market entrants from abroad are much less likely to compete for a particular contract, the market structure provided by the remaining suppliers is correspondingly less competitive. In combination with other factors, the situation described above tends to facilitate collusive practices. Hence, the loss of openness frequently also entails a loss of competitiveness.

Lastly, it should be noted that the Japanese system tends to combine this pre-qualification screening with a rating system. This system classifies suppliers into different categories/orders. The practical effects of such a system, even in the case

of “open and competitive” procedures, are quite similar to those resulting from the establishment of a permanent list of suppliers. As a result, procuring entities tend to continue making their procurements from the same pool of suppliers.

As an illustration of this systemic problem, MLIT clarified recently that “all public works contracts worth 200 million yen or more will be subject to open competitive bidding, down from 730 million”. Nevertheless, the implementation of this measure during the next fiscal year will increase the ratio of the MLIT's contracts awarded through bidding only from 2.3% to 15% in absolute terms, or, in terms of value, from 27% to 57%. One has to assume that the remainder of the projects will still be awarded through bids among designated contractors or without any bidding at all.

As a comparison, in the EU, 80% of procurement procedures for public work contracts were awarded under an open tendering procedure, as defined by the GPA, during the 1999-2003 period.

Technical specifications

There are reports that technical specifications are often too narrowly prescribed and do not allow bidders to bring any added value or innovative solutions. In this context, the EU recalls that Article VI of the GPA requires that technical specifications be set in terms of performance rather than design or descriptive characteristics. Moreover, requirements, or references, for a particular trademark or trade name, patent, design or type, specific “origin, producer” or supplier are not permitted unless words such as “or equivalent” are included in the tender document. Otherwise, procuring entities will forgo their access to the diversity of technical solutions. Thus, in order to be able to demonstrate equivalence, suppliers should be permitted to use any appropriate form of evidence, and procuring entities have to be capable of providing reasons for any decision rejecting equivalence.

Transparency

In accordance with Japan's 1994 Action Programme on Government Procurement, the Ministry of Foreign Affairs organises an annual briefing on government procurement at the beginning of each fiscal year (as soon as the Budget is approved by the Diet). The EC welcomes this initiative which provides enhanced transparency and predictability.

The EU regrets, however, that the annual briefing on government procurement does not cover public works and public construction. The EU understands that this type of information is not released centrally, but rather individually by MLIT or its local branches, depending on which entity is directly responsible for a given procurement project.

In the EU, the central tender database “TED” provides an instant overview of all tenders launched - or to be launched - for any member of the public in any of the EU's Member States. In terms of coverage, this transparency tool goes far beyond the range of calls for tenders covered by the GPA.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- a) In addition to the MLIT certification system, the EU recommends allowing direct recognition of foreign experience by the procuring entities in the Keishin evaluation and during the qualification phase. No distinction should be made between foreign and national experience; both should be considered equally.
- b) The EU recommends eliminating the obligation for companies to undergo the business evaluation prior to tendering. If the system is maintained, it should be optional for suppliers to have the business evaluation carried out centrally or by the procuring entities themselves regarding each procurement procedure.
- c) As far as public work contracts are concerned, the EU recommends eliminating compulsory registration or replacing it with a centralised registration at MLIT, valid for all procuring entities nationwide.
- d) The EU recommends suppressing the current price ceiling practice or to replace it by a mechanism similar to the one applied in the EU, i.e. indicating the earmarked budget for a given contract.

Abnormally low priced tenders should not be automatically rejected. Instead, suppliers should be given the possibility to justify and explain the reasons for their pricing.

- e) The EU recommends allowing procuring entities to consider “equivalent” solutions which do not comply with the design or descriptive characteristics of the technical specifications, but do clearly meet the requirements thereof and are equivalent for the purpose or needs of the procuring entities in question. The EU encourages Japan to consider innovative solutions as an alternative to rigid technical specifications.

In this context, the EU requests Japan to introduce more flexibility in the technical requirements for green procurement and accept “equivalent” production solutions, instead of prescribing manufacturing processes and specific content.

- f) The EU recommends reviewing the current legislation and practices on examination of qualification to allow suppliers to tender, without any prior check of their capacity where an open tendering procedure is used.
- g) The EU recommends that the price reference books used by procuring authorities should include foreign products, especially where international competition is mature in overseas markets. Sole reliance on a firm’s domestic market share tends to perpetuate closed markets.

In this context, the EU also suggests that the Government of Japan recalls to procuring entities at prefecture and municipal level that they

are not bound to purchase products only from among those listed in the price reference books.

- **h) With a view to enhancing the competitive elements of the procuring process, the EU recommends facilitating market entry by publishing the list of all procurement planned during the fiscal year on the website of MoFA / MIC for the information of companies not established in Japan and wishing to participate in public procurement.**

Pending the introduction of such a centralised system enhancing transparency, the EU recommends expanding the scope of the annual seminar to cover all public works projects to be carried out during the fiscal year.

3. Information and Communications Technology (ICT)

General remarks

The EU notes that since the last round of discussions on the EU proposals, Japan has started to initiate reforms in the ICT sector, in particular as regards interconnection, frequency allocation, and the establishment of a new framework to carry out assessments of the state of competition. The EU welcomes these initiatives, but considers that more progress will be needed before a proper evaluation can be made. Meanwhile, some aspects remain a matter of concern.

The GOJ has embarked on a national "IT Strategy" designed to improve the information technology infrastructure in Japan. Internet access costs have fallen dramatically and access to broadband infrastructure is among the most developed in the world. At the same time, Japanese service providers are developing new information and communication technologies in such areas as 3rd Generation (3G) wireless commercial applications faster than anywhere else in the world. This is an outstanding national achievement, one of the few bright spots in an otherwise difficult global market environment for information and communications technology.

At the same time, it is very important for the GOJ to respect current trends towards globalisation when implementing its ICT policies. The EU supports an industry-led, global approach to standards and platform development, and is encouraged by signs that the GOJ supports these initiatives as well. The EU appreciates that the EBC (European Business Council) is able to contribute to the Ministry of Internal Affairs and Communications (MIC) policy committees as an official participant.

The EU is pleased to note that the GOJ introduced a Supplier's Declaration of Conformity (SDoC) on January 26th, 2004. Such a system has already been introduced in Europe, which has made it easier for manufacturers to quickly introduce new products in the rapidly developing telecommunications market. Unfortunately, the SDoC process will only be applied to a limited range of equipment in Japan. We feel that the Japanese SDoC system should be as broad-based as possible, comprehensively covering all wired terminal equipment and specified radio equipment as is the case in Europe.

We note that the Japanese government will grant new licenses to newly set-up 3G wireless operators on 1700MHz and 2GHz towards the end of 2005.

Fragmented qualification procedures, sole sourcing, as well as selectively disclosed specifications regarding certain projects continue to prevent foreign companies from supplying GOJ entities with telecommunications equipment. We would encourage the GOJ to introduce further improvements in areas such as disclosure, bid criteria/performance specifications, qualification procedures, and open bidding procedures to ensure public sector procurement of foreign telecommunications equipment keeps pace with the private sector.

Summary of previous EU reform proposals and follow-up

Regarding the independence of the telecommunications regulatory authority, the EU appreciates the progress made but still feels that the situation leaves room for further improvement.

On the application of the long-run incremental cost (LRIC) model on interconnection, some progress has been made. However, the EU is concerned both about the time-scale and the possibility that any advances made will be off-set by an increase in other charges which would have to be borne by competitors of NTT.

Regarding the establishment of a technologically neutral regulatory framework for electronic communications, it seems obvious from the responses received by Japan that the current situation remains mixed: while in some areas competition appears to be a reality, in other areas, in particular in the local fixed line market, this is obviously not the case.

On the recognition of joint dominance in Japan's regulatory framework, the response has been duly noted.

Regarding maintenance of wholesale and retail tariffs notification requirements for carriers with significant market power and/or having control over essential facilities, further clarification on the situation of non-designated carriers would be welcome.

On implementation of universal service, cross-subsidies between different parts of business as well as the maintenance of uniform prices both lead to market inefficiencies in particular, which constitute barriers to new market entrants.

Regarding additional spectrum allocation for the additional IMT-2000 bands for 3G mobile communication systems, the EU welcomes Japan's proposal to continue to exchange information and takes note of the current activities.

Regarding obligations under the TBT agreement to render market access regulations as least trade restrictive as possible, the general concern expressed is shared, but the EU would still welcome the opportunity to discuss this further.

On a ban of prepaid mobile phones, we understand that this is no longer being considered as a policy option and welcome this development.

Current situation

Institutional reform

It is clearly inappropriate for the GOJ to act both as regulator and shareholder. The MIC has wide-ranging statutory powers of intervention and control in the Japanese telecommunications sector. The exercise of such powers in an environment without clear separation between the government as owner and regulator introduces a high degree of uncertainty and unpredictability into the regulatory process. Most other countries have established independent regulators whose decisions are the basis for promoting the long-term interests of consumers and a competitive market

environment. Japan needs to ensure that there is full privatisation of NTT and that the regulator is truly independent. Accountability could also be improved by strengthening the public consultation process.

Strengthening competitive safeguards

Regulatory constraints have not been effective in preventing anti-competitive behaviour by the NTT group. In many ways, revisions to the Telecommunications Business Law (TBL) enacted in 2003 have made this situation worse. For example, NTT is no longer obliged to notify and price its tariffs, which makes it difficult to police anti-competitive behaviour. There is evidence that NTT is actively using its dominant position to expand into new business areas, including by cross-marketing new services to its customer base in areas where it is currently dominant. Aggressive action should be taken to strengthen firewalls and ensure complete and transparent accounting separation, horizontally across different business lines and vertically between network and retail parts of the business. If this proves inadequate, the local access network should be separated from the rest of NTT's business, to remove any possibility for NTT to abuse its dominance.

Fixed-line interconnection and Universal Service

The welcome decision to exclude NTS (Non Traffic Sensitive) costs from fixed interconnection charges has been undermined by two other steps that have been taken. Firstly, the five-year period being given to NTT to phase out NTS charges is excessively long. Rebalancing of charges should take no longer than three years. More importantly however, the EU is extremely concerned that NTS costs have been merely transferred to the Universal Service Fund (USF) which is to be established by Japan. This effectively eliminates the competitive progress that was made by excluding these costs from the interconnection charges. Allowing for recovery of these costs through a USF **effectively reintroduces on competitors**, and ultimately on consumers **a tax** which was previously recovered through the interconnection charge.

Spectrum

The recently announced spectrum allocation policy for 1.7GHz and 2.0GHz spectrum has the potential to result in the concentration of 3G spectrum in the hands of dominant operators thus causing significant damage to the competitive environment in Japan. An allocation policy based upon a methodology that allocates growth spectrum based on subscriber numbers and which fails to distinguish between dominant and non dominant operators ignores the unmatched advantages of revenues, volumes, scale and scope which benefit the dominant operators. This provides the opportunity for dominant operators to consolidate their position further through the concentration of spectrum.

The potential for concentration is exacerbated by the failure to require dominant operators to take into account the available spectrum to be reframed for 3G. The allocation policy therefore does not promote the most efficient use of spectrum, creating the possibility for reframing of 3G spectrums to be withheld while applications for 1.7GHZ spectrum are made. The practical application of the guidelines must therefore be monitored and Japan should be prepared to amend the

current policy by introducing measures such as a spectrum cap or revised thresholds or alternatively ensure the application of the policy in a manner which prevents the concentration of spectrum by dominant operators. Further concentration of spectrum in the hands of dominant operators will aggravate existing spectrum imbalances among mobile operators, further distorting competition in the mobile market.

