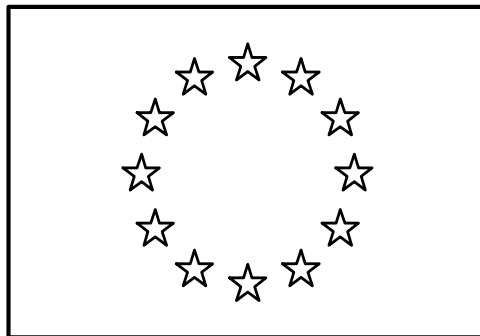


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**EU Proposals
for Regulatory Reform in Japan**

Final version



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Introduction

1. The European Union continues to highly value the EU-Japan regulatory Reform Dialogue as an important means for enhancing understanding, regulatory reform and economic relations among partners. Its long-standing success story over the last 12 years clearly bears witness to the wisdom of its founders and the role dialogue and cooperation can play in advancing our economic agendas for the benefits of employers, employees and investors in both Japan and the EU.

2. This year's EU contribution is aimed at supporting economic reform and restructuring activities in Japan, while it takes place against a sharply differentiated economic and political background in Japan. Economic growth, positive inflation and interest rates as well as hikes in employment bear witness to the radically changed economic landscape in Japan when comparing to the long years of economic stagnation, deflation and zero interest rates. The EU strongly welcomes this development which makes Japan again one of the best performing economies among OECD countries and thus an important contributor to economic recovery around the globe.

3. 2006 also meant a political watershed as the new Japanese government under the leadership of PM Abe has taken over from PM Koizumi's 5-year stable and reform-oriented tenure. Indeed, the leadership of PM Koizumi has allowed Japan to restructure its economy, to open its markets and also bringing about better access to other markets like the EU, and to start tackling major issues at the doorstep of Japanese society such as budget deficits, ageing population or public sector reform. The EU stands firmly behind continued efforts of Japan and its new government to continue the path of reform for the benefit of the Japanese people as well as economic partners of Japan such as the EU. At a time when multilateral trade talks are in a period of reflection, continuing the bilateral path to more openness, transparency and unimpeded market access is even more of the essence, and the EU is looking forward to comprehensively engage with the new Japanese government at the earliest opportunity.

4. The EU expresses its sincere hope that this contribution aimed at highlighting areas where the EU sees a need for further reform or deepening of implementing measure of existing legal and other engagements will be taken fully into consideration by the Council for the Promotion of Regulatory Reform (CPRR) in elaborating its recommendations for 2006 and by the Government of Japan in

continuing the path of necessary reform measures. Current economic and political circumstances would allow for an ambitious approach to be followed through.

5. The new EU proposals for regulatory reform in 2006 have taken due note of progress made by the government of Japan or policies under active discussion. First and foremost, the revision of the Corporate Law has undoubtedly been a major step towards modernising the legal structure of business in Japan. However, some legal components are still not in place for addressing key concerns of foreign investors. These concern in particular rules for cross-border mergers and acquisitions such as shareholders' rights (Art. 309) and taxation deferrals, and the status of foreign legal branches (Article 821). Regarding taxation issues, the EU regrets that hitherto it has not been possible to enter into any meaningful dialogue with the Japanese Ministry for Finance which is rejecting such dialogue on the alleged grounds of an absence of EC competence while addressing taxation issues in the framework of Japan's RRD proposals to the EU. In case of continuation of this unsatisfactory situation the EU will not be able to address Japan's requests in this area in substance in the future.

6. Positive developments include the implementation of the public comment procedures under the revised Administrative Law, and measures taken by the Japanese government to further the accessibility of legal texts so that EU requests in both areas have been dropped. Also the EU-Japan Wood and Building Expert Dialogue has been established and we hope to be able to address a number of regulatory issues more deeply in future.

7. Measures and activities which correspond to longstanding EU demands include the intensified crack-down on bid-rigging, privatisation of state-owned financial institutions, introduction of more competition regarding port services, and the political recognition of the need for a shake-up of the telecommunication sector as well as of the public auditing sector. However, work in all of these areas is in progress, and has not yet yielded substantive changes. The EU thus urges the government of Japan to accelerate progress in the respective areas.

8. In the public procurement market, especially also against the background of prominent bid-rigging cases, procedures including tender and evaluation mechanisms still need further enhancement of transparency and control. Existing procedures continue to discourage the entry of outside firms, thus depriving public authorities and ultimately the Japanese taxpayer of better value for money. At the same

time, the EU welcomes in principle the recent revision of the “Guidelines on Public Work”. In the telecommunication sector, the reform of the regulatory framework has to be accelerated in the light of new competition rules which are not allowing continued dominance as exercised by NTT. Laws and regulations pertaining to human resources have still not been altered, especially as regards pension refund and visa rules, and are rendered more cumbersome because of the existing system of re-entry permits. While beef imports from the US have been liberalised, even in light of recent problems with sanitary obligations, EU beef import requests are still not dealt with in a satisfactory manner. The continued refusal of competent Japanese authorities to enter discussions to bring about standardised air service agreements with EU Member States is delaying larger cooperation in the civilian aviation sector. Recently discovered loopholes in the regulatory framework of public auditing firms also necessitate urgent action by competent Japanese regulatory authorities. In the area of regulation of food safety and agriculture, little progress has been achieved in liberalising existing burdensome procedures or moving towards accepting international standards.

9. The 2006 EU – Japan Summit not only acknowledged the continuing relevance of the Regulatory Reform Dialogue, but also addressed some issues on its agenda directly. At the same time, the EU-Japan Business Round Table also dealt with a number of issues on the RRD agenda and asked for reinforced political leadership to help resolve long-standing issues on its agenda. It therefore would be particularly welcome if the government of Japan was able to address the issues proposed by the EU in a timely fashion in order to advance the common agenda of deregulation effectively. The EU stands of course ready to continue addressing questions of concern to Japan, while noting that existing procedures offer a wide range of participatory instruments to Japanese stakeholders already.

The stalemate of the Doha Development Round, economic problems in some regions of the world, the high level of energy costs and the implications of an ageing population both in the EU and Japan represent challenges that need to be addressed swiftly by political leaders. Measures to reduce statutory and regulatory impediments to free flow of trade and investment, as well as destined for offering equal treatment of domestic and foreign market participants, thus seem all the more crucial in bringing about benefits for all market participants, including employers, employees and consumers.

1. Investment

1.1 Corporate restructuring and related tax measures

The EU welcomes the continued commitment by the Government of Japan (GOJ) to increase foreign direct investment (FDI) coming to Japan. Following on from the 2003 policy objective to double the cumulative stock of FDI within 5 years, the new target, announced earlier this year, is to reach an FDI level equivalent to 5% of GDP by the year 2011.

This strong signal to foreign investors that Japan welcomes their engagement is all the more important since the 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 transactions in 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.

Against this background, the EU attaches great expectations to the entry into force of the new Corporate Law in May 2007 allowing cross-border stock-for-stock mergers, under the 'triangular merger' formula (foreign parent companies using their shares through a 100% Japanese subsidiary when merging with or acquiring another Japanese company). The EU attaches utmost importance to its request that no further qualifying conditions such as a requirement to be listed on Japanese stock markets will be necessary, be it *de jure* or *de facto*. For such cross-border transactions to have a realistic chance of being implemented, though, it will be indispensable that the threshold requirements for shareholder meeting resolutions will be no different from those applicable in the domestic context. The EU would appreciate a re-assurance by the Ministry of Justice (MOJ) to that effect, in particular with regards to the details for classification of compensation, and the requirements for such shareholder resolutions.

This is a key element for the EU-Japan investment relations to take a new upward swing, even more so since Japan did not accept the earlier suggestion made by the EU to allow straight cross-border share swaps. Since the triangular merger model already requires the additional step of establishing an 'intermediate' legal entity in Japan, there should be no further obstacles or limitations introduced for the foreign parent company, or its Japanese subsidiary, which would make an M&A transaction more onerous than it would be in a purely domestic context.

In addition, the EU also notes a potential problem concerning the practical application of this 'triangular merger' scheme for European companies. The acquisition of shares of the European parent by its Japanese subsidiary to conduct a share-to-share swap with a Japanese entity is, according to many Member States' laws, not possible or extremely limited. To be more precise, the triangular merger scheme in its current form would not be very helpful for European companies if the new Corporate Law would imply that full legal ownership of shares by the subsidiary is necessary. On the other hand, if Article 749 of the Corporate Law can be interpreted in such a way that it would be sufficient for the Japanese subsidiary of

the European company to offer options or equivalent rights on the parent company's shares without actually owning them, the scheme might be workable for European companies. A clarification on this issue would be helpful.

A second important issue continues to be related taxation aspects. The Corporate Law does not address these, and thus the rules for qualified tax-neutral mergers are not applicable. Therefore, shareholders of the Japanese company involved in such a triangular merger transaction would 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 already in March 2003 by the Japan Investment Council 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 EU appreciates the assurances already given by the Ministry of Finance (MoF) that domestic and cross-border merger transactions will be dealt with in an equitable manner. Since tax deferral is already granted to domestic M&A transactions – both direct and triangular – tax deferral should, therefore, also be granted to cross-border transactions, and on the same criteria as applied to wholly-owned subsidiaries created through stock swaps between Japanese domestic companies on the basis of Section 352 of the Corporate Law.

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.

Last but not least, the EU would like to underline that the continued refusal by the GOJ to address taxation issues in the RRD-context, as referred to also in the introductory part of this year's proposals, is not acceptable, and thus urges the GOJ to offer comprehensive responses in this regard.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- **a) The EU would appreciate re-assurance by the GOJ that triangular mergers will become possible for European companies as of spring 2007 without further qualifying conditions, and that notably the threshold requirements for shareholder meeting resolutions will not differ from those applicable in the domestic context.**
- **b) The EU would also appreciate clarifications as to whether Article 749 of the Corporate Law requires full legal ownership of the shares**

of the European parent company by its Japanese subsidiary in order to conduct a triangular merger, or whether the transfer of option or equivalent rights would suffice.

- c) The EU strongly urges the GOJ to facilitate corporate restructuring by allowing tax-neutral share-for-share M&A by foreign companies in all cases.
- d) The EU continues to request the GOJ to enable companies 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.

1.2 Legality of branches: quasi-foreign companies

Article 821 of the new Corporate 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 provides that such companies are not allowed to engage in transactions on a continuing basis in Japan (Art. 821 para 1). Persons acting in violation of this rule are liable to contractual countermeasures (Art. 821 para 2), with the possibility of sanctions (Art. 979 para 2).

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 main reason why basically all European companies used such business structures.

However, a literal reading of Article 821 means that those business entities engaging in transactions on a continuous basis risk to be prosecuted. Companies which are not prepared to accept this 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 a number of 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 constitutes 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.

While the Ministry of Justice (MoJ) has made interpretative statements (*touben*) on the record during the Diet hearings on the scope of application of Article 821, and the Diet has taken the rare step of issuing a Parliamentary Statement (*futai ketsugi*) together with the adoption of the bill, many corporate headquarters continue to be concerned about the legal risks entailed. 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 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 offer the legal clarity and certainty 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 nor for the financial services sector specifically. Moreover, legal uncertainty of this kind is counter-productive to 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 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.

The EU takes note of the reluctance by GOJ to engage in an "early warning mechanism" on pending regulations. With specific regard to regulations which may impact on investment activities, however, both sides committed to give higher priority to dialogue on new regulations. A key element for this to happen is to make the draft rules available for comment at an early stage. The EU suggests that some thought should be given on how to avoid recurring incidents of this kind in the future, whereby the EU has reacted to the new legislation once it had become aware.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- **a) The EU continues to urge the GOJ to amend Article 821 of the new Corporate Law at the earliest possible opportunity in order to create legal certainty. The EU would appreciate an early indication of a commitment by the GOJ towards that end, as well as an assurance that the European business community in Japan will be given an appropriate opportunity to participate in the revision process.**

- **b) In line with the two-way investment framework agreed at the EU-Japan summit in 2004, the EU would suggest considering jointly how to improve the consultation mechanism on pending legislation.**

1.3 Human Resources

The importance of human resources for a dynamic investment environment is recognised by the Japanese government and the EU. 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 some rules and procedures related to immigration and residence status as well as existing pension schemes can significantly limit the incentive for expatriates to engage in professional activity in Japan. For instance, foreigners living in Japan with a resident visa status need to apply, whenever they leave Japan and for whatever purpose, for a re-entry permit in person, and in advance of departure, for a fee (¥3,000 for single, ¥6,000 for multiple re-entry permit, valid for the same period as the resident visa, but no more than 3 years). Moreover, all foreign residents are required to possess a resident visa in addition to the Alien Registration Card (*Gaikokujin-toroku-sho*). Therefore, the re-entry permit does not contain any unique information which would not already be registered somewhere else. The EU considers this peculiar system as unnecessarily burdensome and moreover redundant.

It has been argued that the re-entry permit system is a simplification since foreign residents would, in its absence, be required to undergo an entry procedure for each temporary departure and re-entry. It therefore appears that the underlying root cause of the issue is the automatic loss of residence status for foreign residents, each time they leave Japanese soil. While legally an option of convenience, the re-entry permit thus becomes a *de facto* obligation. It is not clear why this loss of resident status would apply to permanent residents, and why the existing system of multiple visa does not suffice for an effective immigration control of foreigners. Since a frequent travel activity is an essential part of many expatriates' working schedule, the EU suggests a swift abolition of the re-entry system.

In addition, European companies face difficulties in securing personnel with specific skills. 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 to obtain a working visa.

Regarding pension schemes, 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, and the EU welcomes the conclusion of a number of bilateral social security agreements with EU Member States. 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 2005 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. highly-skilled workers such as in the field of IT).

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. Also, more flexibility in the application of the pension schemes would benefit many European expatriates.

Reform proposals

The EU requests the GOJ to consider the following proposals:

I. Concerning the rules and procedures related to immigration and residence status to:

- **a) Abolish the system of re-entry permits.**
- **b) Further relax the visa requirements to meet the needs of European companies, especially regarding personnel with specific skills.**

II. Concerning pension schemes to:

- **c) Conclude bilateral social security agreements with all EU Member States as soon as possible.**
- **d) Increase the cap for the partial refund of contributions 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.**
- **e) Make contributions to foreign-based pension plans subject to the same tax relief as contributions made to pension plans in Japan.**
- **f) Improve the defined-contribution pension scheme by increasing tax-exempt contribution levels, allowing matching contributions, and plan-holders to borrow against their pension reserves.**

1.4 Transparency

An area of continuous concern remains the transparency 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** is one of the major instruments to promote transparency. It is designed to allow all interested parties to comment on administrative measures and draft regulations, as well as guidelines and recommendations. It has recorded significant progress since its creation in 1999, most importantly through its integration into the Administrative Procedure Law, in force since 1 April 2006, providing a legal basis while ensuring a general and uniform application across the GOJ, including a standardised comment period of 30 days.

According to the latest annual survey of the Ministry of Internal Affairs and Communications (MIC) released in May 2006, 611 Public Comment Procedures took place in fiscal year 2005. One of the main continuing 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 EU regards the 30 days period as reasonable but regrets that this rule is often not respected. In fiscal year 2005, about 35% of public comments fell short of the 30 days period.

No data for FY 2005 is available to assess whether the shortening of the period for public comments has been justified (this was the case in only 10% of cases in 2004) nor whether, or to what extent, the input received during the comment period did actually have an impact or led to modifications of the draft texts (as happened in only 30% of cases in 2004). With those data not centrally monitored by MIC any more, it is becoming increasingly difficult to assess whether this regulatory tool really fulfils its function. The EU suggests the GOJ continue to monitor the development centrally, with special attention being paid to the way in which suggested modifications received during public comment are being integrated or discarded, as the case may be.

It is essential to apply this procedure also to draft laws in their entirety, rather than to consult publicly on excerpts or summaries only. The case of the Corporate Law, where the problematic Article 821 remained undetected until the bill was already presented in the Diet, is a perfect illustration of the difficulties encountered in case stakeholders are not being made aware of the precise text of draft laws in due time.

The **No-Action Letter (NAL)** system has, overall, not seen a very broad usage as of yet. Only 8 cases were recorded in FY2005, and this number is down two-thirds of the figure from FY2004. Some of the reasons seem to stem from the fact that either the scope of NAL had been restricted (e.g. to new products or services) or that the eligibility of those wishing to use the NAL system is being very narrowly defined (e.g. only entities under the remit or control of a certain ministry or agency). This seems to have caused problems as of late in particular in the financial services

industry. As a consequence, it appears that many issues of interest cannot be submitted for clarification; in other cases, business associations - representing many members - have found themselves denied access to the use of the NAL system because of the heterogeneous nature of their membership.