Harmonisation in requirements for Ultra-Wide Band (UWB) equipment

The Japanese Government is studying the regulatory framework to introduce radio equipment based on UWB technology. UWB has significant potential in the CE and IT mass markets, but also raises interference concerns with existing and future radio systems in the bands between 2 and 10 GHz, which are used by all main radio services (mobile, broadcasting, aeronautical, military, etc.). Given the expected dissemination of UWB-enabled devices, globally and regionally harmonised technical requirements would be beneficial to consumers and reduce the use of illegal equipment. While the US has already regulated UWB, close similarities exist among more restrictive technical/regulatory solutions under consideration in the EU and in Japan. It would therefore be useful to explore whether the two parties could reach similar regulations concerning these applications.

Mutual Recognition Agreement

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

Suppliers Declaration of Conformity (SDoC)

The EU welcomes the introduction of SDoC by the Japanese Government at the beginning of 2004, as has been introduced in Europe. However, the EU is disappointed that this system will be limited to wired telecommunications terminals, with limited application to wireless/radio equipment.

Reform proposals

The EU has the following proposals:

- **a) The institutional structure of Japan's telecommunications regulatory environment should be reformed. Fundamental steps should include the full privatisation of NTT and the creation of a regulator who is truly independent of both government and commercial interests. While intrusive micro-management should be avoided, more emphasis should be put on macro-level economic criteria designed to promote economic efficiency, innovation, investment, and effective competitive outcomes. More efforts should be made to include public concerns in the decision-making through a genuinely open consultation process.**

- **b) Japan should strengthen competitive safeguards against abuse of dominance by reinstating the obligation for NTT to notify and price its tariffs in all market segments where it is dominant; requiring NTT to publish regulatory accounts horizontally across its different businesses and vertically between the network and retail parts of its horizontal business; strengthening firewalls to prevent NTT from abusing its dominant position in the local access network for entering into new business areas.**
- **c) Japan should ensure that Non Traffic Sensitive (NTS) costs which are eliminated as part of the interconnection charges are not transferred to the Universal Service Fund (USF), thus creating a continuing taxation of competitors.**
- **d) The GOJ should ensure that the implementation of its recently announced spectrum allocation policy does not lead to the concentration of 3G spectrum in the hands of dominant mobile operators, thus distorting competition in the mobile market.**
- **e) The EU urges the GOJ to harmonise technical requirements of ultra wide band (UWB) radio equipment with global and European standards.**
- **f) The EU urges the GOJ, in cooperation with EU authorities, to implement all parts of the EU-Japan Mutual Recognition Agreement (MRA) without delay.**
- **g) SDoCs issued by European producers should be accepted in Japan without any additional testing or administrative requirements, not only for wired terminals, but for specified radio equipment as well.**

4. Financial Services

The EU warmly welcomes the new forward-looking Program for Further Financial Reform – Japan’s challenge: Moving towards a Financial Services Nation, which shifts the emphasis from financial system stability to financial system vitality. If effectively implemented, it will allow further liberalisation of Japanese financial markets, eventually leading to an integrated financial industry in Japan, with enhanced domestic and international competitiveness.

European and Japanese financial institutions and markets are likely to become more, not less, interdependent in the coming decade. Market dynamics will force regulators and supervisors in both markets to make further adjustments. Close co-operation between the EU and Japan is very much in our joint interest as it will allow us to address effectively common challenges and create a global financial framework based on equivalent norms and international standards.

The EU thus shares the Japanese view that, as globalisation progresses, the necessity of strengthening partnerships with overseas regulators is increasing, while the movement towards global convergence of regulations and standards is accelerating. The EU therefore particularly welcomes indications that Japan will (1) strive to adhere to the principle of equal treatment of domestic and foreign financial institutions, (2) make the Japanese financial system and financial markets universal, and (3) play a leading role in international standard-setting activities regarding financial services. A legal framework to improve the transparency and predictability of financial administration and to achieve full accountability is of equal importance.

The new program takes a strong global perspective and it addresses, entirely or partially, many issues previously raised by the EU in the Regulatory Reform Dialogue. This will generate a positive long-term effect on market stability and investor confidence. The EU also welcomes the recent changes made to the Securities Exchange Law (2004), the Insurance Business Law (2005), the proposals to revamp the Banking Law, as well as the preparations for the upcoming Investment Services Law and for the legal framework for financial conglomerates.

4.1 Banking and investment services

The *Program for Further Financial Reform* includes steps to introduce a legal framework that can address the inspection and supervision of financial conglomerates, the treatment of cross-sectoral problems, the emergence of new forms of transactions and products as well as an increased user-friendliness through the spread of ‘one-stop financial services’.

The EU acknowledges the steps that are being taken to ease some of the restrictions which keep banking, securities and insurance operations separate (such as the joint use of premises by banks and securities companies). So far, these measures have nevertheless fallen short of addressing a key EU concern: the abolition of Article 65 of the Securities and Exchanges Law prohibiting universal banking. The remaining

barriers due to this separation have been particularly detrimental to European financial services firms as most are part of universal banking groups.

As long as these separations remain, it would be a helpful step for the European financial groups to be able at least to develop some common functional authorities (e.g. a 'group senior representative') for the banking and securities business, so as to allow them to consolidate central functions such as compliance or legal supervision, instead of being forced to operate with two separate management teams.

The *Program for Further Financial Reform* calls for the unification of the market surveillance system and appropriate partnerships with self-regulatory organisations so as to strengthen market supervision. The Financial System Council has recommended that a review of the plethora of self-regulating bodies and their functions be carried out as part of the current financial system reform. The current overlap of functions between various regulators needs to be eliminated and the overall burden of reporting requirements to those various bodies should be streamlined.

In this context, the EU notes that the Investment Services Law will be enacted as a new umbrella law to establish a framework of comprehensive and cross-sectional protection of users of a wide range of financial products on the basis of the current framework of the Securities and Exchange Law and the Securities Investment Advisor Law. It will incorporate other laws and rearrange them by their functions in a cross-sectional manner.

The EU believes that this will provide the perfect opportunity to merge two hitherto separated legal instruments, i.e. the Securities Investment Advisory Law and the Securities Investment Trust Law, into one consistent set of rules. As a consequence, this would allow the industry to work in a consolidated legal environment, thus avoiding disparate licensing, filing and customer disclosure requirements. It could also lead to a consolidation, in due course, of the two self-regulating bodies in this field (the Japan Securities Investment Advisers Association and the Investment Trusts Association, Japan), and eliminate the current duplication of procedures.

Furthermore, although most major financial markets allow asset managers to place orders in domestic securities markets on behalf of overseas group affiliates, this is not possible in Japan without a securities business license. This is an impractical solution for asset management firms given the costs involved in setting up the necessary firewalls (see the request related to Article 65). The EU reiterates its request that the necessary amendments be made to the Investment Advisors Business Law in this regard.

Japanese city banks have been allowed to engage in trust and banking business concurrently since 2002. But neither these reforms nor the recent changes following the revision of the Trust Business Law (2005) apply to foreign bank branches. The EU therefore repeats its request that the relevant definitions (Article 1 of the Concurrent Operations Law and Article 2 of the respective enforcement ordinance) be modified so as also to include foreign banks in the scope of definition. In the EU, concurrent

operation of banking and trust business is possible in those countries of the EU where trust business is practised.

Furthermore, the EU would like to remark that some of the replies given by the GOJ to the various proposals below refer to specificities in the legal and regulatory environment of Japan (example: firewalls under the Securities and Exchange Law, Article 65), while other issues touch upon considerations relating to reciprocity (e.g, concurrent banking and trust business, Concurrent Operations Law, Art. 1). The EU would like to better understand whether and how, under the *Program for Further Financial Reform*, the criteria of reciprocity is anchored as a factor of consideration for the ongoing reform process.

Reform proposals

- **a) The EU renews its request to allow financial institutions to undertake the full spectrum of activities e.g. banking, insurance and securities activities, thereby ensuring a sound integrated financial industry in Japan. The provisions of Article 65 of the Securities and Exchange Law, which prohibit integrated management of banking and securities businesses, should thus be abolished.**

As an interim step, companies in the same group should be allowed to build up common functional authorities within a virtual holding company thus permitting efficient group management within global financial industries.

- **b) The EU requests the GOJ to ensure that the review of the self-regulating bodies and their functions be carried out as part of the current financial system reform, with the aim of removing overlaps of functions between regulators and self-regulatory organisations, and thus streamlining the overall burden of reporting requirements.**
- **c) The GOJ should revise the Investment Advisors Business Law to allow asset managers licensed in Japan to place orders to buy or sell Japanese securities on behalf of group affiliates.**
- **d) No difference should be made between foreign and domestic branches as regards trust banking in that foreign bank branches in Japan should also be able to engage in trust and banking businesses concurrently.**

4.2 Insurance

The EU appreciates that the Financial Services Agency (FSA) is actively promoting regulatory reform in the insurance sector. In June 2005, the FSA announced an expansion of the scope of insurance products sold by banks, together with some new consumer protection measures. As from December 2005, banks will be allowed to sell single premium endowment/single premium whole life policies, personal non-life insurance other than automobile insurance, and maturity-refund type personal accident policies.

While this represents a positive step, it only affects a few single premium savings products that are similar to policies that banks are already allowed to sell. The increase in the variety of products offered to the consumer, therefore, remains limited. The EU expresses its hope that all remaining insurance products will be liberalised promptly, i.e. well ahead of the final target date of end-2007, in order to offer a better choice of insurance products as well as distribution channels to consumers.

The revised Insurance Business Law (IBL), due to enter into force in April 2006, will include a revision of the current safety net for insurance policyholders. The calculating method for financial contributions to the Life Insurance Policyholder Protection Corporation will be revised by FY2009. The current pre-funding method does not take into account the economics of specific product classes and potential risks to policyholders. Only those firms whose policyholders are actually protected by the system should have to contribute. The problem is similar for the non-life sector.

The amendments to the IBL also aim at imposing oversight on hitherto-unregulated *kyosai* (or mutual aid associations), which sell quasi-insurance products to a "specified group" of people and are not subject to the laws governing insurers. They are now being defined as *small-amount short-term insurance providers (SASTIP)*, and will come under FSA supervision as from April 2007. While the EU welcomes the fact that these entities are being brought under uniform supervision, the IBL does not touch on those *kyosai* that are established under other laws and are not regulated by the FSA but by other Ministries (such as agricultural cooperatives or associations in the health sector). Unlike licensed insurance companies, these entities are not required to contribute financially to the policyholder protection corporation. They pay lower corporation taxes. The EU would like to see also these *kyosai* brought under the scope of the IBL.

Some *kyosai* (whether SASTIP or not) cede re-insurance to hedge against business risks. The size of the *kyosai*-related re-insurance market in Japan is estimated at some ¥20 billion (half of which is for life *kyosai* policy and the other half for non-life *kyosai* policy). At present, most of the re-insurance ceded by *kyosai* is underwritten by European companies.

According to Article 16 of the Supplementary Provision of the revised IBL, the SASTIP will have to obtain re-insurance cover for the portion exceeding the maximum amount allowed until March 2013. They are obliged to seek re-insurance within

Japan first before they are able to identify potential re-insurers abroad. Article 16 states that if no insurer based in Japan can provide re-insurance on better terms than foreign companies, SASTIP can cede re-insurance to foreign companies, but, in such case must obtain an explicit prior approval from the Prime Minister; the need for customers' protection and to ensure proper prudential supervision is being given as the main reason for these requirements. This distinction is new and surprising since there are no indications that the activity of foreign re-insurers has hitherto not created any problems. Article 16 has caused EU re-insurers to lose existing business. Current estimates by the industry foresee a 30% drop in the volume of re-insurance of an EU company for permanent disability/death caused by sickness until 2008. The EU notes that traditional, licensed insurers face no restrictions on their re-insurance placements.

The EU considers that the provision mentioned above constitutes an unjustified discrimination. The right to provide re-insurance services without having an establishment in Japan is foreseen under the GATS Agreement. The need for prudential supervision is certainly justifiable in principle, but it is not understandable why the place of establishment or legal registration should be the decisive criteria. If necessary, international rating systems could be used to ensure proper prudential supervision.

The EU is about to adopt a Directive on re-insurance, which will introduce a regulatory framework for the supervision of re-insurance companies throughout the EU. This should offer a further guarantee for insurance companies or *kyosai* to cooperate with European re-insurers.

The EU has also been made aware of the fact that some *kyosai* which are under the supervision of ministries or agencies other than the FSA may be under the impression that they are obliged to contract their re-insurance business via domestic rather than foreign companies. In order to dispel any doubt, the EU would appreciate if the GOJ could clarify this point and make it known, in an appropriate manner, that those *kyosai* are entirely free in their choice of re-insurer.

Reform proposals

- **a) All remaining restrictions on the sale of insurance products through financial institutions should be abolished.**
- **b) The GOJ should consider ways to alleviate the substantial financial burden associated with pre-funding for the policyholder protection corporations.**
- **c) Kyosai that are established under laws other than the Insurance Business Law should also be brought within the scope of that Law.**
- **d) The EU urges the Government of Japan to abolish the distinction made in Article 16 of the Supplementary Provision of the Insurance Business Law and treat all re-insurance firms – whether established**

in Japan or in the EU – on an equal footing when providing re-insurance for small-amount short-term insurance providers (SASTIP).

- **e) The EU urges the Government of Japan to ensure that kyosai are not hampered in their choice of re-insurer. A respective clarification should be communicated to that effect by the relevant ministries to the kyosai under their supervision.**

5. Privatisation of Japan Post

The EU welcomes the strong political leadership taken by Prime Minister Koizumi for the bold and ambitious postal privatisation plan. The passage of the legislative package in the Diet is a significant milestone in the reform process of Japan and should help to enhance the overall efficiency of the Japanese economy.

Key to the success of the privatisation process will be the capacity to ensure a smooth transition without market disruptions, while ensuring a level playing field between the successor entities of Japan Post and its private competitors. In this regard, the EU notes with satisfaction that the new legislation, as well as statements made by the Government of Japan, is responding to many of the requests made by the EU in previous years.

The privatisation process will begin in 2007 with the division of the current Japan Post into 4 entities: the Post Office Company, the Postal Delivery Company, the Postal Savings Bank and the Postal Insurance Company. The 4 entities will operate under the Japan Postal Services Corporation (a holding company). The Government will transfer all of its shares to the Postal Savings Bank and the Postal Insurance Company in stages between 2007 and 2017, while retaining a stake of at least one-third in the holding company, i.e. Japan Postal Services Corporation.

Splitting up of the huge postal savings and insurance units (with some ¥335 trillion of funds in the postal savings and insurance system at end-March 2005, about one-quarter of total financial assets of Japan's households) will require strict supervision and control mechanisms so as to ensure a level playing field and fair competition between the to-be-privatised postal entities and private-sector companies. This will be beneficial for all market players, the consumers and the Japanese economy as a whole. The supervision by an independent regulator for mail services is of utmost importance. In addition, the Postal Privatisation Committee which will oversee the process should include representatives from the European financial services sector.

The EU appreciates recent statements made by the Government of Japan according to which no preferential tax treatment will be granted to the successor entities of Japan Post. The need to ensure equitable tax treatment concerns the Corporation Tax, the Consumption Tax, the Property Tax and other relevant taxes.

A nationwide post office network will be maintained to continue universal mail service. The Postal Savings Bank and the Postal Insurance Company will continue to offer their financial services nationwide through the existing over-the-counter network of the Post Office Company. In this context, it is important to ensure that access to, and usage of, this network will be accessible for private competitors on fair and equitable terms.

A special ¥2 trillion fund is earmarked to compensate for possible losses incurred through privatised services in sparsely populated areas. The fund will be financed by proceeds of shares of the Postal Savings Bank and the Postal Insurance Company, dividend, etc. Therefore, there should be no need to impose any burdens – be it universal service obligation or financing obligations – on other potential competitors in the correspondence (*shinsho*) delivery business.

Finally, there should be no restrictions on foreign investors to acquire any of the stakes which the Government of Japan will sell over the next years.

Reform proposals

- **a) In order to establish a level playing field, the GOJ should establish a new independent regulator for postal services, separate from MIC.**
- **b) The Postal Savings Bank and the Postal Insurance Company should not be allowed to use their privileged position to further expand into new product areas during the transitional period. In order to ensure appropriate measures, interests of the European financial business industry should be properly represented in the Postal Privatisation Committee which will oversee the process.**
- **c) The GOJ should not grant any favourable tax treatment to the Japan Postal Services Corporation, the Post Office Company, the Postal Delivery Company, the Postal Savings Bank and the Postal Insurance Company.**
- **d) The Post Office Company should be obliged to accept agency requests made by private-sector players such as banks and insurance companies on the same basis as requests by the Postal Savings Bank or the Postal Insurance Company.**
- **e) In sectors open to competition where a universal service obligation will be imposed on the incumbent, private competitors should not have to meet undue obligations.**
- **f) The GOJ should not impose any restrictions on foreign investment in the securities market in acquiring shares of the Japan Postal Services Corporation, the Postal Savings Bank and the Postal Insurance Company.**

6. Transport

6.1 Air transport

The EU-Japan aviation relationship

In recent years, significant developments have taken place on the EU side. In this context, EU Transport Ministers at their Council meeting in June 2005 discussed how best to develop international relations in the aviation sector in coming years.

Ministers emphasised the important complementary roles that Member States and the European Community play in relation to negotiations with third countries. They underlined that the bilateral system of agreements between Member States and third countries will remain, for the time being at least, the principal basis for international relations in the aviation sector. They recognised that the judgments of the European Court of Justice of 5 November 2002 have clarified the respective competences of Member States and the Community in external aviation relations. They stressed the importance that Member States and the Commission strengthen further their cooperation and coordination and provide full mutual support in pursuit of the shared aim of bringing all such bilateral air service agreements into conformity with European Community law as soon as possible, thereby restoring the legal certainty for Community as well as partner country air carriers on international routes. They underlined the need for the Commission and the Member States to work together in a concerted manner, using all available means, to avoid interruptions in bilateral agreements between Member States and partner countries.

It is in the context of the ECJ judgment as well as of the conclusions of the Transport Ministers that the European Commission addresses air transport issues in its contacts with the Japanese authorities. Commission and Member States share the same aims, a point emphasised by Commission Vice-President Barrot in his recent letter to Minister Kitagawa. It is in this sense that the EU looks forward to continued cooperation with the Japanese authorities with a view to amending those provisions of bilateral Air Service Agreements which are not in conformity with European Community Law.

General business environment

Japan is among the EU's most important partners in the transport area. Japanese companies have set international standards for efficiency and customer satisfaction. The EU is confident that the Japanese Government will be successful in promoting increased efficiency in the area of air transport services and looks forward to making a significant contribution to these efforts.

A number of steps might usefully be taken. At present, limitations on pricing and distribution of air tickets, high operating costs for airlines and delays in development of infrastructure all have an unnecessary negative impact. The EU believes that better infrastructure, lower costs, and greater freedom to set prices in the interest of consumers would bring about enhanced openness of the market and allow European airlines to make a major contribution to the Government's goal of doubling tourism

by 2008. The Japanese regulatory authorities have a major role to play in achieving these goals.

Pricing and distribution

In Japan, regulation places many limitations on direct sales of air tickets to consumers. Airlines are only allowed to advertise and sell fares for international travel to and from Japan at IATA approved rates, or in the case of group travel, at lower rates set by the Ministry (MLIT). As IATA rates do not reflect market conditions, most individual fares sold in Japan take the form of repackaged group discount fares sold through licensed travel agents. European carriers do not have de facto direct distribution channels through captive agencies and affiliated travel offices, and therefore have limited control over the ultimate costs of their tickets. As a result, the consumer pays more for his ticket than is necessary.

The EU appreciates the earlier response of the Japanese authorities, stating that flexible fare setting reflecting market trends is possible and expresses the hope that even greater flexibility will follow.

Infrastructure, landing shortages, and slot allocation

The EU continues to be concerned as regards air transport infrastructure in the Kanto region. For a number of reasons – some of which are not fully within the control of the Japanese authorities - facilities at Narita are not yet at a desirable level of development. The EU nevertheless believes that these facilities, and those of other airports in the Tokyo region, might be used more efficiently. We do not understand, for example, why slots for the two runways at Narita are allocated under separate systems.

The EU encourages the Japanese authorities to review current policies on usage of aviation infrastructure in the Kanto region, giving appropriate consideration to issues like fair and effective usage of slots, access to down-town Tokyo and transferability between international and domestic flights. In order to ease the pressure for new slots, even opening Yokota airbase to civil aviation might be an option for the future. At Narita itself, we would ask that the current slot allocation methodology be reviewed with the aim of improving efficiency, while respecting the increasing level of bilateral economic exchange between Europe and Japan, and achieving more equal treatment regarding slot allocation between American and European airlines.

Reducing the cost of doing business

Airlines doing business at Japan's major international airports face high landing fees, navigation charges, airport terminal rents, airport terminal common user charges, and cargo handling fees. In fact, the cost of air transport in Japan remains the highest in the world.

The EU is therefore pleased to note that negotiations between IATA and the newly privatised Narita Airport have resulted in lower landing charges. The EU welcomes this development, and the efforts made by the Narita International Airport Corporation. However, even after this reduction, Narita airport remains the most

expensive airport in the world. The EU earnestly hopes that efforts will continue further to reduce landing, navigation and user charges at Narita.

Security

Security is a major concern for the airline industry and for regulators. The EU and the GOJ share the aim of increasing security and reducing threats in this area. The EU and the GOJ work together towards improving aviation security. To this end, we consider that, whenever introducing new transport security measures, the GOJ will seek to ensure transparency and information of the EU. It is with this understanding that the EU welcomes that a transport security cooperation meeting has taken place and allowed to address the issues mentioned. This cooperation has been endorsed during the last EU-Japan Summit and will continue in the future.

The EU has on its part introduced strict legislation on personal data protection. We are concerned that the proposed Advanced Passenger Information System (APIS) might be in conflict with our legislation, and hope that consultations will take place to avoid unnecessary complications.

Finally, despite the fact that the use of English is generally accepted internationally regarding technical documentation, the Japanese authorities require translation of all documents into Japanese. The EU would appreciate if Japanese authorities could, in line with international practice, and in the interest of efficiency, accept submission of technical documents in English only.

Reform proposals

- **a) The EU encourages the GOJ to deregulate distribution, pricing and settlement of airfares, allowing airlines to offer competitive net fares in a transparent fashion directly to the consumer, including over the Internet.**
- **b) As a first step, the EU suggests the introduction of a wide range of advanced-purchase fares into the system, and the removal of limitations on internet sales. Ultimately a simple file-and-use system for pricing approval should be introduced; and restrictions terminated as regards the direct transfer of net-remittances on market fares sold through IATA travel agents.**
- **c) The EU suggests a review of current policy on usage of aviation infrastructure in the Kanto region, looking at fair and effective usage of slots, access to down-town Tokyo and easier transfer between international and domestic flights.**
- **d) At Narita, the EU requests that the current slot allocation methodology be reviewed with the aim of improving efficiency, and achieving more equal treatment regarding slot allocation between**

American and European airlines. Haneda airport should be opened to regular international traffic on a non-discriminatory basis.