The EU welcomes that a revision of the Cabinet decision of 19 March 2004 during FY2005 now expands the scope to cover "business activities by private enterprises" generally. Still, the almost total lack of usage gives rise to questions about the effectiveness of this regulatory tool, and the EU would appreciate if the GOJ would share its assessment of the current situation and experiences made.

Concerning a more general issue of **participation of foreign stakeholders in the decision-making process**, the EU notes a continuing difficulty for European business to get access to crucial information at an early stage, and to make its voice heard whenever its interests are affected. The preparation of the Corporate Law, again, illustrates the importance of early involvement. The same applies to other recent examples, such as the privatisation of Japan Post, or the initiative to translate key legislation into foreign languages.

Last year, the EU suggested the idea of an 'early warning mechanism' on draft legislation, following the 2004 Co-operation Framework for Promotion of EU-Japan Two-Way Investment. The EU understands that the GOJ is currently not inclined to consider such a mechanism in detail. The EU would suggest, therefore, as an alternative, to consider how foreign business organisations can, in a general manner, be given better access to advisory councils (*shingikai*), study groups (*kento kaigi*) and similar consultative organs during the consultative process leading to eventual new legislation. By doing so, issues of importance to European business interests could be identified at an early stage and addressed, where needed, rather than being put on the agenda of the Regulatory Reform Dialogue as a *fait accompli* once laws and rules have been put in place. Again, the example of Article 821 of the Corporate Law serves as an example underpinning this suggestion.

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 attached by the GOJ to RIA, as demonstrated for instance by the Government Policy Evaluations Act. In order to make the RIA a more objective and efficient tool, the EU suggests that the GOJ should reflect 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. The EU would appreciate an update on where the GOJ currently stands with regards to its policy assessment.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- I. With regard to the Public Comment Procedure, the EU urges the GOJ to improve its implementation and furthermore
 - a) To make available for public comment complete draft laws rather than mere summaries before such drafts are submitted to the Diet for deliberation
 - b) To 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.
 - c) To ensure that ministries and agencies allow sufficient time to take properly into account public comments in draft regulations, and continue to monitor the results
- II. With regard to the No-Action Letter system, the EU urges the GOJ to reconsider the scope and eligibility of users, with a view to facilitate its use by those who are affected.
- III. With regard to the general participation of European-affiliated stakeholders in the decision-making process, the EU suggests that the GOJ may consider involving foreign business organisations in advisory councils (shingikai), study groups (kento kaigi) and similar consultative organs
- IV. With regard to the use of Regulatory Impact Analysis, the EU requests the GOJ
 - d) To extend the use of RIA to all fields of activity, enhancing its use in public works, R&D, and official development assistance
 - e) To take into account public input while processing the RIA
 - f) To provide public information access and publish the RIA conclusions

2. Government Procurement

The EU welcomes the continuation of the bilateral dialogue on government procurement. It helps to enhance mutual awareness 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.

If potential suppliers have first to navigate through a complex web of administrative procedures before they are able to 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. In this light, the virtual absence of EU suppliers from many parts of the Japanese procurement market indicates that the opportunities are not currently perceived as sufficient.

The EU welcomes Japan's revised "Guidelines on Promotion of Prosper Tendering and Contracting for Public Works" of 23 May 2006. The EU proposes discussing these measures further at the 2006 Expert and High Level Meetings of the Regulatory Reform Dialogue. These measures also provide an opportunity to review together with the respective Japanese authorities market access obstacles that EC suppliers are facing in the Japanese procurement market. Such a bilateral discussion seems timely as ongoing market access negotiations in the WTO GPA are entering their final phase. Many of the problems that foreign suppliers encounter in Japan could be addressed in Japan's revised offer to the GPA.

Placing procurement policy in the wider context of economic policy, the EU welcomes that the incoming Japanese Government is determined to continue to promote regulatory reform in this area. 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 to find 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 sufficiently compatible with transparent, open and competitive tendering systems. 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 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 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.

While the EU understands that it is often impossible to manage the business evaluation process within this time frame, such delays result in excluding 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 an overall 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. However, 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, the registration requirement is administered 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 that Japan has recently started to improve the system. Nevertheless, these changes are not going far enough to remedy concerns raised by the registration process.

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

The EU has noted with interest recent developments concerning price ceilings contained in revised guidelines published by the GOJ on Promotion of Prosperous Tendering and Contracting for Public Works. The EU understands that the GOJ now recommends not announcing the ceiling price system or the threshold price in advance but only after the opening of the bids. The EU considers that this new measure is a step forward and could contribute fighting endemic bid rigging in Japan. However, the EU regrets that this measure is not wide-spread mandatory and applies only to certain central procuring authorities.

As already indicated last year, 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 lower prices. As a result, particularly efficient suppliers may be 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 and welcome 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. 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 an automatic 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-statutory 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 perpetuating the existing market situation, demonstrating a substantial market share in Japan should not be a qualifying criterion.

The EU understands that many local authorities consider themselves bound to buy the 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 aware that they are free to buy products directly from overseas suppliers.

Thresholds of public works contracts

The EU welcomes the recent GOJ decision to domestically lower the thresholds of work contracts subject to open bidding from 720 million yen (GPA thresholds) to 200 million yen in fiscal 2006. However, the EU regrets that this change will only apply to central procuring entities and does not affect sub-central entities, or those listed in Annex 3 of Japan's GPA commitments.

The EU notes that central procuring entities only account for roughly one-third of the total amount of public work contracts awarded in Japan. This proportion is even likely to decrease if administrative and tax reforms currently under way in Japan led to greater decentralisation and local autonomy. The EU notes that Japan public work procurement thresholds in the GPA are three times higher than those of other main GPA Parties. In this context, the EU wishes to recall its request to the GOJ to align its public work procurement thresholds in the GPA to those of the other developed Parties (i.e. 5 millions SDR) as a means of promoting competition in this sector.

Use of "operational safety" derogation in supplies procurement

Note 4 of Japan's appendix to the GPA allow Japan to exclude procurement awarded in the telecom or railways sector because of "operational safety" reasons. The EU regrets the extensive use of this derogation by Japanese procuring entities in particular in the railway equipment sector. Because of this extensive use, the EU notes that too many procurement operations in the railway sector are excluded from public tendering. As a result, neither JR East, nor JR West ever awarded a contract to EU companies during the period 1996-2000 (the last for which data has been provided by the GOJ). The EU is of the view that the apparent lack of penetration of the Japanese market is a direct consequence of the extensive use of this derogation.

The EU wishes to underline the importance it attaches to its request to delete this note in Japan's revised offer to the GPA. The EU considers that GPA already provides exceptions to the Agreement for public safety reasons (see article XXIII), which all other GPA Members consider sufficient.

Open and selective tendering

As is spelled out in Article VII of the WTO GPA, open tendering procedures are procedures under which all interested suppliers may submit a tender. In contrast, in selective tendering procedures, 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 commonly be considered 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 fully 'open'. In the experience of the EU, such barriers to entry tend to facilitate collusive practices and lead to 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 yen. Nevertheless, the implementation of this measure during the next fiscal year will increase the number of the MLIT's contracts awarded through bidding only from 2.3% to 15%, which means in value terms 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 open tendering procedures, as defined by the GPA, during the 1999-2003 period.

Technical specifications

Reports show that technical specifications are often too narrowly prescribed and do not allow bidders to bring any added value or innovative solutions. The EU has very positive experience of expressing technical specifications in terms of performance rather than design or descriptive characteristics, as incidentally also required under Article VI GPA. The EU understands that the GOJ's recently revised guidelines go some way in this direction, and encourages the GOJ to continue amending them accordingly.

In practice, this would mean that requirements, or references, for a particular trademark or trade name, patent, design or type, specific "origin, producer" or supplier would always be accompanied by words such as "or equivalent" in the tender document. Otherwise, procuring entities will not avail themselves of the full diversity of technical solutions available on the market. 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. The EU 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.

The EU has had very good experiences with its own central tender database "TED". It 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. In case the system is maintained, suppliers should have the choice that business evaluation regarding each specific procurement procedure is carried out centrally or by the procuring entities themselves.
- 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 to lower public work contracts thresholds to all procuring entities (central, sub central authorities) and to open up these contracts to international competition by aligning these new thresholds to international standards as accepted by the main GPA Parties (i.e. 5 million SDR).
- e) The EU recommends suppressing the current price ceiling practice or to replace it by a mechanism similar to the one recommended in the revised guidelines on public work.

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.

- f) The EU recommends reviewing the current practice of relying too frequently on "operational safety exceptions" to exclude procurement from international competition in specific sectors. This is also in line with the EU's request to delete footnote 4 of Japan's appendix to the JPA.