- **e) The EU welcomes progress achieved in negotiations between IATA, airlines and the newly privatised Narita International Airport Corporation. As, however, costs remain extremely high even after this reduction (Narita airport remains the most expensive airport in the world!), the EU requests the GOJ to pursue further significant reductions in charges for landing, navigation and common user fees.**
- **f) Airlines should be allowed to recover extra charges imposed whenever measures are introduced which increase their operating costs, as in April 2005.**
- **g) The EU requests the GOJ to enter into consultations in order to discuss the impact of the proposed Advanced Passenger Information System (APIS) on EU data protection legislation.**
- **h) The EU would appreciate if Japanese authorities could accept submission of technical documents in English in line with international practice and in the interest of efficiency.**

6.2 Sea transport (international shipping)

The main problems faced by the European shipping industry in Japan arise from restrictive working practices on the waterfront. These practices limit competition and operational flexibility and raise the costs of doing business. The “super hub port” strategy of the Ministry of Land, Infrastructure and Transport (MLIT) seeks to reduce costs by as much as 30% at three ports where container handling activities would be concentrated and charges and rents reduced. This welcome policy represents a recognition that costs at Japanese ports – amongst the highest in the world – have been critically undermining their competitiveness *via-à-vis* other ports in East Asia, to the detriment of domestic and foreign users in Japan. Clearly, removing constraints on competitive conditions for the provision of stevedoring services will be essential if cost-cutting targets are to be met. Also, foreign shipping lines, which carry over 60% of Japan’s international containerised trade in and out of Japan and have an extensive international experience, should be engaged in the Japanese Government’s discussions over Port Development Initiatives.

The situation regarding the Prior Consultation System in Japan remains unchanged. The Japan Harbour Transportation Association (JHTA) has an agreement with relevant parties to hold consultations with shipping lines prior to any changes that might reduce employment or adversely affect working conditions. Shipping lines are therefore required to consult the JHTA for approval of certain changes to their operations, including even minor issues such as substitution of vessels.

While there have been no serious difficulties so far with the Four-Party Agreement in force, the large discretionary power of the JHTA and the *de facto* restraint this puts on free competition in harbour service provision are anomalous. The system continues to inhibit the development of competitive pressures which might decrease service charges. The current situation is based solely on good will. Whether or not, as MLIT contends, the number of cases handled through the JHTA has dropped by 95%, the existence of the JHTA’s powers in practice inhibits shipping lines from seeking out competitive bids for port services.

The JHTA fulfils an obsolete regulatory function while also representing the interest of only one side of the regulatory equation – in this case the domestic port services industry. The EU upholds a principle position that regulatory functions, if indeed at all necessary, should be separated from promotional functions in order to ensure a level playing field for new entrants, promote competition, and avoid conflicts of interest.

The Three-Party Agreement remains, in addition, unimplemented. There remains considerable potential to rationalise and simplify regulations as well as to accelerate reform of regulatory procedures in the area of prior consultation. The EU in particular requests MLIT to address proposal (b) below, since it has remained unanswered since first presented.

On a separate issue, foreign shipping lines should be allowed to trans-ship their own overseas cargo on their own vessels in Japan just as vessels under Japanese flag can. Granting foreign lines the same rights would benefit Japanese ports as it would reduce the need to trans-ship such cargo in countries other than Japan. European shipping lines should also be allowed to operate feeder vessels for the purposes of

pre- and onward carriage of their own containerised international cargo between ports in Japan.

Reform proposals

The EU requests the GOJ to

- **a) Ensure that the prior consultation and alternative prior consultation procedures are transparent, equitable and swift.**
- **b) Further review the role of the JHTA in dealing with applications for changes to shipping line operation, with a view to eliminating all vestiges of undue influence on the free play of competition in the provision of harbour transport services in Japan.**
- **c) Allow European shipping lines to tranship and operate feeding vessels for their own international cargoes in and between Japanese ports.**

7. Healthcare and Cosmetics

7.1 Pharmaceuticals

The European Union acknowledges that the Japanese healthcare system is facing great challenges due to changes in demography, public finances and issues related to the industrial competitiveness of the Japanese pharmaceutical industry. However, it has to be underlined that the availability of affordable, state-of-the-art drugs, irrespective of their origin, will generally benefit the Japanese population. Thus, the review and reform of the Japanese healthcare sector should be undertaken in a comprehensive manner and take into account aspects like innovation, shortened drug approval times, and adequate rewards for innovations.

The EU acknowledges and welcomes the positive developments in the regulatory field which have led to the establishment of the Pharmaceutical Medicine and Device Agency (PMDA), intended to streamline the consultation and review. However, concerns persist with regard to the need for reduction of processing and approval times for registration clinical trials as well as New Drug Applications (NDA). European firms still consider the target review times set by the Japanese authorities and, in particular, the actual processing times still to be slower than would be justified. The EU, therefore, reiterates its request for the PMDA to streamline the drug evaluation and approval process in Japan and reduce the time needed for processing NDA applications.

As regards the Pharmaceutical Medicine and Device Agency (PMDA) concerns have been raised that the increase of fees has not led to an improved quality of drug assessment and services in general.

With regard to intellectual property rights, the EU strongly favours the current consideration given to improving the protection time for data submitted for drug registration purposes. The Commissions would like to draw the GOJ's attention to the fact that the EU has expanded its protection regime to a de facto 10-year period with an additional year in case of new indications.

Reform proposals

- **a) Improve the quality, efficiency and time of the registration process for new drug applications and ensure that the fees for drug approval are adequate and reflect the services rendered.**
- **b) Improve the level of IPR protection for new innovative drugs, namely introducing an extended data protection period.**

7.2 Medical devices

Japan's rapidly aging population and rising societal expectations for quality of life necessitates innovative health technology to help deliver quality health care to the Japanese people. The EU encourages Japan to progress in harmonising its regulatory requirements with those of its major trading partners. Regulatory reform in Japan should be further promoted to enable beneficial technological innovations to enter the market expeditiously, without compromising patient and user safety. To this end, Japan's active involvement in global regulatory harmonisation activities such as the Global harmonization Task Force (GHTF), and the adoption of its recommendations, is strongly recommended. Furthermore, the EU urges the GOJ to embrace innovations in health care technologies that allow health care resources to be used more effectively and thereby better the quality of life and productivity of Japanese patients.

The EU welcomes the replies received from the Japanese government and the progress made in more closely aligning many regulatory requirements with the recommendations of the GHTF as a result of the Pharmaceutical Affairs law (PAL) revisions in 2002 (that took effect in April 2005). While welcoming progress achieved, the EU is of the opinion that administrative guidance regarding implementation remains to be issued and/or clarified. Moreover, the Pharmaceuticals and Medical Devices Agency (PMDA) resources, especially as regards pre-market review and quality systems auditing, have not yet been increased in line with needs. The EU would also like to reiterate the importance of ensuring that pricing and reimbursement policies are supportive of the innovation process and therefore aimed at stimulating continued investment in medical devices industry by both domestic and foreign producers and importers alike.

Many health technologies are characterised by short product life cycles and high innovation rates. In practical terms, a parallel, rather than sequential, handling of regulatory approval and reimbursement procedures in Japan could significantly reduce the time for market entrance, which is now one to two years, or even longer for some new products. The EU also urges Japan to implement measures to expedite the access, insurance coverage and payment of "new-to-Japan" health technologies, including by accepting information regarding cost effectiveness based on foreign clinical data. Manufacturers continue to report significant delays and difficulties as regards acceptance of foreign clinical data, including information provided by conformity assessment bodies and regulators in Europe and the United States. Thus, the overall time until market entrance, including pre-marketing conformity assessment/safety review and pricing approval, remains significantly longer in Japan than in Europe or the United States.

Reform proposals

- **a) The EU requests the GOJ to further implement regulatory reform by streamlining and improving the transparency of product approval, taking into account available global data, and applying sound science and risk benefit assessments in line with GHTF Guidance documentation.**

- **b) The EU recommends in the field of medical devices the further adoption and use of international standards (ISO and IEC standards) without additional national requirements. Such a policy would be consistent with the recommendations of the Global Harmonisation Task Force (GHTF) on the role of standards and should be matched by continuing efforts to promote greater understanding and flexibility in interpretation of data by PMDA reviewers.**
- **c) The EU requests the GOJ to implement adequate measures to reduce time for market entry for new health technologies by handling regulatory approval and reimbursement approval in parallel, and to improve access further for new products by accepting cost-effectiveness information based on foreign clinical data.**
- **d) The EU recommends the adoption of a pricing policy for new medical materials without causing significant delays in patient access to new technologies but rather creating incentives for continuing investment in research and development in beneficial new technologies.**

7.3 Blood plasma

A stable and sufficient supply of blood plasma is essential for any medical care system. Since large volumes of plasma are required to manufacture plasma-derived medicinal products, international trade in plasma products helps to ensure sufficient supply and minimises risks which may arise due to single-sourcing.

The Commission is aware of the co-operative approach applied by the Japanese governments in recent months and encourages the Japanese side to continue to do so. However, the Commission would like to point out one element of concern:

The Japanese government's implementation of amendments to Japan's "Blood Law" contains, among other things, a supply and demand plan under which companies are obliged to provide specific information about future supply, in order to allow this information to be compared with estimated demand. As already pointed out last year, this provision is likely to create a regime under which the government reserves the right to take action to restrict the importation of plasma-derived medicinal products whenever it determines that such imports are reducing demand for domestically sourced blood products. Non-compliance with the plan, i.e. increased imports, may lead to fines or even the closure of business operations in Japan. To date, no complaints concerning actual trade hurdles have been brought to our attention as demand in Japan continues to outstrip local supply. However, the Commission would like to urge the Japanese government to address this issue by revising the wording so as to avoid potential problems in the future, especially as the provisions of the Blood Law referred to are clearly of discriminatory nature.

Article 25.3 of "Blood Law":

"Blood collection businesses and blood product manufacturers, etc., (i.e., manufacturers and importers/sellers; same hereinafter), in order to contribute to the preparation of supply-demand plans, must report each year to the Minister of Health, Labour, and Welfare the volume of blood plasma basic ingredient they expect to supply, the volume of blood products they expect to manufacture or import for the following year, and other items governed by Ministry of Health, Labour, and Welfare ordinance. (Emphasis added.)"

Reform proposals

- **a) The EU encourages the GOJ to continue its dialogue with the industry on pricing and reimbursement.**
- **b) The EU requests the GOJ to reconsider the wording of the supply/demand provisions of the Blood Law which may lead to a bias towards domestic blood plasma in case local supply would suffice to meet demand in Japan**

7.4 Cosmetics

Japan is the world's third largest market for cosmetics. EU manufacturers have successfully established brands in the Japanese market. The changes in cosmetics legislation of 2001 have been welcomed by the EU since they have shifted, for most categories of products, the responsibility for product safety towards manufacturers. The present regulatory framework therefore includes provisions that are also part of the European Regulation i.e. the use of a negative ingredient list, limited positive ingredient lists and full ingredient labelling.

In 2005, Japan and the EU have re-energized cooperation in cosmetics and certain over-the-counter drugs harmonization activities under the Cosmetics Harmonization and International Cooperation (CHIC) process. The last meeting took place in March 2005, where new terms of reference to guide future cooperation were developed and approved. In the framework of CHIC, Japan and DG Enterprise and Industry have exchanged extensively information on our respective regulatory systems, safety concerns, and alternative test methods to animal testing, including the discussion on the establishment of a rapid alert system to exchange data on adverse reactions. The next CHIC-meeting is scheduled for spring 2006 in Japan.

The exchange of information is, however, only a first step: It is equally important that the Japanese and EU-authorities take each other's findings into consideration when regulating cosmetic products (including certain "quasi-drugs") and their ingredients.

As already pointed out in previous discussions, the Japanese positive lists still differ significantly from those used in Europe. To date, no mechanism has been established to make them more compatible. Certain conservation agents, sun filters and coal/tar pigments which are included in the EU's positive lists are forbidden in Japan. Given the cumbersome requirements and lengthy processes for amending ingredient lists in Japan, new ingredients enter the Japanese positive lists at a very slow pace. These requirements often call for tests in addition to the extensive testing already done in the EU, despite the fact that these products have established a proven record of safe use in the EU over several years. In addition to market entry delays, these practices lead to extensive and costly reformulation of products for the Japanese market. (This is an issue that was addressed specifically in the EU-Japan Investment Framework which stipulates that both sides will promote the acceptance of test results and related data.)

The importance of taking each other's findings into consideration holds true in particular for the development of alternative methods of animal testing: the EU would welcome Japan's official confirmation that it will recognise safety data generated from non-animal alternative testing methods in accordance with the OECD guidelines. Mutual acceptance of testing methods (such as agreed between the EU and the US) would be a major benefit for international harmonisation.

Reform proposals

- **a) The EU requests a strengthened effort to take EU-regulation into consideration when regulating cosmetics and certain quasi-drugs. This holds in particular true for the drawing up and amending of positive and negative lists.**

- **b) The EU requests Japan to engage in a formal commitment to accept alternative testing methods validated by the EU and/or OECD.**

8. Food safety and agricultural products

8.1 Food additives and flavourings

Many food additives, which are in common use around the world and recognized as being safe by international food safety bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA) are not allowed in Japan. Conversely, numerous substances have been approved in Japan that have not been reviewed and approved by the international scientific community. This situation indicates major problems in the way food additives are approved for use in Japan.

The GOJ has decided to give priority to evaluation for authorization of 46 food additives, including 38 priority substances proposed by the EU. Although these substances were evaluated by the JECFA, and are used in many countries, the GOJ insists that they must be evaluated individually, unless they can be grouped in the same category. The GOJ will treat globally distributed flavouring agents in the same manner as these 46 substances.

The EU welcomes the recent approval of some additives and flavouring agents (3 additives and 8 flavouring as of September 2005), and asks for further approval of remaining substances without delay.

The EU also notes that the GOJ has increased the level of human resources in the expert committee (three members have been added, two in April and one in August 2005, making 10 members in total). The EU notes, however, that this is still not sufficient to meet the demands and therefore requests a further acceleration of the approval process.

The current practice remains redundant and inefficient, as it will likely take around 6 years for the Japan Food Safety Commission to work through a priority list of 46 substances, which have already been thoroughly evaluated elsewhere. It appears unlikely that the isolated review of GOJ will reveal any formerly unknown information. On the contrary, issues of data ownership sometimes stand in the way of making all studies evaluated elsewhere available also to the Japanese authorities.

At the same time, the approval of the 46 substances should not be considered the end of the process of approval for food additives, rather a first step towards harmonization of Japanese legislation on food additives with international standards.

The following websites provide useful information on the EU data requirements and regulatory system, as well as evaluations done:

Legislation, Guidance, and other introductory documents:

http://europa.eu.int/comm/food/food/chemicalsafety/additives/index_en.htm

Evaluations by the Scientific Committees:

http://europa.eu.int/comm/food/fs/sc/scf/outcome_en.html

Evaluations done by the new Scientific Panels at European Food Safety Authority:

http://www.efsa.eu.int/science/efsa_scientific_reports/catindex_en.html

Reform proposals

- **a) The EU urges the GOJ to modernize Japan's practice of authorisation of food additives in line with the CODEX Alimentarius , and to accept flavourings recognized as being safe by food safety evaluation bodies such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA), the EC Scientific Committee on Food or the European Food Safety Authority. The use of these bodies will improve the trade environment as it helps authorities to be able to decide on applications in a reasonably short period.**

- **b) More specifically, the EU invites the GOJ to speed up the evaluation and authorisation process for the remaining substances on the EU priority list.**

- **c) The EU sees the approval of the 46 priority substances only as a first step of an ongoing process of evaluation, as the Japanese current food additives' regime still excludes many food additives considered safe by international standards. Other additives should be examined for approval and the use of some approved additives should be extended (e.g. hydroxypropylmethylcellulose in potato preparations).**

8.2 Imports of bovine and ovine products, notably beef

The EU has been monitoring with interest the evolution of measures the GOJ has been taking in order to facilitate the domestic and international trade of beef, while ensuring consumers' protection against Bovine Spongiform Encephalopathy (BSE).

In November 2004, the European Commission sent a letter to the GOJ asking for a dialogue with a view to opening the Japanese market for bovine meat from the EU. Also, some EU Member States have requested the resumption of their imports of bovine meat to Japan. Until now, Japan has refused these requests on the basis of BSE without accepting further dialogue.

Following the recent development regarding domestic and OIE rules for beef trade, the European Commission send again in August 2005 a letter to the GOJ on this matter, to which so far no response has been received.

The EU welcomes the recent Japanese decision to modify its BSE testing regime and in particular to establish the principle that cattle aged less than 20 months do not need to be tested systematically.

Concerning imports into Japan, the EU is concerned that the Food Safety Commission (FSC) has been requested to study the conditions for the resumption of bovine meat trade only from the US and Canada. In the EU's view, there can be no justification for an approach which discriminates against the EU products. The EU is able to provide the highest possible guarantees based on the most informed scientific opinions in the world. Therefore, the EU urges Japan to establish fair and transparent rules for the import of bovine meat originating not only from countries like the US and Canada but also from EU member states.

In this respect, the EU also likes to remind the GOJ that the World Organisation for Animal Health (OIE), at its annual meeting in Paris in May 2005, adopted significant changes in its recommendations on trade in beef products. In particular, the OIE has incorporated de-boned skeletal muscle meat from cattle 30 months age or less into the list of commodities that can be safely trade regardless of the BSE status of countries. The EU believes that the OIE recommendations as well as the EU measures in place to ensure the safety of bovine products (such as full traceability and comprehensive and rigorously enforced feed law) are a good basis for preparations regarding resumption of EU-Japan trade in bovine meat.

Reform proposal

- **The EU urges the GOJ to resume at the earliest stage discussions with EU Member States on EU-Japan trade in bovine meat**
- **The EU urges the GOJ to undertake in parallel all necessary steps in order to allow for an early lifting of the existing ban on EU beef and lamb.**

- **The EU urges the GOJ to align its legislation with OIE guidelines on trade in beef and lamb and establish fair, non-discriminatory and transparent rules for the import of bovine and ovine meat;**

8.3 Organic food certification

The new Japan Agricultural Standards (JAS) law, effective 1 March 2006, introduces a new procedure for registration of all certifying organisations for organic products. The EU recognises that this amendment to the JAS law aims to establish a food labelling system which is in compliance with ISO 65 guidelines. However the EU notes that this new registration procedure imposes severe administrative and financial obligations on prospective certifying organisations. In particular, certifying organisations will have to pay registration tax, to bear costs for on-site inspections and to provide increased administrative information compared with the previous system. In particular, the EU is seriously concerned regarding two areas.

Firstly, foreign certifying organisations will be penalised by being obliged to pay higher costs than domestic organisations, particularly in terms of travel costs for on-site inspections (travel to Europe, per diem costs and interpretation expense) and translation of documents. They should not have to pay the full cost of such on-site inspections, even for reduced air tariffs for inspectors and grouped visits.

Secondly, and of utmost importance, organisations which are already registered will have to go through exactly the same procedure as organisations applying for the first time, thereby facing excessive administrative and financial burdens. The EU requested that MAFF exempt currently registered organisations from the re-registration obligation or facilitate their re-registration at minimum cost and burden. However, this proposal was rejected by MAFF by letter of 8 August to DG AGRI.

The EC would like to draw the attention of the GOJ to the difficulties already experienced by the 14 EU certifying organisations in registering under the previous JAS law for organic products. The EU is concerned that the cost and administrative difficulties will prevent EU certifying organisations from re-applying and will seriously disrupt the supply of organic product from the EU to Japan.

Reform proposal

- **a) The EU strongly reiterates its request for MAFF to implement measures exempting certifying organisations already registered under the previous JAS law fully or partially from the re-registration procedure under the new JAS law.**
- **b) The EU requests that all measures be examined in order to minimise administrative burden and financial costs for newly as well as already registered organisations in order to avoid discrimination in comparison to domestic organisations.**

8.4 Phytosanitary regulations

Japanese list of non-quarantine organisms

The EU welcomes the efforts made so far by the Japanese authorities in identifying non-quarantine organisms, not subject to quarantine measures. The EU notes that it has been requesting the Japanese Government for years to bring respective regulations in line with international standards.

The EU evaluates progress achieved as a first step, and notes that much more remains to be done. *Myzus persicae*, *Aphis fabae*, *Neomyces circumflexus*, *Brevicoryne brassicae*, *Aphis gossypii*, *Panonychus ulmi* and *Frankliniella occidentalis* are only a few of the other organisms that urgently should be added to the list.

Access to the Japanese market for fresh fruits and vegetables

Without prejudice to EU requests to bring Japanese plant quarantine regulations in line with international standards, in some cases export of vegetables from certain member-states have been only made possible by establishing detailed protocols, setting out a comprehensive list of prevention and inspection measures. This is against international practice, however, applied in order to offer the Japanese authorities very strict guarantees that any entrance of quarantine organisms is prevented. Establishing such costly protocols has proved to be helpful in achieving market access to Japan.

The EU invites the GOJ to bring these protocols in line with international practice. In addition, the Commission continues to be informed of serious regulatory issues with respect to market access for fruit and vegetables as follows:

- i. The cost of market access is in certain cases excessively high and thereby represents an effective barrier to trade. Export figures regarding French apples under the negotiated strict protocol show an added cost of € 11.33 per kg. These additional costs have terminated exports in French apples to Japan.
- ii. Japanese authorisation requirements of new varieties and types of fruit and vegetables are not in conformity with international practice. Protocols for Italian Tarocco oranges cannot be applied to other orange varieties, such as Navals, Valencias, etc. In addition, a protocol negotiated with one Member State should be extended to cover other interested Members States too.
- iii. Requirements to use methyl bromide fumigation against Med fly affect the quality of the products. Member States phytosanitary experts would welcome to discuss alternative forms of treatment that are less damaging to the environment than the use of Methyl Bromide and have an equivalent result (e.g. methods such as indicated by the US manual on treatment of insects, such as cold treatment scheme for Med fly, foreseeing a treatment period of 14-18 days).

Regulatory procedures for fresh fruit and vegetables, plants in approved growing media and cut flowers

The EU notes that phytosanitary regulatory procedures continue to hamper trade. Procedures may take too much time in case additional checks have to be done, causing products to perish. Japanese phytosanitary inspectors should be able to determine the various organisms without delay. This does not only apply to the non-quarantine pests not subject to quarantine measures as mentioned in the amended Enforcement Ordinance under the Plant Protection Law, but also to the 'natural enemies' often found in fruit vegetables. The high incidence of fumigations indicates that organisms not subject to quarantine measures are possibly not always recognised immediately.

National Plant Protection authorities would be most grateful for the quickest possible information on interceptions of plant material consignments. The EU recognises that formal channels exist to exchange this kind of information, but notes that less formal information via embassies would help authorities in exporting countries.

Destruction of damaged vegetable shipments

In some cases, export of vegetables from certain member-states to Japan has been enabled by establishing detailed protocols (see above). Shipments arriving in Japan have to be packed in netted and labelled boxes. To reduce the costs of these boxes (no other destination requires them), exporters have shown some preference to wrap shipments in nets. However, any damage to the nets (or the boxes) and absence of labelling leads to immediate destruction, even if the damage occurred during off-loading in Japan. The Japanese authorities admit that torn nets or the absence of a label do not pose a phytosanitary danger. It is purely a regulatory problem: the protocol stipulates nets should be intact, and if not, shipments are declared contraband and destroyed.