- g) The EU encourages Japan to consider allowing innovative solutions as an alternative to rigid technical specifications. The EU recommends that procuring entities at all levels should be obliged 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. This applies not least with regard to "green procurement".
- h) 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.
- i) The EU recommends that the price reference books used by procuring authorities should include foreign products, especially where international competition is established 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 issues an administrative notice formally reminding 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.

- j) With a view to enhancing the competitive elements of the procuring process, the EU recommends facilitating market entry by publishing free of charge all Japanese tender notices on an electronic single point of access 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

We welcome the ongoing debate in Japan on the changes required to address the challenges in the electronic communications sector, deriving from the rapid transition towards a new environment dominated by IP-based networks and the increasing convergence in the sector. Such a process offers a unique opportunity to establish an open, fair and technologically neutral regulatory framework to boost the electronic communications sector in Japan.

We would encourage MIC to implement as quickly as possible such reforms, in particular regarding the competition framework, even before the target date of 2010. Having a new clear set of competition rules in place at an earlier stage would undoubtedly facilitate a smooth transition to the new model. It would also allow industry players to plan ahead and make key strategic and investment decisions for the future.

We commend Japan's efforts in the admittedly difficult building of a competition model that promotes both facility-based and service-based competition and seeks an appropriate balance between the two. Indeed, regulation can be rolled back once concerns about market dominance, in particular associated with "bottleneck" facilities, have been eliminated. However, for this reason, ex ante regulation should exist for as long as such bottlenecks or competitive concerns remain. This is especially important in view of the extremely high market share of NTT East and West in the local fixed telephony markets, to give an example.

Such an exercise requires a continued effort to identify and analyze those markets where such dominance and competition concerns exist. While Japan has made a considerable effort to undertake over the last years an analysis of a number of markets, it is important that a clear and well-defined competition analysis process remains in place.

Summary of previous EU reform proposals and follow-up

Regarding the independence of the telecommunications regulatory authority, the EU takes note of the financial, national security and public policy reasons that explain the current governmental shareholdings in NTT and the reassurances provided regarding the observance of Japanese telecommunications regulations by MIC when exercising its regulatory functions regarding NTT.

In the past we have praised the Japanese Government for maintaining asymmetrical regulations for dominant operators and in particular imposing specific obligations on telecommunications carriers to open designated essential telecommunications facilities. In this respect we welcome additional elements of information provided. This being said, the latest Japanese reply also recalls the work carried out by MIC's "Study Group on a framework for competition rules to address progress in the move to IP", and other ongoing work on the principles for competition policy in the IP era and future interconnection and pricing policy. Some of our proposals this year will refer to this forward looking exercise.

We also welcome the explanations of the GOJ as to the goals pursued by the latest review of the ministerial ordinances related to the Japanese Universal Service Fund. We have never called into question the legitimacy of the goals pursued by such a reform. Our comments wanted to draw attention to the need for the GOJ to preserve the benefits derived from its former decision to exclude non-traffic sensitive costs from fixed interconnection charges. We fear that the latest review of the universal service fund might have the unintended consequence of eliminating de facto many of these benefits to the detriment of both NTT competitors and the Japanese consumer. In addition, we still consider the five-year period being given to NTT to phase out NTS charges excessively long and would welcome a more rapid rebalancing.

Current situation regarding NTT's dominance in most fixed-line markets and the adequacy of competitive safeguards

Japan still regulates largely specific facilities of carriers with a significant market position. However we note a trend to progressively reduce "ex-ante" regulation in favour of an "ex-post" application of competition rules, starting with a noticeable deregulation of certain prices and tariffs. Ongoing discussions in Japan seem to suggest that the forthcoming review of the Japanese Regulatory framework, intended to respond to the transition towards full IP-based networks, will reinforce these trends towards "ex-post" regulation.

At the same time we believe that there is room for improvement in the current system of competition review in Japan. In particular, several markets have been exposed to a competitive environment, but the conclusions of reviews neither automatically nor necessarily translate into the adoption of remedies or regulatory measures through a clear and transparent process.

In the existing context where NTT East and West are still largely dominant in fixed telephone lines, there is therefore a strong case for maintaining and even reinforcing competitive safeguards to avoid any possible abuse of dominance.

The cost of fixed line interconnection and the need for competition neutrality in the funding mechanism of universal service obligations

Interconnection charges in Japan have for a long time been considerably above international benchmarks. We welcome the efforts already undertaken by the GOJ to correct this situation, in particular to avoid that high interconnection rates by dominant operators coupled with little or no increase in their retail rates to users could increase the danger of an exclusive price squeeze.

In this respect, the use of non-traffic sensitive elements for the calculation of interconnection charges has been criticized in past years. It has been argued that it is inefficient to recover non-traffic sensitive costs from per-minute interconnection charges and that such costs should be absorbed directly by the subscribers' network, not interconnecting networks.

We have welcomed the positive decision of MIC to eliminate non-traffic sensitive costs from per-minute interconnection charges, but NTT will be allowed five years to do so, starting in 2005. This been said, this transition should be accelerated and at

the same time steps should be taken to ensure that NTT is not engaging in price squeeze behaviour.

In addition, universal service obligations in Japan have been traditionally financed by cross-subsidization from profitable to non-profitable areas within NTT East and West. Previous reforms in the Universal Service system have substantially modified this situation. However, there is a risk that the reform of the Fund will eliminate the positive effects of the elimination of the non-traffic sensitive costs from per-minute interconnection charges, if payments to NTT via this mechanism increase excessively. This is the case even if there is no direct link between both processes, as has been explained by Japan. The requirement in other jurisdictions has been for the incumbent to absorb NTS costs or eliminate them by way of efficiency improvements. Only a net loss to the provider of Universal Service without the addition of NTS costs should justify the activation of the universal service fund.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- **a) Japan should take into account the competitive situation of the markets affected before rolling back ex-ante regulation. Proper ex-ante regulation should exist for as long as competitive bottlenecks or concerns remain. This is especially important in view of the extremely high market share of NTT East and West in the local fixed telephony markets, for example.**
- **b) The benefits of eliminating non-traffic sensitive costs from per-minute interconnection charges should be maximized by keeping transitions to a minimum and below the current target of five years, with a fixed starting date in 2005.**
- **c) Japan should ensure that changes in the Japanese electronic communications sector likely to have a negative impact on the provision of universal service are addressed in a way which does not unduly penalize the competitors of the universal service providers. Otherwise, this would risk eliminating any benefits expected from recent changes in the interconnection regime.**

4. Financial Services

The EU warmly welcomes the achievements of the Program for Further Financial Reform, in particular the reform allowing banks to act as sales agents for securities companies, the revamping of the bank agent system, the implementation of Basel II as of March 2007, the adoption of the Guidelines for Financial Conglomerate Supervision and the adoption of the new Financial Instruments and Exchange Law (FIEL) which provides a comprehensive legislative framework for investor protection. These reforms clearly go in the direction of a more integrated financial industry in Japan.

European and Japanese financial institutions and markets are likely to become more interdependent in the coming decade. 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. In this respect, the EU highly appreciates the work that Japan is undertaking regarding the convergence of its accounting standards with IFRS. The EU also welcomes the FIEL whose approach is similar to that taken in the EU Market in Financial Instruments Directive.

4.1 Banking and investment 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 (to be replaced by Article 33 of the FIEL) 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.

Arguments put forward by Japan to keep these firewalls intact are the need to prevent conflicts of interest stemming from commercial banks' engagement in the securities business due to their excessive influence on enterprises and the need to ensure sound bank management. Nevertheless, the EU notes that such possible negative effects arising from the abolition of Article 33 of the FIEL could be excluded in case where banks strictly comply with the "Guidelines for Financial Conglomerates Supervision" introduced in June 2005. Under this Guideline, an EU bank in Japan may establish a holding company if it wishes to operate as a group. However, branches of a foreign bank and a foreign securities firm would first have to establish banking and securities companies in Japan. This approach proves very costly. While the abolition of all firewalls should remain the final goal, the EU believes that deregulation of some of the firewalls could and should be envisaged in the near future. For example, it would be a helpful step for 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 EU notes that the “Financial Instruments and Exchange Law” has been enacted as an umbrella law to establish a framework for comprehensive and cross-sectional protection of users of a wide range of financial products. As such, the FIEL amends no less than 89 laws (including the Securities and Exchange Law and the Law concerning Investment Trust and Investment Corporation) and abolishes 4 laws (i.e. the Securities Investment Advisory Law). However, despite this streamlining effort, discretionary investment advisors and investment trust management firms continue to be regulated by two different regulations and their respective associations (the Japan Securities Investment Advisers Association and the Investment Trusts Association, Japan) will therefore not be consolidated. The EU regrets this situation which leads to disparate licensing and customer disclosure requirements. Merging the two regulations into one consistent set of rules would allow the industry to work in a consolidated legal environment and could also lead to a consolidation, in due course, of the two self-regulating bodies in this field, thus eliminating the current duplication of procedures.