Plant Health facilities at Narita airport

The cost of fumigation, warehousing and cooling facilities at Narita Airport are still significantly higher than at comparable airports in other countries. On 9 August 2001, following an investigation, the JFTC concluded that the two fumigation companies at Narita Airport had engaged in cartel practices since 1987, in violation of the Anti-Monopoly Act. Despite these conclusion arrived at by the JFTC, the EU notes that the actual costs have not changed at all. During a meeting in November 2004, JFTC committed to investigate the non-application of its conclusions. The EU urges therefore that JFTC will ensure fair competition in this regard.

Reform proposal

- **a) The EU invites the GOJ to extend the list of Non-Quarantine organisms and requests the inclusion of the remaining organisms suggested by the EU**
- **b) The EU urges the GOJ to be transparent on the decision-making procedures regarding pending applications and to shorten the time involved in reaching a decision. Approval decisions and**

rejections have to be scientifically justified. The EU also invites Japan to accept alternative treatment against Med Fly.

- **c) The EU invites the GOJ to shorten the quarantine inspection period for plant products. Therefore a swift and efficient system to exchange information with EU exporting competent authorities needs to be developed**
- **d) The EU requests the Japanese authorities to elaborate more adapt solutions than the destruction of otherwise fully healthy food items**
- **e) The EU request the GOJ to bring about reductions in the cost of fumigation, warehousing and cooling facilities through greater competition in the provision of such services. In particular, the EU encourages the JFTC to ensure the actual implementation of their decision regarding the cartel practices**

8.5 Minimum residue levels (MRL)

MRL List

The GOJ intends to introduce a new “positive list system” for pesticide residues, veterinary drugs and feed additives, within the framework of the revised Food Sanitation Law (published in May 2003). Under this new system, a positive list of Maximum Residue Limits (MRLs) for agricultural chemicals will be established by May 2006, and products containing chemicals in excess of the established MRLs will be banned.

The EU welcomes the public consultation process regarding this question and the opportunity to submit comments to the draft list. The EU points out that MRLs to be established in Japan should be consistent with the standards applied in the EU in order to avoid any negative effects on EU-Japan trade.

Proposed MRL for butylhydroxyanisole (BHA, index number 87)

The GOJ has proposed a MRL for BHA of 0.05 mg/kg in salmoniformes and pectiformes in the final draft. This would cause a problem for the European salmon farming industry and its current existing significant trade with Japan as the levels of BHA in salmon fillets resulting from the legal use of BHA in the salmon feed would exceed the suggested MRL.

According to international standards (as set by JECFA) the ADI (acceptable daily intake) of BHA is 0.5 mg/kg body weight. This means that a 60 kg person can have a daily intake of BHA of 30 mg during the life-time. If you allow 10% of this to come from fish meal, you could still eat a 200 gram fillet with a BHA level of 17.5 mg/kg fillet and be within 10% of the daily JECFA ADI.

A Japanese scientific report indicates that the intake of BHA in Japan is in fact only 0.5% of the JECFA ADI levels (Ishiwata, H. et Al., 2003, J. Food Hygiene. Soc. Jap., 44:132-143). This data supports a higher MRL than 0,05 mg/kg.

Reform proposal

- **a) EU invites the GOJ to bring MRL regulations fully in line with EU standards**
- **b) EU suggests the MRL for BHA to be raised to 5 mg/kg fish fillets for salmoniformes and perciformes.**

8.6 Breeders' rights (farmers' privilege)

European breeders¹ face problems with the application of the 'farmers' privilege system' (FP) in Japan as it represents a barrier against European exports. In essence, the so-called farmers' privilege allows granting farmers the right to use on their own land the product of the harvest which they have obtained by planting the protected variety. In Japan, Farmers' privilege can be used for many crops, not only for agricultural crops, including also regarding ornamental and vegetable crops, of which farmers can make use of by exploiting the materials gained (seed, cuttings etc.), multiplied on their farm for their own use. For ornamentals there is a (relatively small) negative list of species where farm saved material is not permitted for use.

In the EU view, Japan should apply a more restrictive use of the farmers' privilege exemption. This would be in line with the amendment agreed upon by the diplomatic conference of the Union for the Protection of New Varieties of Plants (UPOV) in 1991 (contained in Article 15(2) of the 1991 Act of the International Convention for the Protection of New Varieties of Plants; official recordings of the diplomatic conference published in UPOV publication No. 346/e). In this understanding, farmers' privilege should be restricted to agricultural crops (**not** for horticultural crops) where the product of the harvest is used for propagating purposes. Therefore, the Japanese approach would not seem to comply with the intention of art. 15 (2) of the UPOV Convention (1991), to which Japan is Party.

Article 15 Exceptions to the Breeder's Right

- (1) **[Compulsory exceptions]** The breeder's right shall not extend to
 - (i) acts done privately and for non-commercial purposes
 - (ii) acts done for experimental purposes and
 - (iii) acts done for the purpose of breeding other varieties, and, except where the provisions of [Article 14\(5\)](#) apply, acts referred to in [Article 14\(1\)](#) to [Article 14\(4\)](#) in respect of such other varieties.

- (2) **[Optional exception]** Notwithstanding [Article 14](#), each Contracting Party may, within reasonable limits and subject to the safeguarding of the legitimate interests of the breeder, restrict the breeder's right in relation to any variety in order to permit farmers to use for propagating purposes, on their own holdings, the product of the harvest which they have obtained by planting, on their own holdings, the protected variety or a variety covered by [Article 14\(5\)\(a\)\(i\)](#) or [Article 14\(5\)\(a\)\(ii\)](#).

Recommendation Relating to Article 15(2)

"The Diplomatic Conference recommends that the provisions laid down in Article 15(2) of the International Convention for the Protection of New Varieties of Plants of December 2, 1961, as Revised at Geneva on November 10, 1972, on October 23, 1978, and on March 19, 1991, should not be read so as to be intended to open the possibility of extending the practice of commonly called "farmer's privilege" to sectors of agricultural or horticultural production in which such a privilege is not a common practice on the territory of the Contracting Party concerned".

¹ As far as is known at this stage, problems only encountered by Dutch exporters

We are also aware of ongoing discussions within the Japanese administration (Plant Breeder Right Committee) regarding this issue and would encourage the GOJ to take measures to limit the use of the farmers' privilege in the near future, the actual legal situation offering breeders the possibility to exempt farmers' privilege by contract not being a suitable solution.

Reform proposal

- **The EU encourages the GOJ to take measures in the near future to apply a more limited use of the farmers' privilege exemption.**

8.7 Regionalisation

General aspects

The EU applies the principle of regionalisation in accordance with international guidelines as explained in G/SPS/GEN/101. Japan has also applied regionalised trade restrictions to EU Member States, in accordance with the principles of regionalisation. However, bilateral negotiations and evaluations between Member States and GOJ are frequently cumbersome and slow and there is a clear desire to create efficiency gains. Aiming at further increasing the level of understanding within the GOJ on the EU harmonised measures in the event of a disease outbreak in a Member State, a case study was submitted to the GOJ in February 2004. It describes in detail the measures taken in the European Union how to manage and regionalise diseases to be notified. The goal of the case study was to build knowledge and confidence among Japanese experts to streamline and speed up future evaluations in order to allow for lifting of trade restrictions imposed on EU Member States in the event of an outbreak of a disease.

The GOJ has evaluated the case study; in its response of November 2004 the experts conclude that the *“technical approach to controlling disease is not fundamentally different from that espoused in the Japanese manual compiled to deal with any potential disease outbreak.”* The EU hopes that further dialogue on animal disease control will take place on the basis of the above-mentioned understanding. The Commission invites the GOJ to specify areas of interest, e.g. Avian Influenza.

In the meantime, while Japan applies regionalisation zones with regard to the EU, these zones are bigger than deemed necessary by European Commission and Member States. At the same time, the unacceptably long delay for authorizing imports of pork meat originating from EU Member States, for example Hungary and Portugal, has to be mentioned as well. The EU requests that Japan should have confidence in the veterinary services of the EU by adopting the legal Decisions taken at a European level with respect to regionalisation in the case of an outbreak of a disease to be notified in the Community. Any disease/pest free area recognised in such an EU Decision went through scrutiny of all 25 Member States.

Regulatory approval procedures for live bivalve molluscs

The EU notes delays in the approval procedure regarding exports of French and Irish Oysters to Japan. The GOJ should clarify the reasons for impeding the import of oysters of EU origin. The EU would welcome transparent information on procedures applied including a timeframe.

Reform proposal

- **a) The EU requests the GOJ to recognise EU regionalisation decisions in this area when applying import measures on products from the EU. At least, the GOJ and the Commission should establish a pragmatic process to achieve such recognition within the shortest delays.**
- **b) The EU invites the GOJ to be transparent on its procedure to approve exports of bivalve molluscs, including providing a time**

frame. The EU invites the GOJ to grant authorizations regarding pending requests for exports of pork meat from Hungary and Portugal in a speedily manner.

9. International Standards

9.1 Building Standards

Standards (formaldehyde emission regulations)

New regulations on formaldehyde emission levels for construction products for use in building interiors have been introduced by the Ministry of Land, Infrastructure and Transport (MLIT), and entered into force on 1 July 2003. The EU does not dispute the Japanese government's aim to improve the interior environment of new buildings for reasons of human health. However, the implementation of these regulations continues to cause concern for EU exporters, as the implementation of these regulations is de facto excluding EU products from the Japanese market.

Testing and performance evaluations are required under JAS or JIS rules, or via the Ministerial Approval scheme of the Building Standards Law (BSL). The majority of wood-based products exported by the EU are covered by either the Ministerial Approval or JAS schemes. EU exports are thus subject to considerable costs and delays because of capacity bottlenecks amongst the Japanese performance evaluation bodies and testing institutes approved by MLIT.

The EU appreciates the answers given to questions put previously and would like to make the following comments:

- The EU regrets the slow progress regarding the fact that since last year only one body in the EU has been accepted for testing and evaluation of formaldehyde (WKI in Germany). They have however not carried out any tests or evaluations for the Japanese market but are solely promoting their status with European manufacturers. In addition, another body in the EU (SP, Sweden) has been subcontracted by a recognised Japanese body for testing, still awaiting recognition to carry out testing and evaluation as a recognised certification organisation (RCO).
- In case there are any problems regarding the co-operation of EU testing organisations, the EU side would appreciate being kept informed.
- The EU would be grateful for confirmation that there are no additional requirements for these bodies to be fulfilled before they are able to work for their customers within the EU.
- Concerning the JAS and JIS rules, NTI (Norway), became the first and so far the only organisation in Europe - but not for the EU - to be recognised for certification and factory production control of structural glued laminated timber and structural lumber for wood frame constructions on March 11 2003. RCOs for these products exist today only in USA, Canada, Australia and Norway (NTI is working with 23 EU companies and 1 Chinese on structural glued laminated timber and structural lumber for wood frame constructions).

Wood and wood products

Japan is a big market for wood and wood product exporters. In 2004, 1.26 million new houses were built, and more than 40% of family houses were built in wood (540 million units in 2004) either by the traditional so-called post & beam method or by the American two-by-four wood frame system. Exports of wood from Europe have increased remarkably: lumber exports surged from virtually nil in 1993 to more than 3 million cubic meters in 2004. On the other hand, European wood suppliers and their common promotion organisation continue to express interest in solving outstanding regulatory issues regarding the difference in technical requirements between the "CE (Communauté européenne) marking system" of the EU and Japanese regulations for construction products.

Against this background, the EU would like to suggest a forum in order to discuss and pursue some of these issues more in-depth. Besides an exchange of views on issues of mutual interest, this could include issues such as best industry practices, sustainable building technologies and housing standards, dialogue could also touch upon fire endurance tests and fire regulations, lumber grading, import and inspection rules, accreditation of testing institutes, testing procedures etc. The exact scope and the set-up of such a forum would need to be discussed and mutually agreed upon by both sides.

Reform proposals

- **a) The EU requests the GOJ to continue the efforts made to accelerate the process of ministerial approval for products.**
- **b) The EU requests the GOJ to continue its efforts in order to promote and facilitate subcontracting by Japanese performance evaluation bodies of the testing function under the ministerial approval scheme to EU testing institutes.**
- **c) The EU proposes to establish a forum for EU and Japanese government and industry experts to discuss the further improvement of the regulatory environment and related questions concerning wood and wood products.**

9.2 Motor vehicles

Adoption of UN Regulations

The EU believes that the international harmonisation of automobile regulations is in the fundamental interest of all producing nations, especially as the auto industry is in every aspect a truly global industry. The EU thinks that the high number of UN-ECE regulations (more than 90) the EU has adopted is a clear sign of the strong EU commitment towards international harmonisation. The EU would appreciate it if Japan made a similar effort, as Japan has only adopted about 30 UN-ECE regulations up to now.

The EU notes that Japan has acceded to only three UN-ECE regulations in 2004. Japan has expressed its willingness to apply more UN-ECE Regulations, though it has always underlined that this will be done subject to their impact on safety and environment, the effects of harmonization on the Japanese economy, etc. While this is understandable, it should not exclude an accelerated rhythm of adoption. The EU, therefore, maintains its request that the adoption rate should be speeded up. In doing so, Japan should concentrate on the adoption of regulations in areas where the absence of harmonisation with the international standards is the most disruptive to trade. Early adoption of the maximum number of UN-ECE regulations will help to build on and consolidate the improvements which have already been made in reducing the time needed for type approval of motor vehicles in Japan

Japan has recently indicated that it was about to adopt several UN-ECE regulations, whilst indicating that it does not have the intention to adopt certain other UN-ECE regulations not in line with its domestic requirements, unless they are modified.

500mm provision for control devices

A Japanese requirement dating from 1951 stipulates that control devices for operating motor vehicles should be located 500mm to the left or right of the steering wheel (Article 10 of the Safety Regulations for Road Vehicles in the Road Vehicles Act). This has created serious difficulties for European manufacturers which place the defroster switch on one of their models outside the 500mm range from the steering wheel, and which are therefore obliged to reconfigure the control panels of these vehicles when exported to Japan.

Japan has argued that it is difficult to amend this requirement because of safety considerations. The EU notes that statistics show that the average height of men and women in Japan is today significantly higher than when this regulation was introduced.

A UN-ECE regulation is being discussed. Japan supported the draft proposal of the UN-ECE Regulation but claimed that it remained vague and announced the intention to present a proposal for quantitative definition.

Head clearance of 800 mm

Article 20 of the Automobile Safety Regulation states that "The passenger accommodation of a motor vehicle shall comply with the standard established by the

announcement relative to the structure so that it may ensure safe boarding and may not cause the occupants to fall off or stumble.” The Detailed Notice that prescribes specifications of safety regulations for road vehicles, in its Article 26 (Riding Accommodation), states that: “(2) The distance from the point on the seat surface level that is 200 mm behind from the front edge of the seat to the point on the ceiling that is obtained by a line parallel to the seat back shall be 800 mm or more”.

At the same time, Chapter 2, Article 104 of the same Detailed Notice applicable to Parallel Imported Motor Vehicles does not require a similar head clearance.

In order to be registered as a “Type Designated Motor Vehicle”, the shape and/or seatback angle of some passenger seats installed in **imported vehicles** must be changed to comply with the above-mentioned Japanese requirements. Where these changes are impossible, the vehicle must be registered as a “Parallel Imported Motor Vehicle”.

Even though the requirements for the dimension of a passenger seat have been simplified, the head clearance requirements remain unchanged. In some cases, imported vehicles, such as sports cars, designed to carry four passengers, must be registered in Japan as two-seaters, which penalizes the vehicle users. Parallel importers are however able to register such vehicles as four passengers cars. The modifications necessary to meet this unique requirement impose additional costs without offering any benefit to the consumer.

At present, work is proceeding on the development of a GTR on head restraints which will be based on the requirements of existing UN-ECE regulations (17 and 25), FMVSS 202 and corresponding EU Directives. This work will provide minimum possible heights for head restraints and provide specifications regarding clearance to rooflines. Accordingly, the need for an additional regulation on roofline height is superfluous and potentially a source of confusion.

Pneumatic suspension for passenger cars

Domestic and foreign manufacturers increasingly use pneumatic shock absorbers for the front and rear suspension of passenger cars. Under current practice, vehicles equipped with metal springs and those with pneumatic suspensions are treated as different types for the purposes of certification.

Separate applications for Type-Designation must be made both for a standard vehicle with metal springs and a vehicle with pneumatic absorber. Two Type-Designation fees must be paid even where the application is made only for Type-Designation of a vehicle with a pneumatic shock absorber. Under the Preferential Handling Procedure, separate Proximity Noise Tests and 10.15 Mode Emission Gas Tests are required.

Reform proposals

- **a) The EU reiterates its long standing request to the GOJ to speed up its adoption of UN-ECE regulations, thereby considerably increasing the number of regulations adopted per year.**

- **b) The EU requests the GOJ to provide a precise timetable for adoption of the following UN-ECE regulations: 37 and 113 on filament lamps and headlamps equipped with filament; 98, 99 and 112 on headlamps with gas-discharge light sources, gas-discharge light sources and headlamps emitting an asymmetrical passing beam; 14 on safety-belt anchorages, 16 on safety-belts and restraint systems, 44 on child seats; 53 and 74 on motorcycles.**
- **c) The EU requests the GOJ to provide as soon as possible proposals for amendment of UN-ECE regulations 13 on braking devices (as far as its application to heavy-duty vehicles is concerned) and 51 on noise in order to allow Japan to adhere to these regulations in the near future.**
- **d) Concerning regulation 48 on the installation of lighting and light-signalling devices (as far as its application to heavy-duty vehicles is concerned), the EU invites the GOJ table together with the EU an amendment of the regulation to bring it in line with the future GTR, as soon as an agreement on the GTR is reached, while understanding that Japan is waiting for the finalisation of the corresponding draft GTR;**
- **e) The EU requests the GOJ to adopt regulation 89 on speed limiters.**
- **f) The EU requests the GOJ not to apply the provision concerning the location of control devices necessary for operating a motor vehicle in the case of control devices specified in article 10.1.3 of the Safety Regulations for Motor Vehicles (classified as not 'vital' according to the ISO 4040 definition), when these devices are installed in vehicles for which no technical standards have been prescribed. The Japanese standard JIS D 0033 is identical with ISO 4040.**
- **g) The EU request the GOJ to accept a relaxation with regard to the 500mm distance until the UN-ECE regulation on uniform provisions concerning the approval of vehicles with regard to the location and identification of hand controls, tell-tales and indicators is adopted. Once the UN-ECE regulation is adopted, the GOJ should take the appropriate steps to adopt and implement this regulation.**
- **h) The EU requests the GOJ to delete the domestic requirement for head clearance.**
- **i) The EU requests the GOJ to change legislation in a way that vehicles equipped with a metal spring or pneumatic shock absorbers will be regarded as variants of the same type and not as different types, as is the current practice (e.g. vehicles equipped with a drum brake system or a disc brake system).**

9.3 Packages for foodstuffs

The Japanese regulation applicable to packages for food is the Food Sanitation Law, (announcement from the Ministry of Health, Labour and Welfare n°370, issued on 28 December 1959). This regulation sets mandatory product and testing requirements for packages which may in turn create an unnecessary obstacle to trade. While most Japanese packages for retort food are pouches, made of aluminium and plastic, European companies have chosen a somewhat different approach by using retort packages similar to a milk carton pack equally suitable for serving as a container for food or beverages. For the time being, the retort carton package is submitted to the same tests as retort pouches, despite the fact that the material used and the shape of the packages are different. As a consequence, some of the testing requirements, more specifically the tensile test, cannot be applied to this new kind of package because the test procedure destroys the integrity of the pack before it is tested. As was shown by the Japanese Canners' Association in a report issued on 25 April 2005, the retort carton package meets the current safety and health requirements. The report, based on scientific evidence, emphasises that this kind of package satisfactorily resists the burst test as defined by the JIS. The burst test, which is already applied to other products such as retort cups, could therefore replace the tensile test to ensure the safety of the retort carton package.

The problem faced by the European industry could be solved by submitting the different retort packages to tests which are technically adapted to the respective material and shape. This would allow taking advantage of the benefits of the different packaging systems.

Reform proposal

- **The EU urges the GOJ to modify Japan's Food Sanitation Law in order to accept packages for food which comply with the current safety and health requirements, but which use other techniques to achieve the same results. Therefore, testing requirements should be modified according to the state of the art of technology in this field. Innovation should be taken into account by Japanese authorities and allow for new products to be placed on the market.**

10. Distribution

Distribution networks in Japan are undergoing a period of widespread change, and there has been significant recent EU investment in the retail sector. However, complexities and inefficiencies still persist, raising the price of products for consumers. While recent market developments have reduced the number of layers in the distribution system, limited access to distribution networks continues to impair competition and to reduce the choice available to intermediate business purchasers and final consumers.

10.1 Retail licenses for large stores

The EU welcome the introduction of the Large Scale Retail Store Location Law (*dai ten ricchi ho*, LSRSSL) in June 2000 and the revision of the guidelines of March 2005. Although the overall transparency of the notification procedures and the details of implementation rules have improved, foreign retailers are still left in a disadvantageous position when it comes to the actual implementation of the law. As concrete example, the timing of the submission of a notification to local governments is left to the discretion of applicants. Foreign retailers, which have less experience in working with local communities, usually wait until the clearance on the notification procedure to start construction. In order to shorten their project lead-time, many Japanese companies submit notifications and start construction simultaneously. Whilst this practice is at their own risk as subsequent changes to their plans may be required, it often enables them to get substantial advantages in respect to their competitors.

Another outstanding weakness is the lack of coordination between the LSRSS, the Building Permit and the Environment Impact Assessment procedures, whereby these different produces often show inconsistencies, which renders the overall store opening application procedure too complex, opaque and in many ways redundant.

The EU understands that the Ministry of Economy Trade and Industry and the Ministry of Land, Infrastructure and Transport are currently working together on a plan to prevent hollowing out of city centres to revitalize local cities. We express our hope that that this will not lead to a tighter control in new store opening in suburbs.

Reform proposal

- **a) The EU suggests streamlining the necessary administrative procedures concerning opening of large scale stores through improved coordination of the procedures related to the Large Scale Retail Store Location Law, the Building Permit and the Environment Impact Assessment. A “one-stop shop” approach should be implemented in order to ensure the consistency of procedures and their fair implementation by relevant authorities.**
- **b) The EU request the GOJ to ensure that the policy of revitalisation of local cities does not lead to further restrictions on new larger scale store opening in suburbs.**

10.2 Alcohol licensing

Alcohol sales licensing has been progressively liberalized, in January 2001 and September 2003. The restrictions based on distance and population have been abolished. However, the "Temporary Adjustment Law for the improvement of Business Conditions of Liquor Retailers" enacted in August 2003 (Law No. 34) effectively eliminates beneficial effects of liberalisation. According to the new rules, the director of the local tax office can designate his jurisdiction as an "Urgent Adjustment Area" (*kinkyu chosei chiiki*) for the duration of one year if supply exceeds demand and if sales volumes for the next fiscal year have dropped by more than 10% of the average of the three previous years for more than 50% of the incumbent retailers.