Under the FIEL, investors are classified into 2 categories of professional and general investors. Less strict rules are applied for sales of financial instruments to professional investors. The FIEL will provide the registered investment trust management firms with a new type of license to offer certain categories of securities including offshore funds. If the investment trust management firms will be allowed to offer the offshore funds with such licenses, discretionary investment advisors should be allowed to do the same or, at least, to promote the offshore funds to qualified institutional investors. Both are classified as “investment management business firms” and are required to satisfy minimum capital and net asset requirements under the FIEL.

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 specific brokerage license. This is an impractical solution for asset management firms given the costs involved in setting up the necessary firewalls. The EU reiterates its request that the necessary measures to remove this requirement are taken under the FIEL.

Japanese city banks have been allowed to engage in trust and banking business concurrently since 2002. But neither these reforms nor the recent changes (FIEL) apply to foreign bank branches. The EU therefore repeats its request that the relevant legislative provisions 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.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- a) While welcoming the recent Guideline for Financial Conglomerates Supervision, 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 33 of the Financial Instruments and Exchange Law, which prohibit integrated management of banking and securities businesses, should thus be abolished.

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

- b) The EU requests the GOJ to merge the regulations applying to discretionary investment advisors and investment trust management firms for the sake of consistency and alleviating the overall administrative burden. In the same vein, the GOJ should ensure that the review of the self-regulating bodies and their functions is carried out as part of the current financial system reform, with the aim of removing overlaps of functions between regulators and self-regulatory organisations. This would streamline the present excessive burden of reporting requirements and duplicate inspections.
- c) As regards the sales of offshore funds, equal treatment should be granted to registered investment trust management firms (which will be allowed to offer offshore funds with a new specific type of license) and discretionary investment advisors.
- d) The GOJ should take the appropriate implementation measures under the Financial Instruments and Exchange Law to allow asset managers licensed in Japan to place orders to buy or sell Japanese securities on behalf of group affiliates.
- e) Foreign and domestic branches should be treated in the same way as regards trust banking. The GOJ should revise the Law on concurrent operations of the trust business and the banking business in order to enable foreign bank branches in Japan 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. Since December 2005, banks are 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 hopes 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 full liberalisation of bank insurance activities takes on even greater importance with the Japan Post privatisation process starting in October 2007 and the likelihood for the privatised postal entities to launch new product lines. A discriminatory situation where the Postal Savings Bank would be able to sell a wider range of insurance products than private banks should be avoided.

The revised Insurance Business Law (IBL), which entered into force in April 2006, includes 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 (SASTIPs)*, and will come under FSA supervision as from April 2008. While the EU welcomes the fact that these SASTIPs 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, cooperatives in the health sector or consumers' cooperative societies – e.g.: the Seikyo Group of Cooperatives). Having millions of customers, these so-called "regulated" *kyosai* directly compete on the market as large-scale insurance companies. However, unlike licensed insurance companies, these entities are not required to contribute financially to the policyholder protection corporation, are not submitted to the same amount of corporation taxes nor the same reserving rules as their private insurance competitors, and are not submitted to FSA supervision. The EU would also like to see these *kyosai* brought under the scope of the IBL in order to ensure a level playing field with the private insurance sector, especially if these

Kyosai allowed to expand their scope of activities and sell products outside of its membership to the general public (amendments to the Seikyo Law under discussion).

Some *kyosai* (whether SASTIPs 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). Up to now, most of the re-insurance ceded by *kyosai* has been underwritten by European companies.

According to Article 16 of the Supplementary Provision of the revised IBL, the SASTIPs 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 equal or better terms than foreign companies, SASTIPs can cede re-insurance to foreign companies, but, in such cases must obtain an explicit prior approval from the FSA.

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 created any problems. Article 16 is causing EU re-insurers a great loss of business. It is an established fact that Kyosai were forced to switch reinsurance. In addition, the distinction between the ¥10 million ceiling (under which reinsurance is not compulsory and can be freely contracted) and the ¥50 million ceiling is not valid since no Kyosai will split its reinsurance cover, resulting therefore in a total loss of business for EU reinsurance companies not licensed or headquartered in Japan. Moreover, the seven years transitional period is unacceptably long and means in practice that the loss of business will be definitive. As a practical consequence, the affected EU companies have no other choice than giving up this market share or establishing a branch office, with direct consequences in terms of capitalisation, reporting requirements, etc. 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 EU recalls that Japan has full Mode 1 commitments in reinsurance and cannot therefore ban cross-border business in this area. 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.

In addition, the EU has recently adopted a Directive on re-insurance introducing a coordinated regulatory framework for the supervision of re-insurance companies throughout the EU. This should offer a further guarantee for Japanese insurance companies or *kyosai* to as regards co-operation 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

The EU requests the GOJ to consider the following proposals:

- a) All remaining restrictions on the sale of insurance products through financial institutions should be abolished ahead of the final target date of end-2007.
- b) The GOJ should consider ways to alleviate the substantial financial burden associated with pre-funding for the policyholder protection corporations.
- c) The EU urges the GoJ to end the favoured status of Kyosai that are established under laws other than the Insurance Business Law by bringing them within the scope of that Law.
- d) The EU urges the GoJ 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 (SASTIPs).

4.3 Auditing

The EU welcomes new Japanese legislation in preparation on auditing. It hopes that the public oversight system to be put in place by the new law will allow for reciprocity and equivalence recognition on both sides, meaning the EU and Japan. This is very important since quite a number of Japanese firms are involved in the audit of companies listed in the EU, and vice versa.

The EU and EU audit regulators are interested in minimising additional regulatory burdens on issuers and their auditors in non-EU countries. This is precisely the purpose of the questionnaire which was sent by the European Commission to the Japanese FSA and a number of other national authorities outside this EU last summer: obtaining an overview of the arrangements for audit regulation in their jurisdictions in order to determine how to approach an equivalence assessment of the regulatory arrangements for auditors in their country.

Under the new 8th Company Law Directive on Statutory Audit, each EU Member State will have to set up a public oversight system to regulate auditors by mid-2008 at the latest. This means that, by mid-2008, Japanese auditors or audit firms of companies whose securities are listed in the EU will have to be registered with the relevant Member States' authorities where the listing takes place. However, Article 46 of the Directive foresees possibilities of exemptions from the registration requirement for third countries where public oversight systems could be considered as equivalent, and if there are reciprocal working arrangements. The EU looks forward to moving towards equivalent public oversight with Japan provided that the new law under preparation on audit facilitates this process and reciprocity can be envisaged.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- **a) Given the importance of moving towards equivalent public oversight in the audit field, the EU asks the GOJ to ensure transparency in the preparation of the new law on auditing and keep the EU informed on this ongoing process.**
- **b) The EU urges the GOJ to consider the setting up of a public oversight system which would allow for equivalence recognition by the EU under the 8th Company Law Directive, and provided that reciprocity can be ensured.**

5. Privatisation of Japan Post

The EU considers the postal privatisation plan a major achievement of the Koizumi administration.

Key to the success of the privatisation process will be the capacity to ensure a smooth transition without market disruptions, while guaranteeing a level playing field among 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 GoJ, have responded to many of the requests made by the EU in previous years.

The privatisation process will begin in October 2007 with the division of the current Japan Post into 4 entities: the Post Office Company, the Postal Delivery Company, the Postal Savings Bank (Yucho Bank Company) and the Postal Insurance Company (Kampo Life Insurance Company). The 4 entities will operate under the Japan Postal Services Corporation (a holding company). The Government will sell shares of the Japan Postal Services Corporation after October 2007 but will retain a stake of at least one-third. The Japan Postal Services Corporation will hold a 100% stake in the Post Office Company and the Postal Delivery Company and will transfer all of its shares to the Postal Savings Bank and the Postal Insurance Company in stages between 2007 and 2017.

Splitting up of the huge postal savings and insurance units (with some ¥198 trillion of deposits at Yucho Bank and ¥120 trillion of total assets for Kampo Life Insurance as of end-March 2006) 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 Financial Services Agency will supervise the Yucho Bank and the Kampo Life Insurance from October 2007 onwards while the Ministry of Internal Affairs and Communications (MIC) will continue to supervise the Postal Delivery Company and the Ministry of Land, Infrastructure and Transportation (MLIT) will supervise mail and package delivery services by the Postal Delivery Company. The EU considers that supervision by a separate and independent regulator for the monopoly postal services is of the utmost importance.

On 31 July 2006, the Japan Postal Services Corporation submitted an "outline of an implementation plan for the successor to Japan Post" to the MIC. This skeleton plan shows how Japan Post will be spun off when it is privatised and what business activities the postal privatised entities will carry out after privatisation. The EU welcomes the fact that this draft business plan was made public. Transparency in Japan Post's privatisation process is vital to ensure that transition to the private sector will be conducted smoothly and fairly.

According to the skeleton plan, at the outset of the privatisation, Yucho Bank Company and Kampo Life Insurance Company will be allowed neither to sell new

financial products nor to raise the upper ceiling of deposits and insurance policies per customer (from ¥10 million currently). However, the plan indicates that Yucho and Kampo will seek to expand their financial services operation for individuals after October 2007. Yucho Bank wishes to provide mortgage loans and credit card services, as well as handling foreign currency-denominated accounts at an early stage of the privatisation. In addition, the Bank will seek to raise or abolish the current ¥10 million ceiling on deposits held by individual customers. On the other hand, Kampo Life Insurance seeks to introduce new products, such as one that would provide greater coverage for policyholders who agree to undergo physical checkups. It is also expected to develop so-called third sector products, including medical insurance policies that would cover hospitalisation costs.

The Postal Privatisation Committee will first have to review any plans of Yucho Bank and Kampo Life Insurance to offer new services. The EU understands that the Committee has started discussions on criteria for approving new financial services to be offered by Yucho and Kampo. However, it is not clear whether the approval criteria will be released, and whether or not a public comment procedure will be undertaken. The EU is also concerned that Yucho Bank and Kampo Life Insurance are allowed to offer new services before they are fully privatised and thus their longstanding advantages as protected government entities have been completely eliminated. The draft business plan gives fuel to this concern by indicating that both companies will aim to go public in FY2011 and end capital ties with the holding company by FY 2016.

The EU appreciates recent statements made by the GoJ 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.

The EU also appreciates recent statements by the FSA that Yucho and Kampo will be required to disclose their financial results based upon the same accounting rules as those applied to private sector companies, and will be submitted to the same inspection and supervision regime as their private competitors.

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 in this field of activities 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, it does not appear to be justified to impose any burdens – be it universal service obligation or financing obligations – on other potential competitors in the personal correspondence (*shinsho*) delivery business. In addition, MIC regulations and adequate control should ensure that no cross-subsidies occur.

At present, Japan Post's delivery business is largely exempt from security regulations (in particular parking rules under the revised Road Traffic Law) recently implemented by the MLIT and enjoys preferential customs treatment. The EU considers that the competitive businesses of the Postal Delivery Company should be subject to the same laws and regulations, including all transportation and security regulations, customs laws and competition laws, imposed upon private carriers. There should be good justification for any exemption and preferential treatment now that Japan Post is partnering with private competitors and expanding into new lines of business (Cf. alliance between Japan Post and All Nippon Airways).

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

Reform proposals

The EU requests the GOJ to consider the following proposals:

- a) In order to establish a level playing field with the private sector, the GOJ should establish a new independent regulator for monopoly postal services, separate from MIC.
- b) The GOJ should ensure transparency in the privatisation process and organise public consultations on every implementation measure of the Postal Privatisation Law.
- c) Yucho Bank Company and Kampo Life Insurance Company should not be allowed to further expand into new product areas before they are fully privatised.
- d) 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.
- e) 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.
- f) 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.
- g) Adequate regulations and controls should be established to ensure that the ¥2 trillion social contribution fund cannot be used for cross-subsidisation purposes.

- h) Mail and package delivery by the Postal Delivery Company should be subject to the same laws and regulations - including all traffic and transportation regulations, customs laws and competition laws - which apply to private carriers.
- i) The GOJ should not impose any restrictions on foreign investment in the securities market in acquiring shares of the successor entities of Japan post.

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 set out a road-map for developing international relations in the aviation sector in the coming years.

Ministers emphasised the important complementary roles that EU 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 (ECJ) 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 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.

Bilateral air services agreements are legally unsustainable

Bilateral air services agreements between Japan and EU Member States are infringing EU law and in effect are legally unsustainable and therefore need to be amended.

The EU considers air transport relations between the EU and Japan to be far too important to be based on bilateral air services agreements which are legally vulnerable. The consequences are uncertain and doing nothing is not an option.

This is why taking a serious approach to restoring legal certainty to bilateral air services agreements would provide the best possible guarantee of avoiding any risk related to the existing bilateral agreements.

Bilateral air services agreements may be amended either through bilateral negotiations with individual EU Member States or through Community-level negotiations of a "Horizontal Agreement".

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. The European Commission and Member States share the same aims and 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 and which thus represents a legal and commercial risk for all

operators concerned. The EU therefore expects progress to be made as a matter of priority in restoring legal certainty. This would pave the way for a closer and more productive relationship between the EU and Japan and allow us to move on to a broader and forward-looking co-operation agenda including on other aviation issues such as safety and security.

General business environment

Japan is among the EU's most important partners in the air 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 are needed. At present, limitations on pricing and distribution of air tickets, high operating costs for airlines and infrastructure bottlenecks all have an unnecessary negative impact on our aviation relations. 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 economic goals set by the Government of Japan. The Japanese regulatory authorities have a major role to play in achieving these goals.

The success of our economies depends to a large extent on well functioning links between the EU and Japan and with other countries. It is hard to overstate the significance of aviation networks in the modern globalised world. Air transport is indispensable for the smooth and efficient functioning of global trade and the integration of the world economy. An improved infrastructure, enhanced possibilities in setting prices, and lower charges will enable international airlines to contribute to the economic development of Japan and help achieve the ambitious goals of the Japanese Government of doubling the number of tourist visitors by the year 2008 and doubling foreign direct investment by 2011.

Further reform of the regulatory framework in the air transport field in Japan is still crucially needed with a view to allowing foreign carriers to better contribute to these goals.

Pricing and distribution

In Japan, regulation places considerable limitations on direct sales of air tickets to consumers and the pricing and distribution mechanism for air travel still has shortcomings in terms of efficiency and consumer friendliness. Airlines have limited means to sell their products and services directly and transparently to consumers. They are only allowed to advertise and sell fares for international travel to and from Japan at rates officially approved by the IATA, or in the case of group travel, at lower rates set by the Ministry of Land Infrastructure and Transportation. As the rates set by the IATA do not accurately reflect current market conditions, most individual fares are repackaged group discount fares sold through licensed travel agents. This places European carriers at a disadvantage, as they are not allowed to match offers by travel agents, should the price be lower than the minimum level accepted by the ministry.

Many restrictions continue to inhibit the development of direct sales to consumers, more so for air travel to Europe than for domestic or other international routes. The EU welcomes, however, the new principle assuming “automatic concurrence” by Japanese carriers on any price filed by European carriers to the Ministry, a positive approach which should enable faster and more market oriented fare setting processes.

Infrastructure, landing shortages, and slot allocation

The EU continues to be concerned as regards air transport infrastructure in the high-intensity Kanto region. Little progress has been made to increase capacity in the Kanto region, with existing facilities continuing to be used inefficiently. The extension of Narita’s second runway to handle larger aircraft is not scheduled for completion until 2009, while the discussion on regularly scheduled international flights to and from Haneda has merely started.

The EU is pleased, however, that recently some slots at Narita were reallocated and offered to EU Member States for operations on the second runway, though the runway is not long enough for take off of fully loaded long-distance aircrafts. Therefore, only a few slots will in effect be utilised. The extension of the second runway at Narita should include an adequate taxiway system. The construction of a fourth runway at Haneda will be finalised by 2009 at the earliest. International operations at this airport so far are planned only to/from other Asian countries.

Thus, the EU encourages the Japanese authorities to continue improving current policies on usage of aviation infrastructure in the Kanto region, giving appropriate consideration to issues like efficient and non-discriminatory usage and allocation of slots, access to down-town Tokyo and transferability between international and domestic flights. In order to ease the pressure for new slots, opening Yokota airbase to civil aviation might be an option for the future.

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.