The EU regrets that the Diet has decided to extend this temporary measure for another fiscal year and re-designated all 1,274 areas, which had been designated as "Urgent Adjustment Area" in FY 2004. Instead of slowly phasing these areas out, their ratio to the total number of areas nationwide stood at 37.7% in FY2004, and there has been no improvement since. The status of these "Urgent Adjustment Areas" is being reviewed annually until the expiry of the rules, currently scheduled for 31 August 2006. The EU would appreciate confirmation that the Law No. 34 regarding the "Urgent Adjustment Areas" will effectively be allowed to expire as scheduled. The EU is concerned that, if these rules were to be prolonged further, it would continue to affect foreign investment as it is considerably hinders predictable planning.

In addition, under the current scheme, once a large scale store liquor license which allows the sale of a limited range of alcoholic beverages (no Japanese *sake* and beers) is acquired, the license holder will not be able to apply for a new wider-scope liquor retail license and must hold the current one until its expiry. If the large-scale store liquor license is in an "Urgent Adjustment Area", the application for a wider-scope liquor license is refused. A change in these rules before FY 2006 would be desirable.

There has been no deregulation of liquor licensing for wholesale activities. It remains extremely difficult for European firms to obtain a wholesale license. Some firms have managed to do so, but are not allowed to offer wholesale domestic *sake*, beer and *shochu*. In other cases, foreign firms that want to wholesale liquor in Japan have been forced to purchase a Japanese firm that owns such a wholesale license for the sole purpose of using it. However, firms that choose this route are *de facto* forced to maintain two businesses as the Liquor Tax Law renders it difficult for firms to merge and transfer the license to the merged entity. The EU would appreciate information as to what measures Japan intends to take pursuant to Article 3 of the supplementary provisions of the law in question.

Reform proposals

- **a) The "urgent adjustment areas" (*kinkyu chosei chiiki*) should be abolished and not be renewed after expiry of the respective law in August 2006.**

- **b) Companies should be able to apply for a liquor license under the new licensing scheme without having to await expiry of their large-scale store license.**
- **c) Liberalisation of the retail liquor system should be extended to wholesale licensing as well.**
- **d) The EU requests the GOJ to clarify pertinent issues in the context of its overall regulatory reform policy.**

10.3 Customs control and boarder inspections

The import approval procedure and border inspection of consumer products under the Food sanitation Law impose a heavy burden on European exporters of tableware. Although the Ministry of Health, Labour and Welfare (MHLW) accepts certificates issued by designated testing institutes, the test certificate is valid only if the product is exported to Japan directly from the country where the certificate was issued. The EU is concerned that the validity of certificates issued by foreign testing institutes is not necessarily endorsed if the product is exported to Japan via a third country.

The Food Sanitation Law requires border control of all shipments of products requiring import approvals. In order to simplify the import procedure without increasing health risks, the current border control system should be replaced by a random sample control system.

Moreover, the Product Safety Law has imposed additional burdens on exporters of consumer products, not only of tableware but also of baby cots, baby clothes and other textiles by requiring expensive testing and marking solely for the Japanese market. Japan should accept internationally accepted testing methods and data by harmonising its import application procedure with international standards (ISO CE/EN).

Reform proposals

- **a) The import approval procedure for tableware under the Food Sanitation Law should be internationally harmonised and internationally accepted test methods and data be used. The current border control system should be replaced by a random sample control system.**
- **b) The Product Safety Law should be reviewed in order to bring it in line with international standards.**

11. Other issues

11.1 Animal health products

The approval process for animal health products in Japan continues to be more cumbersome than necessary and delays the introduction of products or even prevents foreign manufacturers from introducing innovative products into the Japanese market; this is clearly to the detriment of the Japanese livestock industry, the consumers of products of animal origin and pet owners. While Japan has made some welcome efforts to harmonize its standards with international practice, through *fora* such as the Veterinary International Co-Operation on Harmonization (VICH), the process of product approval remains more time-consuming and costly than in many other countries.

Anecdotal evidence from industry suggests that the number of dossiers to be submitted in the approval process is as much as 10 times higher as compared to some of the EU Member States. The ratio of registration costs to the expected revenue for certain products may be 6-7 times higher, and the approval period for new animal drugs has become increasingly longer, not just for livestock products after the establishment of the Food Safety Commission, but also for companion animal products; it is nowadays almost always in the order of two years and more. Also, the Post Marketing Surveillance (performed during several years after registration is granted), as well as the newly introduced resistance monitoring scheme for some classes of anti-infective (annual for poultry, bi-annual for other animals), require significant resources. Whereas these are all sensible schemes, annual costs for resistance testing alone can amount to more than Yen 10 million in certain cases.

The GOJ seems to be moving away from the current National Assay system of batch release for biological products (vaccines) by the National Veterinary Assay Laboratory. Whereas this is a positive development, the industry is waiting for a time frame within which a new system is going to be implemented. This new system should contain a seed-lot system with the release of batches being approved according to checked reports submitted by manufacturers based on their own in-house controls. In the EU, most Member States recognize the manufacturers' quality control laboratory as an Approved Laboratory (pursuant to Council Directive 90/677/EEC).

On a more general note, the regulator for human drugs, the Ministry of Health, Labor and Welfare (MHLW) has acted to simplify the implementation of pharmaceuticals regulations in recent years, whereas the Ministry of Agriculture, Forestry and Fisheries (MAFF), in charge of animal drugs, has been less flexible in its approach. This leads to a situation where, in certain ways, processes relating to animal drug applications are more cumbersome, costly and time-consuming for manufacturers to comply with than equivalent processes relating to human drugs.

As an example, in-vitro diagnostic products used by veterinarians to diagnose diseases and monitor treatment of animals, are classified as biological products and, as a consequence, are subject to the National Assay. This concerns all antigen-detection products and some antibody-detection products, including those which are

used for diagnosis of non-epidemic diseases. By contrast, the MHLW classifies in-vitro diagnostic products for human use in a different category, and none of these products are requested to go through an equivalent of the National Assay process for veterinary biological products; not even products designed for the diagnosis of major infectious diseases like hepatitis or HIV undergo such a process. The EU sees no reason why what is possible for products destined for human use should not be possible for products destined for animal use.

Another case in point concerns the fact that for new drug applications for human drugs it is now accepted practice in Japan that applicants submit reports based on foreign data on pre-clinical and clinical trials in English only, accompanied by a summary in Japanese. However, for New Animal Drug Applications (NADA), this is still not possible. It seems reasonable to suggest that at least for certain parts of the application (e.g. standard toxicological and safety studies), the acceptance of a Japanese summary of the original study report might be sufficient for a thorough review by the authorities. The Japanese argument that the submission of English-only reports might lead to delays in granting market authorization of products disregards the fact that MAFF is staffed with highly-experienced experts who are all well-versed in scientific English. Also, experience clearly tells us that in the course of the review process both sets of reports, the English and the Japanese ones, are scrutinized intensively, an obviously very time-consuming practice.

Finally, the EU continues to suggest the introduction of a brand-specific listing system for antibiotic and other feed additives, akin to the EU system, to clarify the responsibility of each respective manufacturer. In Japan, the current system under the Feed Safety Law leads to a situation where generic producers can sell their products without submitting any additional data once an original manufacturer has obtained a new listing, as long as their products meet the listed specifications of that original listing. A brand specific listing clearly provides much better protection of the significant development expense and intellectual property involved. It is this kind of protection that encourages manufacturers to invest more into R&D of safe and effective new products in the future which in turn creates benefits for the producers and consumers of livestock products.

Reform proposals

The EU request the GOJ to

- **a) Improve the efficiency in the product approval process for new animal health products.**
- **b) Eliminate the National Assay for vaccines and approve the release of batches according to checked reports submitted by manufacturers based on their own in-house controls.**
- **c) Abolish the current process of national assay for all veterinary in-vitro diagnostics (IVD), those for antigen and antibody detection.**

- **d) Permit reports on pre-clinical and clinical trials to be submitted in English, accompanied by a summary in Japanese, when applying for approval of a new animal drug.**
- **e) Switch from a compound listing system to a brand-specific listing for antibiotic and other feed-additives. Japan's current system puts generic producers at a considerable advantage by enabling them to get a free on the investments and developments by manufacturers of original products.**

11.2 Leather and shoes

Leather

The EU concerns in the leather sector are related to undue restrictions under the Japanese quota system, especially in light of elimination of textile and clothing quotas in 1 January 2005 under the WTO agreement. The Japanese tariff rate quota system allows for out-of-quota rates to be applied and it is therefore formally in line with the current WTO rules. However, it is clear that the spirit of liberalisation would suggest, especially in an advanced industrialised country as Japan that the ultimate aim is to dismantle such tariff quotas.

In fact, the present system with imports allowed above the tariff quotas at higher rates counters the potential demand for high quality leather in Japan and frustrates the vital interest of the Japanese manufacturers to enhance their competitiveness. Access to the Japanese leather market is hampered in the regulatory area by the current quota distribution system, as METI allocates only a small quota eligible to enter the Japanese market under a reduced tariff rate.

A European Commission investigation of 1998 into the complexity of the management of the tariff quota system for leather and the subsidies granted to leather industry concluded that the implementation of these practices is restricting imports of Community finished leather in Japan. The subsequent WTO consultations on 26 November 1998 on this issue did not lead to a satisfactory solution. However, Japan indicated at that time that all sectors would be on the table in the new WTO negotiation round on tariffs without any a priori exclusion.

In the present context where further liberalisation of Non-Agricultural Market Access (NAMA), including a complete elimination of all tariff quota systems, is currently discussed in the framework of the Doha Development Agenda by the EU and other WTO members, the Japanese tariff quota system for leather appears as unduly restrictive for trade, both quantitatively and qualitatively in light of higher rates applied.

Tariff quotas applicable to raw materials, crust and finished leather are deemed an extremely damageable impediment for the European industry. Thus the EU maintains that time is due for Japan to take steps to progressively but fully dismantle its tariff quota system within a realistic timeframe. For European producers this would offer the possibility to service a finished leather market with great potential, and for Japanese companies it would ensure supply of quality leather for producing leather consumer goods demanded by quality-conscious domestic and foreign consumers.

Leather Footwear

The issue of tariff quotas, very similar to the leather issue above, is also deemed damageable for the European industry as well as for those Japanese consumers interested in high quality leather footwear. Japan maintains tariff quotas on footwear at extremely low levels not corresponding to the market potential.

It is conceptually difficult to see the reasons why the tariff quota system should be maintained. Economically it is not sustainable as the system is leading to further weakening of a long-protected sector and to its total loss of competitiveness. Therefore, EU's request is similar to the one raised for leather tariff quotas.

Reform proposals

- **a) The EU requests the GOJ to elaborate a plan under which, within a reasonable time span, the current leather quota system is progressively and completely phased out. This should lead to swift reduction and ultimately dismantlement of the Japanese quota system in the leather sector which unduly restricts trade, irrespective of its WTO compatibility.**
- **b) The EU requests the GOJ to elaborate a plan under which, within a reasonable time span, the current leather footwear quota system is progressively and completely phased out. This should lead to swift reduction and ultimately dismantlement of the Japanese quota system in the leather sector which unduly restricts trade, irrespective of its WTO compatibility.**

11.3 Ski boots

EU exports of ski boots to Japan are subject to 27% tariff. These tariff duties are excessively high compared to other similar products, i.e. snow board shoes (8%).

Reform proposal

- **The EU requests the GOJ to apply the same tariff of 8% as for i.e. snow board shoes to the highly technical ski boots exported from the EU to Japan, pending tariff negotiations in the present DDA.**