Insufficient progress has been seen in improving this cost structure. While the EU welcomes the drive to lower costs initiated by the management of the newly privatised Narita airport, the EU would urge the Japanese Government to continually work towards reducing charges overall. To date, the scope and pace of change in this respect have been disappointing.

Reform Proposals

The EU requests the GOJ to consider the following 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 via the internet.**

- b) As a first step, the EU suggests the gradual introduction of a wider range of advanced-purchase fares into the system and to abolish outdated IATA Full Economy fares as a minimum requirement to set Business Class fares. Ultimately, a simple file-and-use system for pricing approval should be introduced and restrictions on the direct transfer of net-remittances on market fares sold through IATA travel agents should be eliminated.
- c) The EU encourages the GOJ to continue improving current policies on the usage of aviation infrastructure in the Kanto region, ensuring efficient and non-discriminatory usage and allocation of slots, access to down-town Tokyo and easier transfer between international and domestic flights.
- d) Haneda Airport should be opened to regular international traffic including Europe on a non-discriminatory basis, flight movement per hour at Narita increased, and slots from the two runways at Narita pooled. The 2nd runway at Narita Airport should be extended to 2500 m at the earliest date possible, and existing facilities should be used more efficiently. Opening up Yokota airbase in western Tokyo for civil aviation should also be considered when air space control of the military base is handed back to Japan in 2009.
- e) Prohibitive landing, navigation, and common user fees charged by airport authorities should be substantially reduced. The Japanese Government should strive to reduce the costs associated with the provision of air transport in Japan (e.g. with a target of up to 50%) in order not to lose out in the competition with other Asian hubs.
- f) The GOJ should engage as a matter of priority in bringing bilateral air services agreements between Japan and EU Member States into conformity with Community law.

6.2 Sea transport (international shipping)

In light of lack of progress and the non-committal nature of Japanese responses to last year's EU requests, the EU would like to repeat its requests made in 2005 and would hope that Japanese responses would be of a more forthcoming and engaging nature.

The continuing 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 vis-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 consider the following proposals:

- **a) To ensure that the prior consultation and alternative prior consultation procedures are transparent, equitable and swift**
- **b) To 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) To allow European shipping lines to tranship and operate foddering 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 like the ones in many other industrialised countries is facing great challenges due to changes in demography and public finances. However, it has to be underlined that the need to find a balance between drug expenditures and the soundness of public finances should also take into account the benefits associated with modern drug therapy. The European Union, therefore, encourages a constructive and comprehensive dialogue between industry representatives and all public Japanese authorities affected by the issue of drug spending and related aspects of industrial competitiveness. The review and reform of the Japanese healthcare sector should be conducted in a comprehensive way taking into account aspects like innovation, shortened drug approval times, and adequate rewards for innovation.

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). However, concerns continue to exist with regard to the processing and approval times for registration of clinical trials as well as of 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 longer than justified. The EU, therefore, reiterates its request for the PMDA to streamline the drug evaluation and approval process in Japan and to reduce the time needed for processing NDA applications.

As regards the Pharmaceutical Medicine and Device Agency (PMDA) concerns are still voiced concerning the adequacy of the raised fees and the only incremental improvement in drug assessment and services rendered by this body.

With regard to intellectual property rights, the EU supports considerations aimed at 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 and considers this move a measure to reward innovative companies.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- a) Continue to 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 environment for innovation, 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

The EU requests the GOJ to consider the following 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

The EU shares the Japanese government's objective to ensure a stable and sufficient supply of blood plasma and considers it essential for any medical care system. However, it has to be equally pointed out that international trade in plasma products helps to ensure sufficient supply and minimises risks which may arise due to single-sourcing.

Being aware of the more co-operative approach applied by the GOJ in recent months, the EU encourages the GOJ nevertheless to expedite a resolution of the current situation favouring domestic producers over importers.

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

The EU requests the GOJ to consider the following proposals:

- a) The EU encourages the GOJ to continue its dialogue with the industry on pricing and reimbursement in order to allow an even playing field for domestic and foreign companies.
- b) The EU requests the GOJ to amend or clarify (in a legally binding explanatory document) the wording of the supply/demand provisions of the Blood Law, particularly those provisions which may lead to a bias in favour of domestic producers.

7.4 Cosmetics

a) Transparency of regulation

The EU welcomes Japan's general willingness to accept credible safety data obtained in the EU.

However, the EU considers that further efforts are necessary to improve international alignment of cosmetics regulations. The re-launch of the informal multilateral regulatory dialogue CHIC (*Cosmetics Harmonization and International Cooperation*) should be supportive to make progress in international regulatory alignment.

b) Animal testing – trade in cosmetics

The EU welcomes the clear commitment to accept alternative (non-animal) testing methods for cosmetics. However, clarification is required that validated alternative tests are also accepted for those “quasi-drugs” in Japan which are considered as cosmetics in the EU.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- **As progress in international alignment of cosmetics regulation has been slow, the EU invites the GOJ to intensify efforts whereby the re-shaped CHIC-dialogue is going to provide a good basis to make progress.**
- **Clarification is required that alternative tests validated by OECD are accepted with regard to all products defined as “cosmetics” in the EU, i.e. including certain products which are regulated as “quasi-drugs” in Japan. These products include, for example, deodorants, hair dyes, certain hair growers and depilatories, certain whitening agents and certain medicated toothpastes.**

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.

In 2004, 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 approval of 4 food additives and 12 flavouring agents as of September 2006 and asks for further approval of remaining substances without delay.

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 EU also notes that during the past year the process of evaluation of food additives is slowing down and is concerned that this is caused mainly by administrative delays. The EU has been informed that for certain food additives Japan requires additional tests. The EU fails to understand why this seems to mean that - while waiting to get funding for such testing - other food additives can not be reviewed. Rigid application of the so-called 'first in first out' principle makes it more difficult for the EU to remain confident that Japan is willing to solve this issue.

The EU therefore requests that the GOJ evaluates the current procedures with a view to take a more flexible approach and increases resources for the evaluation process in order to further accelerate the approval process. 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

The EU requests the GOJ to consider the following proposals:

- a) To modernize Japan's practice of authorisation of food additives in line with the CODEX Alimentarius, and to accept additives and 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 as reference will improve the trade environment as it would help authorities to be able to decide on applications in a reasonably short period of time.
- b) The EU urges the GOJ to evaluate the current procedures with a view to take a more flexible approach and to increase resources for the evaluation process in order to further accelerate the approval process.
- 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.

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).

Concerning imports into Japan the EU is concerned that solely based on a study by the Food Safety Commission (FSC); the GOJ has resumed trade of bovine meat trade from the US. At the same time, EU import requests are not handled in the same manner. 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 traded 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.

Nevertheless, the EU notes that the GOJ agreed on the principle to study EU member states' import requests. In order to submit these EU import cases to the Food Safety Commission for risk assessment, both the Ministries of Agriculture (MAFF) and of Health (MHLW) have to request such information. In preparation both Ministries have sent a questionnaire to two Member States (MS), namely France and the Netherlands. The EU also notes fruitful technical discussions between Japanese and Commission and MS experts on BSE took place in September. It invites the GOJ to proceed in a timely manner once it receives answers to these questionnaires.

However, Ireland, Slovak Republic and Spain have also made formal requests to start negotiations to resume beef trade. The EU requests the Government of Japan to provide these countries also with the questionnaires in order to be able to start the procedure to assess respective safety.

Reform proposal

The EU requests the GOJ to consider the following proposals:

- **The EU urges the GOJ to proceed with the requests from all EU Member States (IR, SL, and ES) who have applied for trade in bovine meat and did not receive any questionnaire yet.**

- 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 since 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 onerous administrative and financial obligations imposed on prospective certifying organisations by new registration procedures. In particular, certifying organisations have to pay registration tax, bear costs for on-site inspections and provide increased administrative information in comparison to the previous system. Particular concerns for the EU are outlined below.

Firstly, foreign certifying organisations are disproportionately impacted from a financial point of view 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 expenses) and translation of documents. They should not have to pay the full cost of such on-site inspections, even if reduced air tariffs for inspectors and grouped visits apply. Secondly, and of utmost importance, organisations which are already registered have to go through exactly the same procedure again 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 EU is concerned that the cost and administrative difficulties prevent EU certifying organisations from re-applying and seriously disrupts the supply of organic product from the EU to Japan. The EU underlines that these concerns and proposals have been expressed beforehand, without, however, substantive response from the Japanese side.

Reform proposal

The EU requests the GOJ to consider the following proposals:

- **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 burdens and financial costs for newly as well as already registered organisations in order to avoid discrimination in comparison to domestic organisations.**
- **c) The EU would ask the GOJ to clarify how countries having organic equivalency status with the Japanese system can have facilitated access to the Japanese market under to the new JAS law.**

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.

In the Enforcement Ordinance under the Plant protection Law as amended 28 July 2006, added 3 pests indicated as a priority by the EU to category 1 or category 2, bringing the total to five out of nine. The EU welcomes the addition of these pests to the list of non-quarantine organisms. However, it should be noted that two pests classified as category 2 (i.e. non quarantine, if used for direct consumption such as vegetables, fruits and cut flowers etc.) *Frankinella occidentalis* and *Myzus persicae* should be reclassified to category 1 without delay.

The EU evaluates progress achieved as a first step, and notes that much more remains to be done. EU invites the GOJ to extend the list of Non-Quarantine organisms and requests the inclusion of the remaining organisms suggested by the EU.

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 EU Member States have been only made possible by establishing detailed protocols, setting out a comprehensive list of prevention and inspection measures. This is, however, against international practice, and seemingly applied in order to offer the Japanese authorities 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 European 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. EU 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). The EU notes that the GOJ has accepted the low temperature treatment on sweet oranges produced in Italy and would like to encourage the GOJ to extend this approach to other EU Member States.

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 often 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.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- 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; it also invites the GOJ to reclassify *Frankinella occidentalis* and *Myzus persicae* to category 1 without delay.
- b) The EU invites Japan to extend its approved protocol for one variety of certain fruit to other varieties of the same fruit
- c) The EU invites the GOJ to allow EU Member States with similar plant health status to use protocols already established for another EU Member State for imports into Japan of the same fruit.
- d) 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.
- e) The EU invites Japan to accept the low temperature treatment on sweet oranges produced in Italy, as an alternative treatment against Med Fly for other EU Member states
- f) The EU invites the GOJ to shorten the quarantine inspection period for plant products.

8.5 Breeders' rights (farmers' privilege)

The EU is pleased to note that the GOJ has taken measures to limit the use of the farmers' privilege and has amended the ordinance of the Ministry of Agriculture, Forestry and Fisheries to enlarge the scope of plants genera or species to which the farmers' privilege exemption does not apply. The EU notes however that species suggested by one Member State are not included at this stage and invites the GOJ to enlarge the scope of plants genera or species to which the farmers' privilege exemption does not apply.

The EU encourages the GOJ that the Working Group on Plant Variety Protection will actively continue to hold discussions and coordinate on the issue of farmers' privilege with both breeders and farmers' organizations to facilitate appropriate measures on this matter and to promote the exercise of the breeders' rights.

In order to protect Japanese and foreign breeders rights, the EU encourages the GOJ to step up controls of possible infringements.

Reform proposal

The EU requests the GOJ to consider the following proposals:

- **The EU encourages the GOJ to further enlarge the list of plant genera and species to which the farmers' privilege exemption does not apply.**
- **The EU encourages the GOJ to continue discussions with stakeholders and step up controls of possible infringements.**

8.6 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. The EU observes that, while Japan applies regionalisation zones with regard to the EU, these zones are bigger than deemed necessary by European Commission and Member States.

The GOJ indicated it would like the EU to demonstrate expected concrete advantages of its proposal, such as how the import-export procedures would be further simplified and facilitated.

The EU proposes 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. An example where such an approach would have given advantages is the outbreak of Highly Pathogenic Avian Influenza early 2006. In that case Japan would not have temporarily suspended trade with the whole territory of affected Member States for quite some time. Only products from the affected region in those Member States would have been excluded from trade, and in this way the GOJ would have applied an even more balanced approach and taken measures appropriate to the risk.

The EU invites the GOJ to have detailed technical discussions with relevant experts with a view to establish a pragmatic process to achieve such recognition within the shortest delays.

Reform proposal

The EU requests the GOJ to consider the following proposals:

- **The EU requests the GOJ to recognise EU regionalisation decisions when applying import measures on products from the EU**
- **The EU considers that at least the GOJ and the European Commission should establish a pragmatic process to achieve such recognition within the shortest delays. In this respect, the EU invites the GOJ to have detailed technical discussions**

9. International Standards

9.1 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 a truly global industry in all aspects. The high number of UN-ECE regulations (more than 90) adopted by the EU is a clear sign of the strong commitment towards international harmonisation. The EU would appreciate for Japan to make a similar effort, as Japan has only adopted about 30 UN-ECE regulations up to now.

The EU appreciates that Japan has recently emphasised the importance of the 1958 Geneva Agreement in contacts with other Asian countries as the only practical and realistic means for mutual recognition in the area of motor vehicles. Nevertheless, the EU also notes that Japan acceded to only three UN-ECE regulations in 2004 and a further two in 2005 (nrs 116 on protection against unauthorised use of vehicles and 119 on cornering lamps). 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 accelerated. 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.

Reform proposals

The EU requests the GOJ to consider the following proposals:

- a) The EU reiterates its long standing request to the GOJ to accelerate 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) in order to allow Japan to adhere to this regulation 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 to 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 set a timetable for its review and eventual adoption of regulation 89 on speed limiters.

9.2 Wood standards

The EU is grateful for the positive manner in which the Government of Japan has embraced the new 'EU-Japan Wood and Building Expert Dialogue'. The first meeting was held in Brussels on 22 March 2006, and a second one is scheduled for this autumn, in Tokyo. It is a useful and important forum to exchange information on market trends and best practices, as well as research and technical development and to identify potential areas for collaboration.

In the context of trade in wood, there are also a number of regulatory issues which should be discussed more deeply in future meetings. In particular, the following issues have been identified as important to further develop the bilateral trade in wood-based products and facilitate technical development.

Reform Proposals

The EU requests the GOJ to consider the following proposals:

- a) The EU suggests that the GOJ recognises and accepts European Spruce (*Picea abies*) as a separate species from other spruces (in the wood classification).
- b) The EU suggests that the GOJ reviews the fire-endurance tests and fire regulations so as to allow the import of innovative, large-scale wooden products from Europe.
- c) The EU suggests that the GOJ considers ways to simplify the accreditation of testing organisations under the JAS/JIS and Ministerial Approval Schemes, and to provide a treatment equal to standardisation schemes in other areas.
- d) The EU suggests that the GOJ reviews the current test methods regarding secondary wood-based products (such as flooring, doors and windows) in order to make it easier for imported products to be tested and used in multi-storey buildings.
- e) The EU suggests that GOJ reviews the implementation of the JAS – WCLIB (West Coast Lumber Inspection Bureau) equivalency agreement in order to allow European Products with WCLIB marking to be treated equally to JAS marked products.

9.3. Packages for foodstuff

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 – amended in 1979 to include two new testing methods for plastic pouches). 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 which is 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 Cannery 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 airburst test as defined by the JIS. The airburst 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.

Moreover, because of rapid technological developments in the foodstuffs packaging sector, regulations setting test standards concerning mechanical properties might not be able to keep up with them. The high standards already set on the materials which come into contact with food should be sufficient to guarantee food safety nowadays.

Reform proposal

The EU requests the GOJ to consider the following proposals:

- **The EU urges the GOJ to modify the regulations concerning the Food Sanitation Law to only contain food safety requirements on materials intended to come into contact with food, instead of setting mechanical testing requirements also.**
- **As a second best option, the EU urges the GOJ to speedily 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.**

10. 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.

However, the EU would like to acknowledge Japan's efforts to harmonize its standards with international practice, through *fora* such as the Veterinary International Co-Operation on Harmonization (VICH).

Another welcome development is that the GOJ is moving away from the current National Assay System of batch release for biological products (vaccines) by the National Veterinary Assay Laboratory. In that context, the EU is acknowledging progress made by the GOJ on Seed Lot system introduction and on pharmacovigilance. In particular, the Ministry of Agriculture, Forestry and Fisheries (MAFF) gave the information in the 16th VICH Steering Committee that it has been decided to implement the Seed Lot system in relation with the Japanese pharmaceutical industry JVPA. The project has started in March 2005 with duration of three years, and should thus be finished by March 2008. The EU will continue to monitor this positive development.

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 requests the GOJ to consider the following proposals:

- a) To continue to improve the efficiency in the product approval process for new veterinary medicinal products.
- b) To confirm the continued Japanese commitment in VICH process as it should help solving and harmonize discrepancies in data requirements for approval between EU and Japan, therefore facilitating and shortening the approval time for new veterinary medicinal products.

- c) To 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.